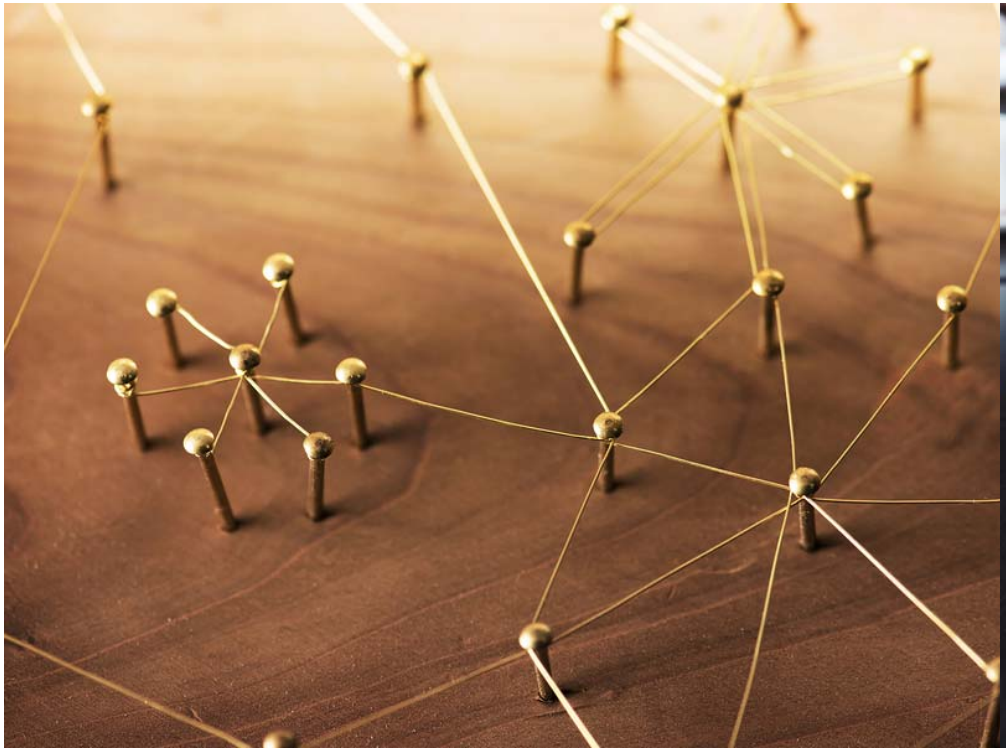
KCE REPORT 277

Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
Belgian Health Care Knowledge Centre

GOVERNANCE MODELS FOR HOSPITAL COLLABORATIONS



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HEALTH SERVICES RESEARCH

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1 INTRODUCTION

There is an international trend for hospitals to become part of larger care networks rather than to function as single entities. Also in Belgium the number of collaborations between hospitals has vastly increased during the last decade. The reasons for collaboration vary and include financial pressure (e.g. the common exploitation of shared services such as a HRM department), government regulations (e.g. cardiac care programmes), sharing scarce human resources (e.g. interventional radiology) and providing patient-centred integrated care. Following the new regulation guidelines in the Action Plan of the minister of Social Affairs and Public Health (April 2015), hospitals have to become part of a larger care collaboration,[1] in which they will need to join forces to better coordinate and integrate patient care across hospital boundaries and enhance task distribution. Possible examples of such collaboration and task distribution are the concentration of highly-specialised services, such as rare cancers, in reference centres[2, 3] or the rationalisation of general care services such as maternity services.

As mentioned in several policy documents[1-3] the collaborations and governance structures in the current Belgian Hospital Act[1] are not sufficient to guide these new developments. New governance models are needed to support hospital collaborations that facilitate task distribution and the care coordination across hospital boundaries. The overall goal is to provide better quality of care in an efficient way. This study aims to identify governance models that support collaborations enhancing task distribution and cost-effective care and to define recommendations for the Belgian legislator to adjust the current Hospital Act accordingly. We focus on collaborations between hospitals involving at least clinical services (e.g. cardiac care programme) and/or major medical equipment and not only focusing on collaborations for support services (e.g. IT, maintenance, etc.).

[1] Article 67 of the coordinated Law of 10 July 2008 on hospitals and other healthcare institutions (hereinafter referred to as the 'Hospital Act') provides that special norms can be enacted for hospital groups, mergers and associations of hospitals.

In order to investigate which legal forms and governance models support these task distribution and collaboration, the first chapter in this study gives a brief overview of the several definitions and concepts within the field of governance and hospital governance. A framework to identify different forms of collaboration is outlined and four possible forms of governance are discussed. Thereafter the scope of the study is delineated and the structure of the next chapters is outlined.

1.1 The governance concept

1.1.1 Definition of governance

Together with leadership, governance is identified by the World Health Organization (WHO) as one of the six key building blocks of a well-functioning national health system. 'Governance' is a standard term and is frequently used in political science, public administration, social policy, human development and administrative research. It essentially refers to the complex interplay of rules, values, procedures and structures – generally referred to as 'checks and balances' – that determine how decisions are taken and implemented.[4] The Institute on Governance[2] defines governance as 'the traditions, institutions and processes that determine how power is exercised, how citizens are given a voice, and how decisions are made on issues of public concern'. In this study we start from the overall definition that governance is:[5]

- an interaction between people or a group of people (governance-actors);
- wherein the decision-making is not the responsibility of only one of the two parties;
- but where a complex interplay of control and balancing mechanisms should enable them to make decisions whereby the interests and goals that lie in the foundations of their relationship are realised.

In the literature, a dominant dichotomy can be found in defining the concept 'governance'. While the first approach has a societal point of view, i.e. **public governance**, the second approach originates from the field of business administration and organisational management, i.e. **corporate governance**.

1.1.2 Public governance

Public governance provides the essential framework that spells out societal expectations and norms that, in turn, guide resource allocation, and protects the interests and rights of citizens. It also establishes the principles that shape legal and other institutions.[6] In the public policy and management literature, governance has, until recently, been equated with government. The basic principle used to be the distribution of power, i.e. the legislative, the executive and the judicial power. During the past 25 years, however, one has witnessed strong political pressures to reduce government's scope and shift responsibilities for public policy implementation to nongovernmental entities.[6-8] Due to the growing complexity within our society, governance tasks have been outsourced to external private and not-for-profit organisations. As a consequence the well-known and clear division between **three types of governance mechanisms** is no longer reality. These mechanisms are 1) authority and hierarchy of the state, 2) markets and 3) civil society.[9]

When the healthcare sector is centrally steered, the governance mechanism '**authority**' is most present. If authority is the core concept, central administrative regulations and orders, rules and planning are used to govern the different actors. In Denmark, for example, the system is to a large extent steered by the regional authorities.[10, 11] As such, there are no boards on hospital level but only one overarching board on a regional level wherein regional politicians participate. Also in Belgium, the government intervenes through planning, authorisation and financing regulations, but leaving substantial freedom to the healthcare sector.

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2 http://iog.ca/

'Markets' are characterised by competition, negotiations and exchange between several actors and their working is based on price mechanisms. The logic is that through competition, hospitals will increase quality while reducing costs.[12] Hence, the market is assumed to balance the healthcare sector without the need of the government to intervene a lot. This mechanism is present in the United States healthcare system. Intermountain Healthcare,[13] for example, invests in the best quality of care but also in efficiency to attract patients in their region. The competition has increased the performance of Intermountain. Because of its success, the organisation kept on growing which complicated governance and decision-making. To maintain the quality and the task distribution in their services, they became an integrated health system.

'**Civil society**' is comprised of groups or organisations working in the interest of the citizens but operating outside the public and for-profit sectors. Organisations and institutions that make up civil society include labour unions, not-for-profit organisations and other service agencies that provide an important service to society.[9] As most healthcare organisations are not-for-profit in Belgium, the healthcare sector is mostly influenced by this mechanism.

Nowadays, societal needs like housing, healthcare and education, are more and more fulfilled by a combination of the three mechanisms. These three mechanisms affect the way governance in hospitals and collaborations is organised and mixed forms, such as regulated competition, occur which makes the already complex interplay of control and balancing mechanisms, i.e. good leadership[14] and good governance structures[15] even more complex. As a result networks occur to engage public, private and civil society actors at transnational, national, regional and local scales in shaping the future of our societies.[16]

Government decisions are made on international, national, regional and local level.[5] Hence, 'government decisions' have become both vertically and horizontally separated.[17] The mechanisms and behaviours within public governance practices should be adjusted to reflect these new trends.

1.1.3 Corporate governance

Corporate governance is the system by which companies are directed and controlled. It involves a set of relationships between a company's management, its board, its shareholders and other stakeholders. Corporate governance provides the structure through which the objectives of a company are set and the means of attaining those objectives and monitoring performance.[18] It is the set of rules, systems and regulations intended to protect stakeholders' interests, and especially shareholders' interests. These rules define rights and responsibilities of the firm's managers and board members, define how a company is managed, articulate the mechanisms by which board members and stakeholders monitor managers, ensure organisational solvency, and protect corporate assets.[19, 20] Until recently, corporate governance regimes were primarily based on agency theory, as expressed in the shareholder model. **Agency theory** assumes there will be a conflict of interest in a relationship of agency where one party (the shareholders) delegates work to another (the executives).[21] Later, a stream of studies on **stakeholder theory** and **corporate governance** have investigated new ways to integrate more stakeholders into the governance of corporations, e.g. through representation in the governing boards. Consequently, corporate governance evolved to a broader perspective than the set of relationships between a company's management and its shareholders. Within this broader perspective corporate governance has also been applied to not-for-profit organisations. It refers to the process of providing leadership, direction, and accountability for specific nongovernmental, not-for-profit organisations.[22]

1.1.4 Public versus corporate governance

Although there are many differences in both definitions of public governance and corporate governance, there are also some similarities. An important common theme is the **polarisation in the vision on governance**. First, there was a narrower vision in both concepts, i.e. the distribution of power of the government and the shareholder model in enterprises. Thereafter, this vision has evolved to a broader scope, public governance has further vertically and horizontally developed and the stakeholder model is more often applied.[5] Corporate governance systems are more and more grounded in a society's legal codes (e.g. regulations).

Hence, the **relationship between corporate and public governance is dynamic**. Imperfections in corporate governance may induce changes in public governance; the opposite is also true. An important example of this congruence is the evolution in the literature on public sector management reform. Management concepts applied in the private sector, are now applied in a context of civil services. This development has been described in terms of New Public Management (NPM) and New Public Governance (NPG).[23] NPM is a shift away from the bureaucratic hierarchical structure of governments that are part of the classical or traditional form of administration towards the integration of the private sector approach and culture. There is a clear emphasis on outputs rather than on input factors and on re-sizing the public sector. The goal changes to more cost-effective methods of production of goods and services.[24] NPG, on the other hand, in contrast with the emphasis on competitive markets and outputs as in NPM, places citizens rather than government at the centre of its frame of reference. The NPG approach emphasises interorganisational relationships and the governance of processes, in which trust, relational capital and relational contracts serve as the core governance mechanisms, rather than organisational form and function.[25]

The **boundaries between corporate governance in not-for-profit organisations and public governance** are increasingly fluid and overlapping, and the theoretical understanding as well as empirical work on governance had to expand to encompass this relationship.[26, 27] Drawing on one another can strengthen both public and corporate governance research literature. Research should expand and go beyond a functional, organisational, and board-focused construct that often misses important governing behaviour and activities taking place outside the boardroom. Because of this fluid and unclear distinction, new concepts in governance arise such as network governance. **Network governance** can be termed as a collection of persons or institutions engaged in a policy dialogue that are not accountable to the state (although the state may have initiated the formation of the network and may be involved in directing the network); that interact in an environment that is open and trusting, thus facilitating the free flow of views and information within and to other networks; that are specifically targeting a policy problem.[28]

In this study we do not make the explicit distinction between corporate and public governance, since there is an overlap between these two concepts, especially when we study hospitals. We will also use a wider search including concepts as network governance and not-for-profit governance to investigate the governance practices in acute hospitals. This broader perspective of governance can be motivated by the goal of this project to explore the establishment of governance in acute hospitals with respect to governmental and stakeholder's influence and control.

1.1.5 Governance in the hospital sector

Within the world of health, Preker and Harding (2003)[29] identified **four main levels of governance**. First, there is the **global or international level.** An example of a specific topic at this level is the decision-making procedures to address international pandemics. Second, there is **multi-sectoral governance**. This level addresses policy sets that control the behaviour and use of resources in the broader economy of a nation. Third, there is **sectoral governance**, where the government of healthcare seeks to promulgate policies and allocate resources among providers, payers, and technology-pharmacy producers to not just restore health, but to protect and promote health. And finally, there is **institutional governance**, which deals with the control of a specific organisation's (for example a hospital, pharmaceutical company or health insurance plan) resources for mission accomplishment.

Good governance practices

Former research has investigated **'good governance practices' in hospitals**. First, a **clear demarcation of the governance structures** has shown to contribute to a more transparent decision-making process. Evidence shows that operational decisions must be taken by management, while the hospital board must be entrusted with all tasks of a supervisory nature.[30] Secondly, health policy debates recognise the important role of hospital boards in overseeing **patient quality and safety**, and a growing body of empirical research has sought to elucidate that role.[31] The composition and methods applied by the hospital's board have an influence on the quality of care within hospitals.[32] The analysis of Verenosi (2013)[33] reveals a significant and positive association between a higher percentage

of clinicians participating in the board and the quality ratings of service providers.

These new findings of 'good hospital governance' have led to the development of **new checks and balances**. Recently, public indicators, accreditation and stakeholder consultations are becoming more important.[5] As a consequence, the concept of 'clinical governance' is gaining importance in healthcare literature.[34] Clinical governance, however, is not focused on the governance of the organisation, it aims to improve the quality and safety checks in healthcare. It was initially established as a framework through which National Health Services (NHS) organisations are accountable for continually improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.[35]

Current governance guidelines and structures do not suffice in guiding the new developments. On organisational level, this will lead to an increased necessity of vertical and horizontal integration of healthcare services. The collaboration within **horizontal networks** is between similar organisations, which is within the scope of this study. **Vertical networks** are identified as collaboration between organisations with different service offerings (out of scope).

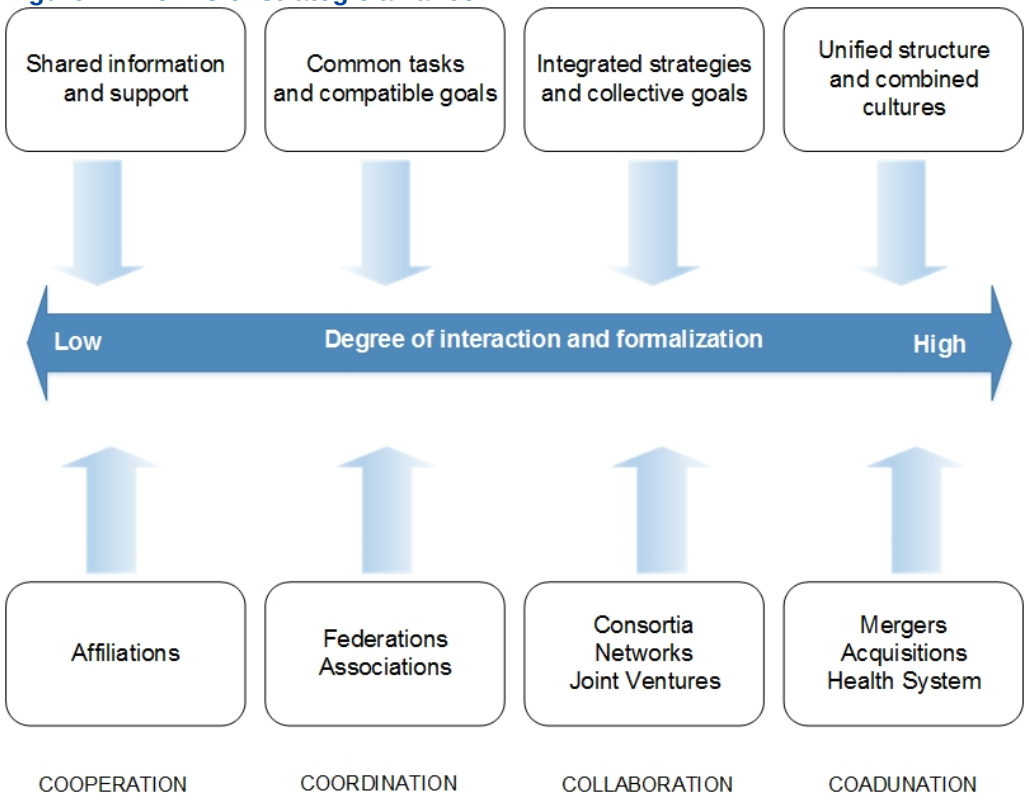
This new demand for streamlining the different configurations of care provisions induces equal demands to integrate concepts of hospital governance and healthcare governance in general.[36] The current governance model on meso- and micro level with its roles and responsibilities needs to be evaluated. The traditional collaboration forms are no longer sufficient and several other forms of collaboration emerge bottom-up.[37] Hence, there is the need for a new concept of network forms and their governance.

1.2 Collaboration in the healthcare sector

The term 'network' is often used to indicate any form of collaboration in the healthcare sector. However, more differentiation is required. To be able to clearly define the concept network, we first elaborate on the more general concept of collaboration. Collaboration can be defined as 'the cooperative way that two or more entities work together toward a shared goal'.[38] Scholars outline different collaboration models and frameworks. Peterson (1991)[39], for example, postulates that there is a three point continuum of interaction for strategic alliances: 1) cooperation, whereby fully independent groups share information that supports each other's organisational outcomes, 2) coordination, whereby independent parties align activities or co-sponsor events or services that support mutually beneficial goals and 3) collaboration, where individual entities give up some degree of independence in an effort to realise a shared goal.

Hodges et al. (2003)[40] suggested five levels of community linkage: networking, cooperation or alliance, coordination or partnership, coalition, and collaboration. The levels differ by purpose, the structure of decision-making, and the nature of leadership. Bailey and Koney (2000)[41] offered a model similar to these, with four steps ending with complete unification: cooperation, coordination, collaboration, and coadunation (see Figure 1).

Figure 1 – Forms of strategic alliance



Source: Bailey and Koney (2000)[41]

1.2.1 Types of strategic alliance

1.2.1.1 Cooperation

The first form of alliance is cooperation. This form of alliance is a very loose form of partnership between two or more organisations with the same interests. All organisations maintain their own identity; the exchange of knowledge is the most important element in this relationship.[41]

1.2.1.2 Coordination

The second form of alliance is coordination. This refers to organisations that work together with a complementary organisation to realise their own goals. This form of strategic alliance still assumes a low degree of cooperation and integration of the organisations and does not imply a collective goal. The organisations maintain their own identity while the coordinated alliance, e.g. a federation or an association, executes specific tasks. Examples of these tasks are funding, training and education, planning, marketing and legal assistance.[41]

1.2.1.3 Collaboration

Consortium

A consortium joins forces and knowledge to obtain a joint goal. A consortium is a collaboration of two or more individuals, companies or organisations with the objective of participating in a common activity or pooling their resources to achieve a common goal. Within the consortium, each participant retains separate legal status and the consortium's control over each participant is generally limited to activities involving the joint endeavour. A consortium is formed by a contract.[42] Examples of a consortium in the healthcare sector are hospitals, private organisations and research groups that work together to develop a new technology.

Joint venture

In a joint venture two or more organisations work together with an economic purpose. They want to carry out an economic activity together and profits and losses will be shared. This form of collaboration may have a permanent character or can be temporary. The main difference with a consortium is that the participating parties agree to create a new entity by contributing equity, and then share in the revenues, expenses and control of the new enterprise. The participating organisations preserve their own identity and participate equally in the joint venture. Keuning and Eppink[43] articulate that the access to information and the shared risks are two big advantages of this collaboration form. Also the rather small investments to start with this form of collaboration are evaluated as positive. An example of this in a healthcare setting are centres of excellence organised as joint ventures. The oncology department of the University Hospital Brussels collaborates in a research joint venture with the Hercules foundation of the Flemish government and Brainlab AG. An international example is the Joint Venture Hospital Laboratories Network (JVHL). JVHL was established in 1992 to offer hospital and health system outreach laboratory programmes the organisational model to attract and administer health plan laboratory service agreements. Today, there are more than 120 hospitals across Michigan, Ohio, and Indiana participating in the network and providing laboratory services to more than 4.5 million members residing in these areas.

Networks

Bailey and Koney[41] developed a specific definition for networks in healthcare organisations. A network is identified as an integrated service system with the goal of improving service delivery. The authors differentiate two network forms: horizontal and vertical networks. The collaboration within **horizontal networks** is between similar organisations, which offer more or less the same services. **Vertical networks** are identified as collaboration between organisations with different service offerings.

Following Bailey and Koney (2000)[41], a network is the answer to the restructuring initiatives within healthcare policies to implement new strategies with the goal of reducing expenses. Healthcare policies are focused on the responsible use of resources and the elimination of abuse of funding in healthcare service delivery. These restructuring initiatives also occur in the Belgian healthcare system.

1.2.1.4 Coadunation

The term coadunation refers to a more radical form of collaboration. Coadunation can be translated as a strategic restructuring.[41] Mergers and acquisitions are the best-known examples of coadunation. Merger involves the coming together of two or more organisations in which one organisation survives as a legal entity and the others dissolve to become part of the surviving organisation. Acquisition describes mergers between unequal organisations; it is the complete integration of one organisation into the other in which the integrating agency loses its independent existence and becomes part of the acquiring agency.[44]

1.2.2 Collaboration and networks

Bailey and Koney (2000)[41] have a very specific definition of a network. We see, however, that some authors use a much broader definition. Perri et al. (2006)[45] define a network as 'any moderately stable pattern of ties or links between organisations or between organisations and individuals, where those ties represent some form of recognisable accountability, whether formal or informal in character, whether weak, or strong, loosely or tightly bounded or unbounded'. In this perspective a network is any form of alliance between organisations or between organisations and individuals and includes all four categories discussed in the framework of Bailey and Koney (2000).[41] However, the first two forms of alliance, i.e. coordination and cooperation, have a rather low level of integration and formalisation. Since these forms are only focused on information exchange and administrative tasks and assistance and do not have a collective goal, these are not within the scope of this project. **In this study we focus on organisational collaboration with a collective goal and an integrated strategy to achieve this goal.** The study focuses on the last two forms within the framework of Bailey and Koney (2000)[41], i.e. **collaboration and coadunation**.

Bazzoli et al. (1999)[46] outline two large categories of interorganisational collaboration: health networks and health systems (Table 1). A **health network** can be positioned as a form of collaboration in the framework of Bailey and Koney (2000).[41] Health networks are created to function as interdependent wholes while maintaining each organisation's separate legal identity. It refers to the relationship formed by a group of hospitals through strategic alliance. A health network consists of autonomous units that have joined together to achieve a common purpose.

A health system is a corporate body that owns and/or manages health provider facilities as well as non-health-related facilities. The health system is an example of coadunation. It is a legally recognised permanent arrangement in which common ownership, management, or leasing exists for all or most of the components.[47] The concept of 'a health system' is slightly different from the concept 'merger' in the Belgian Hospital Act. A merger leads in Belgium to the development of a new organisation where there is common ownership, while a health system refers to the integration of more than one entity wherein all organisations still exist as entities but transfer part of their governance to the level of the system.[47] Health systems are typically governed on principles of hierarchical control and coordination by a central administrative or governing authority.[48] The central governing body is assumed to have ultimate authority over management and governance of owned and sponsored affiliate organisations.[49] Consequently, in this study a health system is included as a form of coadunation within the framework of Bailey and Koney (2000).[41] In the following section, the types of collaboration in the Belgian Hospital Act are positioned within the adjusted framework of Bailey and Koney (2000).[41]

Collaboration in the healthcare sector

In the remainder of this study the concept 'collaboration' is used as an overall concept. It encompasses all types of collaboration, including mergers, acquisitions and health systems.

Table 1 – Health networks and systems

	Health networks	Health systems
Forms	More loosely coupled multihospital arrangement, in which hospitals are linked in a number of ways such as informal relationships and contract agreements to pursue specific objectives	Formally structured multihospital system, in which hospitals are tightly coupled and are linked through formal and structured relationships
Ownerships	Multiple ownerships	Single ownership
	Each hospital maintains its separate legal identity	Owned and managed by a certain legal entity
Decision-making	Joint planning and decision-making	Planning by a central administrative authority
	Independent implementation	Jointly pursue common interests
Governance structure	Intermediate mechanisms	Hierarchy mechanisms
Autonomy	Function as interdependent wholes	Part of an owned system
	Preserve moderate to high independence and autonomy	Low independence and autonomy

Source: Yu and Chen (2013)[50]

1.2.3 Collaboration forms in the Belgian Hospital Act

Three forms of collaboration are defined in the Belgian Hospital Act. They can be positioned in the last two forms of alliance: collaboration and coadunation.

The first form of collaboration is a **hospital group** ('groepering van ziekenhuizen'/'le groupement d'hôpitaux'). The hospital group can be positioned as a **network** in the framework of Bailey and Koney (2000)[41]. An important condition is the maximum distance of 25 km between the collaborating hospitals. This agreement includes specification on task distribution and complementarity on the level of services, disciplines and equipment. The hospital groups may not result in monodisciplinary hospital sites (with the exception of geriatric and Sp-services)[3]. Hospitals of the group should achieve efficient task distribution to obtain complementarity.

A second form of collaboration is the **hospital association** ('ziekenhuisassociatie'/'l'association d'hôpitaux'). The hospital association is also an example of a **network** in the framework of Bailey and Koney (2000)[41]. A hospital association in the Belgian Hospital Act can be defined as two or more hospitals with the joint exploitation of one or more care programmes/ hospital departments/ hospital functions/ hospital units/ (medico-)technical departments. The association agreement contains a detailed description of the activities that are run by the association and to which catchment area (population) this applies. This form of collaboration is of interest when the activity volume determines quality of care and/or authorisation.

The third form of collaboration as defined in the Hospital Act in Belgium is the **hospital merger** ('fusie van ziekenhuizen'/'la fusion d'hôpitaux'). This is an example of **coadunation** and includes the integration of two or more hospitals (maximum distance of 35 km between hospitals that merge) under one single administrator with a single authorisation. The legislation contains rules about the distribution of different hospital services and functions on the different hospital sites.

However, looking at the broad framework of Bailey and Koney (2000)[41], these three forms of collaboration defined in the Belgian legislation are still limited. In general, **other forms of collaboration** such as consortia and joint ventures and other examples of coadunation such as mergers, acquisitions and health systems exist.

1.3 Governance of collaboration initiatives

1.3.1 Governance mechanisms

In the previous section, there was no discussion on how these forms of collaboration should be governed. Since networks and different forms of collaboration are a very broad and complex topic, the governance of these different forms will be even more complex. Hence, this section describes several forms of governance within the healthcare sector.

Provan and Kenis[51] explain that governance of health networks 'involves the use of institutions and structures of authority and collaboration to allocate resources and to coordinate and control joint actions across the network as a whole.' The governance of health networks is about: 1) structures for collaboration (governance structure), and 2) collaboration in networks (governance mechanisms)[52]. As the governance of interorganisational collaboration can be organised in different ways, several forms of governance structures exist. Governance mechanisms refer to the mechanisms used in the network to coordinate tasks. Three types of governance mechanisms occur:

- **authority** and **hierarchy** of the state;
- **price mechanisms** in economic **markets**;

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3 Sp-services are specialised services for the treatment and revalidation of certain pathologies and disorders, for example neurological problems or chronic diseases.

- and the **civil society** wherein relational governance is an important governance mechanism.[9]

These are the same mechanisms that have an influence in public governance (discussed under section 1.1.2).

Powell (2003)Powell [53] suggests that it is not the choice of governance mechanisms or structures in itself that affects network effectiveness, but the fit of governance mechanisms with governance structure. Governance structure and governance mechanisms are related and interdependent, and can be seen as two dimensions of network governance that can exist in several combinations. The structure, for example, influences the possibilities for effectively using certain governance mechanisms.[51]

1.3.2 Governance structure

Following Provan and Kenis (2008)[51], two distinctions in the structures for collaboration are made. First, network governance **may or may not be brokered**. At one extreme, networks may be governed completely by the organisations that comprise the network. Every organisation would interact with every other organisation to govern the network, resulting in a dense and highly decentralised form. This is what is called **shared governance**, i.e. no other parties are involved in the governance of the network. At the other extreme, the network may be highly brokered. This implies that an external party or a member in the network arranges agreements and governance between the several parties involved. Few direct organisation-to-organisation interactions exist, except regarding operational issues such as the transfer of business, clients, and information on services. Instead, network governance occurs by and through a single organisation, acting as a highly centralised network broker, or **lead organisation**, regarding issues that are critical for overall network maintenance and survival. At the mid-range, a single organisation might take on some key governance activities while leaving others to network members. Alternatively, network members may divide governance responsibilities among various subsets, or cliques of network members, with no single organisation taking on significant governance tasks.

A second distinction regarding governance can be made in brokered networks by focusing on whether the network is **participant-governed or externally governed**. As discussed below, participant-governed networks are, at one extreme, governed either collectively by the members themselves (i.e. shared), or at the other extreme, by a single network participant that takes on the role of a lead organisation. Externally governed networks are governed by a unique network administrative organisation (NAO), which may be either voluntarily established by network members or mandated as part of the network formation process.

1.3.2.1 Participant-Governed Networks

The simplest and most common form is participant governance.[36] This form is governed by the network members themselves with no separate and unique governance entity. There is no separate administrative entity set up specifically to govern the network. Participant-governed networks can be highly decentralised, involving most or all network members interacting on a relatively equal basis in the process of governance. Shared participant-governed networks depend exclusively on the involvement and commitment of all, or a significant subset of the organisations that comprise the network. Network participants are themselves responsible for managing internal network relationships and operations as well as external relations with such groups as funders, government, and customers.[54] Power in the network, at least regarding network-level decisions, is more or less symmetrical, even though there may be differences in organisational size, resource capabilities, and performance.

1.3.2.2 Lead Organisation–Governed Networks

While shared participant-governance involves many or all network members, this form of governance is not always appropriate. In particular, the inefficiencies of shared governance may mean that a far more centralised approach is preferred. At the extreme, network governance can occur through what is conceptualised as a ‘lead organisation’.[36] There is a core provider agency that performs the role of network leader because of its central position in the flow of clients and key resources. In lead organisation governance, all major network-level activities and key decisions are coordinated through and by a single participating member, acting as a lead

organisation. Thus, network governance becomes highly centralised and brokered, with asymmetrical power. A lead organisation provides administration for the network and/or facilitates the activities of member organisations in their efforts to achieve network goals, which may be closely aligned with the goals of the lead organisation.

1.3.2.3 Network Administrative Organisation

A third form of network governance is the NAO model.[36] The basic idea is that a separate administrative entity is set up specifically to govern the network and its activities. Although network members still interact with one another, as with the lead organisation model, the NAO model is centralised. The network broker (in this case, the NAO) plays a key role in coordinating and sustaining the network.[55, 56] Unlike the lead organisation model, however, the NAO is not another member organisation providing its own services. Instead, the network is externally governed, with the NAO established, either through mandate or by the members themselves, for the exclusive purpose of network governance. The NAO may be a public organisation, or a not-for-profit organisation, which is often the case even when the network members are for-profit firms.

1.3.2.4 Health System

Collaboration structures within the category of coadunation, share common ownership and have the joint purpose of pursuing common interests. This form of collaboration can have a different governance structure than the structures discussed within the framework of Provan and Kenis.[51] In a health system a hierarchical control method is applied, meaning that a central administrative authority is in charge of management and coordination.[57] A sole party holds this single ownership in the health system.

1.4 Scope and objectives of this report

In this report four forms of governance are conceptualised:

- the participant-governed networks;
- the lead organisation-governed networks;
- the network administrative organisation;
- the health system.

The first three all refer to networks wherein the organisations still are individual operating elements in the network. The fourth form goes a step further by developing a health system with a single ownership, which is owned and managed by a certain legal entity. This form of governance implies a high level of hierarchy. Each of these forms has certain key structural characteristics and is utilised in practice for a variety of reasons. Each form has its own particular strengths and weaknesses, leading to outcomes that are likely to depend on the form chosen.

This study investigates which forms of governance are applied in the various models of collaboration and coadunation. First, to gain a better understanding of several combinations of hospital governance and forms of alliance, an **in-depth literature review** is conducted. The review investigates which governance models (structures and mechanisms) aim to support task distribution and collaboration between hospitals and what lessons can be learned. Second, different types of collaborations are identified in the current legislation and the **barriers and facilitators in the current (legal) context** are interrogated. Third, a **multiple case study** is performed, exploring the legal Belgian context of current initiatives that aim to support the task distribution and collaboration between hospitals. Three cases are studied in both French- and Dutch-speaking regions. At least one form of collaboration outlined in the framework of Bailey and Koney (2000)[41] is investigated, for example consortium, joint venture, network and coadunation in combination with at least one of the four examples of governance structure. At the same time **international practices** are investigated building on a literature review (non-systematic) and a multiple case study of four countries/regions/best-practice initiatives. Also healthcare systems abroad that underwent reforms leading to new governance models

are analysed. In a last phase **options for best governance practices for the Belgian context are identified**. The **legal possibilities and constraints in Belgium and the EU legislation** are identified. In addition, the different solutions for the Belgian context are checked with important stakeholders to explore the possibilities for hospital governance within Belgium.

This scientific report includes two legal chapters. The first legal chapter (Chapter 2) analyses current legislation on types of collaborations between hospitals to identify barriers and facilitators to collaborate. The second one (Chapter 4) assesses legal possibilities and constraints to introduce new governance models that support task distribution and care coordination. Three new models are briefly described in Chapter 3. These models are based on a literature review, national and international case studies and round-table discussions with Belgian stakeholders. This information is not included in the scientific report but is available on request from the authors as a working document.

2 CURRENT BELGIAN LEGAL CONTEXT OF COLLABORATION BETWEEN HOSPITALS – A DESCRIPTIVE ANALYSIS

2.1 Introduction

The legal context of the current types of collaboration between or with hospitals is described in order to be able to identify the legal barriers and facilitators (section 2.2). This consists of three parts. The first part involves a description of the legally structured types of collaboration among hospitals. The second part analyses other types of collaboration between hospitals and care providers that are authorised by the competent public authority. The third part analyses types of collaboration that are not authorised by the competent public authorities.

In section 2.3 we evaluate more in detail the manner in which the current legislation can divide the healthcare landscape in regional and/or supra-regional collaborations. We evaluate the facilitators and obstacles to collaboration between hospitals. We analyse the legislation on the legal forms of collaboration of hospitals as well as other legislation (e.g. related to competition law, constitutional law, labour law, etc.) that can facilitate or hinder collaboration between hospitals. When analysing the facilitators and obstacles, we mainly focus on governance and in particular on the direct and indirect aspects of governance. With the direct aspects we refer e.g. to the way the collaboration is governed by committees, the way hospital physicians are involved in decision-making of/for the collaboration, the position of the hospital physician working in a collaboration of hospitals, etc. The indirect aspects of governance are related to e.g. certain issues of external accountability[5] like the processing of data, the ombudsfunction, etc.

2.2 Different forms of actual collaboration: descriptive analysis

2.2.1 Formalised types of collaboration between hospitals that are authorised by the competent minister

We discuss the legal characteristics of the three legal forms of collaboration that currently exist: a hospital association, a hospital group and a merger.

2.2.1.1 An association of hospitals

Art. 67 of the coordinated Act of 10 July 2008 on hospitals and other healthcare institutions (hereinafter referred to as the 'Hospital Act') provides that special norms can be enacted for hospital groups, mergers and associations of hospitals.[4]

By Royal Decree of 25 April 1997[5], the King has clarified the concept of an association of hospitals and has set specific norms to which such an association must adhere to.

Definition and scope

The association is a sustainable collaboration, legally formalised, between two or more hospitals, focused on the joint exploitation of one or more care programmes, services, functions, hospital sections, medical services, medical-technical services or technical services and authorised by the minister empowered to authorise hospitals.[6]

Collaboration between acute, categorical or psychiatric hospitals

The association has the advantage of having a wide scope, allowing acute, categorical or psychiatric hospitals to form an association.[58] The Royal Decree provides that the rules concerning an association apply to all hospitals[7] and that the association can take place between two or more hospitals.

Collaboration agreements on one or more topics

The association is a relatively simple and more flexible form of collaboration between hospitals than hospital groups. It allows hospitals to collaborate in a limited way on a specific topic. The explanatory report to the King of the Royal Decree of 25 April 1997 explains the original purpose of an association. The report states that a hospital alone is not always able to obtain the level of activity required to operate in a profitable way. Therefore, it was useful to create the possibility of a functional and specific collaboration between hospitals.[8] The association consists of a joint exploitation by two or more hospitals that are the object of the association in order to ensure an optimal use of available resources, avoiding duplication in the provision of services and to ensure quality care and to optimise the operation and infrastructure of participating hospitals.[9] The association enables hospitals to organise a tailor-made collaboration in specific fields. The participating hospitals stipulate in an agreement the object of the association, in particular the type of care programmes, services, functions, hospital sections, medical services, medical-technical services or technical services[10]. There may be multiple purposes of an association between two or more hospitals and they may involve for example several care programmes or services. The association is a tool with a wide scope. According to Vandeurzen and Veys[58], a tailor-made joint exploitation allows rationalisation which leads to

4 Art. 67, al. 1er, 3° of the Hospital Act

5 Royal Decree of 25 April 1997 houdende nadere omschrijving van de associatie van ziekenhuizen en van de bijzondere normen waaraan deze moet voldoen, *B.S.* 18 June 1997 (hereinafter referred to as 'Royal Decree of 25 April 1997')

6 Art. 2, 1° of the Royal Decree of 25 April 1997

7 Art. 1 of the Royal Decree of 25 April 1997

8 Report to the King of the Royal Decree of 25 April 1997

9 Art. 4 of the Royal Decree of 25 April 1997

10 Art. 2, 2° of the Royal Decree of 25 April 1997

an increase in the quality of care and the optimisation of the operation or infrastructure.

Legal forms

The collaborating hospitals can choose the legal form of the association. Art. 67, paragraph 2, of the Hospital Act provides that the association can result in the creation of a legal entity. Such a new entity will have the aim of managing the association. In this case, only legal entities operating hospitals that are part of the association, and/or natural or legal entities appointed by the legal entity that operate the hospital, may be a member or a partner of the legal entity that operates this association.[11] The agreement of the association will regulate the legal form of the association and the composition of the management boards.[12] It is also possible to organise an association without creating a new legal entity. In that case hospitals will directly decide as stated in the agreement.

Conditions of authorisation

Art. 3 of the Royal Decree of 25 April 1997 provides that in order to be authorised as an association, it is necessary to comply with the authorisation norms as set by the King.

1. The creation of an association must ensure optimal use of available means and quality of care. The objective is to optimise the functioning and infrastructure of the participating hospitals.[13]
2. An association does not itself aim to make it easier to obtain authorisation. Participation in an association is not by itself sufficient to meet the authorisation norms and to obtain the authorisation of certain care programmes, services, etc. Art. 9 of the Royal Decree provides that, except for specific situations as set by the King, when it is needed for an hospital in order to be authorised or to obtain an authorisation for certain care programmes, medical services, hospital functions, etc., it is not sufficient to participate at an association that operates such programmes, services or function. In such cases each hospital will have to meet the required authorisation norms as defined by the legislation over the specific care programme, medical services, hospital function, etc. For example, Art. 17, 1° of the Royal Decree of 15 July 2004 concerning the authorisation standards for a cardiac pathology care programme states that it is necessary in order to be authorised as a 'care programme B in cardiac pathology' that the hospital has a function of intensive care. In this case, except if it is otherwise foreseen by the King, the hospital has to comply with the authorisation norms concerning the function of intensive care stated in the Royal Decree of 27 April 1998 and cannot only use the fact that the hospital is associated with another hospital which has an authorised function of intensive care.
3. The association must be authorised by the competent minister.
4. Participating hospitals must provide evidence concerning the need of the activity concerned in an attractive area[14] and/or a sufficient level of activity of the association. The Royal Decree provides that the King is responsible for determining what is meant by 'a need for association in a particular attractive area' and the 'activity level' for each type of activity on the basis of national and international standards.[15] To date, such precision has not been provided.
5. Each hospital that participates in an association must identify in its accounts the cost of the object of the association[16] and provide related statistical data concerning the object of the association that is located on its site. [17]

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11 Art. 67, paragraph 3 of the Hospital Act

12 Art. 16, 6° of the Royal Decree of 25 April 1997

13 Art. 4, of the Royal Decree of 25 April 1997

14 It is the population to be served by the object of the Association, art. 2, 3°, of the Royal Decree of 25 April 1997

15 Art. 5, §2, of the Royal Decree of 25 April 1997

16 Art. 7, §1er, of the Royal Decree of 25 April 1997

17 Art. 8, §1er, of the Royal Decree of 25 April 1997

If the object or a part of the object of the association lies outside the site of the participating hospitals, the association will then need to produce its own audit showing the cost of the association[18] and communicate the above mentioned statistical data.[19]

To be authorised as an association, it is furthermore necessary to fulfil a number of norms related to the structure of the association. These include having an association committee, a common medical committee ('Gemeenschappelijk Medisch Comité'/'Comité Médical Commun'), a general coordinator, a medical coordinator and a nurse coordinator.[59]

6. The administrators of the participating hospitals have to conclude an agreement, named 'the agreement of the association', which has to be approved by the competent minister.

The agreement must regulate at least:[20]

- the object of the association,
- the general objectives,
- the concept and the integration of the activity in the participating hospitals,
- the site where the object of the association is located,
- the evidence of need of the activity in the attractive area and / or a sufficient level of activity,
- the legal form that is chosen,
- the composition, tasks and functioning of the decision majorities of the association committee,
- the organisation and coordination of the administrative activities, the manner of appointing the general coordinator included,
- if applicable, the manner of structuring the medical activity, including the manner of appointing the medical coordinator,
- if applicable the way of structuring the nursing activity, including the way of appointing the nurse coordinator,
- the general organisation and coordination of the medical activities by the medical coordinator in consultation with the CMOs of the participating hospitals and, if applicable, the medical head of the department concerned,
- the general organisation and coordination of nurse activities by the nurse in consultation with the heads of the nursing departments of the participating hospitals and, in applicable, the head of nursing concerned,
- the means possessed by the association, in particular the provision of equipment and premises,
- any financial problems related to the association, including cost accounting and the proportion in which a potential operating deficit will be charged to the participating hospitals or relating to any bonus that will be paid,[21]
- matters relating to personnel,
- the rules in case of disputes among the parties, and
- the duration of the agreement and the terms of its possible termination.

18 Art. 7, §2, of the Royal Decree of 25 April 1997

19 Art. 8, §2, of the Royal Decree of 25 April 1997

20 Art. 16 of the Royal Decree of 25 April 1997

21 Art. 16, 12°, of the Royal Decree of 25 April 1997

It should also be noted that such an agreement needs the approval of the CEO of each participating hospital. The Hospital Act provides that this approval can only be given after obtaining an advice of the medical council.[22]

As a result of the Royal Decree of 10 June 2006,[23] there is no restriction on the possibility of an association across several participating hospitals, and therefore at several sites.

Art. 82 of the Hospital Act provides that it is possible, as part of an association of hospitals, to operate a hospital service from multiple sites, a hospital function, a hospital section, a care programme, a heavy medical device or medical or medico-technical service except if the King has otherwise provided.

If the service, function, section, care programme, heavy medical device or medical or medico-technical service is operated on different sites, it is required that each site:

- is authorised,
- meets all authorisation norms, and
- is considered as one service, one care programme, etc. as regards the implementation of the planning rules.

Nevertheless, art. 82, § 3 of the Hospital Act provides that the King may make exceptions, what has been done in some matters. This is for example the case with the radiotherapy service: not every hospital has to have authorisation from the government to be part of an association. It is therefore an exemption to art. 82, § 2, 3 ° of the Hospital Act, provided that other conditions are met.[24]

The King has also made an exception for the paediatric care programme[25] and the cardiac programme,[26] which by exemption to art. 82, §1, of the Hospital Act, can only be operated on one site. When a region ('gewest'/'région') has no tertiary paediatric care programme which meets on one site all authorisation requirements, two tertiary care programmes could be created in the region by means of an association of hospitals on several sites that jointly meet all the authorisation standards, by exemption to art. 82 §2 of the Hospital Act.[27]

Other exceptions can be found in regulations such as for Reproductive Medicine[28] or the Positron Emission Tomography (PET) scan.[29]

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22 Art. 137, 12° of the Hospital Act

23 Royal Decree of 10 June 2006 tot wijziging van het koninklijk besluit van 25 april 1997 houdende nadere omschrijving van de associatie van ziekenhuizen en van de bijzondere normen waaraan deze moet voldoen, *B.S.* 22 June 2006

24 Art. 5 of the Royal Decree of 5 April 1991 houdende vaststelling van de normen waaraan een dienst radiotherapie moet voldoen om te worden erkend als [...] medisch-technische dienst zoals bedoeld in artikel 44 van de wet op de ziekenhuizen, gecoördineerd op 7 augustus 1987, *B.S.* 17 April 1991modified by the Royal Decree of 1 August 2006 houdende vaststelling van de afwijkingen op de toepassing van artikel 76*secties* van de wet op de ziekenhuizen, gecoördineerd op 7 augustus 1987

25 Art. 3 of the Royal Decree of 2 April 2014 houdende vaststelling van de normen waaraan het zorgprogramma voor kinderen moet voldoen om erkend te worden, *B.S.* 18 April 2014 (hereinafter referred to as 'Royal Decree of 2 April 2014')

26 Art. 11, paragraph 1, of the Royal Decree of 25 April 1997

27 Art. 54, § 5, of the Royal Decree of 2 April 2014

28 Art. 28 of the Royal Decree of 15 February 1999 houdende vaststelling van de normen waaraan de zorgprogramma's 'reproductieve geneeskunde' moeten voldoen om erkend te worden, *B.S.* 25 March 1999

29 Art. 2 of the Royal Decree of 25 April 2014 houdende vaststelling van het maximum aantal PET-scanners en diensten nucleaire geneeskunde waarin een PET-scanner wordt opgesteld, dat uitgebaat mag worden, *B.S.* 8 Augustus 2014

Governance structures

ASSOCIATION COMMITTEE

Regarding the structure of the association, the Royal Decree of 25 April 1997 provides that each association must have an association committee.[30] This committee is composed of the administrators appointed by each participating hospital. The exact composition of the committee has to be described in the association agreement.[31] According to Vansweevelt and Dewallens, the fact that only administrators can be a member of the association committee does not allow *stricto sensu* CEOs to participate in the association committee.[60] However, CEOs can to our opinion always be invited by the committee as an expert even if they are not allowed to vote.

The association agreement must describe the tasks and functioning of the committee. The agreement must also mention the required majorities in order to take decisions.

COMMON MEDICAL COMMITTEE

The association must have a common medical committee composed of physicians appointed by the different medical councils of each participating hospital. Unlike the association committee, the composition and functioning of the common medical committee does not have to be mentioned in the association agreement, but in another written agreement concluded between the medical councils of the participating hospitals.[32] This agreement should be attached to the agreement of the association.

The objective of creating such a common medical committee is to reach a consensus on matters concerning the association, particularly in areas where an advice or an agreement of one or more medical councils is required.

It must be noted that the common medical committee is not competent to make a final decision. Ultimately, it is the medical council of the participating hospitals that must express their opinion. If a consensus is reached in the common medical committee, the mandated members will only have to defend this position in their own medical council.[33] According to the National Council for hospital facilities, members of the common medical committee have no autonomy from the medical committee of the participating hospitals.[34]

PERMANENT CONSULTATION COMMITTEE

The Royal Decree of 25 April 1997 also provides the possibility to create a permanent consultation committee (PCC) ('Permanent Overleg Comité'/ 'Comité Permanent de Consultation').[35] This decision is made upon a joint proposal of the participating hospitals' boards of administrators. This committee is composed of the members of the association committee and the members of the common medical committee.[36] This PCC decides on matters related to the association for which the advice or the agreement of one or more medical councils is required under the Hospital Act.

The purpose of the PCC is to facilitate the decision by attempting to find a consensus. If such a consensus is reached, the members mandated by the administrators and medical councils of the participating hospitals will be required to defend the consensus.

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30 Art. 10 of the Royal Decree of 25 April 1997

31 Art. 16, 7° of the Royal Decree of 25 April 1997

32 Art. 11, §2, of the Royal Decree of 25 April 1997

33 Art. 11, §4, of the Royal Decree of 25 April 1997

34 Nationale Raad voor Ziekenhuisvoorzieningen, *Maatregelen om samenwerking tussen ziekenhuizen te bevorderen*, 14 June 2012, Brussels, 7

35 Art. 12 of the Royal Decree of 25 April 1997

36 Art. 12, §2, of the Royal Decree of 25 April 1997

General coordinator

Each association must appoint a general coordinator who is responsible for organising and coordinating the administrative activities in collaboration with the participating hospitals' CEOs.[37] The method of appointment of the coordinator and the collaboration arrangements with the CEOs must be included in the association agreement.

The association agreement will also cover the organisation and coordination of the administrative activity of the association.

Medical coordinator and nurse coordinator

In each association, the medical and nursing activities should be structured and organised in order to become an integral part of the activity of the participating hospitals. The modality of appointing the medical coordinator[38] and the nurse coordinator[39] must be included in the association agreement. Each coordinator is responsible for organising and coordinating its activities.

The objective is to organise a co-operation with medical and nursing managers of each participating hospital. The medical coordinator will thus cooperate with the CMO of the participating hospitals and, if applicable, with the medical head of the department concerned. The association agreement must outline such possibilities for collaboration.

Association of catchment area

Specialise or concentrate care a minimum number of hospital sites in the concerned catchment area

The concept of 'association of catchment area' was introduced by the Royal Decree of 10 June 2006 to adjust the hospital supply to the actual needs of the target population within a particular catchment area. The objective is to specialise or focus hospital functions, medical services, medico-technical services or care programmes operated by the association of catchment area at a minimal number of sites within a maximum period of ten years from the approval of the convention of the association.[40]

Such an arrangement represents an association as mentioned in art. 2, 1° of the Royal Decree of 25 April 1997 between hospitals located within a certain territory, described as a 'catchment area'. The joint exploitation of the object of the association aims therefore to adjust the supply of hospital care to the actual need of the target population within the concerned catchment area, through specialisation or concentration of care on a minimum number of sites.[60]

A catchment area has at least 150 000 inhabitants

To be authorised as an association of a catchment area, the association must fulfil the authorisation norms for associations as well as additional norms. This includes in particular the territorial criterion which must be the object of the association. Indeed, a territory is determined as an administrative district or jointly adjacent administrative districts having at least[41] 150 000 inhabitants.[42] Due to this geographical criterion, the rules require that if a hospital has multiple sites, only the activities organised on sites that are located in the territory of the catchment area will be integrated in the association of the catchment area.[43] In this regard, it should be noted

37 Art. 13 of the Royal Decree of 25 April 1997

38 Art. 14 of the Royal Decree of 25 April 1997

39 Art. 15 of the Royal Decree of 25 April 1997

40 Art. 16*bis* of the Royal Decree of 25 April 1997

41 Only contiguous districts from a geographic perspective can join in a single catchment area (art. 16ter, §1, paragraph 2, of the Royal Decree of 25 April 1997)

42 Art. 16ter, §1, of the Royal Decree of 25 April 1997

43 Art. 16*ter*, §2, of the Royal Decree of 25 April 1997

that the agreement of the association of the catchment area must specify the territory of the association and the measures taken to ensure that the population of the region of care concerned have access to specialised healthcare according to their needs.[44]

Not compulsory for all hospitals of a territory to participate

It is not necessary that all hospitals in the specified territory participate in the association of a catchment area. However, if it is the case, it will be necessary to indicate, when submitting the agreement for authorisation, the reasons why the association does not include all the hospitals in the territory.[45]

If the association is operated by a legal entity, the association will then need to have its own accounts and will have to communicate the statistical data related to the association.[46]

Following a parliamentary question on 13 February 2009[47], the Minister of Health answered that, concerning financial mechanisms for associations of a catchment area, the Royal Decree of 25 April 2002 on the fixing and liquidation of the Budget of Financial Means (BFM) contains specific measures for hospitals, particularly in the context of association of a catchment area, which would see its budget decrease as a result of an internal restructuring or a collaboration agreement with one or more hospitals. So there are financial incentives to participate in such associations. However, this form of collaboration has not had much success. According to Vansweevelt and Dewallens (2014) this form of collaboration was used to offer a solution for specific problems in Walloon hospitals and was not used in Flanders.[48]

2.2.1.2 A group of hospitals

Definition and scope

A hospital group is a legally structured and authorised sustainable partnership among hospitals whereby appointments are made regarding the allocation of tasks and the complementarity for the provision of services, disciplines or equipment, in order to meet the needs of the population and to improve the quality of healthcare. Art. 8, second paragraph of the Royal Decree of 30 January 1989 explains that the group may not lead to mono-specialist hospital sites, with the exception of sub-acute geriatric- and Sp-services.[49]

The concept of the hospital group allows hospitals to enter into forms of collaboration that are focused on allocation of tasks. The goal of a 'group' is to support complementarity of hospitals.[50] In a group agreements are made regarding the allocation of tasks and adjustments to healthcare provision that do not imply a common exploitation.[61]

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44 Art. 16*sexies* of the Royal Decree of 25 April 1997

45 Art. 16*septies*, a), of the Royal Decree of 25 April 1997

46 Art. 16*quater* and 16*quinquies* of the Royal Decree of 25 April 1997

47 Question n° 4-3006 from Anne-Marie Lizin of 13 February 2009 (F), *Q.R.,* Senate, 2008-2009, 13 February 2009

48 F. Dewallens, 'De gezondheidszorgvoorzieningen' in T. Vansweevelt en F. Dewallens (eds.), *Handboek Gezondheidsrecht Volume I: Zorgverleners: statuut en aansprakelijkheid*, Antwerpen, Intersentia, 2014, 206.

49 Art. 8 Royal Decree 30 January 1989 houdende vaststelling van aanvullende normen voor de erkenning van ziekenhuizen en ziekenhuisdiensten alsmede tot nadere omschrijving van de ziekenhuisgroeperingen en van de bijzondere normen waaraan deze moeten voldoen, *BS* 21 February 1989.

50 Report to the King of the Royal Decree 25 April1997 houdende nadere omschrijving van de associatie van ziekenhuizen en van de bijzondere normen waaraan deze moet voldoen, *BS* 18 June 1997.

Collaboration between acute, categorical or psychiatric hospitals

Psychiatric hospitals and isolated Sp-services (specialised services for treatment and revalidation), alone or together with H-services (services for ordinary hospitalisation) or T-services (neuropsychiatry services for treatment of adult patients) do not fall under the scope of the royal decree.[51] Before 1997 the concept of 'a group' was often used as an opportunity for hospitals that did not comply with the minimum requirements of being a hospital (i.e. a minimum of 150 beds, having a C/D-service, another basic service, six basic functions and 24/7 medical on duty). This is no longer possible[52] since each member of the group must comply with the norms regarding the minimum concept of a hospital (see below).

Legal forms

It is possible to create a new legal entity for a group. However, a group can also be based on a contract between hospitals. In such cases it is not necessary to create a different legal entity.

Conditions of authorisation

A group must comply with several conditions in order to be authorised:[53]

1. The hospitals in a group cannot be located more than 25 km away from each other.
2. The hospitals in a group have to comply separately with certain norms regarding structure. The basic services must comply with the minimal bed capacity for each site. With the exception of isolated geriatric services (character G), each hospital must have:
   a. A minimum of 150 beds, not taking into account the beds in specialised services for treatment and revalidation (character Sp), intended for patients with psychogeriatric and chronic diseases and those intended for patients with an incurable disease in a terminal phase and in need of palliative care, whereby each theoretical place is considered as one bed. In case of a group or merger with an isolated G-service, the beds of this isolated service are not taken into account for determining the minimum number of beds.[54]
      - However, it is possible for a hospital to have a minimum of only 120 beds not taking into account the beds of specialised services for treatment and revalidation (character Sp), intended for patients with psychogeriatric and chronic diseases and those intended for patients with an incurable disease in a terminal phase and in need of palliative care if the hospital is located in a town of 25 000 inhabitants or less and the nearest hospital (with the exception of psychiatric hospitals and isolated Sp services, alone or together with H-services or T-services is located at least 15 km away).[55]

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51 Art. 2 Royal Decree 30 January1989 houdende vaststelling van aanvullende normen voor de erkenning van ziekenhuizen en ziekenhuisdiensten alsmede tot nadere omschrijving van de ziekenhuisgroeperingen en van de bijzondere normen waaraan deze moeten voldoen, *BS* 21 February 1989.

52 According to the amendment decree 6 May 1997 (*BS* 18 June 1997), annulled by the Council of state (Judgement nr. 70502 of 23 December 1997, *BS* 26 February1998) and confirmed by the Decree of 21 January 1998 (*BS* 7 March 1998); W. Vercruyssen, *Basisbeginselen inzake ziekenhuiswetgeving*, 2015-16, 205.

53 Art. 9 Royal Decree 30 January 1989 houdende vaststelling van aanvullende normen voor de erkenning van ziekenhuizen en ziekenhuisdiensten alsmede tot nadere omschrijving van de ziekenhuisgroeperingen en van de bijzondere normen waaraan deze moeten voldoen, *BS* 21 February 1989.

54 Art. 2, §1, 1° Royal Decree 30 January 1989 houdende vaststelling van aanvullende normen voor de erkenning van ziekenhuizen en ziekenhuisdiensten alsmede tot nadere omschrijving van de ziekenhuisgroeperingen en van de bijzondere normen waaraan deze moeten voldoen, *BS* 21 February 1989.

55 Art. 3, §1 Royal Decree 30 January 1989 houdende vaststelling van aanvullende normen voor de erkenning van ziekenhuizen en ziekenhuisdiensten alsmede tot nadere omschrijving van de ziekenhuisgroeperingen en van de bijzondere normen waaraan deze moeten voldoen, *BS* 21 February 1989.

- Contrary to the previous rule, a hospital may have less than 120 beds, if the nearest hospital of the same community is located at a distance of at least 50 km away (e.g. Sint Augustinus hospital at Veurne and Centre de Santé des Fagnes at Chimay).[56]

b. The following types of hospital services:
   - a service where surgical activity as well as activity in the field of internal medical science is carried out (C/D service);
   - a geriatric service (character G) or a service for neuropsychiatric observation and treatment (character A) or a maternity department (character M) or a service for paediatrics (character E).[57]

c. The following functions:
   - anaesthesiology;
   - radiology;
     - basic activities of clinical biology. Regarding the activities that go beyond the basic activity, it is sufficient that the hospital can invoke an entire extended function through a collaboration agreement;
     - revalidation;
     - basic activities of the hospital pharmacy. Regarding the activities that go beyond the basic activity, it is sufficient that the hospital can invoke an entire extended function through a collaboration agreement;
     - palliative care.[58]

d. The following care programmes:
   - A care programme for basic oncology care if the hospital does not have an authorised care programme for oncology.[59]

e. The permanent presence of a physician:
   - Each hospital with a maternity department (character M) must have a function for neonatal care (N*-function).[60]
   - Exceptions to points 2.a., 2.b. and 2.c. are allowed by the competent minister only for hospitals that have both surgical

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56 Art. 3, §2 Royal Decree 30 January 1989 houdende vaststelling van aanvullende normen voor de erkenning van ziekenhuizen en ziekenhuisdiensten alsmede tot nadere omschrijving van de ziekenhuisgroeperingen en van de bijzondere normen waaraan deze moeten voldoen, *BS* 21 February 1989.

57 Art. 2, §1, 2° Royal Decree 30 January 1989 houdende vaststelling van aanvullende normen voor de erkenning van ziekenhuizen en ziekenhuisdiensten alsmede tot nadere omschrijving van de ziekenhuisgroeperingen en van de bijzondere normen waaraan deze moeten voldoen, *BS* 21 February 1989.

58 Art. 2, §1, 3° Royal Decree 30 January 1989 houdende vaststelling van aanvullende normen voor de erkenning van ziekenhuizen en ziekenhuisdiensten alsmede tot nadere omschrijving van de ziekenhuisgroeperingen en van de bijzondere normen waaraan deze moeten voldoen, *BS* 21 February 1989.

59 Art. 2, §1, 4° Royal Decree 30 January 1989 houdende vaststelling van aanvullende normen voor de erkenning van ziekenhuizen en ziekenhuisdiensten alsmede tot nadere omschrijving van de ziekenhuisgroeperingen en van de bijzondere normen waaraan deze moeten voldoen, *BS* 21 February 1989.

60 Art. 2, §1, 5° Royal Decree 30 January 1989 houdende vaststelling van aanvullende normen voor de erkenning van ziekenhuizen en ziekenhuisdiensten alsmede tot nadere omschrijving van de ziekenhuisgroeperingen en van de bijzondere normen waaraan deze moeten voldoen, *BS* 21 February 1989.

and medical activities solely for children or for the treatment of tumours.[61]

3. Homogeneity of group services must be guaranteed within two years after signing the group contract. If a hospital of the group has one or more types of services that have a bed capacity lower than 2/3 of the minimum required bed capacity, the beds of that type of service must be grouped at the same site. Moreover, the above mentioned basic services[62] on each site must always comply with the minimal bed capacity for each service.[63]
4. In order to ensure good collaboration the hospitals must create a common medical committee and a coordination committee. The common medical committee is composed of the representatives of the different medical councils. A CMO-coordinator, a coordinator of the nursing department and a general coordinator are to be appointed.
5. The hospitals of the group must realise an efficient allocation of tasks to ultimately ensure that they are complementary. To achieve this aim a plan is needed. The plan must be sent to the competent minister.
6. Each decision for investment, creation of a new service or a new medical technical service by the hospitals of the group must be approved by the coordination committee. Without such approval no authorisation will be given.

The administrators of the hospitals of the group should enter into a group agreement.[64] This agreement must be approved by the competent minister.

The group contract must deal at least with the following items:

- The aim sought;
- The legal form of the collaboration agreement;
- The allocation of tasks concerning the provision of services and specialisms including the equipment;
- The rationalisation that may follow from the allocation of tasks;
- The creation, composition, the tasks and the functioning of the coordination committee;
- The decisions of the board that may require the approval of the coordination committee;
- The admissions and dismissal policy, the coordination of medical policy, the functioning of the medical staff and the organisation of the on duty medical personnel;
- The organisation of common activities, if applicable;
- The means that will be used for common activities as well as their administration and use;

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61 Art. 2, §1bis Royal Decree 30 January 1989 houdende vaststelling van aanvullende normen voor de erkenning van ziekenhuizen en ziekenhuisdiensten alsmede tot nadere omschrijving van de ziekenhuisgroeperingen en van de bijzondere normen waaraan deze moeten voldoen, *BS* 21 February 1989.

62 *i.e.* a service where surgical activity as activity in the field of internal medical science is carried out (C/D service) and a geriatric service (character G) or a service for neuropsychiatric observation and treatment (character A) or a maternity department (character M) or a service for pediatrics (character E).

63 Art. 14 Royal Decree 30 January 1989 houdende vaststelling van aanvullende normen voor de erkenning van ziekenhuizen en ziekenhuisdiensten alsmede tot nadere omschrijving van de ziekenhuisgroeperingen en van de bijzondere normen waaraan deze moeten voldoen, *BS* 21 February 1989.

64 Art. 12, §1 Royal Decree 30 January 1989 houdende vaststelling van aanvullende normen voor de erkenning van ziekenhuizen en ziekenhuisdiensten alsmede tot nadere omschrijving van de ziekenhuisgroeperingen en van de bijzondere normen waaraan deze moeten voldoen, *BS* 21 February 1989.

- Problems in terms of staffing linked to common activities as well as the transfer of the staff from one entity to another if applicable;
- The rates and the modalities of the institutions in the group;
- Financial agreements;
- Insurance;
- The regulation of disputes among parties;
- The duration of the agreement and the means of termination, including the trial period, if applicable;
- The nomination of the CMO-coordinator, the coordinator of the nursing department, the general coordinator and the composition of the common medical committee;
- The way to achieve efficient allocation of tasks and complementarity. This is written in a plan.[65]

Parties do enter into an agreement for at least ten years, unless the group leads to a merger before the end of that period.[66] The trial period must be at least one year. The conditions for terminating the agreement must be at least two years before the end of the agreement.

In conformity with art. 137, 12° of the Hospital Act of 10 July 2008, the board must ask the medical council to give its advice on the group agreement.[67]

The group agreement can be considered as an agreement with a third party that may have an effect on the medical activity in the hospital.

Governance structures

Medical council

The common medical committee of the hospital group is composed of representatives of different medical councils.

A CMO-coordinator, a coordinator for the nursing department and a general coordinator are appointed. These coordinators should attend the meetings of the coordination committee.

Each hospital group has a coordination committee.[68] The coordination committee is composed of representatives of the administrators of different hospitals of the group. The coordination committee complies with the requirements described in the group agreement.

Coordination committee

The coordination committee has at least the following tasks:

- It supervises the execution of the group contract;
- It should aim, through an allocation of tasks, to achieve the highest possible level of complementarity and to ameliorate the quality of healthcare;

65 Art. 12, §2 Royal Decree 30 January 1989 houdende vaststelling van aanvullende normen voor de erkenning van ziekenhuizen en ziekenhuisdiensten alsmede tot nadere omschrijving van de ziekenhuisgroeperingen en van de bijzondere normen waaraan deze moeten voldoen, *BS* 21 February 1989.

66 Art. 12, §3 Royal Decree 30 January 1989 houdende vaststelling van aanvullende normen voor de erkenning van ziekenhuizen en ziekenhuisdiensten alsmede tot nadere omschrijving van de ziekenhuisgroeperingen en van de bijzondere normen waaraan deze moeten voldoen, *BS* 21 February 1989.

67 Art. 137, 12° Hospital Act 10 July 2008 states: '*In the context of the purpose formulated in art. 136, the medical council provides advice to the administrator about the following matters: agreements with third parties that have an impact on the medical activity in the hospital.*' art. 138, §1 Hospital Act 10 July 2008 states: '*In all the matters enumerated in art. 137, the administrator is obliged to obtain the advice of the medical council. […]*'.

68 Art. 13, §1 Royal Decree 30 January 1989 houdende vaststelling van aanvullende normen voor de erkenning van ziekenhuizen en ziekenhuisdiensten alsmede tot nadere omschrijving van de ziekenhuisgroeperingen en van de bijzondere normen waaraan deze moeten voldoen, *BS* 21 February 1989.

- It should be consulted on all decisions regarding new buildings, extensions, rebuilding of hospitals, changes relating to the type of beds or of the services, taking into account the complementarity and the quality of healthcare, and;
- It should meet several times a year and draft a yearly report. This report must be communicated to the minister having competence for the authorisation of hospitals.[69]

Each decision regarding investment, the creation of new services or of new medico-technical services by the hospitals of the group, must be approved by the coordination committee. Without this decision no authorisation can be given.

2.2.1.3 Merger of hospitals

Definition and scope

A merger of hospitals is the bringing together of two or more separate authorised hospitals (that may or may not be controlled by different boards of administrators) that are located at different sites, under one administrator with one single authorisation.[70] A merger is the most far-reaching form of collaboration.[62]

Collaboration between acute, categorical or psychiatric hospitals

Psychiatric hospitals and isolated Sp-services (specialised services for treatment and revalidation), alone or together with H-services (services for ordinary hospitalisation) or T-services (services for neuropsychiatry for treatment of adult patients) do not fall under the scope of the royal decree of 31 May 1989 concerning mergers and the specific standards to which they must comply.[71] They may merge but not on the basis of the articles of the royal decree of 31 May 1989.

Given that binding guidance concerning the conditions of such a merger does not exist, mergers with psychiatric and specialist hospitals may lead to problems, for example concerning the authorisation.[63]

Legal forms

From a legal viewpoint several ways to merge hospitals exist. A legal entity may disappear, create another legal entity or absorb an existing legal entity.[59]

Conditions of authorisation:

Concerning the homogeneity of services art. 82 of the Hospital Act prevails that a hospital merger must always comply with several conditions in order to be authorised.[72]

1. The hospitals may not be located more than 35 km away from each other. This rule is however not absolute. Two exceptions are possible. Hospitals can be located more than 35 km from each other if there are no two acute care hospitals within 35 km. Moreover, hospitals can be more than 35 km from each other, if they belong to one group (since

69 Art. 13, §2 Royal Decree 30 January 1989 houdende vaststelling van aanvullende normen voor de erkenning van ziekenhuizen en ziekenhuisdiensten alsmede tot nadere omschrijving van de ziekenhuisgroeperingen en van de bijzondere normen waaraan deze moeten voldoen, *BS* 21 February 1989.

70 Art. 2 Royal Decree 31 May 1989 houdende nadere omschrijving van de fusie van ziekenhuizen en de bijzondere normen waaraan deze moeten voldoen, *BS* 5 July 1989.

71 Art. 1 Royal Decree 31 May 1989 houdende nadere omschrijving van de fusie van ziekenhuizen en de bijzondere normen waaraan deze moeten voldoen, *BS* 5 July 1989.

72 Art. 3 Royal Decree 31 May 1989 houdende nadere omschrijving van de fusie van ziekenhuizen en de bijzondere normen waaraan deze moeten voldoen, *BS* 5 July 1989.

1 December 1996). However, to be authorised as a group, the hospitals may not be located more than 25 km away from each other.[73] From the reading of the abovementioned exception concerning the distance of mergers and the abovementioned rule concerning the distance of groups, it can be concluded that this second exception lacks any logical basis.

2. Homogeneity of the services must be realised within the merger. If a merged hospital has a hospital service dispersed over several sites, the beds of the service must be grouped on the same site if the bed capacity on one of the sites is lower than 2/3 of the required minimum capacity. However, the minimum capacity of 30 beds on each site suffices for a C/D service. The hospitals possess a transit period of two years after the signing of the merger agreement to comply with this requirement.

3. If the merged hospital has several similar hospital services spread over different sites, each service must separately comply with the existing authorisation norms. This applies notwithstanding the rules regarding homogeneity of services and minimum bed capacity. Hospitals involved in the merger must at least comply with the minimum concept.[64]

There is at present no maximum limit of authorised beds of merged hospitals.[74] The National Council for Hospitals Facilities was of the opinion that the maximum limit of beds was no longer required.[75] The required reduction of the amount of beds in the past in case of a merger has been abolished since it was an obstacle for collaboration.[76,77]

The hospitals involved in the merger must jointly comply with the norms provided in the royal decree of 30 January 1989.[78]

With the exception of the isolated geriatric services (character G) each (merged) hospital must have:

1. 150 beds, not taking into account the beds in specialised services for treatment and revalidation (character Sp) intended for patients with psychogeriatric and chronic diseases and for patients with an incurable disease in a terminal phase and in need of palliative care whereby a theoretical place is considered as one bed. In case of a group of merger within an isolated G- service, the beds of this isolated service are not taken into account for determining the minimum amount of beds.
2. The following types of hospitals services:
   - a service where surgical activity as well as activity in the field of internal medical science is carried out (C/D service);
   - a geriatric service (character G) or a service for neuropsychiatric observation and treatment (character A) or a maternity department (character M) or a service for paediatrics (character E);

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73 Art. 9, 1° Royal Decree 30 January 1989 houdende vaststelling van aanvullende normen voor de erkenning van ziekenhuizen en ziekenhuisdiensten alsmede tot nadere omschrijving van de ziekenhuisgroeperingen en van de bijzondere normen waaraan deze moeten voldoen, *BS* 21 February 1989.

74 This maximum limit was removed by the Royal Decree 17 September 2005 to amendment of the Royal Decree 31 May 1989 houdende nadere omschrijving van de fusie van ziekenhuizen en de bijzondere normen waaraan deze moeten voldoen, *BS* 18 October 2005.

75 Nationale Raad voor Ziekenhuisvoorzieningen, *Eerste advies met betrekking tot de fusies* 2005, Brussels 10 March 2005, http://www.health.belgium.be/eportal/Healthcare/Consultativebodies/Nationalcouncilforhospitalfaci/714739#.VsRQL7c5A_w.

76 Royal Decree 17 September 2005, *BS* 18 October 2005; Nationale Raad voor Ziekenhuisvoorzieningen, *Eerste advies met betrekking tot de fusies* 2005, Brussels 10 March 2005, http://www.health.belgium.be/eportal/Healthcare/Consultativebodies/Nationalcouncilforhospitalfaci/714739#.VsRQL7c5A_w.; S. Callens, M. Leire, L. Boddez, L. Van Leuven and J. Peers, 'Het aanbod in de gezondheidszorg', in S. Callens and J. Peers (eds.), *Organisatie van de* gezondheidszorg, Antwerp, Intersentia, 2015, 164.

77 For the financial aspect regarding this reduction, see Durant, G, *Le financement des hôpitaux en Belgique*, Waterloo, Kluwer, 2010, 75

78 Royal Decree 30 January 1989 houdende vaststelling van aanvullende normen voor de erkenning van ziekenhuizen en ziekenhuisdiensten alsmede tot nadere omschrijving van de ziekenhuisgroeperingen en van de bijzondere normen waaraan deze moeten voldoen, *BS* 21 February 1989.

3. The following functions:
   - o anaesthesiology;
   - o radiology;
   - o basic activities of clinical biology. Regarding the activities that go beyond the basic activity, it is sufficient that the hospital can invoke an entire extended function through a collaboration agreement;
   - o revalidation;
   - o basic activities of the hospital pharmacy. Regarding the activities that go beyond the basic activity, it is sufficient that the hospital can invoke an entire extended function through a collaboration agreement;
   - o palliative care;[79]
4. The following care programmes:

   A care programme for basic oncology care if the hospital does not have an authorised care programme for oncology;[80]
5. The permanent presence of a physician.

   Each hospital with a maternity department (character M) must have a neonatal care capability (N*-function).

A merger plan must be drafted by the administrators of the hospitals involved in the merger.[81] The drafting of such a plan is obligatory. The merger plan must at least regulate the following items:

- o General aims of the merger, including:
  - The improvement of quality of care;
  - The rationalisation of the functioning and of the infrastructure of the hospital; The unity of the concept, the management and the organisation of the hospital.
- o The legal form of the merger;
- o The financial problems related to the merger;
- o A plan of realisation regarding:
  - The rationalisation associated with the merger;
  - The intermediate phases to achieve the aims of the merger, including the division of tasks between the different hospitals involved in the merger, concerning the offer of services and the specialisms, including the equipment;
- o The staffing problems associated with the merger;
- o The way in which the conditions concerning the homogeneity of the services within the merger will be complied with and the principle that (if the merged hospital has several similar hospital services spread over different sites) each service must separately comply with the existing authorisation norms.

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79 Art. 2, §1, 3° Royal Decree 30 January 1989 houdende vaststelling van aanvullende normen voor de erkenning van ziekenhuizen en ziekenhuisdiensten alsmede tot nadere omschrijving van de ziekenhuisgroeperingen en van de bijzondere normen waaraan deze moeten voldoen, *BS* 21 February 1989.

80 Art. 2, §1, 4° Royal Decree 30 January 1989 houdende vaststelling van aanvullende normen voor de erkenning van ziekenhuizen en ziekenhuisdiensten alsmede tot nadere omschrijving van de ziekenhuisgroeperingen en van de bijzondere normen waaraan deze moeten voldoen, *BS* 21 February 1989.

81 Art. 6 Royal Decree 31 May 1989 houdende nadere omschrijving van de fusie van ziekenhuizen en de bijzondere normen waaraan deze moeten voldoen, *BS* 5 July1989.

The merger plan must contain a minimum content which is determined by the Hospital Act. This content is clearly related to the medical activity in the hospitals. Strictly speaking, the hospitals of a merger are still third parties in relation to each other, when they are drafting the merger plan.[65] At that moment, the merger has not been authorised.

The board of the hospitals must also ask their medical council to give an advice concerning the merger plan, since it concerns an agreement with a third party which has an impact on the medical activities at the hospital.[82] It concerns an advice of the medical council as referred to in art. 137, 12° of the Hospital Act of 10 July 2008. This advice does not bind the administrators of the hospitals, unless otherwise provided in the general regulation document of the hospital containing the rights and obligations of the administrators and the hospital physicians.

Governance structures

The merger plan must be drawn up in such a way that there is one administrator, one CEO, one CMO, one head of the nursing department and one medical council for all the hospitals involved in the merger.[83] The merger plan must be submitted to the minister responsible for the authorisation of hospitals. A copy of the plan must also be submitted to the Federal Minister of Health.[84]

2.2.2 Types of collaboration between hospitals and other care providers that are authorised by the competent minister

2.2.2.1 Collaboration on the basis of Art. 11 of the Hospital Act

Increasingly, collaboration between different institutions has become necessary to make healthcare safer, more efficient and more affordable. Hospitals create a chain with other healthcare providers. In this way healthcare professionals that are few in number can be used in a broader collaboration.[59] Various healthcare stakeholders think that hospitals should better position themselves in collaboration initiatives.[66]

The collaboration between institutions and the development of collaborations was emphasised in the Flemish and in the federal Government Declaration of 2014. The objective of the politicians was to start from the existing structures.[59] KCE emphasizes in its report of 2014[37] the importance of collaborations, which do not have to be limited to hospitals only. According to the KCE strategic care programmes by geographical area, based on the needs of the population and the financial resources allocated by public authorities, should be important factors in the scope in which healthcare providers can deploy their offer. The ultimate goal is to achieve a reduction of the number of acute beds, the centralisation of highly specialised, complex or expensive care, and care organised in collaborations per care zone, over all hospitals and other care providers.[59]

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82 Art. 137, 12° Hospital Act 10 July 2008 states: 'In the context of the purpose formulated in art. 136, the medical council provides advice to the administrator about the following matters: agreements with third parties that have an impact on the medical activity in the hospital.'; art. 138, §1 Hospital Act 10 July 2008 states: 'In all the matters enumerated in Art. 137, the administrator is obliged to obtain the advice of the medical council. […]'.

83 Art. 6, §3 Royal Decree 31 May 1989 houdende nadere omschrijving van de fusie van ziekenhuizen en de bijzondere normen waaraan deze moeten voldoen, *BS* 5 July1989.

84 Art. 6, §4 Royal Decree 31 May 1989 houdende nadere omschrijving van de fusie van ziekenhuizen en de bijzondere normen waaraan deze moeten voldoen, *BS* 5 July 1989.

Definition and scope

The collaboration aims to provide for patients care circuits associated with the main focus of the collaboration in the context of a legally formalised collaboration agreement. Care circuits are generally offered in a specific geographic zone.

Collaboration between acute, categorical or psychiatric hospitals

Clinical collaborations emphasise the curative aspect of care and acknowledge the need to evolve towards a reallocation of tasks and a differentiated practice between hospitals. Task agreements are made between general hospitals providing basic care and/or specialised care, revalidation centres and psychiatric hospitals, in order to provide a complementary care offer in a collaboration. Within the clinical collaboration hospitals can offer a broad range of acute hospital services (C, D, E, M etc.), or (partially) opt for the expansion of niche services. It is possible that a hospital, for certain complex, expensive or rare pathologies may participate in multiple collaborations. The ultimate goal is to have a good spread of hospitals, hospital services and medical-technical equipment. This requires not only regional hospitals to cooperate with other hospitals in the same region, but also supra-regional collaboration for rare and/or complex treatments.[59, 67]

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These are healthcare professionals, institutions and services, 1) which do not fall under the competence of the authorities referred to in articles 128, 130 or 135 of the Constitution and 2) which jointly offer one or more care circuits as part of an agreement of legal collaboration within and outside institutions for a target group of patients in a geographic area to be defined and chosen by them.

The care circuit is defined as all care programmes and other healthcare facilities, which do not fall under the competence of the authorities referred in articles 128, 130 or 135 of the Constitution and are organised through a collaboration of healthcare facilities and that can be followed by the target group or target subgroup.

To understand the concept of circuits of care, it is necessary to refer to the concept of care programmes. Art. 12 of the Hospital Act defines the concept of care programme. This is actually a Royal Decree of 15 February 1999[85] which sets the list of care programmes referred to in art. 12 of the Hospital Act. The Royal Decree of 15 February 1999 issued under art. 12 of the Hospital Act considers the following care programmes: reproductive medicine, cardiac pathology, oncology, paediatric care programme, geriatric care programmes and care for stroke patients. [86] The King stipulates for each care programme the target group, the type and content of care, the minimum level of activity, the infrastructure needed, the expertise and medical and non-medical staff required, the quality standards and standards relating to the quality monitoring, the micro-economic criteria and the criteria for geographic accessibility.[87]

In Belgium, the concept of collaborations is built around these care programmes. However the collaboration is not necessarily built around a care programme as for example is the case for the collaborations for rare diseases which are built around a specific disease (function or reference centre). There are already clinical collaborations that are regulated by different Royal Decrees on the basis of art. 11 of the Hospital Act. This is

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85 Royal Decree of 15 February 1999 tot vaststelling van de lijst van zorgprogramma's zoals bedoeld in artikel 12 van de gecoördineerde wet van 10 juli 2008 op de ziekenhuizen en andere verzorgingsinrichtingen en tot aanduiding van de artikelen van de gecoördineerde wet van 10 juli 2008 op de ziekenhuizen en andere verzorgingsinrichtingen die op hen van toepassing zijn, *B.S.* 25 March 1999 (hereinafter referred to as « Royal Decree of 15 February 1999 »)

86 Art. 1er of the Royal Decree of 15 February 1999

87 Art. 12, §2, of the Hospital Act

the case for collaborations for cardiac pathology[88], paediatric care[89], care for stroke patients [90] and rare diseases.[91] There are therefore currently four types of collaborations in Belgium.

Conditions of authorisation

The conditions of authorisation for the care covered by the collaboration are specific for each collaboration. It is therefore important to refer to the specific rules of each to know the conditions of authorisation.

With the exception of the 'rare diseases' collaboration, it must be noted that the conditions of authorisation require the inclusion of hospitals in the collaboration that have the care programme related to the activity concerned by the collaboration. Therefore, in addition to the authorisation requirements mentioned in the regulation of collaborations, it is also important to refer to the regulation of each healthcare programme.

A care provider can also participate in multiple collaborations within the area covered by the collaboration. In any case, the care provider must have the opportunity to participate in the collaboration that exists within its area if the care provider meets the conditions.

Conditions of authorisation for the 'cardiac pathology' collaboration

The cardiac pathology collaboration aims to provide care circuits, in a specific area, for patients with heart disease, as part of an agreement of intra- and extramural legal collaboration.

The cardiac pathology collaboration can offer different care circuits, but must in any case offer at least a circuit of care for patients with acute myocardial infarction with ST-elevation (STEMI heart attack). This care circuit must meet the norms laid down by the Royal Decree to ensure that in case of an emergency or if a patient is in a hospital only with limited care programme cardiac pathology, the patient can be quickly referred to a hospital with a more completed care programme cardiac pathology and accompanied to the cardiac catheterization laboratory.[92]

The collaboration must include hospitals with care programmes cardiac pathology A, B ,P, E, T and C or partial programmes B1 and B2.[93] The collaboration must furthermore also include hospitals with a function medical emergency care unit ('MUG'/'SMUR') and circles of general practitioners (GPs).[94] The care providers must be located in the area covered by the collaboration. If the area covered by the collaboration does not provide the services mentioned above, the collaboration will have to conclude a collaboration agreement with one or more of these care providers.

Each care provider located in the area covered by the collaboration should have the opportunity to participate in the collaboration. A care provider can also be part of multiple collaborations.

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88 Royal Decree of 12 June 2012 tot vaststelling van de erkenningsnormen voor het netwerk 'cardiale pathologie', *BS* 15 June 2012 (hereinafter referred as 'Royal Decree of 12 June 2012')

89 Royal Decree of 2 April 2014 houdende vaststelling van de erkenningsnormen voor het netwerk 'pediatrie', *BS* 18 April 2014 (hereinafter referred as 'Royal Decree of 2 April 2014')

90 Royal Decree of 19 April 2014 tot vaststelling van de erkenningsnormen voor het netwerk `beroertezorg', *BS* 8 Augustus 2014 (hereinafter referred as 'Royal Decree of 19 April 2014')

91 Royal Decree of 25 April 2014 tot vaststelling van de erkenningsnormen voor het netwerk `zeldzame ziekten' *BS* 8 Augustus 2014 (hereinafter referred as 'Royal Decree of 25 April 2014')

92 Art. 2, of the Royal Decree of 12 June 2012

93 Royal Decree of 15 July 2004 houdende vaststelling van de normen waaraan de zorgprogramma's 'cardiale pathologie' moeten voldoen om erkend te worden, *B.S.* 13 September 2004

94 Art. 3 of the Royal Decree of 12 June 2012

Conditions of authorisation for the 'paediatric' collaboration

The 'paediatric' collaboration aims to provide, in a specific area, care circuits, as defined in articles 11, §1, 2°, of the Hospital Act, to children under 15 years old, as part of a legal collaboration agreement.

The 'paediatric' collaboration must at least offer a severe trauma care circuit, an acute renal failure care circuit, an acute liver failure care circuit, a cardio-respiratory failure and an intracranial hypertension care circuit.[95]

The collaboration is composed of hospitals that have as a minimum a basic healthcare programme for children, a specialised care programme for children and a tertiary referral programme for children. For each hospital with a basic care programme or a specialised care programme in the collaboration, the nearest tertiary care programme is also part of the same collaboration to ensure a quick and effective transport of critically ill children. The collaboration must also contain hospitals with a local (N*- function), an intensive neonatal unit[46] and hospitals which do not have a paediatric care programme. Paediatricians that are not linked to a hospital and circles of GPs may also join the collaboration.

If the area covered by the collaboration does not have any of the above care providers, the collaboration must conclude a collaboration agreement with one or more of these care providers.

Conditions of authorisation of the 'stroke care' collaboration

The 'stroke care' collaboration aims to provide care circuits in a specific area, to patients suffering from an acute stroke, as part of a collaboration agreement legally formalised between different institutions.

The collaboration must at least offer a care circuit designed for patients suffering from an acute ischemic stroke and an acute haemorrhagic stroke. The conditions are set by the Royal Decree and are mainly concerned with the organisation of transfer of patients.[96]

The collaboration must include hospitals with an authorisation for a basic 'stroke care' programme and hospitals with an authorisation for a specialised care programme 'stroke care relating to acute brain involving invasive procedures' and a hospital with an authorised mobile emergency unit.[97] The collaboration may also include hospitals without specific authorisation in this regard and circles of GPs.

Conditions of authorisation for a 'rare diseases' collaboration

The 'rare diseases' collaboration aims to provide care circuits to patients with rare diseases as part of a legally formalised collaboration agreement. A rare disease is a disease that involves life-threatening and/or which causes chronic disability, and whose prevalence is less than 5/10 000 inhabitants.[98]

The collaboration includes a care circuit which at a minimum ensures that patients with a rare disease are treated and followed by the most appropriate 'rare disease' function or, provided that these centres have been designated, by the most appropriate expertise centre of 'rare diseases'.

The collaboration must include general hospitals that are not authorised to provide a function 'rare disease' or a 'rare diseases' centre of expertise and hospitals with these functions and / or centre of expertise. The collaboration must also include human genetic centres. Circles of GPs can also be part of these collaborations.

A 'rare disease' function needs to participate to the appropriate collaboration in order to be authorised.[99]

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95 Art. 2 of the Royal Decree of 2 April 2014

96 Art. 2 of the Royal Decree of 19 April 2014

97 Art. 3 of the Royal Decree of 19 April 2014

98 Art. 1 of the Royal Decree of 25 April 2014

99 Art. 18 of the Royal Decree of 25 April 2014

Governance structures

The clinical collaborations have a similar management structure. There is always a coordinator, the creation of a consultative committee, the redaction of a quality manual, an agreement on the (re)referral of patients, and finally, the awareness of healthcare providers.[59]

Role of the coordinator

A coordinator should be appointed according to the conditions provided in the legal collaboration agreement formulated by the different care providers in the collaboration. He is responsible for organising and coordinating the activities of the collaboration in agreement with the participating care providers. For the collaboration 'care of the acute stroke', it is a medical coordinator and specialist in neurology designated according to the conditions established in the collaboration agreement.[100]

Consultation committee

The collaboration must also have a consultation committee composed of representatives of each of the participating care providers and designated according to the terms of the collaboration agreement. Depending on the activity concerned by the collaboration, this consultation committee will have different tasks:

- It must always ensure the enforcement of the collaboration agreement and take the necessary initiatives to improve the quality of care. In particular, agreements should be concluded regarding transfers and re-transfers of patients and to develop methods to jointly monitor the processes and the quality of such transfers. It must conduct regular consultations with care providers involved in this activity. The consultation committee also aims to support healthcare providers in creating a multidisciplinary quality manual. Basic structures for multidisciplinary quality manuals were defined for oncology[68] and cardiac care.[69]
- The consultation committee is expected to meet at least once a year in order to fulfil its duties.

2.2.2.2 Collaboration on the basis of article 10 of the Hospital Act

Definition and Scope

On the basis of article 10 of the Hospital Act, collaboration between hospitals and other care services can be authorised. Certain articles of the Hospital Act are relevant to these collaborations. The special thing of this collaboration is that collaboration is possible in fields other than typical care domains. Such collaboration already exists in the domain of psychiatric care, palliative care and the removal and transplantation of organs. The Royal Decree of 10 July 1990 provides the norms for the authorisation of collaboration of psychiatric institutions and services.[101] A particular collaboration must aim either for the creation and the management of sheltered accommodation or a so called 'consultation platform'.

Collaboration between acute, categorical or psychiatric hospitals

The collaboration must include at least a general hospital that has a neuro-psychiatry service for observation and treatment (character A) or a psychiatric hospital and a service or centre for psychiatric care. The collaboration includes a written agreement that has to be approved by the competent authority. Moreover, the collaboration must be created through a not-for-profit association or an association as provided in article 118 of the Act of 8 July 1976 on public centres for social welfare ('OCMW'/'CPAS'). Art. 1 §2 of the Royal Decree on the Conditions to be fulfilled by an 'ombudsfunction' in Hospitals provides that such collaboration can take place through the conclusion of a written collaboration agreement between the hospitals. Moreover, it is provided in article 1, § 3 of the Royal Decree of 8 July 2003 that psychiatric hospitals can comply with article 11 of the Act on patient rights (i.e. the right for a patient to file a complaint related to his rights before a competent ombudsman) through the ombudsman of a

100 Art. 4 of the Royal Decree of 19 April 2014

101 Royal Decree of 10 July 1990 houdende vaststelling van de normen voor de erkenning van samenwerkingsverbanden van psychiatrische instellingen en diensten, BS, 26 July 1990

collaboration of psychiatric institutions and services as consultation platform as mentioned in the Royal Decree of 10 July 1990.

Legal Forms

The Royal Decree of 19 June 1997 lays down the norms to which collaboration for palliative care must comply with in order to be authorised.[102] The collaboration must cover a geographic zone (territorially separated) consisting of between 200 000 and 1 000 000 inhabitants and each Community must have at least one collaboration. One of the aims of the collaboration is to provide information and boost awareness amongst the population. Others include updating knowledge on palliative care for physicians, nurses and paramedics etc. Organisations tasked with helping families and patients with palliative care, organisations of home care, local or regional organisations of GPs and other care providers, elderly homes and hospitals can be part of a collaboration. The written agreement of the collaboration must be approved by the competent public authority. The collaboration must have a coordinator and a committee with members representing the parties to the collaboration.

Collaboration concerning the removal and transplantation of organs is regulated by the Royal Decree of 10 November 2012.[103] To be authorised, such collaboration must include at least the categories 'local donor coordination', transplantations centres, care programmes 'heart and heart lung transplantation' T-services, functions specialised in emergency care, functions for intensive care, clinical laboratories where Human Leukocyte Antigen (HLA) -tests are performed and centres for the treatment of chronic renal failure. Such collaboration requires a written agreement, a coordinator and a committee with the members representing the parties to the collaboration.

2.2.2.3 Collaboration on the basis of Art. 107 of the Hospital Act

Definition and scope

Art. 107 of the Hospital Act provides that the King may make specific financing arrangements to allow, on an experimental basis and for a limited time, a prospective financing of care circuits and collaborations, focusing on care programmes. This possibility allows a reallocation of existing financial resources to develop care circuits and collaborations. It is a financial technique that allows the reallocation of part of the BFM so that resources and manpower can be devoted to a specific area of work in order to adapt the current supply of care.[70]

Based on this article, many projects have been established in psychiatric care. Art. 63 §2 of the Royal Decree of 25 April 2002 on the fixing and the liquidation of the BFM allows the conclusion of agreements within the framework of pilot projects with psychiatric hospitals in particular to allow the implementation of article 107 of the Hospital Act.

Regarding the projects in the context of mental healthcare, we see in practice that this allows part of the healthcare staff of hospital psychiatric services to create a mobile team that can operate to provide home care to patients rather than in a hospital. Such a situation risks challenging compliance with authorisation standards in hospitals, especially in terms of personnel. It is therefore necessary to adapt the Royal Decree of 23 October 1964 with a provision allowing for hospitals that have been selected to participate in a project under article 107 so that the staffing standards for A- and T-services apply at the level of the institution and not at the hospital service level.[71]

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102 Royal Decree of 19 June 1997 houdende vaststelling van de normen waaraan een samenwerkingsverband inzake palliatieve zorg moet voldoen om te worden erkend, BS 28 June 1997

103 Royal Decree of 10 November 2012 tot vaststelling van de erkenningsnormen voor het samenwerkingsverband 'wegneming en transplantatie van organen', BS 23 November 2012

2.2.3 *Types of collaboration between or with hospitals that are not legally authorised by the competent minister*

Many hospitals have so-called informal agreements with other hospitals that have not been authorised by the competent minister. These collaborations have different functions including the referral of patients, supporting specialists from other hospitals, the purchase of medical products through public procurement, the exchange of information, the support of information and communication technology (ICT), the sharing of trainees, etc.

The type of collaboration may differ in description and may range from two hospitals to a collaboration of many hospitals. The collaboration may be based upon a contract or may be conducted through a legal entity, such as a not-for-profit association.

2.2.3.1 *Holdings: including extra-muros surgery centres*

Some hospitals may form a hospital holding. The holding is not regulated by the Hospital Act. It refers to the situation whereby independent units are governed by a common board.[72] The authorisation numbers of the independent units are maintained. Specialised medical care, including surgery is not only practiced in hospitals. More and more surgery is performed by external surgery centres, for instance external eye surgery centres.[104] These centres do not fall within the definition of a 'hospital' in the sense of the Hospital Act and do not have the legal obligation to comply with the authorisation and norms applicable to authorise hospitals.[73] Certain external centres, such as external eye surgery centres are able to obtain surgery room authorisation certificates. The certificate guarantees compliance with the norms predefined by the Belgian working group for extramural eye surgery.[73] This working group was set up by the Belgian Society for Cataract and Refractive Surgeons, the Belgian Professional Association for Ophthalmologists and the Ophthalmologic Trade Union. The conformity assessment is carried out by an independent institution (National Institute of Health (ISS), accredited by the Belgian Accreditation Organisation) specialised in hygiene and expertise.[105]

In order to take into account the situation of these external centres or private clinics, the physician or dentist may be authorised to keep a deposit of pharmaceuticals and medical devices and so to purchase pharmaceuticals and implants, in either a pharmacy open to the public or a hospital pharmacy.[106] Nevertheless, this physician or dentist can only deliver the pharmaceuticals or implants in the context of a medical act. The physician must also sign an agreement with the holder of an authorisation for a pharmacy open to the public or a hospital pharmacy.[107]

2.3 Facilitators and obstacles to collaborate

In this section we will analyse varying viewpoints on whether the common legal forms of collaboration are able to create regional and/or supra-regional collaboration initiatives based on law expert viewpoints. Legally speaking, the word '**regional**' refers to one of the three national regions. Belgium has three regions, i.e. the Flemish Region, the Brussels Capital Region and the Walloon Region. The Regions normally refer to economic topics. Competence for healthcare is however vested with the Federal State and the Communities (and not the Regions). In terms of Communities there exists the Flemish Community, the French Community and the German-speaking Community. The concept of 'Community' refers to persons that make up a community and the bond that unifies them, namely their language and culture. In some reports on regional hospital collaborations, reference is made to a care area and within this care area a certain type of (specialised) services must be available within a certain response time (e.g. 30 minutes). References in this section to 'regions' and 'regional' are used

104 Extramural centres are private for-profit clinics.

105 *Id. 21.*

106 Art. 20, eerste lid Wet 10 May 2015 betreffende de uitoefening van de gezondheidszorgberoepen, *BS* 18 June 2015.

107 Art. 20, eerste lid Wet 10 May 2015 betreffende de uitoefening van de gezondheidszorgberoepen, *BS* 18 June 2015; art. 8 Act 10 May 2015 betreffende de uitoefening van de gezondheidszorgberoepen, *BS* 18 June 2015.

to refer to these care areas but also to larger areas, such as 'communities'. The word **supra-regional** will be used in the context of collaborations with hospitals located in different care areas, not excluding hospitals located in different Communities or different Member States of the European Union (EU).

It is necessary to evaluate the facilitators and obstacles of current legislation in order to divide the care landscape into collaborations. The analysis below looks at the legislation on the legal forms of collaboration of hospitals but also at other legislation that can facilitate or hinder collaboration between hospitals. When analysing the facilitators and obstacles, we mainly focus on governance and in particular on the direct and indirect aspects of governance. With the direct aspects we refer to the way the collaboration is governed by committees, the way hospital physicians are involved in decision making of/for the collaboration, the position of the hospital physician working in a collaboration of hospitals etc. With indirect aspects of governance we refer e.g. to certain issues of external accountability[5] like the processing of data, the ombudsfunction, etc.

2.3.1 Facilitators to collaborate within the current legal framework

2.3.1.1 Facilitators created by the current legal forms of collaboration strictly related to governance

Coordinator and coordinating committees

The current legislation provides the obligation to organise the collaboration between hospitals by the creation of coordinating committees and coordinators. These committees and coordinators can make a collaboration between hospitals much easier.

In the case of an association of hospitals or a group of hospitals, the participating hospitals must create a coordinating committee (article 10 Royal Decree of 25 April 1997 for the association and article 13, §1, of the Royal Decree of 30 January 1989 for the group of hospitals). This committee is composed of the administrators appointed by each participating hospital. The agreement concluded between the participating hospitals must describe the exact composition, the tasks and functioning of the committee. Each association or group of hospitals must also appoint a general coordinator who is responsible for organising and coordinating the administrative activities in collaboration with the participating hospitals CEOs. When hospitals decide to merge, there must be one board and one CEO (Art. 6, §3 of the Royal Decree of 31 May 1989).

Involvement of physicians via medical councils

Common medical committee for different hospitals

After a hospital merger, a medical council must be established on the basis of elections. The creation of the medical council in the context of a merger must guarantee that the different disciplines and sites are represented in the new medical council in a proportionate way.

It is possible however under the existing act, to create a common medical committee of two hospitals that are not yet merged. If hospitals work closely together, e.g. in a 'group', there is the possibility to create one medical council for the two hospitals. Art. 5, § 6 of the Royal Decree of 10 August 1987 provides that in case of different collaborating hospitals, the board and the medical staff may send a common and concurrent request at the Joint Committee Hospital Administrators and Hospital Physicians at the Federal Health Department to organise elections for one single medical council. In deciding whether to consent to this request the Commission will look at the integration of governance structures and of the medical activities in the hospitals.

Involvement of a medical council before signing a collaboration agreement

The different classic types of collaboration, such as the 'group' and the 'association' foresee the creation of a medical council.

It follows from article 137, 12° of the Hospital Act that medical councils give an opinion where its hospital enters into agreement with another party that may have an impact on the medical activities. Unless otherwise provided in the General Rules of Rights and Obligations of Hospital Administrators and Hospital Physicians, the opinion is non-reinforced for the hospital administrator. This is why this topic can also be considered an obstacle. The

advice of the medical council is indeed for the administrator not a reinforced opinion.

Votes and activities in different hospitals

For the first elections in the merger of hospitals, a physician gets a number of votes in relation to his activities in the hospital. If he does not work fulltime or exclusively in the hospital, the physician will have less votes (see further). However, in case of activities in hospitals which were regrouped in a hospital merger, the activities are counted together in order to determine the total activity (and the total number of votes).[108]

CMOs and heads of medical services can work in different hospitals of the collaboration

The CMO and the head of a medical department have to work exclusively in the hospital. However, this rule does not apply if they work in several hospitals in a group of hospitals.[109] Within a 'group', the CMO can practice his function as a fulltime job or with a part-time job together with other functions in the hospitals of the group.[110]

Freedom of care providers to participate in collaborations

In the current regulation of collaborations, each care provider (specifically defined by the relevant Royal Decrees) is free to participate in collaborations created within its area of practice. Care providers are also in principle free to join multiple collaborations.

Flexibility of legal form

The legislator does not provide for a specific structure of a 'group', 'merger' or 'association'. The form in each case is created by the drafting of an agreement[59] or by the creation of a legal entity, accompanying the drafting of an agreement. The type of legal entity is not specified, although the most common legal form is a not-for-profit association.

No exclusivity

One of the advantages of an association is the fact that exclusivity is not required. A hospital may participate in several associations.[58] In case of a merger or a group of hospitals, the participating hospitals have to restrain of collaboration with hospitals or hospital services being a third party according to the collaboration.

Different parties to the collaboration

Certain legal forms provide a broad scope of participation to the collaboration. An 'association' has the advantage of having a wide scope, so it is possible that acute, specialist or psychiatric hospitals are able to form an association.[58]

With regard to collaborations, article 11 of the Hospital Act defines the 'collaboration of care providers' as a set of care providers, healthcare professionals, institutions and services (which **do not fall under the competence of the authorities referred to in articles 128, 130 or 135 of the Constitution**) and which jointly offer one or more care circuits as part of an agreement of legal collaboration within and outside institutions for a

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108 Art. 2, §4 Royal Decree 10 August 1987 tot vaststelling van de regels met betrekking tot de samenstelling en de werking van de medische raad in uitvoering van de artikelen 24, 25 en 26 van de wet van 23 december 1963 op de ziekenhuizen, *BS* 18 August 1987.

109 Art. 7 en 17 Royal Decree of 15 December 1987 houdende uitvoering van de artikels 13 tot en met 17 van de wet op de ziekenhuizen, as coordinated by the Royal Decree 7 August 1987.

110 Art. 8 Royal Decree of 15 December 1987 houdende uitvoering van de artikels 13 tot en met 17 van de wet op de ziekenhuizen, as coordinated bythe Royal Decree 7 August 1987, *BS* 25 December 1987.

target group of patients in a geographic area defined by the institutions concerned.

2.3.1.2 Other facilitators created by law

Hospital pharmacy

To be recognised as a hospital there must be a basic activity of the hospital pharmacy.[111] A hospital pharmacy must meet some architectonical standards.[112] The hospital should form a functional unit which must be so located that it is easily accessible and that the distribution and supply of medicines can run smoothly and the hospital pharmacy must have a certain surface.[74]

In a 'group' it is possible to organise a collaboration amongst the hospitals to have a more efficient function of the hospital pharmacy for the following topics:

1. the compounding of medicinal products, the packaging of medicinal products and the sterilization of medical products;
2. the analysis and control of the quality of substances and medicinal products;
3. the buying of medicinal products, and;
4. the medico-pharmaceutical information.[113]

Moreover, it is possible, within a group of hospitals, to create an 'on-duty' system to guarantee the continuity of care.[114]

An association of hospitals can also organise an association of the hospital pharmacy.[115]

Art. 107 of the Hospital Act – agreements

Art. 107 of the Hospital Act provides that the King may make specific financing arrangements to allow, on an experimental basis and for a limited time, a prospective financing of care circuits and collaborations, focusing on care programmes. This possibility allows a reallocation of existing financial resources to develop care circuits and collaborations. It is a financial mechanism that allows the reallocation of part of the BFM so that resources and manpower can be devoted to a specific area of work in order to adapt the current supply of care.[70]

Many projects have taken place in psychiatric care based on this article. Art. 63 §2 of the Royal Decree of 25 April 2002 on the Fixing and the Liquidation of the BFM permits the conclusion of agreements within the framework of pilot projects with psychiatric hospitals, in particular to allow the implementation of article 107 of the Hospital Act.

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111 Royal Decree of 4 March 1991 houdende vaststelling van de normen waaraan een ziekenhuisapotheek moet voldoen om te worden erkend, *BS* 23 March 1991, *err., BS* 30 April 1991.

112 Royal Decree of 4 March 1991 houdende vaststelling van de normen waaraan een ziekenhuisapotheek moet voldoen om te worden erkend, *BS* 23 March 1991, *err., BS* 30 April 1991.

113 Art. 23, §1 Royal Decree 4 March 1991 houdende vaststelling van de normen waaraan een ziekenhuisapotheek moet voldoen om te worden erkend, *BS* 23 March 1991, *err., BS* 30 April 1991.

114 Art. 13, §1 en §2 Royal Decree 4 March 1991 houdende vaststelling van de normen waaraan een ziekenhuisapotheek moet voldoen om te worden erkend, *BS* 23 March 1991, *err., BS* 30 April 1991.

115 National Council of the hospitals, *Tweede advies inzake 'ziekenhuisassociaties'*, 9 January 1997

Common ethics committee in a group

Each hospital must have a local ethics committee.[116] In the case of an authorised hospital group, a common ethics committee can be created for all the hospitals of the group, or separate ethics committees can be created for each hospital. All hospitals in a group may therefore have an ethics committee. This is provided in the Royal Decree of 23 October 1964. This is notable when viewed from the context of Regulation n° 536/2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC. This is because article 9.1 of the Regulation provides that Member States shall ensure that the persons validating and assessing the application do not have conflicts of interest, are independent of the sponsor, of the clinical trial site, the investigators involved and of persons financing the clinical trial, as well as free of any other undue influence. In order to guarantee independence and transparency, Member States must ensure that persons assessing the application falling under Parts I and II of the assessment report have no financial or personal interests which could affect their impartiality. These persons must make an annual declaration of their financial interests. In the case of a committee working for a group, it is easier to comply with article 9 of the Regulation n° 536/2014.

A common ombudsfunction for collaborating hospitals

Art. 71 of the Hospital Act provides that to be authorised, every hospital must have a mediation function. Such a function can be shared between hospitals under the conditions described by the King.

Art. 1 §2 of the Royal Decree on the conditions to be fulfilled by an 'ombudsfunction' in hospitals provides that such collaboration can take place through the conclusion of a written collaboration agreement between the hospitals. Moreover, it is provided in article 1, § 3 of the Royal Decree of 8 July 2003 that psychiatric hospitals can comply with article 11 of the Act on patient rights (i.e. the right for a patient to file a complaint related to his rights before a competent ombudsman) through the ombudsfunction of a collaboration of psychiatric institutions and services as consultation platform as mentioned in the Royal Decree of 10 July 1990.

The purchasing of medicines via a central purchasing body centre or framework agreements

There exist in the current legislation on public procurement opportunities to facilitate the purchase of pharmaceuticals by several hospitals. This may be the case via a central purchasing or via the use of a framework agreement.

A framework agreement is an agreement between one or more contracting authorities and one or more economic operators, the purpose of which is to establish the terms governing contracts to be awarded during a given period, in particular with regard to price and, where appropriate, the quantity envisaged.[117] To conclude a framework agreement, the contracting authorities use the normal procedures and consequently the normal rules apply– with modifications depending on the procedure chosen-, in particular concerning publicity, time limits, criteria for exclusion, selection and award.[118] The duration of framework agreements is in principle limited to four years. According to Casteleyn[75] the framework agreement is particularly useful to conclude a procurement in a short term and at the most advantageous conditions of the time assignments. Indeed, once the framework agreement is concluded, the conclusion of a part-procurement can take place very quickly because it is no more necessary to follow an entirely new procurement procedure. In addition, the part-procurement will be awarded to the best conditions of the moment, since it is possible for the economic operators who were admitted to the framework agreement still to question.

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116 Annex A.III., 9°ter Royal Decree 23 October 1964 tot bepaling van de normen die door de ziekenhuizen en hun diensten moeten worden nageleefd, *BS* 7 November 1964.

117 Art. 3, 15° of the Act of 15 June 2006 on public procurements, *B.S.* 15 February 2007

118 European Commission, *Explanatory Note – Framework agreements – classic directive*, Brussels, 14.7.2005, CC/2005/03_rev 1

Another possibility to make the purchasing between hospitals easier is the central purchasing body. This is a contracting authority which acquires supplies and/or services intended for contracting authorities, or awards public contracts or concludes framework agreements for works, supplies or services intended for contracting authorities.[119] The central purchasing body is a contracting authority in its own[120] which must respect the procurement procedures in order to conclude a procurement.[121]

eHealth makes information collaborations easier

The current eHealth platform Act of 2008[122] does not oppose the creation of information collaborations, which are at present progressively structured into five major collaborations in Belgium, each with a server or 'hub' for data exchange:[123]

- The *Collaboratief Zorgplatform* (CoZo)
- The *Antwerpse Regionale Hub* (ARH)
- The *Vlaams Ziekenhuisnetwerk KU Leuven*
- The *Abrumet*
- The *Réseau Santé Wallon*

Patient data exchange raises many questions pertaining to the legality of these exchanges. The federal government supports the electronic exchange of health information and in 2008 created the eHealth platform for such purposes. This platform allows *inter alia* the linkage of data from between these five hubs through a 'metahub'[124]

The European Commission and Member States put a lot of efforts in eHealth. The eHealth Action Plan 2012-2020 e.g. aims to create a fully mature and interoperable eHealth system.[125] eHealth can deliver more citizen-centric healthcare and reduce the length of hospitalisation. However, the lack of health data exchange can contribute to one market failure, but can be tackled by addressing in a coordinated way fragmented legal frameworks, lack of legal clarity and lack of interoperability.[126] The eHealth Collaboration set up by Directive 2011/24/EU of 9 March 2011 on the application of patients' rights in cross-border healthcare is the main strategic and governance body at EU level to work towards interoperability of cross-border eHealth services. One of the aspects of interoperability, organisational interoperability, implies integrating business processes and related data exchange and finding instruments to formalise mutual assistance, joint action and interconnected business processes in connection with cross-border service provision.[127]

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119 Art. 3, 10, of the Directive 2004/18/EC of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts

120 Art. 2, 1°, e), of the Act of 15 June 2006 on public procurements

121 There is also in Belgium, beside the central purchasing body a central market (art. 2, 4° of the Act of 15 June 2006 on public procurements)

122 Act of 21 Augustus 2008 houdende oprichting en organisatie van het eHealth-platform en diverse bepalingen, *B.S.* 13 Oktober 2008

123 Annexe - Fiche info financement des hôpitaux, MC-Informations, September 2013, n° 253, 11

124 Annexe - Fiche info financement des hôpitaux, MC-Informations, September 2013, n° 253, 11

125 European Commission, *eHealth Action Plan 2012-2020: Innovative healthcare for the 21st century*, COM (2012) 736 final, 6 December 2012, 3.

126 European Commission, *eHealth Action Plan 2012-2020: Innovative healthcare for the 21st century*, COM (2012) 736 final, 6 December 2012, 5.

127 European Commission, *eHealth Action Plan 2012-2020: Innovative healthcare for the 21st century*, COM (2012) 736 final, 6 December 2012, 8.

Towards European reference collaborations

Directive 2011/24/EU of 9 March 2011 on the application of patients' rights in cross-border healthcare promotes the use of European reference collaborations. The Commission supports the continued development of European reference collaborations between healthcare providers and centres of expertise in the Member States. A European reference collaboration can improve access to diagnosis and the provision of high-quality healthcare to all patients who have conditions requiring a particular concentration of resources or expertise, and could also be focal points for medical training and research, information dissemination and evaluation, especially for rare diseases.[128] Directive 2011/24/EU of 9 March 2011 on the application of patients' rights in cross-border healthcare, in particular article 12, accordingly provides incentives to Member States to reinforce the continued development of European reference collaborations. European reference collaborations are based on the voluntary participation of their members, but the Commission has developed criteria and conditions that the collaborations are required to fulfil in order to receive support from the Commission. The criteria and conditions that European reference collaborations and healthcare providers wishing to join a European reference collaboration must fulfil were set out in a delegated decision of the European Commission.[129] Another decision of the European Commission sets out the criteria for establishing and evaluating European reference collaborations and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such collaborations.[130]

Art. 12, 3, of Directive 2011/24/EU provides that Member States are encouraged to facilitate the development of the European reference collaborations:

(a) by connecting appropriate healthcare providers and centres of expertise throughout their national territory and ensuring the dissemination of information towards appropriate healthcare providers and centres of expertise throughout their national territory;

(b) by fostering the participation of healthcare providers and centres of expertise in the European reference collaborations.

European reference collaborations should have at least three of the following objectives:

1. to help realise the potential of European collaboration regarding highly specialised healthcare for patients and for healthcare systems by exploiting innovations in medical science and health technologies;
2. to contribute to the pooling of knowledge regarding sickness prevention;
3. to facilitate improvements in diagnosis and the delivery of high-quality, accessible and cost-effective healthcare for all patients with a medical condition requiring a particular concentration of expertise in medical domains where expertise is rare;
4. to maximise the cost-effective use of resources by concentrating them where appropriate;
5. to reinforce research, epidemiological surveillance like registries and provide training for health professionals;
6. to facilitate mobility of expertise, virtually or physically, and to develop, share and spread information, knowledge and best practice and to foster developments of the diagnosis and treatment of rare diseases, within and outside the collaborations;

128 Directive 2011/24/EU of 9 March 2011 on the application of patients' rights in cross-border healthcare promotes the use of European reference networks, point 54

129 Delegated decision of the European Commission of 10 March 2014 (2014/286/EU)

130 Implementing the decision of the European Commission of 10 March 2014 (2014/287/EU)

7. to encourage the development of quality and safety benchmarks and to help develop and spread best practice within and outside the collaboration;
8. to help Member States with an insufficient number of patients with a particular medical condition or lacking technology or expertise to provide highly specialised services of high quality.

2.3.2 Obstacles to collaborate in the current legal framework

2.3.2.1 The relationship between committees of the collaboration and the board and/or medical councils of the hospitals participating at the collaboration

It must be noted that the common medical committee of an association is not competent to make a final decision. It will ultimately be the medical councils of the participating hospitals concerned that will have to express their opinion. If a consensus is reached in the common medical committee, the mandated members will only have to defend this position in their own medical council.[131] According to the National Council of the Hospitals, members of the common medical committee are not independent of the medical council of the participating hospitals. [132]

The Royal Decree of 25 April 1997 regarding the association of hospitals also provides the possibility to create a PCC.[133] The decision to create a PCC is made on a joint proposal by the boards of administrators of the participating hospitals. This committee is composed of the members of the association committee and the members of the common medical committee,[134] This PCC will decide on topics related to 'associations' for which the advice or the agreement of one or more medical councils is required under the Hospital Act. The purpose of the PCC is to facilitate a decision by attempting to find a consensus. If such a consensus is reached, the members mandated by the administrators and medical councils of the participating hospitals will be required to defend the consensus.

Unless otherwise provided in the agreement between the collaborating parties, it is not always obvious what the legal value is of a decision of a coordination committee for the council of administrators of the individual hospital that is a member of the collaboration.

2.3.2.2 The composition of association committees in case of an association

Regarding the structure of the association, the Royal Decree of 25 April 1997 provides that each association must have an association committee.[135] This committee is composed of the administrators mandated by each participating hospital. The exact composition of the committee shall be described in the association agreement. [136] According to Vansweevelt and Dewallens (2014),[60] this limited list does not allow *stricto sensu* CEOs to participate in the association committee.

The association agreement must describe the tasks and functioning of the committee. The agreement must also mention the required majorities in order to take decisions.

2.3.2.3 Collaboration and conflicts of interest

CEOs of hospitals may be appointed as an administrator in another hospital that is member of a collaboration or they may be appointed as the administrator of the legal entity that is created to facilitate collaboration among hospitals. This CEO may even become an administrator in another

131 Art. 11, §4, of the Royal Decree of 25 April 1997

132 National Council of the Hospitals, Advies inzake maatregelen om samenwerking tussen ziekenhuizen te bevorderen, 14 June 2012, Brussels, 7

133 Art. 12 of the Royal Decree of 25 April 1997

134 Art. 12, §2, of the Royal Decree of 25 April 1997

135 Art. 10 of the Royal Decree of 25 April 1997

136 Art. 16, 7° of the Royal Decree of 25 April 1997

hospital. There are no specific legal rules to make this decision transparent for the medical staff. This may lead to conflict of interests for administrators. A specific decision of a hospital X or collaboration Y may be bad for a specific hospital Z in which the administrator is also a CEO. It may not always be obvious to the medical staff of the hospital that their CEO is serving the interests of another hospital or a collaboration, rather than the interests of the hospital where he is a CEO. Moreover, the fact that Belgium is a relatively small country makes it difficult to nominate expert-administrators e.g. for regional collaborations that do have a good knowledge of the hospital sector but have no links with individual hospitals that are members of the collaboration.

2.3.2.4 Organisation of polyclinics

The current legislation does not provide specific rules for the organisation of polyclinics. One may therefore ask whether the hospital legislation, including the Hospital Act, is applicable to polyclinics that may be 'run' by a 'collaboration'. Further questions are raised concerning the storage of medical files in the clinic. What are the conditions to be met in case of problems with a particular collaboration? Should the activity practiced in the polyclinic of the hospital be seen as part of the activity considered for the medical council elections? These are questions that currently do not have explicit answers but that should be taken into account in the context of collaborating, and namely concerning activities performed outside the hospital. The more the sphere of activity of healthcare professionals increases, the more the scope of the Hospital Act will be incompatible with the activity carried out by hospital physicians.

2.3.2.5 Statutory purpose of the legal entity

Art. 15 §2 of the Hospital Act specifies that hospitals are operated by a legal entity whose sole statutory purpose is the operation of one or more hospitals, healthcare institutions or medical-social institutions.

The operation of a hospital is therefore limited. This may pose difficulties for the development of large collaborations with other care providers than hospitals.

2.3.2.6 Status of the hospital physician

Most physicians are self-employed. They often form an association with other self-employed physicians of a similar discipline at the hospital where they are working. They are, however, mostly not a party to the agreement of collaboration between hospitals. The current rules on collaboration of hospitals include rules to involve the medical council but do not provide specific rules regarding self-employed physicians as parties to the collaboration. Decisions regarding referrals taken at the level of the collaboration have to take into account that hospital physicians have the right of professional autonomy (see article 144, § 1 of the Hospital Act).

The hospital legislation provides in article 145 Hospital Act the need to conclude a written agreement between the hospital and the physician in order to be authorised as a hospital physician. The rights and obligations of both parties must be specified in that written agreement. However, no rules are provided with regard to the relation between a collaboration, group or association of hospitals and physicians given that the rules relating to the status of the physician are only provided for the relation hospital-based physician. Therefore, a physician who has a contract with a hospital A and who works on the site of a hospital B following a hospital group or an association of hospitals for example, will in principle always be considered as a hospital physician of the hospital A. As long as the collaboration is not running a hospital, the rights of physicians as laid down in the Hospital Act results from the relationship between the hospital and physician and not from the relationship between collaboration and physician.

If on the basis of a collaboration, hospital A of the collaboration enters into agreement with hospital B to allow physicians of hospital A to work in hospital B, these physicians are not considered as hospital physicians of hospital B. As a consequence, the medical council of hospital B does not have to give its opinion on an appointment of this physician given that this physician is not a 'hospital-based physician' of hospital B. A hospital-based physician is a physician who enters into an agreement with the hospital. If there is no contract between the physician of hospital A and hospital B, the physician will be not be considered a hospital-based physician of hospital B. A collaboration may lead to the situation whereby (many) physicians therefore start working in different hospitals without the prior opinion of the medical council of that hospital. Nevertheless, the medical council of

hospital B will have to give its opinion before signing a collaboration agreement. This follows from art. 137, 12° of the Hospital Act. According to this article, agreements with third parties that have an impact on the medical activity in a hospital require the prior opinion of the medical council. This opinion is not a reinforced opinion, unless otherwise provided in the working rules relating to the rights and obligations of the hospital administrators and the physicians.

2.3.2.7 Exclusiveness of the physician in the hospital

A CMO of a hospital or the chief of the medical services must in principle work exclusively at one hospital.[137] This does not allow the creation of large regional collaborations with one CMO or one medical head of service. However, it is only provided in the rules regarding 'hospital groups' that the CMO and the head of medical services can be working in one or more hospitals within a group.

2.3.2.8 The advice of medical council

Art. 137, 12 of the Hospital Act provides that the board of the hospital must request an advice from the medical council before concluding an agreement with a third party concerning matters that can have repercussion on the medical activity. This consultation is required for all agreements that are signed within the framework of a particular collaboration with other hospitals or care providers.

It seems that the power of the medical council is not strong enough in case of collaboration between hospitals because the hospital manager can decide not to take into account the advice of the medical council unless it is otherwise foreseen in the general regulation. A general regulation may provide more protection for hospital physicians. It can be provided that the hospital can only start a collaboration with a collaboration or another hospital if there is e.g. an approval by the medical council. What is written above has to be nuanced with regard to the association of hospitals. It is indeed provided that the medical councils of the participating hospitals must conclude a written agreement which will be annexed to the association agreement.[138] According to Vansweevelt and Dewallens (2014),[60] the requirement to conclude an agreement between the medical councils of participating hospitals implies that all medical councils have a decisive voice in the establishment of an 'association'. If one of the medical councils does not sign the agreement for the establishment of a common medical committee, the association cannot be authorised by the competent minister.

Election of medical council

The difficulty of the medical council elections perfectly reflects the inadequacy of the current hospital legislation vis-à-vis the collaboration of hospitals at present. If two hospitals A and B decide to cooperate and, as part of this collaboration, organise services on different hospital sites so that physicians of hospital A will also work in hospital B, it will be no longer possible for this physician – if he works fulltime – to have the maximum of 4 votes. Instead, he will have only maximum 3 votes. Moreover, if he works at least two half days in the other hospital, he will have to decide where he will vote for the elections of the medical council and if he wants to vote in both hospitals, he will have only 2 votes divided over the two hospitals.[139]

The election of a medical council - or the organisation of a general assembly of the physicians (the medical staff) - is a complex issue within the framework of collaboration between hospitals. Current legislation does not promote working in different hospitals. It weakens the number of votes a physician has for the elections of a medical council.

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137 Art. 7 and art. 17 of the Royal Decree of 15 December 1987 enforcing art. 13 until 17 of the Hospital Act

138 Art. 11, §2, of the Royal Decree of 25 April 1997

139 Royal Decree of 10 Augustus 1987 tot vaststelling van de regels met betrekking tot de samenstelling en de werking van de medische raad in uitvoering van de artikelen 24, 25 en 26 van de wet van 23 december 1963 op de ziekenhuizen, *B.S.* 18 Augustus 1987

Other legal relationships

Besides the individual agreement between the hospital and the physician, the Hospital Act provides the need to have in writing a general regulation related to the legal relationship between the hospital administrator and the physicians working in the hospital.[140] There is no legal obligation to have a regulation related to the rights and duties of the collaboration administrator and the physicians working in the collaboration. Moreover, if each hospital of a collaboration has its own general regulation and if some physicians of a collaboration hospital start working in another hospital of the collaboration, having different general regulations regarding the rights and obligations may hinder the quality of care and the good collaboration among hospital physicians. In order to have a physician of hospital A working also in hospital B of the collaboration being bound by the general regulation of hospital B the physician must agree to be bound by the general regulation of hospital B. The Court of Cassation is of the opinion that a general regulation is only binding for a physician after he has given his individual consent.[141]

2.3.2.9 The retrocession system

The Hospital Act provides in article 155 a system of retrocessions or deductions. This system offers the possibility to retain a certain percentage of a physician's fees to cover matters such as the (administrative) costs of the central collection of fees and costs related to the medical activities, etc.[76] The Hospital Act provides *inter alia* that the physician fees related to hospitalised patients (art. 147 of the Hospital Act) or related to services accomplished in medical-technical services for patients who are examined or treated in hospital but are not hospitalised (art. 148 of Hospital Act) have to be centralised.

The hospital manager may also deduct a certain percentage of physician fees to allow the implementation of measures to maintain and promote medical activities at the hospital. In this case, the hospital manager and the medical council will fix the percentage by mutual agreement. This agreement is binding on hospital physicians. The situation is not always clear in hospitals and this leads often to disputes between physicians and hospitals.

This retrocession system which is one of the hospital's financial sources of income is regulated by the Hospital Act. It is unclear as to whether such a system can be used by a collaboration (instead of a single hospital), whether it can be used to cover the costs from other hospitals, whether it can be applied to cover costs for care delivered at home etc.

2.3.2.10 Data and privacy

Art. 20, §1, of the Hospital Act states that medical file must be kept by the hospital and that the CMO supervises the patient file. It is not regulated whether a collaboration (or network) can keep the patient files and if so, which CMO will supervise the patient file.

Liability of the hospital collaboration

If medical staff is working on behalf of a collaboration, one may wonder whether the collaboration is responsible to make sure that the patient rights are complied with. The current article 30 of the Hospital Act provides that the hospital complies with the Act on patient rights. It is the hospital that must be sure that the healthcare professions do comply with these rights. Moreover, the hospital will be liable for non-compliance of the Act on patient rights by the healthcare professionals working in the hospital, unless otherwise communicated to the patient. There are no rules regarding the responsibility and liability of a collaboration of hospitals, especially if this collaboration will receive authorisation for certain services, care programmes, or if this collaboration will hire medical staff.[142]

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140 Art. 144 of the Hospital Act

141 Cass., 8 April 2002, C000118N, www.cass.be

142 The existing hospital legislation does provide certain rules related to supervision in the field of e.g. nephrology. A main centre will have to supervise the low-care activities carried out in another hospital (see art. II, B, c and art. II, B, e of Annex of the Royal Decree of 27 November 1996 houdende vaststelling van de normen waaraan de centra voor de behandeling van chronische nierinsufficiëntie).

2.3.2.11 Collaboration and human resource management

Larger collaborations often require staff to work in different hospitals. The existing legal forms of collaboration between hospitals do not take into account of the provision of staff for another employer. Art. 31 of the Act of 24 July 1987[143] prohibits the provision of staff from one employer to another. Areas of precarious and temporary employment form exceptions to this rule. However, art. 186 of the Act of 12 August 2000 on social, budgetary and other regulations provides that despite art.31 of the Act of 24 July 1987 it is possible to give employers within groups the possibility to provide staff for its users. Since the Act of 25 April 2014 regarding various provisions on social security, modifying the Act of 12 August 2000 the employer's group must have the form of an economic collaboration (as mentioned in book XIV of the Corporate Act) or of a not-for-profit organisation and the provision of staff must be the only statutory purpose of the group.

In principle, a hospital or a collaboration cannot allow its own personnel to work as employees for other hospitals of the collaboration. Nevertheless, the system of the so-called employers groups, that is modified by the Act of 25 April 2014 regarding several regulations on social security, provides a procedure to be followed to allow the use of employees of an employer's group for different users. This type of employer's group permits, under certain conditions, the creation of a pool of employees or co-sourcing.
This represents an opportunity to have employees working at several sites of a collaboration and on several days of the week.[144]

It is not easy to give a general account of a common policy of employees in view of fiscal rules and rules related to employees and social security.[145]

With regard to the agreements based on article 107 of the Hospital Act, part of the health staff of hospital psychiatric services are used in a mobile team that can operate to provide home care to patients rather than care in the hospital. Such a situation could, however raise compliance issues with authorisation norms in hospitals, especially in terms of personnel. As a result it is arguably necessary to adapt the Royal Decree of 23 October 1964 with a provision allowing, for hospitals that have been selected to participate in a project under article 107, to use staffing standards for A and T services at the level of the institution and not at the hospital service level.[71]

2.3.2.12 Incompatibility of the legislation concerning the hospital pharmacy

The regulations applicable to the hospital pharmacy are provided in particular by the Royal Decree of 4 March 1991 laying down the standards to which a hospital pharmacy must meet to be authorised and the Royal Decree of 19 October 1978 regulating the dispensaries and drug deposits in care institutions. It must also take into account an old Royal Decree of 31 May 1885. According to this regulation, and in particular article 4, paragraph 2, of the Royal Decree of 19 October 1978, the hospital pharmacist is not able to deliver medicines to non-hospitalised patients, except in certain situations explicitly specified by the King. It is also provided that the use of medicines and medical devices delivered by the hospital pharmacist should only be used within the hospital. The regulations on hospital pharmacies can therefore constitute an obstacle to the formation of large collaborations whereby pharmaceuticals will have to be delivered to patients not staying in the hospital. Pharmaceutical delivery should optimally be part of the services offered to patients through a collaboration, meaning it should be necessary to be able to deliver a medicine to a patient who is not hospitalised at a particular location. The question is whether this should be done by a hospital pharmacy or a pharmacy open to the public.

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143 Act of 24 July 1987 betreffende de tijdelijke arbeid, de uitzendarbeid en het ter beschikking stellen van werknemers ten behoeve van gebruikers, *B.S.* 20 Augustus 1987

144 See in detail Hendrickx, F. and Vanderpoorten, A., 'Poolen van personeel, co-sourcing en de werkgeversgroepering in het arbeidsrecht', in *Recht in beweging*, 2016.

145 National Council of Hospitals, Advies inzake maatregelen om samenwerking tussen ziekenhuizen te bevorderen, 14 June 2012, Brussels, 7

2.3.2.13 Conditions related to the area

The three classic formalised forms of collaboration, i.e. the 'group', the 'merger' and the 'association' may hinder the division of the care landscape in larger collaborations as long as they continue to refer to a specific area. With regards to 'groups' the hospitals cannot be located more than 25 km from each other.
In a 'merger' the hospitals concerned can in principle not be located more than 35 km from each other. In the Royal Decree on 'associations' there is no reference to a distance but the hospitals forming the association must provide the evidence of the need of the concerned activity in an attractive area [146] and/or a sufficient level of activity. The Royal Decree provides that the King is responsible for determining what is meant by 'the need for association in a particular attractive area' and the 'activity level' for each type of activity on the basis of scientific national and international standards.[147]

With regard to 'association of catchment area', there are no specific references made to distance. However, it is specified that the territory of the 'association of catchment area' is determined by an administrative district or by joint adjacent districts[148] covering a minimum population of 150 000 inhabitants.[149] Due to these criteria, the regulations require that if a hospital has multiple sites, only the activities organised on sites that are located in the territory of the catchment area, will be integrated in the 'association of a catchment area'.[150]

The existing rules on collaborations are mainly inspired by larger collaborations, although it is still unclear whether they will lead to the creation of regional collaborations as described above. Art. 11 of the Hospital Act defines a 'collaboration of care providers' as a set of care providers, healthcare professionals, institutions and services, (which not fall under the competence of the authorities referred to in art. 128, 130 or 135 of the Constitution) and which jointly offer one or more care circuits as part of an agreement of legal collaboration within and outside institutions for a target group of patients in a geographic area to be defined by the institutions concerned.

The typical forms of collaboration are still based upon physical infrastructure such a buildings that are located close to each other. They do not take into account collaboration between hospitals at a distance using ICT, cloud platforms, apps ('clicks' i.e. instead of bricks).[77] At the same time European healthcare systems are converging and cross-border care is becoming more common. The eHealth and mHealth market are transforming the way health services are managed. Integration of care should improve through eHealth[151] and mHealth resulting not only in an improvement of the integration of care, but also having an impact on the movement of healthcare providers and patients. In general, a shift from inpatient to outpatient treatment is expected. Patients will not always be physically present in hospitals when they are monitored. They will often be monitored at a distance. Developments such as these entail transformation of health services and of the type of collaboration from that which exists at present. The current legal forms of collaboration do focus too much on buildings and physical distance instead of focusing also on mHealth.

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146 It is the population to be served by the object of the Association, art. 2, 3°, of the Royal Decree of 25 April 1997

147 Art. 5, §2, of the Royal Decree of 25 April 1997

148 Only contiguous districts on a geographic perspective can join in a single catchment area (art. 16ter, §1, paragraph 2, of the Royal Decree of 25 April 1997)

149 Art. 16ter, §1, of the Royal Decree of 25 April 1997

150 Art. 16*ter*, §2, of the Royal Decree of 25 April 1997

151 European Commission, *Annual Growth Survey* 2016, 26 November 2015, p. 15.

2.3.2.14 Who is the competent legislator?

The Special Act of 8 August 1980 on institutional reform is important with regard to care policy both inside and outside the hospital context, in particular with the competence of the Communities vis-à-vis the Federal State.[78] According to art. 5 of the Special Act, the Federal State possesses competence for the 'organic ('organiek'/'organique') legislation' concerning health policy.

The question is what is meant by this concept of organic legislation. The legislator does not define the concept in the legal text itself. According to the case law of the Constitutional Court, 'organic legislation' refers to the basic rules and guidelines of a hospital as enshrined in the Hospital Act.[152] This does not mean that topics regulated by the Hospital Act will be considered as 'organic legislation'. It is therefore not sufficient to include a provision in the Hospital Act to ensure that the provision falls under the federal competence. If the Communities are competent to authorise collaboration between hospitals, the question then is as to whether enacting norms for collaboration belongs to the competence of the Federal Sate. According to the explanation of the proposal of the Act related to the (6th) constitutional reforms, 'organic legislation' includes the basic characteristics of collaboration between hospitals.[153] It is therefore only possible for one legislator, i.e. the Federal State, to enact requirements pertaining to the basic characteristics with regard to the forms of collaboration between hospitals such as the associations of hospitals, the hospital groups and the mergers. With regard to collaborations of hospitals and care providers, the competence of the Federal State may be not extensive. The Constitutional Court held in its decision n° 108/2000 that the Federal State does not have competence to unilaterally enact regulations in this regard.[154] A consensus between the federal and the community authorities should therefore be encouraged, especially if the collaborations imply hospitals and homes for the elderly.

This is incidentally the approach that has been chosen within the framework of the Joint Declaration of 29 June 2015 on the new role of the hospital in the landscape of healthcare signed by all competent ministers of the various levels of authority. One of the principal goals of this declaration (although it is not legally binding), is to organise a systematic joint consultation between the various competent authorities and all the concerned parties so that agreements can be made. These different levels of authorities can realise their strategic visions in a context of optimisation, better collaboration and, if possible, by collaboration and concentration agreements.

The specification of the conditions that must be met, including rules with respect to the quality of services, institutions and hospital organisation is not 'organic' and therefore falls within the competence of the Communities.[155]

It will have to be seen for which type of collaboration the Federal State is competent. Finally, the Federal State can regulate the basic characteristics of the types of collaborations but the question will be what is meant by *basic characteristics.*

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152 GwH 14 February 2008, nr 15/2008; GwH 31 October 2000, nr 108/2000

153 Explanatory Statement of the proposal of bijzondere wet met betrekking tot de Zesde Staatshervorming, *Parl. St.* Senate 2012-2013, nr 5-2232/1, 36

154 B.3.3. Het komt derhalve de federale overheid niet toe unilateraal een regeling te treffen die betrekking heeft op de totaliteit van de zorgverstrekking buiten de ziekenhuizen. Nu de aangevochten bepaling de verplichting inhoudt om aan zorgverstrekking te doen « via een netwerk van zorgvoorzieningen » dat bestaat uit «een geheel van zorgaanbieders, zorgverstrekkers, instellingen en diensten […] in het kader van een instellingoverstijgende juridisch geformaliseerde samenwerkingsovereenkomst », maakt de federale wetgever inbreuk op de bevoegdheid van de gemeenschappen inzake de zorgverstrekking buiten de ziekenhuizen.

155 Explanatory Statement of the proposal of the bijzondere wet met betrekking tot de Zesde Staatshervorming, *Parl. St.* Senate 2012-2013, nr 5-2232/1, 36

2.3.2.15 Collaboration and competition law

Agreements of undertakings, like hospitals and decisions of associations, collaborations or groups of hospitals must not hinder competition in the healthcare market.[156] An entity that practices an economic activity, whatever the legal form it has and the way it is financed, can be considered as an undertaking.[157] In terms of 'economic activity', it is required that the entity independently produces products for and/or provides services to the market.[79] Although hospitals operate on a not-for-profit basis and although they serve the general interest according to art. 2 of the Hospital Act, their activities are classified as economic activities.[80]

Large regional collaborations will only by possible if they comply with competition rules. This means that the collaboration cannot be used to discuss confidential information regarding hospitals. A risk for compliance with competition rules may occur where such information is communicated (e.g. concerning future collaboration of a hospital with other hospitals) and if the communication of the information is not mainly intended to improve the quality of care.

It is important that collaboration agreements place quality of care as a main objective. Moreover, in case of a merger, notification of the competition authorities may be needed. The same can be the case if a collaboration can be considered as a concentration. There is a concentration in the sense of the competition rules if there is a sustainable change of control following either a merger or if one or more persons who had the control over at least one undertaking get the control over another undertaking (or parts of it).[158] The creation of a common undertaking which fulfils all functions of an independent economic unity is a concentration.[159] Concentrations with a change of control on a lasting basis which consist of a merger of two or more previously independent undertakings or parts of such undertakings have to be notified jointly by the parties to the merger to the Competition Prosecutor general before their implementation and after the conclusion of the agreement, publication of the take-over bid or public offer of exchange, or of the acquisition of a controlling interest.[160] The parties may however notify a proposed agreement provided that they declare explicitly that they intend to conclude an agreement which does not differ significantly from the notified proposal as regards all the relevant points of the competition act. The notification can be done in Dutch or French. As long as the Competition College does not pronounce its decision on the permissibility of the concentration, the undertakings concerned may not implement the concentration.[161]

2.3.2.16 Open or closed forms of collaboration – Parties to the collaboration

There is no obligation under the rules for mergers, groups or associations to include all hospitals within a specific area, or even the care providers of that area.

With regard to 'association of catchment area' it is not necessary for all the hospitals in the specified territory to participate in the 'association of catchment area'. It is however necessary to indicate in such cases (when requesting authorisation), the reasons why the association does not include all the hospitals of the territory.[162]

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156 Stipulated in art. IV.1, §1 Wetboek van economisch recht van 28 February 2013 and in art. 101 VWEU.

157 Court of Justice of the EU, C-41/90, *Höfner*, *Jur.* 1991, I, 01979, point 21.

158 Art. IV.6, § 1 Wetboek van economisch recht van 28 February 2013, *BS* 29 March 2013

159 Art. IV.6, § 2 Wetboek van economisch recht van 28 February 2013, *BS* 29 March 2013

160 Art. IV.10, §1 Wetboek van economisch recht van 28 February 2013, *BS* 29 March 2013.

161 Art. IV.10, §5 Wetboek van economisch recht van 28 February 2013, *BS* 29 March 2013.

162 Art. 16*septies*, a), of the Royal Decree of 25 April 1997

With regard to the collaborations of art. 11 of the Hospital Act it is clearly stated in the different Royal Decrees that care providers must have the opportunity to participate in the collaboration that exists within its area if the care provider meets the conditions.

Certain legal forms of collaboration do exclude certain hospitals. The concept of the 'hospital group' allows hospitals to enter into forms of collaboration that are focused on the allocation of tasks. A 'group' aims at the total complementary of hospitals.[163] In a 'group' agreements are made regarding allocation of tasks and adjustment of the offer of care that do not imply a common exploitation.[61] However, psychiatric hospitals and isolated Sp-services (specialised services for treatment and revalidation), alone or together with H-services (services for ordinary hospitalisation) or T-services (services neuropsychiatry for treatment of adult patients) do not fall under the scope of the royal decree.[164]

A 'merger' of hospitals represents the fusion of two or more separate authorised hospitals that may or may not have different boards that are located at different physical sites, under one administrator with one single authorisation.[165] However, psychiatric hospitals and isolated Sp-services (specialised services for treatment and revalidation), alone or together with H-services (services for ordinary hospitalisation) or T-services (services for neuropsychiatry for treatment of adult patients) do not fall under the scope of the royal decree of 31 May 1989. They may merge but not on the basis of the art. of the royal decree of 31 May 1989.

Since binding guidance concerning the conditions of such a merger are missing, mergers with psychiatric and specialist hospitals may lead to problems.[63]

2.3.2.17 Collaboration between hospitals from other regions and/or other Member States

The competence of the Communities with regard to care provided outside hospitals, with regard to norms of hospital services, functions etc., with regard to additional norms regarding the planning requirements and the authorisation of forms of collaboration, may hinder the creation of (supra) regional collaborations, i.e. collaborations with hospitals from other regions and/or with hospitals from other Member States. If a Community will be able to authorise a new structure in the framework of collaborations (specialised clinic for example), one may wonder whether the other Community will be willing to authorise certain types of collaboration with this new structure.

As a consequence of constitutional reform within Belgium and the existing specific rules for the forms of collaboration, clear rules related to the creation of collaborations between all types of hospitals or between totally different healthcare providers, including private hospitals and institutions for the elderly etc. do not exist.

2.3.2.18 Collaboration and physicians - Order of Physicians

The current legislation provides that the physician must be registered at the Provincial Council of the Order of physicians of the province in which he performs his main activity. Art. 21 of the Royal Decree of 6 February 1970 regulating the organisation and functioning of the councils of the Order of Physicians states that physicians must be registered on the list of the Order of the Provincial Council of the physician's site of 'residence'. This is the physician's site of residence determined by the location where the physician mainly practices.

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163 Report to the King of the Royal Decree 25 April 1997 houdende nadere omschrijving van de associatie van ziekenhuizen en van de bijzondere normen waaraan deze moet voldoen, *BS* 18 June 1997.

164 Art. 2 Royal Decree 30 January 1989 houdende vaststelling van aanvullende normen voor de erkenning van ziekenhuizen en ziekenhuisdiensten alsmede tot nadere omschrijving van de ziekenhuisgroeperingen en van de bijzondere normen waaraan deze moeten voldoen, *BS* 21 February 1989.

165 Art. 2 Royal Decree 31 May 1989 houdende nadere omschrijving van de fusie van ziekenhuizen en de bijzondere normen waaraan deze moeten voldoen, *BS* 5 July 1989.

Art. 22 of the Deontology Code, the Code of Conduct of the Council of Physicians, states that the physician practices his practice preferably in one place. However, if he wants to disperse his activities in more than one place, he must inform the provincial council, explain the need for the dispersion of his activities and indicate the location of his main activity. The decision to allow the physician to work elsewhere than at the location of his main activity is the competence of the Provincial Council. The highest Court ('Hof van Cassatie'/'Cour de Cassation')) considers that when the provincial councils refuse to grant a physician permission to disperse his medical activities, they draw their competence in art. 6, 2 ° of the Royal Decree n° 79 which provides that it is the provincial councils' task to 'ensure compliance with the rules of medical ethics and maintain the honour, discretion, probity and dignity of physicians referred to in art. 5, paragraph 1'.[166]

The rules related to registration at the competent provincial council as well as those related to evaluation of requests to work at differing hospitals may represent an obstacle to physicians in the context of large collaborations, where physicians may wish to work in different hospitals or even in different provinces.

2.3.2.19 Procurement and the concept of contracting authority

The concept of contracting authority, which partly defines the scope of the legislation on public procurement, is exhaustively defined by the European directives[167] and by the Act of 15 June 2006.[168] A 'Contracting Authority' means the State, regional or local authorities, bodies governed by public law, associations formed by one or several of such authorities or one or several of such bodies governed by public law. A 'body governed by public law' means anybody:[169]

1. established for the specific purpose of meeting needs in the general interest, not having an industrial or commercial character;
2. having legal personality; and
3. financed, for the most part, by the State, regional or local authorities, or other bodies governed by public law; or subject to management supervision by those bodies; or having an administrative, managerial or supervisory board, more than half of whose members are appointed by the State, regional or local authorities, or by other bodies governed by public law.

Therefore, if the legislation on public procurement is applicable in the context of collaboration between hospitals one might also ask (given that it is a collaboration between two contracting authorities) what the legal situation is concerning collaborations such as collaborations, organised between hospitals and other healthcare providers. In such a case, will the legislation on public procurement be applicable to a collaboration if this collaboration does not get public finance (but only the parties to the collaboration)?

2.3.2.20 Collaboration and finance

It is difficult to create regional or supra-regional collaborations if the financing of the BFM or the financing of infrastructure is related to the legal entity running a hospital. As long as a collaboration is not operating a hospital, it will be difficult to obtain financial support of public authorities. The National Hospitals Council was of the opinion in 2012 that the aim of the legislation was to link financial incentives to the creation of associations. The Council deplores that fact that this has not occurred either by the nomenclature or by the BFM.[170]

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166 Cass., 25 May 2001, D.00.0021.N

167 Directive 2004/18/EC of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts which remains in force until 18.4.2016 and Directive 2014/24/EU of 26 February 2014 on public procurement and repealing Directive 2004/18/EC

168 A reform is currently underway and aims to replace the current Act of 15 June 2006

169 Art. 1,9, of the Directive 2004/18/EC

170 National Council of the Hospitals, Advies inzake maatregelen om samenwerking tussen ziekenhuizen te bevorderen, 14 June 2012, Brussels, 6

It is also important to ponder the effect of European State aid rules where collaborations receive public finance and where they carry out other tasks than public service obligations. What for instance is the legal situation with regards to the use of hospital personnel financed by public means for ambulatory care? Similar questions exist with regards to the selling of medicinal products by hospital pharmacists to patients at home.

2.3.2.21 VAT and collaboration between hospitals

In a circular of 27 November 2012, n° 36/2012, the Belgian fiscal service recognised that collaboration between healthcare institutions in the healthcare field continues to increase. This is mainly an evolution driven by the competent authorities which are involved in the maintenance and improvement of healthcare delivery and the management of the costs relating thereto.[171] However, such collaboration can also arise spontaneously through initiatives of the care providers themselves.

The fiscal authority is of the opinion that, within the framework of collaboration agreements that aim to provide a complete level of care to those needing it, the care institutions themselves provide each other services and supply of goods at cost price. Questions therefore arise concerning the VAT of operations carried out under such contracts of collaboration between care institutions.

The fiscal authority distinguishes five types of collaboration contracts in the care sector:

- The 'type 1' collaboration arises through part of a sustainable collaboration agreement, legally formalised and approved by the competent authority. This includes hospital associations, hospital groups and hospital mergers.
- The 'type 2' collaboration relates to collaboration for the implementation of a care programme or a care project well defined and which is authorised or funded by the federal competent authority. There may be temporary collaboration.
- The 'type 3' collaboration regards the implementation of a care project that is regulated by the Authority without being subjected to a formal authorisation.
- The 'type 4' collaboration intervenes spontaneously between institutions without any intervention or assistance from the authority. It must concern the provision of care.
- The 'type 5' collaboration concerns agreements that are not linked to care (cleaning, food, etc.).

Art. 44 of the Code of Value Added Tax (VAT) provides an exemption regime for certain VAT payers as the healthcare providers. Therefore the tax administration has analysed whether all the services exchanged between healthcare institutions in a collaborative framework could fall under the exemption in art. 44.

In its circular, the fiscal authority has indicated that according the case law of the Court of Justice of the EU, the notion of 'medical care' in art. 132, paragraph 1 (b) of Directive 2006/112/EC, does not call for an especially narrow interpretation. The services covered by that term, like those covered by 'provision of medical care' in letter (c) of the same provision, must have as their purpose the diagnosis, treatment and, in so far as possible, cure of diseases or health disorders. Medical services carried out for a purpose of protecting, including maintaining or restoring, human health may benefit from the exemption under art. 132, paragraph 1, b and c, of the Directive - 2006/112/EC.[172]

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171 Mennig, F., 'Actualités 2012 en matière de TVA', in Le droit fiscal en Belgique, Limal, Anthemis, 2013, 283

172 Circular 36/2012 (E.T.123.129) of 27 November 2012

Based on the transposition of the European case law concerning the exemption of services performed between healthcare institutions, the administration considers that the exemption applies to services rendered when three conditions are met.[173]

- The service must be provided by a care provider (as mentioned in art. 44 of the Code of VAT) to another care provider mentioned in this art..
- The service must be directly related to diagnosis, treatment, convalescence, a host, the provision of assistance or a care for a person in need. The service must be required to achieve the above purpose. It will therefore primarily concern services requiring the intervention of care professionals or the provision of infrastructure or specialised medical equipment. Services that do not concern the provision of care may, however, be exempted if they are part of a complex operation that involves diagnosis, treatment, convalescence, a host or the provision of assistance or care to a person in need of care.
- The exemption of the service may not lead to a distortion of competition towards a non-exempted payer. This third condition is based on art. 134 of Directive 2006/112/EC. It is a question of fact. The fiscal authority stipulates that when a non-exempted economic operator provides the same operation, there is in principle a distortion of competition and the service cannot be exempted.

The collaborations of the type I, II and III are primarily intended to improve the quality of care. It is recognised for these collaborations that the non-application of VAT does not lead to a distortion of competition against other market players. However, should this be the case, the third condition for exemption will not be complied with and the status of collaboration in question would be re-examined by the fiscal authority.

Regarding the type IV collaboration, all transactions between the hospitals must individually comply with the three conditions.

It is important to identify the characteristic features of the transaction in question to determine whether the taxable person delivers to the consumer, several distinct principal services or a single service. A service will be regarded as ancillary to a principal service if it does not constitute for customers an aim in itself, but a means of better enjoying the principal service supplied. The ancillary service will have the tax treatment of the principal service.[174]

The 'type 5' collaboration does not have care as a purpose and therefore does not satisfy to the conditions set to benefit from the exemptions to VAT.

2.3.2.22 Collaboration between hospitals and private clinics

There is no specific binding legislation concerning collaboration between hospitals and private clinics.[175] Evermore surgery is being performed by external surgery centres, for instance external eye surgery centres.[176] Such centres do not fall within the definition of a 'hospital' in the sense of the Hospital Act and do not have a legal obligation to comply with the authorisation and norms applicable to authorised hospitals.[73] A legal definition of external centres does not exist. According to the Belgian Health Care Knowledge Centre[37] Report 225. D/2014/10.273/49, external centres are '*healthcare centres, other than hospitals as defined in the Belgian Hospital Act or a healthcare setting linked to a hospital, where any eye surgical or other invasive procedure requiring general or locoregional anaesthesia, or sedation, including cryosurgery and laser surgery, but without the patients staying overnight, is performed by a physician. This definition excludes ambulatory practices, where only minor interventions are*

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173 Mennig, F., *o.c.,* 283

174 For the viewpoint of Zorgnet-Icuro, see Zorgnet-Icuro, Regionale ziekenhuisnetwerken, Brussel, 2015, 12

175 It is provided in of the Royal Decree n°. 78 of 11 November 1967 regarding the practice of health professions, art. 4, § 4 that physicians who are allowed to hold a storage of medicinal products and implants if they have an agreement with a hospital pharmacy or a pharmacy open to the public.

176 Extramural centres are often private for-profit clinics.

performed belonging to the nomenclature for GPs, dermatologists and dentists.[73] '

For certain risky medical interventions outside a hospital, a notification obligation was provided in a Flemish decree of 22 June 2012 regarding the obligatory notification of risky medical practices.[177] This Decree has been annulled by the Constitutional Court.[178] External centres do not have to comply with the authorisation norms and the quality norms embedded in the Hospital Act and many other rules and initiatives.[81]

In Table 2, the facilitators and barriers are listed.

Table 2 – Synthesis of the facilitators and obstacles

	Facilitators	Obstacles
Coordination of the collaboration	• General coordinator • Coordinating committee • CMOs and head of medical services	• Decision power of the coordinating committee • Composition of the association committee • Conflicts of interest are possible
Representation of the medical staff	• Common medical committee	• Impact of the medical council of the collaboration • Power of the medical council of the participating hospital
Legal form of the collaboration	• Flexibility of the legal form	• Limited statutory purpose of the legal entity that operates a hospital
Hospital pharmacy	• Existence of form of collaboration	• Incompatibility of the legislation concerning hospital pharmacy
Status of the hospital physicians		• Individual contract with a collaboration • Different general regulations • Less votes for medical councils election • Exclusiveness
Provision of staff		• Incompatibility of labour legislation • Non common policy for employees
Purchasing of pharmaceuticals	• Central purchasing body • Framework agreement	• Concept of contracting authority

177 Decree of 22 June 2012 regarding the obligatory notification of risky medical practices of 22 June 2012, *BS* 20 July 2012.

178 Constitutional Court 19 December 2013, nr. 170/2013.

3 THREE GOVERNANCE MODELS FOR HOSPITAL COLLABORATIONS

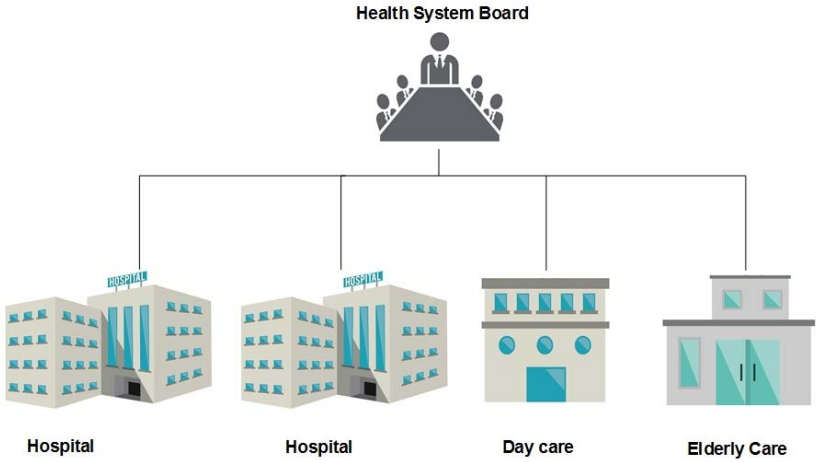
Based on the input from a review of the literature, national and international case studies and an analysis of current legislation, a number of different solutions for governing hospital collaborations in Belgium were drafted. Three governance models that support task distribution and collaboration between hospitals were identified. In this chapter, the final drafts of these potential solutions are presented.

3.1 Model 1: The health system

As identified in the literature and the international cases, integrated governance forms, such as health systems, can enhance task distribution and collaboration. Participants in the national cases also acknowledge that, when the goal of the hospitals is to collaborate on a large number of services, an integrated structure like a health system is appropriate. In a health system, organisations agree to collaborate in some kind of closed system where an overarching board is in charge of the collaboration (Figure 2). The institutions that are part of the health system remain independent entities in the sense that they can be located in separate locations; however, the central board directs all hospitals on the overarching level (Table 3). As such, the main difference between a health system and a merger lies in the fact that all authorisations are maintained. However, it is the health system instead of the single hospital that receives the authorisation. In addition, different types of governance structures are possible and in a health system other organisations besides hospitals can collaborate.

This model answers some challenges identified in the current legislation and Belgian situation. As a health system is a single organisation, authorisation is possible on a higher level, and it is not necessary to provide each service at each location. The budget is allocated to the organisation as a whole, which makes it less important where a patient is treated for the organisation. The exchange of physicians is easier because they all work in the same organisation and follow the same regulations and conditions. The governance structure also enables more integrated care forms of healthcare, since other types of organisations may also be part of the health system. The latter, however, is not a prerequisite: a health system can be focused on hospital collaborations only, certainly in the beginning of this collaboration type. Although this governance structure provides an answer to many currently identified problems, such a high level of integration still represents an enormous step for some of the collaborations.

Figure 2 – Model 1: Health system



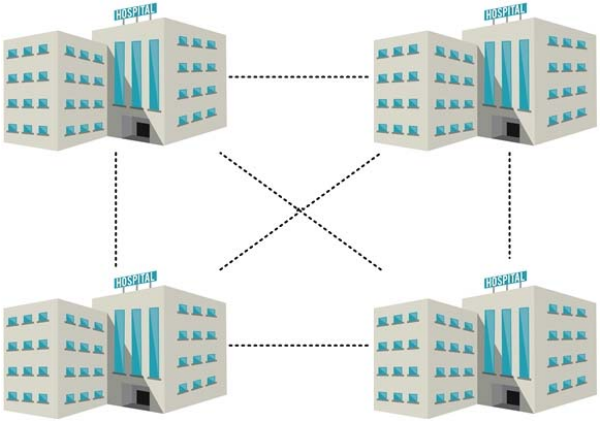
3.2 Model 2: Network

In the Belgian cases, the interviewees indicated that decision making in a network type of collaboration can be too time consuming. Before making a decision on the network level, each medical council (and board) at the hospital level needs to discuss these decisions. An integrated governance form like a health system provides a solution for this problem. However, as an intermediate step between the current situation and the more integrated models, interviewees in the Belgian case studies indicated that it is preferable to have a governance model where delegates in a network configuration have some level of decision-making rights in the overarching governing bodies. Hence, in Model 2, an overarching committee should be able to make certain network-related decisions without having to consult the councils and boards of the hospitals each time (Table 3).

The Model 2 cooperation involves the formation of a participant-governed network. Equal decision-making rights in participant-governed networks were considered a strength, and in lead organisations the decision-making structure evolves (or might evolve) to a participant-governed network. We prefer to select a participant-governed network, although other governance structures (such as lead organisations or NAOs) might be selected and described in the collaboration rules. The characteristic of this type of collaboration is that the decision-making and authorisation remain on the level of the participating hospitals and are not transferred to the overarching collaboration. The collaboration in Model 2 leaves decision making on the hospital level. However, there is a network committee with members representing different actors, such as the hospital physicians and the administrators that are mandated to make decisions. An explicit list of mandated topics should be established. If one hospital does not agree with a decision, they can recall the decision.

The collaboration may serve different purposes and can include not only hospitals, but also homes for the elderly, GPs, and so on. It is not the collaboration that runs the hospital services: the collaboration is not authorised for either services or hospitals. All authorisations stay on the hospital level. The cooperation between hospitals and other health actors of the network may be based solely on a contract without a need for the collaboration to be a separate legal entity, though this is also possible.

Figure 3 – Model 2: Network



Although in the national cases, the importance of authorisation at the collaboration level was often mentioned, Model 2 does not support this. If a collaboration were indeed authorised on the collaboration level, many problems of a legal, financial, and organisational nature can occur when a hospital leaves. A loosely coupled structure complicates this. If organisations aim for authorisation at the overarching level, they will need to form a more integrated structure (as in Model 1); another possibility for more specialised service lines, is described by Model 3.

3.3 Model 3: The new organisation

The interviewees of the different Belgian case studies indicated that there is a need for care programmes, such as diabetic and cardiology programmes, to be authorised on the collaboration level and to be able to receive a BFM. However, the hospitals do not want to integrate all their services with the same partners (as would occur in a health system). Some of the collaborations aimed to collaborate for only one or a limited amount of services. A new organisation should be developed with a limited scope (Figure 4).

Model 3 involves the establishment of a new organisation with its own board and medical council. This organisation should be able to receive a budget from the BFM. Model 3 can be used for supporting medical services – e.g. laboratories, pharmacies, and medical equipment collaborations, as in the case of radiotherapy. The model can also be applied for high-expertise care, for innovative high technology care, and for care programmes, such as diabetic or cardiology programmes, but also for specific service lines (examples exist abroad, such as elective orthopaedic surgery and eye surgery). This model will enhance collaboration for more horizontal networks that aim to provide care for a specific pathology of service with high expertise. At the moment, this final goal may still be difficult to achieve, as hospital activities are paid from a closed-end budget in the BFM, which can hinder pathology-based allocation to the organisation. However, since this new organisation can receive the budget, this model can create opportunities for new legislation to enhance pathology-based allocation of financial means for collaborations.

Model 3 enables collaboration for specific service lines and supporting services. When hospitals do not want to integrate all their services, but instead desire to collaborate intensely on a few services, a new organisation can provide an answer. This model can enhance collaboration for care programmes, although the study also identified that the regulations for care programmes should change. More and adjusted care programmes (e.g. oncology, paediatrics), should also be available.

Figure 4 – Model 3: New organisation

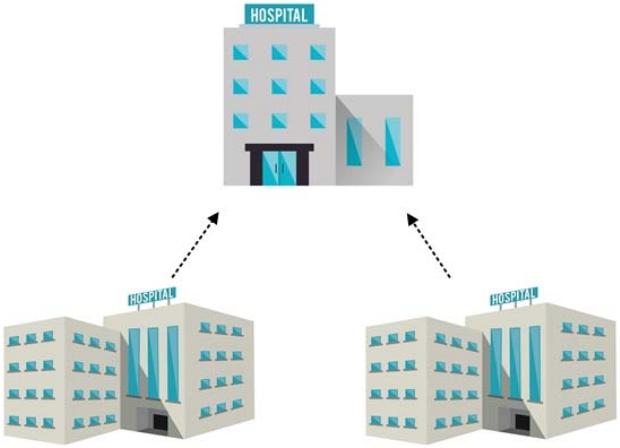


Table 3 – Proposed collaboration models

Model	Description
Health system	Used inter alia by institutions that want an integrated system
	High level of integration, partners that strive for the same goals
	One board at the health-system level
	The health system holds authorisations
	Non-hospitals may also be part of the health system, although this is not a prerequisite
Network	Decision making and authorisation remain within the hospitals
	On the network level: network committee
	The network committee consists of mandated physicians and CEOs/members of the board
	The topics that are mandated and the level of decision-making rights should be described in the regulations of the organisation
	A participant-governed network is assumed (equal partners), but this can also be adjusted through the regulations of the collaboration in other governance forms such as lead organisation or a NAO
	Depending on the goals of a collaboration, the network can encompass all services or a selected group of hospital services (interhospital)
New organisation	Collaboration in terms of one or a limited number of patient groups, pathologies, services, or supporting services
	Authorisation on the level of the new organisation
	Provides medical services at the level of a new institution (in accordance with current hospital legislation)
	Concerns collaboration between several hospital services (interhospital)

4 FACILITATORS AND BARRIERS IN CURRENT LEGISLATION TO ESTABLISH NEW GOVERNANCE MODELS OF HOSPITAL COLLABORATIONS

4.1 Introduction

The legally structured types of collaboration among hospitals, as well as other types of collaboration between hospitals and care providers, whether they are authorised by the competent public authority or not, have been examined in Chapter 2. We evaluated more in detail in which way the current legislation can divide the care landscape in regional and/or supra-regional networks. We evaluated the facilitators and obstacles to collaboration between hospitals from a legal perspective.

Different forms of collaboration were examined. New models have been created on the basis of, *inter alia*, case studies and literature reviews (see Chapter 3).

In this chapter, facilitators and barriers in current legislation, both hospital-specific and non-hospital-specific, to establish the three governance models are examined. It will focus on important points for each of the legal texts that might apply if the models were to be put into practice. In addition to hospital legislation, attention is paid to aspects such as competition rules, public procurement law, labour law, VAT-law, the legislation on not-for-profit association, company law, European law and administrative law.

We first provide a brief description of each model. Next, we analyse the impact of legal rules on each model separately. In a final section, we formulate a legal answer to the following questions: is it necessary for the legislator to make legal rules for different governance models? How can collaboration with other hospitals be achieved? Should the legislator intervene in the decision process? What is the impact of the model on the quality of care and on the payment system?

4.2 Legal feasibility of a health system

4.2.1 The launch of a health system

In a health system, institutions enter into a collaboration in which they work together in a closed system with an overall administrator. Although the institutions that are part of the health system remain independent entities in the sense that they can be located at a separate site, on an overall level, a central administrator is charged with controlling them.

Legally speaking, the entities that enter into the health system will be in most cases dissolved over time. Depending on the complexity of the integration, this may or may not take a long period of time. In extremis, a transitional period of 10 years is not inconceivable. The individual entities will thus continue to exist for a transitional period. This implies that an arrangement should be made, not only for the situation after the integration, but also at the start, a situation where there e.g. still exist a few 'not-for-profit associations' that were involved before the launch of the health system with running a hospital. With regard to the transition period, arrangements will have to be made concerning, but not limited to, the transfer and employment of staff and physicians, the transfer of materials, etc.

This model allows the creation of a collaboration between numerous facilities originating from different sectors located in the health and welfare sector, including general hospitals, mental health facilities, nursing homes, institutions supporting disabled people and child, youth and family institutions. The focus is however, mainly on hospitals.

Please note that the term 'health system' as used in this chapter does not necessarily totally comply with the term 'group' as mentioned in the Royal Decree of 30 January 1989 where a group implies agreements regarding the allocation of tasks and the complementarity for the provision of services, disciplines or equipment used in hospitals, in order to meet the needs of the population and to improve the quality of healthcare. Art. 8, second paragraph of this Royal Decree explains that the group may not lead to mono-specialist hospital sites, with the exception of sub-acute geriatric- and specialised (Sp-services. So, under the Royal Decree the term 'group' does not necessarily refer to an organisation that also runs institutions for the elderly, for children etc. Moreover, the creation of a health system as described in this section

does not necessarily imply a group as in the meaning of the Royal Decree where for example there is no collaboration among the institutions. So the term health system in this section refers more (as was described in part I) to situations such as a hospital holdings, although in reality a health system differs from hospital holdings since non-hospitals may also be part of the health system. As we stated earlier, a holding is not regulated by the Hospital Act. It refers to the situation whereby independent units are governed by a common board.[72]The authorisation numbers of the independent units are maintained.

4.2.2 Legal form for operation

It is important for a health system that chooses a certain legal form to verify whether the current legislation poses requirements in terms of the type of legal form required in order to operate a healthcare organisation or to get funding for the healthcare organisation in question. This section refers to the importance of the legal form needed to operate an institution. In section 4.2.6 we discuss whether a Member State can limit the granting of subsidies to specific types of organisations.

4.2.2.1 Not-for-profit association

The Hospital Act does not require that the hospital is run by a not-for-profit association. The legislator did not choose for a specific legal form for running a hospital, with the exception of the rules related to subsidies for infrastructure. The hospital legislation does not even prohibit a commercial organisation, like a for-profit organisation, to operate a hospital and to receive funding doing so. The hospital legislation only requires that the hospital has the mandatory authorisations. So if a commercial organisation obtains authorisations, that commercial organisation is allowed to constitute a hospital under hospital legislation and it can claim the BFM as it has beds for which it has obtained authorisations.

As will be shown below in the section on financial legislation (4.2.6), the legislation concerning the possibility to receive subsidies for infrastructure, is much more rigid. A commercial organisation will not be able to receive subsidies for infrastructure since it should be a not-for-profit association (or a local government, a public utility or a university (see art. 63 of the Hospital Act).

A possible legal form for a health system is that of a not-for-profit association. Opting for this form brings with it some important legal effects. First of all, the provisions of the not-for-profit association will apply. A not-for-profit association is an independent entity that can possess rights and duties. Such an organisation has legal personality from the day on which its statutes, the documents concerning the appointment of the first administrators and, if applicable, the persons authorised to represent the organisation in and out of court are deposited at the registry of the commercial court.[179] Given that a not-for-profit association has complete legal personality, the members shall not be personally liable for the debts of the organisation.

Both natural persons and legal persons (such as not-for-profit association or commercial companies) can act as the founder of a not-for-profit association.[180] Likewise, an organisation without legal personality as well as an organisation authorised in public law can act as a founding member of a not-for-profit association. When creating a not-for-profit association, at least three founders are required.[181] The founding statutes list the conditions and procedures for admission and *resignation* of members.[182] Moreover, the article of an association can provide additional special conditions of

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179 Art. 3, § 1, first paragraph Act 27 June 1921 betreffende de verenigingen zonder winstoogmerk, de internationale verenigingen zonder winstoogmerk en de stichtingen, *BS* 1 July 1921.

180 M. Denef *et al*, *De VZW*, Bruges, die Keure, 2015, 71 en 72.

181 Art. 2, 3° Act 27 June 1921 betreffende de verenigingen zonder winstoogmerk, de internationale verenigingen zonder winstoogmerk en de stichtingen, *BS* 1 July 1921.

182 Art.. 2, first paragraph, 5° Act 27 June 1921 betreffende de verenigingen zonder winstoogmerk, de internationale verenigingen zonder winstoogmerk en de stichtingen, *BS* 1July 1921.

accession and formalities for which a prospective member must comply if they wish to join a specific not-for-profit association.[183]

4.2.2.2 Company with social aim

Since the purpose of the statutes limits the legal capacity of the individual legal entity concerned, the creation of the entity must fit within the statutory objects of the participating entities.[184] This means that an entity cannot acquire rights or make commitments outside of its object, as defined in the article, in addition, legal restrictions can be imposed on the object or subject field pursued by the legal entity.[185] An example of this is the main specific feature of a not-for-profit association, namely the absence of a profit motive.

This report is not focused on the public hospitals since many of these hospitals disappeared or the legislation related to public centres of social welfare is mainly written now at the level of the regions and the subject of recent/planned modifications. However, the so called company with social aim might be an option next to the not-for-profit association as well ('vennootschap met sociaal oogmerk'/ 'une société à finalité sociale'). This is a company which is not aimed at the enrichment of partners. The statutes stipulate among other things:

- that the partners pursue no or limited power advantage;
- the social purpose of the activities they carry out in accordance with the purpose of the company in which the main objective should not be the granting of an indirect financial benefit to the partners;
- how the profits are spent in accordance with the internal and external objective of the company.

There are many differences between a not-for-profit association and a company with a social aim. Below we describe some of these differences. Where one becomes a member of a not-for-profit association by being accepted, one becomes a partner of the company with a social aim through a contribution.[82] Where there is normally no liability for the members of a not-for-profit association, there is founders' liability for the partners and possible unlimited liability depending on the type of company.[82] Where sharing of profits is prohibited in a not-for-profit association, the distribution of profits in a company with a social aim is either impossible or possible to a certain extent, depending on the choices in the statutes.

A not-for-profit association can organise civil activities and commercial activities to the extent that a commercial activity is not the main activity and is a function of the civil activity. In a company with a social aim one can organize civil activities and commercial activities as main activities.[82] It is obvious that the field of activities of a company with a social aim is even broader than that of not-for-profit association and that the company it may also have commercial activities as their main activity. But this is exactly why under the current legislation it will be difficult to run a hospital with a company with a social aim. Art. 63 of the Hospital Act and art. 4 of the Decree of the Flemish government on 8 June 1999 provide that infrastructure grants are only possible to a local government, a not-for-profit association, an institute of public utility or a university. The company with a social aim is not listed and is therefore under the current legislation not eligible for infrastructure funding.

4.2.2.3 The operation of other organisations

Please note that legislation applicable to organisations that deliver care at home is only applicable if they are e.g. not-for-profit associations.

In the *Woonzorgdecreet* of 13 March 2009 it is provided that home care organisations can only be authorised if they are created by one of the following organisations:

1. a private incorporated society for which it is prohibited by law to provide her members a financial benefit

183 M. Denef *et al*, *De VZW*, Bruges, die Keure, 2015, 131.

184 M. Denef *et al*, *De VZW*, Bruges, die Keure, 2015, 73.

185 J. Ronse, Algemeen deel van het vennootschapsrecht, Leuven, Acco, s.d., 292-293; V. Simonart, La personnalité morale en droit privé comparé, Brussel, Bruylant, 1995, 179, nr. 215.

2. a provincial administration
3. a municipal administration
4. a public welfare centre
5. the Flemish community commission
6. a public organisation
7. an organisation founded in conformity with title VIII of the Decree of 19 December 2008 regarding the organisation of public welfare centres
8. a sickness fund
9. a public institution of category B as mentioned in the Act of 16 March 1954 on the control of certain institutions having public utility
10. another legal person that does not seek profit and which is appointed by the Flemish government.

4.2.2.4 Impact of State aid rules and public procurement legislation on the type of organisation

Healthcare organisations often receive payments from public authorities to operate a hospital or other facilities such as homes for the elderly. If running a (private) hospitals can be considered as a service of general economic interest (SGEIs), then the question is whether a health system can be a profit or a not-for-profit organisation. The Court of Justice has held that, according to the scale of values held by each of the Member States and, having regard to the discretion available to them, a Member State may restrict the operation of certain activities by entrusting them to public or charitable bodies.[186] Any measure of this kind must, however, be suitable for guaranteeing the achievement of one or more legitimate objectives invoked by that Member State and must not go beyond what is necessary to achieve those objectives. National legislation is appropriate for ensuring attainment of the objective pursued only if it genuinely reflects a concern to attain it in a consistent and systematic manner. In any event, such restrictions must be applied without discrimination.[187] Moreover, European State aid rules do not provide for specific criteria on the legal form of the health system.

If public procurement legislation does apply, an individual contracting authority could not, until recently, decide to limit a tender procedure to not-for-profit service providers.[188]

The new public procurement Directive of 2014 (Directive 2014/24) explicitly provides that if a Member State applies the procurement procedures for certain services in the fields of health, social and cultural services these services could be reserved for organisations which are based on employee ownership or active employee participation in their governance, and for existing organisations such as cooperatives to participate in delivering these services to end users. This provision is limited in scope exclusively to certain health, social and related services. Art. 77 of Directive 2014/24 provides indeed that Member States may provide that contracting authorities may reserve the right for organisations to participate in procedures for the award of e.g. public contracts exclusively for those health, social and cultural services which are covered by CPV (Common Procurement Vocabulary) codes 75121000-0 (SC: Supply services of nursing personnel), 75123000-4 (SC: Supply services of medical personnel).

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186 Commission staff working document of 29 April 2013, entitled 'Guide to the application of the EU rules on State aid, public procurement and the internal market to services of general economic interest, and in particular to social services of general interest', Brussels, SWD(2013) 53 final/2, p. 105. For case law, see e.g. CJ, C-447/08 en C-448/08, 8 July 2010.

187 Commission staff working document of 29 April 2013, entitled « Guide to the application of the EU rules on State aid, public procurement and the internal market to services of general economic interest, and in particular to social services of general interest', Brussels, SWD(2013) 53 final/2, p. 105.

188 Commission staff working document of 29 April 2013, entitled 'Guide to the application of the EU rules on State aid, public procurement and the internal market to services of general economic interest, and in particular to social services of general interest', Brussels, SWD(2013) 53 final/2, p. 95.

Such an organisation shall fulfil all of the following conditions:

1. its objective is the pursuit of a public service mission linked to the delivery of the above mentioned services;
2. profits are reinvested with a view to achieving the organisation's objective. Where profits are distributed or redistributed, this should be based on participatory considerations;
3. the structures of management or ownership of the organisation performing the contract are based on employee ownership or participatory principles, or require the active participation of employees, users or stakeholders; and the organisation has not been awarded a contract for the services concerned by the contracting authority concerned pursuant to this art. within the past three years.

Moreover, the maximum duration of the contract shall not be longer than three years.

Even before this new Directive of 2014 on public procurement, the Commission was, in 2013, already of the opinion[189] that national law regulating a particular activity might, in exceptional cases, provide for restricted access to certain services for the benefit of not-for-profit organisations. In this case public authorities would be authorised to limit participation in a tender procedure to such not-for-profit organisations, if the national law is compatible with European law. Nevertheless, such a national law would restrict the working of art. 49 and 56 of the Treaty on the Functioning of the European Union (TFEU), on the freedom of establishment and the free movement of services, and would have to be justified on a case-by-case basis. On the basis of the case law of the Court of Justice, such a restriction could be justified, in particular, if it is necessary and proportionate in view of the attainment of certain social objectives pursued by the national social welfare system.[190]

In conclusion, if it is necessary and proportionate in view of the attainment of certain societal objectives pursued by the national social welfare system it is allowed, under the EU legislation, to restrict Health system services (subsidies and procurement) to not-for-profit organisations. Yet, this should be motivated on a case-by-case basis and may not be in conflict with other national laws.

4.2.3 Delegation of daily management within the health system

If the health system is composed of various institutions, it may opt for installing a managing CEO in the executive committee for the different types of institutions. By special mandate, the board can delegate functions by sector or facility, to board committees. In addition, a kind of coordination service can be added to the board. To ensure internal collaboration and consultation between the various institutions, it is advisable to work with coordinating committees and working groups (as in that case of coordinators of financial-economic projects or coordinators of common purchase agreements and procurement activities) that advise the board and the management of facilities.

4.2.3.1 Not-for-profit association

If a health system works through a not-for-profit association the general assembly decides on the issues mentioned in the Act of 21 June 1921 on not-for-profit associations and in the statutes of the organisation. The board manages and represents the not-for-profit association. All powers that are not expressly conferred by the Act to the general assembly belongs to the board.[191] The power to represent the collaboration can according to the statutes be given to one or more persons. The executive management of the collaboration can also be given according to the art. of the association to one or more persons.

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189 Commission staff working document of 29 April 2013, entitled « Guide to the application of the EU rules on State aid, public procurement and the internal market to services of general economic interest, and in particular to social services of general interest', Brussels, SWD(2013) 53 final/2, p. 95

190 See Judgment 17 June 1997, zaak C-70/95, Sodemare SA, Anni Azzurri Holding SpA en Anni Azzurri Rezzato Srl/ Regione Lombardia, Jurispr. 1997, pag. I-3395.)

191 Art. 13 of the Act of 27 June 1921

4.2.3.2 For-profit structure

If a health system opted for working in a for-profit structure (a public limited company (PLC); 'Naamloze Vennootschap'/'Société Anonyme'), then the board also plays an important role, as is the case in a not-for-profit association. That board cannot simply delegate its powers in general terms.[192] The daily management may however still be delegated to, for example, a CEO. The Highest Court stated in its 2009 judgment[193] that a member of the executive committee is authorised to make transactions that meet the daily needs of the company (and needs that are less important), where an urgent settlement is required that does not allow the intervention of the board.[194] To address the need for more efficient decision-making and the legal uncertainty, the Act on Corporate Governance[195] provided in the ability of a for-profit company (PLC) to create a new provisional institution: the legal executive committee.

The board may be authorised by the statutes to transfer its management powers to this executive committee.[196] The ability to set up such a committee, depends therefore on the existence of a statutory provision.[197] The Act stipulates explicitly that the transfer can never concern the general policy or acts which are reserved by Act for the board. In practice it is often the executive committee that in reality takes the important decisions, which are then subject to ratification by the board.[198]

Art. 522, § 1, third paragraph of the Company Code allows the board to set up in its midst and under its responsibility one or more advisory committees. Upon establishment, their composition and their tasks must be defined. The board has full freedom in the composition of an advisory committee. Both members and non-members, CEOs, employees and external consultants can be appointed to a seat in the committee. It is important to note that such committees only have advisory roles. The creation of such a committee therefore does not imply a delegation of powers by the board.[199] The purpose of an advisory committee is to inform the board on specific matters. The chairman of the committee is expected to write a report after each meeting for the board. Examples of such committees include but are not limited to: audit committees, remuneration committees (both modelled on the obligation for listed public limited companies) and scientific committees.

The Act contains no provision that the establishment, composition, functioning and powers of an advisory committee should be regulated by statutes or must be approved of by the general assembly. The board is however required to establish the internal rules for each committee and include it in the *corporate governance*-charter. This should also include the

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192 S. De Geyter, I. De Poorter en E. Leroux, *Delegatie en taakverdeling in de NV,* Gent, Larcier, 2015, 61.

193 Cass. 26February 2009, *R.W.* 2009-10, afl. 27, 1129, noot W. GOOSSENS and B. CAFMEYER.

194 B. Beele 'Dagelijks bestuur' in B.Beele, J. Huysentruyt en G. Verhaeghe e.d., *Het bestuur van een NV: vennootschapsrechtelijke, sociale en fiscale aspecten,* Heule, UGA, 2005, 347.

195 Act 2 August 2002 houdende wijziging van het Wetboek van Vennootschappen alsook van de wet van 2 maart 1989 op de openbaarmaking van belangrijke deelnemingen in ter beurze genoteerde vennootschappen en tot reglementering van de openbare overnameaanbiedingen, *BS* 22 August 2002.

196 See art. 524bis W. Venn.

197 S. De Geyter, I. De Poorter en E. Leroux, *Delegatie en taakverdeling in de NV,* Gent, Larcier, 2015, 63.

198 S. De Geyter, I. De Poorter en E. Leroux, *Delegatie en taakverdeling in de NV,* Gent, Larcier, 2015, 78, nr. 178. The acts of the executive committee and its existence can only be invoked against third parties after publication in accordance with the art. 76 and 524 bis of the Company Code. If an executive committee is established, the board will take on a supervisory role.

199 S. De Geyter, I. De Poorter en E. Leroux, *Delegatie en taakverdeling in de NV,* Gent, Larcier, 2015, 116, nr. 260; J. De Wolf, 'Niet-uitvoerende bestuurders in een one-tier board system. Begrip en wettelijke toepassing', *RPS* 2011, afl. 2, nr. 7050, 161.

clarification of the composition and functioning of the committee concerned.[200]

4.2.4 Statutory purpose of the legal entity in charge of the health system and participation of other organisations

As written above, the Hospital Act has made no specific choice of the type of legal entity that may operate hospitals. However, in art. 15 of the Hospital Act it is defined what kind of institutions can be governed by the not-for-profit association operating a hospital. Art. 15 §2 of the Hospital Act specifies that hospitals are operated by a legal entity whose sole statutory purpose is the operation of one or more hospitals, healthcare institutions or medical-social institutions.

Originally, numerous not-for-profit organisations were, in the broadest sense of the term, 'responsible' for the operation of nursing homes, meaning that they could run for example both nursing homes and hospitals and often also carry out related activities in the context of healthcare and welfare, or education.[201]

Art. 57 of the Act of 14 January 2002 on healthcare measures radically altered the then applicable art. 10 (now art. 15 of the Hospital Act). This article states:

1. § 1. Every hospital has its own management.
2. § 2. Hospitals are, in accordance with the conditions established by the King, by decree adopted after deliberating with the Council of Ministers, run by a legal person which has, as its sole statutory purpose, the operation of one or more hospitals or health or medical-social establishments.

   The King may specify the healthcare establishments, referred to in the preceding paragraphs, by decree adopted after deliberating with the Council of Ministers.

   The King may, by decree adopted after deliberating with the Council of Ministers, provide exemptions in respect of the provision referred to in the first paragraph.
3. § 3. The King may, by decree adopted after deliberating with the Council of Ministers, determine the categories of legal persons that may operate a hospital.

4.2.5 Authorisation of the health system or institutions of the health system

4.2.5.1 Authorisation belongs to the administrator, not to a building

As was described above, different types of legal persons can run a health system and it remains possible for a Member State to provide in very specific, justified and non-discriminatory situations to limit the operation of a health system to a very specific type of legal person. The question then is to whom belongs the authorisation that was given in the past and was related to an institution that is now operated by the health system.

The legal entity responsible for the exploitation receives authorisation, and not the physical institution itself.

Art. 69 § 1 of the Hospital Act stipulates that every hospital should be authorised by the authorities responsible for health policy on the basis of the art. 128, 130 or 135 of the Constitution. According to art. 72 each service established within a hospital must be authorised by the authorities referred to in the art. 128, 130 or 135 of the Constitution. However, the application for authorisation as a hospital or hospital service is carried out by the 'administration'. For example, art. 1 of the Decree of 25 April 2014 of the Flemish Government concerning the procedures for healthcare facilities defines the 'administration' as one or more persons representing an institution who has legal control of the institution. Strictly speaking, it is not the hospital as a building or as a service that applies for authorisation. It is

200 S. De Geyter, I. De Poorter en E. Leroux, *Delegatie en taakverdeling in de NV,* Gent, Larcier, 2015, 174.

201 W. Vercruyssen, *Basisbeginselen inzake ziekenhuiswetgeving,* Caritas Verbond der Zorginstellingen vzw, Brussel, 2002, 35

the person representing a hospital or service and authorised to legally bind it, who applies for the authorisation (see e.g. art. 4 of the Decree of 25 April 2014) and who will in principle receive it. It is logical that a reference is made in the authorisation to the location to which the authorisation relates, but strictly speaking is it not the building to whom the authorisation relates, but to the person who represents the hospital or service and has legal control of it. So, in other words, if a hospital or a service is operated by a not-for-profit organisation, it will be that not-for-profit organisation to whom authorisation is given. If the not-for-profit association operates various facilities, it will always be that same not-for-profit association that will receive authorisation but such authorisation can in reality then relate to completely different buildings, sites and services.

4.2.5.2 Is a collaboration or a health system contract between hospitals possible if the same legal person operates the institutions within the health system?

Art. 67 of the Hospital Act provides that specific standards can be established for groups, mergers and associations of hospitals, such as those specified by the King and for the specific locations of the hospitals, such as those specified by the King.

Art. 67 is not concerned with issues concerning a group of hospitals as described above. The extent to which institutions within a group as described above may proceed to form an association or a group in the meaning of the Royal Decree of 30 January 1989, even though there is only one legal entity operating the institutions is, however, not clear. In the past, the (Flemish) administration did not contest initiatives in which an institution, being the authorised operator of hospital A, engages in an association or a group according to the Royal Decree of 30 January 1989 with an institution which is the authorised operator of hospital B, even if hospital A and hospital B were operated by the same legal person. The Royal Decree of the 30 January 1989 refers mainly to a group of *hospitals* (rather than the different legal entities operating hospitals).

As for the hospital association, it should be pointed out that if a health system would like to engage in an association, art. 67 of the Hospital Act states that only the legal persons who operate the hospitals that are part of the association as well as physical or legal persons who are proposed by the concerned entity, may be a member or partner of the legal person that exploits this association. If other legal entities are also represented in the health system, other than legal persons who are involved in the operating of hospitals, it will not be possible to conclude an association.

Transfer of authorisation and modification of authorisation

If a hospital is transferred to another organisation, the resulting overarching organisation must also secure authorisation relating to the transferred hospital.

In the Decree of 25 April 2014 of the Flemish Government concerning the procedures for healthcare facilities, it is stated that any change occurring in the course of the authorisation term, in the data contained in the documents transmitted, is immediately communicated to the Care and Health Agency.

If the administration of a hospital, a hospital service, a hospital unit or a form of collaboration decides upon the voluntary cessation of the operation of the hospital, the hospital service, the hospital unit or a form of collaboration, the administrator-general of the Agency must be notified three months in advance, specifying the date on which the decision takes its effect. The voluntary cessation of the operation, will result in the closure of the hospital, the hospital service, the hospital unit or form of collaboration in question.[202] In this case, the planning permission and operating license on which authorisation was based, shall expire six months after the date of conclusion.

According to art. 13 of the Decree of 25 April 2014 the request (with accompanying explanation as to motivation) for authorisation of a hospital unit or a form of collaboration has to be submitted to the agency by the administration through means of a registered letter. That application shall contain the information and documents supporting the aforementioned

[202] Art. 30 of the Decree of 25 April 2014.

reasons and provide evidence of compliance with all the conditions for authorisation. In case of an authorisation for a form of collaboration, art. 1, 12° of the Decree refers to the forms of collaboration regulated on the basis of the Hospital Act, i.e. the merger, association or group. The above mentioned Decree of 25 April 2014 does not provide for specific rules for the method of collaboration in the context of a health system.

4.2.6 Financing of the health system

4.2.6.1 Subsidies for infrastructure

Above we have described which type of legal person can *operate* a hospital. In this section we analyse which type of legal person may *receive subsidies* for infrastructure.

Art. 63 of the Hospital Act states that 'to the extent that the requesting party is the executive management in the organisation, a *not-for-profit organisation*, a public utility or a university referred to in art. 10 of the Decree of the French Community of 31 March 2004 defining Higher education, Favouring its Integration into the European Higher Education Space and the Refinancing of Universities' on the one hand and art. 3 of the Decree of the Flemish Community of 12 June 1991 'concerning universities in the Flemish Community' on the other hand, the government, as meant in art. 128, 130 or 135 of the Constitution, can, through grants, intervene in the costs that occur. This includes costs pertaining to construction and reorientation of a hospital or of a service as well as the first costs of equipping the hospital (including the purchase of appliances), provided that the establishment, maintenance or conversion of the hospital or of the service fits within the framework of the programme mentioned in art. 36.

This art. 63 of the Hospital Act makes obvious that the legal form is important when considering the potential award of infrastructure subsidies. This federal rule has been taken over by the legislator of the Community.

For example, art. 2 of the Decree of 23 February 1994 concerning the infrastructure related to individual requirements ('persoonsgebonden materies'/'matières personnalisables') describes the applicant as the legal entity which is approved or meets the legal requirements to organise care and services in the framework of individual requirements, and which submits an application to obtain an investment subsidy or investment security. The decision of 8 June 1999 of the Flemish Government concerning the procedure governing the infrastructure for individual requirements states in art. 4 the following:

1. The request for subsidies must contain:
2. For the general hospital:
   a. the signed minutes of the meeting of the competent organs of the applicant with the decision to apply for an investment and possibly an investment guarantee;
   b. the mentioning of the company number or the documents or articles which show that the requesting party is either a local or provincial administrator, or a not-for-profit organisation.

From what precedes it appears that applications for investments can only be requested by the person who operates the hospital and that if the applicant is a commercial organisation, it will not be granted subsidies or investment guarantees for a hospital.

If an organisation modifies its purpose of service or institution without previous authorisation it must reimburse the received amounts.

The Decree on care and housing ('Woonzorgdecreet'/ 'Décret sur les soins et le lodgement') of 13 March 2009 provides in art. 63 that subsidies for the building or the modification of homes for the elderly, daily care centres or centres for short stay can only be given to organisations described by art. 50. Art. 50 does, however, not mention commercial organisations and refers only to:

1. a private incorporated society for which it is prohibited by law to provide her members a financial benefit
2. a provincial administration
3. a municipal administration
4. a public welfare centre
5. the Flemish community commission

6. an organisation authorised in public (administrative law)
7. an organisation founded in conformity with title VIII of the Decree of 19 December 2008 regarding the organisation of public centres for societal wellbeing
8. a sickness fund (a mutuality)
9. a public institution of category B as mentioned in the Act of 16 March 1954 on the control of certain institution of public utility
10. another legal entity that is not-for-profit and which is appointed by the Flemish government.

Similar rules are applicable for the Walloon region.[203]

Such services must be provided by not-for-profit organisations, provinces, cities, intermunicipal companies or associations of chapter XII of the Act of 8 July 1976 regarding public centres of societal wellbeing (art. 226). For the homes of the elderly, it follows that the organisation asking for investment grants cannot be a commercial organisation (see art. 1473).

4.2.6.2 Financing for the operation of hospitals

Each organisation operating a hospital receives a specific budget. A draft decision regarding the budget for operating the hospital is sent to the administrator, i.e. the legal body that according to the legal status of the hospital takes care of operating the hospital. When the administrator receives the final budget it will be mentioned (according to art. 106, 2 of the TFEU), that the decision is based on the decision of the Commission of 20 December 2011 regarding the application of art. 106[37] TFEU to State aid in the form of public service compensation granted to certain undertakings entrusted with the operation of SGEIs.

4.2.6.3 Subsidies for collaboration

In conformity with art. 105 of the Hospital Act the King, after taking advice from the section 'financing' National Council for Hospital Facilities ('Nationale Raad voor Ziekenhuisvoorzieningen'/'Conseil National des Etablissements Hospitaliers'), determines the conditions and the rules for fixing the financial means of the different elements. On the basis of art. 105 of the Hospital Act, the Royal Decree of 25 April 2002 on the fixing and the liquidation of the BFM has been taken (MB 30 May 2002 (ed. 3), err. BS 3 October 2002 (ed.2)).

A merger of hospitals will of course have an impact on the calculation of the BFM. A merger occurs when two or more separate authorised hospitals, that may or may not have different boards of administrators, and that are located at different physical sites, are brought under one administrator with one single authorisation (art. 2 of the Royal Decree 31 May 1989).

The BFM of the new entity will be fixed according to the rules of the Royal Decree of 25 April 2002 on the basis of joint parameters and criteria for each of the parts of the budget.[204] Art. 97, § 1 of the Royal Decree of 25 April 2002 provides nevertheless that in case of a merger the parts B1 and B2 of the budget of the new entity will be fixed by counting the parts B1 and B2 of the separate authorised entities of before the merger. Subsequent to a merger it is therefore not the case that the budget of each separate authorised hospital before the merger can be simply added to the other hospital in calculating a new budget. It is possible that there will be a reduction of the BFM after the merger.

In order to avoid discouraging hospitals from merging, art. 97, § 2 of the Royal Decree of 25 April 2002 provides that hospitals that merged on or after 1 January 2004 can temporarily secure an additional amount through part C2. Part C2 of the budget contains the 'catch-up' amounts for a lack or a surplus of revenues in view of the budget fixed for the current year or for one

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203 See Code wallon du 29 septembre 2011 de l'action sociale et de la santé (M.B., 21 décembre 2011 (deuxième éd.)) en de Code réglementaire wallon du 30 juillet 2013 de l'Action sociale et de la Santé (M.B., 30 août 2013, Errat., M.B., 24 septembre 2013 (première éd.)).-Services d'aide aux familles et aux aînés

204 R. Cuypers, K. Degraev E, M. Tuerlinckx en L. Willems, *De financiering van de ziekenhuizen*, Mechelen, Kluwer, 2013, 69

or more previous years (art. 21 Royal Decree of 25 April 2002). For the conditions and the methodology for calculating this amount, see art. 97, § 2 of the Royal Decree of 25 April 2002.

In case of a transfer of activity between two or more general hospitals (with the exception of SP-services, SP-services for palliative care, isolated G-services and units for treatment of serious burns requiring a specialist service, a function or a care programme), in the framework of a legally formalised agreement of collaboration, the hospitals involved will temporarily receive an additional amount through part C2. This can only occur where, for the first complete year following the transfer of the activity based on the agreement of collaboration, part B2 that relates to this activity is smaller than the original transferred part. Part B2 includes a compensation for the costs of clinical services, in particular it concerns:

1. the costs of the nursing and caring personnel, with the exception of the instrument specialists of the operating room
2. the costs of current medicinal products as mentioned in art. 1, 1° of the Royal Decree of 6 June 1960
3. the costs of dressings
4. the costs of medical consumables, products for the care and small instruments
5. the costs of storage of blood
6. the costs of rehabilitation with regard to hospitalised patients in the A, T , K, G and Sp- services
7. additional costs associated with the social profile of the hospital (art. 13 KB April 25, 2002).

Finally, a hospital can on the basis of art. 109 of the Hospital Act temporarily receive a specific amount in order to improve the functioning of the hospital, if there is a structural reduction of the BFM as a result of an internal restructuring of the institution or the result of a collaboration agreement with one or more hospitals, which leads to a specialisation or a greater concentration of hospital activities. The rules and conditions that apply for the grant of the amount are determined in art. 91quater to 91sexiesdecies of the Royal Decree of 25 April 2002. It is the administrator who must submit a request for getting the exceptional grant and who must demonstrate that there is effectively a structural reduction of the budget of the hospital in one or more of the parts A1, A3, B1, B2, B3 or B5, which is the result of an internal restructuring of the institution or the result of a collaboration agreement with one or more hospitals leading to a specialisation or a greater concentration of hospital activities.

For this purpose, the administrator inserts the following information with his application:

1. the nature and the extent of the measures which lead to the structural reduction;
2. the precise list of each of the measures and their impact on the budget of the financial means of the hospital.

The application will subsequently be examined and if the conditions are fulfilled for receiving the amount, a contract will be drawn up between the Minister of Health and the administrator (s). This agreement shall contain at least the following elements:

1. the measures to which the administrator has to conform in accordance with the request, the purpose for which the amount was intended, and in particular the arrangements for the benefit of personnel covered by the internal restructuring measures or taken in the context of the collaboration agreement between the hospitals;
2. the mutual obligations to which the hospitals adhere to by a collaboration agreement to retain the advantage of the exceptional grant (art. 91nonies, § 1 KB April 25, 2002).

Upon agreement of all parties, the terms of the agreement can be revised at the request of a concerned administrator.

4.2.7 Transfer of contracts of the health system

Various private entities (e.g. hospitals, nursing homes) relinquish their autonomy to a coordinating body in order to form a closed system. In the transition phase, the different entities retain their identity in order to repay the debt or to take care of certain ongoing obligations but will eventually disappear and only the health system will exist. Below we analyse what happens to existing contracts (e.g. with staff and physicians working in an institution owned now by the health system).

4.2.7.1 Contracts of the employees (with statutorily authorised rights)

General

Concerning the applicability of collective labour agreement[83] n° 32bis[205] concerning the transfer of undertakings during the transition, the manner in which underlying entities give up their autonomy in favour of the coordinating organisation will determine who the employer will be of the staff working for the underlying entities.

Collective Labour Agreement[83] n° 32bis is a transposition of a European directive.[206] The scope of CLA n° 32bis is limited to employment agreements within the meaning of the Act on employment and employees who perform under an apprenticeship contract.[207] This arrangement, if applicable, applies only in respect of persons who are employed within the different entities with a labour contract.

Analysis of the conditions of application of CLA n° 32bis

CLA n°32bis aims to protect employees against the uncertainty that might result with a change of employer. For the application of CLA n° 32bis it is required that there is (1) change of employer; a transfer of contract; and (3) a transfer of (part of) a company.

CLA n°32bis shall apply if the employee gets a new legal employer. There must be a change in the natural or legal person who operates the undertaking and who therefore has obligations to the employees of the undertaking.[208] This requirement may be satisfied if the overarching body that operates the health system becomes the new employer of the staff. If there is a concentration or restructuring where the underlying undertakings continue to be the employer of their own staff, the use of CLA n°32bis is excluded. The commentary accompanying the CLA clarifies that one may refer to a transfer in case of, for example, a new company, a cession, a merger or an absorption of an undertaking.

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205 Collective labour agreement nr. 32bis concluded on 7 June 1985 at the National Labour Board, betreffende het behoud van de rechten van de werknemers bij wijziging van de werkgever ingevolge de overgang van ondernemingen krachtens overeenkomst en tot regeling van der rechten van de werknemers die overgenomen worden bij overname van activa na faillissement, *BS* 9 August1985.

206 Directive 2001/23/EG van de Raad van 12 maart 2001 inzake de onderlinge aanpassing van de wetgevingen der lidstaten betreffende het behoud van de rechten van de werknemers bij overgang van ondernemingen, vestigingen of onderdelen van ondernemingen of vestigingen, *P.B.* L 82, 22 March 2001, 16.

207 See art. 2, 1° CLA n° 32bis and comments.

208 See art. 6 and comments, CLA nr. 32bis; C. Engels, 'Het toepassingsgebied van de CAO nr. 32bis normaals bekeken', *Oriëntatie Sociaal Recht,* 2014, afl. 5, 123.

The employment agreements are automatically transferred

Art. 7 of CLA n°32bis means that the existing employment contract passes through this transition to the transferee. The transferee should assume the obligations arising from the employment contracts existing at the time of the transfer.[209] The original employment contract concluded by the transferor shall be carried out under the same conditions as before, both with respect to the transferred employee and the transferee.[210] No new employment contract will be created. The employee cannot oppose the transfer. If he refuses to take up the new employment contract, this is considered by the Act as a breach of contract.[211]

The transfer of the employment contracts to the new employer is no reason for termination of the employment contract of the employee

A transfer of an undertaking should not in itself constitute a ground for dismissal either for the transferor nor the transferee.[212] Dismissal remains possible if there is a compelling reason that can be invoked, or when there are economic, technical or organisational reasons entailing changes in the workforce. These reasons may be related to the transfer, but this should not be the only motive.[213] In addition, the contract can be legitimately terminated by mutual agreement at any time.

Maintaining terms of employment after transition

In principle the working conditions remain after the transition,[214] but nothing prohibits the transferee and its employee to change working conditions by mutual agreement. Unilateral changes of the working conditions by the transferee are acceptable, but only when they are in favour of the employee. The transferee must also take into account that a significant unilateral change can be seen as an implicit dismissal.[215]

Joint liability (liability in solidum) between the transferor and transferee

From the moment of the transfer, the transferee and the transferor are jointly liable (liability in solidum) for the payment of the existing debt, which at that time results from existing employment contracts. This does not apply to debts arising from supplementary regimes of social insurance.[216]

Information obligation

In the presence of employee representatives they are entrusted with informing the employees about their rights and the acquisition. If there are no employee representatives in the undertakings where neither a company council nor a trade union representative exists, the workers concerned must be informed in advance of aspects including the date or proposed date of the transfer, the reasons of that transition or the acquisition of assets and the legal, economic and social implications of the transfer or of the transfer of assets to the employees.

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209 R. Parijs en P. Tierens, 'De arbeidsrechtelijke gevolgen van het faillissement en het gerechtelijk akkoord t.a.v. de individuele arbeidsverhouding in geval van voortzetting van de activiteiten door wijziging van werkgever' in H. Braeckmans, *Faillissement en reorganisatie,* 17 July2003, 47, 11.

210 See Explanation of the FPS Employment, Labor and Social Dialogue: http://www.werk.belgie.be/defaultTab.aspx?id=492.

211 Cass. 6 June 1973, *JTT* 1973, 203; Arbh. Antwerp 9 January 2007; Arbh. Brussels 22 February 2008.

212 Art. 9 CLA n°. 32bis.

213 Arbh. Luik 5 May 2003, *,not published.*; Arbh. Luik 27 June 2006, *JTT* 2006, 41.

214 Except the rights resulting from systems of income supplement concerning elderly, survival and disability. These will not be transferred, unless they are fixed in a CLA.

215 Art. 10 CLA nr. 32bis.

216 See art. 8 CLA nr. 32bis.

Involvement of public bodies in the transfer

In Belgian legislation, the public entities do not fall within the scope of the Collective Agreement Act, and hence, not within the scope of the individual collective agreements.[217] According to art. 2, § 3 of the CLA act, the CLA Act does not apply for 'those employed by the State, the Communities, the Regions, the Community Commissions, the provinces, the municipalities, the subordinate institutions and the public utilities'. It could be argued that there is a gap in the Belgian legislation and an incorrect transposition regarding what constitutes 'the public sector with an economic activity'.[218] Directive 2001/23 of the Council of 12 March 2001 on the approximation of the laws of the Member States relating to the safeguarding of the rights of employees by the transfer of undertakings, businesses or parts of undertakings or businesses indicates that the Directive applies to 'public and private undertakings who exercise an economic activity, whether or not-for-profit.' The Belgian courts must always adopt a directive-compliant interpretation of the instruments that were transposed from European law.[219] The Court of Justice has already ruled that a particular (public law) company which for example offers help at home to those in need, may be considered as a 'public company that exercises an economic activity'.[220]

Even if CLA n°32bis is interpreted in conformity with the directive, the CLA n°32bis still offers only guarantees regarding contractual employees. The *ratio legis* of Directive 2001/23/EC is that the employees must be protected during the transfer of the company where they are employed. Consequently, if in the health system there is a transfer of statutory staff, it is possible that they may resign from the undertaking and enter into a new employment contract with the coordination body of the group.

The application of different CLAs within the health system

For each undertaking (i.e., the legal entity involved) there is basically only one competent joint committee. Only the CLA concluded within the joint committee will then apply. The basis of the Collective Labour Act at sectoral level lies in the joint committees, which have their origin in a Royal Decree.

The King may set up a joint committee for any activity on his own initiative or at the request of one or more representative trade unions. The King determines which persons, which company division or undertakings belong to the jurisdiction of each committee.

The scope of the joint committee must be determined for each undertaking and not at the level of the group to which the undertaking belongs. The general rule is that a joint committee is responsible for all workers employed by the same employer, regardless of the profession of the employee.

It is not always clear under which joint committee a company falls. The answer to that question is however important as the applicable CLA sets the earnings and working conditions within a company. A company may request advice from the General Directorate of Collective Labour Relations of the FPS (Federal Public Service) Employment, Labour and Social Dialogue. Ultimately, it is the labour court that is competent to determine under which joint committee a company falls. The scope of a joint committee is in principle determined by the main activity of the company, unless another criterion is defined in the foundation act. When considering which joint committee is competent one should rely on the actual *de facto* activity of the company, i.e., the principle activity carried out by the staff. To determine the main activity, the FPS Employment uses the following criterion: 'the economic activity which most working hours are spent on or which employed most of the staff.' Therefore to concretely examine under which joint committee the group will fall, it is first necessary to conduct an assessment of how many employees exercise which activity. It is then advisable to read

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217 See art. I 2, § 3 CLA-Act.

218 For more information, see C. Vandersnickt, *Overgang van onderneming krachtens overeenkomst,* Mechelen, Kluwer, 2015, (97) 105.

219 K. Lenaerts en P. Van Nuffel, *Europees recht in hoofdlijnen,* Antwerp, Maklu, 1995, 565.

220 Court of Justice 10 December 1998, *Sanchez Hildalgo,* C-173/96.

the foundation act of each joint committee to verify if a different criterion than the main activity is used.

The principle, however, of a joint committee for each employer remains. There are some exceptions to this principle, namely separate joint committees for 'workers' and 'employees' (i.e. with different statutorily authorised terms) or when a company carries out various activities without a mutual relationship, exercised in different rooms with personnel exclusively assigned to each of these activities.

4.2.7.2 Statutory employees

Statutory employees are excluded from the scope of the CLA n°32bis.[221]

For statutory employees, given the current state of the Act, the best solution is to resign of the underlying company and to conclude a new employment contract with the coordination body. This requires the individual consent of each statutorily employed person.

4.2.7.3 Contracts with self-employed and with third parties

For not-for-profit organisations who transferred rights and obligations to a new not-for-profit organisation which may for example lead the health system and operate the institutions, it is important to create legal certainty about the rights and obligations of existing contracts. The question is whether for each contract with a self-employed physician working in a hospital or for each contract regarding the selling of e.g. medical products new contractual clauses have to be written in case of a transfer of activities. So the question is whether a self-employed person who had a contract with an organisation who transferred its activities to another (or new) organisation automatically enters into agreement with the new organisation? Or is an express consent or a new contract with the new organisation required?

Through an amendment to art. 670, paragraph 2 of the Company Code this condition has been satisfied.[222] It stipulates that art. 770 applies to all legal entities, whether or not explicitly intended by this legislation (e.g. not-for-profit organisations), that explicitly choose the forms mentioned in this art. Art. 770 shall specify which agreement is applicable in case of a transfer, whether for free or for payment, of the totality or a division of a company. Art. 58 of the NPA (not-for-profit associations) Act clarifies, that where invoked art. 670, paragraph 2 of the Company Code, art. 770, and the articles to which it refers to, apply mutatis mutandis to the transfer without payment of the totality or a division of a company by a not-for-profit association, a public foundation, a private foundation, an international not-for-profit association (...), in favour of a legal person belonging to any of the preceding categories. Art. 770 of the Company Code provides that in case of transfer for free or for payment of the totality or a division of a company, within the meaning of the definitions given in art. 678 to 680, the parties may subject that transaction to the rules set out in art. 760 to 762 and 764 to 767, or described in the scheme described in art. 768.

If no use is made of art. 670 paragraph 2 of the Company Code, the health system must take into account that many hospital physicians are working as self-employed physicians. Contracts relating to such rules are often *intuitu personae*, especially contracts concluded at the behest of the involved person. There will remain a discussion about whether the totality of such contracts are just automatically continued.[223]

Another issue when creating a health system is whether a new legal status within the health system may simply be imposed on independent hospital doctors. In principle, a hospital physician is not obliged to comply with a new general regulation regarding the rights and duties of hospital physicians and hospital administrators as long as they did not accept the new general

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221 Cass. 2 March 1991, *Arr. Cass.* 1980-81, 733; R. Blanpain, *De collectieve arbeidsovereenkomst,* Bruges, Die Keure, 2011, 59.

222 Seer Coipel, M., Davagle, M. e.a., *Fusions et scissions d'ASBL après la loi du 30 décembre 2009*, Edi.pro, 2010, 256p.

223 M. Davagle en M. Coipel, 'Le régime juridique de l'apport gratuit d'universalité ou de branche d'activités selon la modification législative de décembre 2009' in M. Coipel, M. Davagle e.a., *Fusions et scissions d'ASBL après la loi du 30 décembre 2009,* Luik, Edi.Pro, 2010, 88 ; Gent 25 January 2001, *TRV* 2004, afl. 3, 244, note M. Wauters;

regulation.[224] Hospitals often want to work with a new regulation with the obligations and rights of the physicians and the hospital in case of a change of the entity who is in charge of the hospital, for example after a merger. Many hospitals provide in the regulation that the physician has to adhere to the current general regulation as well as all future modifications of the regulation. This clause is often called a 'perpetual clause' (a so called 'kettingbedingen'/'clause perpétuelle').[225] The notion 'perpetual clause' is not really a good term in this context. A perpetual clause is strictly speaking a clause whereby a contractor undertakes to impose to a third party a certain obligation, if he concludes an agreement with a third party. A clause which provides that physicians commit themselves to agree with a set of subsequently concluded new general regulations, is actually not a perpetual clause but a clause that grant the competence to take a party decision.

There will be a party decision 'if a party, by law or by virtue of a contractual clause, has the power to determine unilaterally to change an element of the agreement.'[226] Even if in a general regulation or in an individual contract concluded between the hospital administrator and hospital physician a clause is provided that allows to take a party decision, a hospital administrator cannot just arbitrarily make use of such a clause. It should be noted that a court can retrospectively examine the party decision itself and thus in this case the changes that the hospital administrator would make to the general regulation. Here, the court will consider whether the agreement was carried out in good faith and whether the hospital administrator has committed an abuse of law.[227] The value of the clause described as a 'perpetual clause' must be to our opinion dramatically reduced. In addition, a general regulation may only be amended in accordance with the provisions of art. 137(1) and 139 and 140 of the Hospital Act. If any changes are proposed that are not acceptable, the medical council will thus be able to give a negative (reinforced) advice. The hospital administrator will have to follow the conciliation procedure provided in art. 139 and 140 of the Hospital Act, if he cannot accept this advice.

4.2.8 Value added tax issues

4.2.8.1 Transfer of a universality or of a company division

If the transfer of a not-for-profit organisation is liable to valued added tax (VAT) at varying rates and makes a contribution of the totality or a division of a company in favour of a mixed-VAT payer not-for-profit organisation, art. 11 of the Code of the VAT can be applied. This article stipulates that a 'delivery' cannot be considered as including the transfer of the totality or a division of a company for payment or free of charge, by way of contribution in a partnership or otherwise, where the purchaser is a taxpayer, who would deduct the tax due by the transfer fully or partially. In that case, the purchaser shall be deemed to continue with the identity of the transferor.

4.2.8.2 Cost-sharing associations in the transition phase?

Pending the establishment of a health system which is the only legal person that operates the various institutions, the various not-for-profit organisations that run the institutions during the transition, can operate together. This may have an impact in terms of VAT issues if there is e.g. a cost-sharing association ('kostendelende vereniging'/'associations de frais').

Since 1 July 2016, the VAT regime of cost-sharing associations has been adapted thoroughly. The Act of 26 May 2016 amending the Code of the VAT regarding the exemption of services provided to their members by

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224 Cass. 8 april 2002, AR C.00.0118.N; S. Callens, M. Leire, L. Boddez, L. Van Leuven en J. Peers, 'Titel II. Het aanbod in de gezondheidszorg' in S. CALLENS en J. Peers (eds.), Organisatie van de gezondheidszorg, Antwerpen, Intersentia, 2015, 91-92

225 F. Dewallens, 'Hoofdstuk III. De gezondheidszorgvoorzieningen' in T. Vansweevelt en F. Dewallens (eds.), Handboek gezondheidsrecht, I, Zorgverleners: statuut en aansprakelijkheid, Antwerpen, Intersentia, 2014, 277

226 See I. Samoy and A. Maes, 'Concerning the clause that authorizes a party to take a decision and whether the inclusion of objective criteria is necessary for the validity' (note under Ghent October 13, 2008), TBBR 2010 , Vol. 6, (309) 310

227 I. Samoy and A. Maes, 312

independent groups of persons, inserted in art. 44 of the Code of the VAT a paragraph 2bis. As the title suggests, it is a modification of the exemption of services that independent groups of persons provide to their members.

The notion 'independent group of persons' means both an organisation with legal personality (such as a not-for-profit association) and an organisation without legal personality, can act under their own name as a separate organisation or group on behalf of its members in dealing with third parties. The group can exist legally independent of its members, but this is not a requirement. If the group has no distinct legal existence from its members, the group needs to operate under its own name towards its members and third parties as a separate entity.

It should be noted that Belgian administrative practice refers to an independent group usually with the notion of a 'cost-sharing association.' A cost-sharing association is a permanent community of interests founded by physical persons or legal entities in order to rationalise and reduce their administrative and operating costs. Typically, the expenditure of its members occurs communally. The objective of the cost-sharing association is to reduce the costs of the exempted or non-taxable activities of their members.

The Act of 26 May 2016 is a partial transposition of Directive 2006/112/EC of 28 November 2006 on the common system of VAT. By inserting paragraph §2bis in art. 44 of the Code of the VAT, Belgium responds to the request of the European Commission to comply with art. 132, paragraph 1, item (f) of the European directive 2006/112/EC which provides that 'services supplied by independent groups of persons are exempt from or are not subject to tax, with the aim of providing services to their members which are directly necessary for the exercise of their activity, where such groups of their members only claim reimbursement of their share of the joint expenses, provided that such exemption is not likely to cause distortion of competition.'

The conditions under which the services of independent groups of persons to their members are exempted from VAT are listed under paragraph 2a of art. 44 of the Code of the VAT. These four conditions must be met cumulatively:

- members of the group exercise on a regular basis an activity that, under art. 44 of the Code of the VAT, is exempted or for which they are not taxable. The exempted activities or activities for which the members do not pay tax, represent a major part of the activity of the members;
- the activities of the group consist of the provision of services to its members which are directly necessary for their exempt activity or their activity for which they are not taxable. If the group also carries out activities for non-members, the activities carried out for its members represent the majority of the activity of the group;
- the fee charged to or money recuperated from each member represents the reimbursement of its share of the joint expenses incurred by the group;
- the exemption does not lead to distortion of competition.

The cost-sharing association has an obligation of notification and information. At the beginning of its activity, the independent group of persons, who carries out only services which are exempt or for which it has not the status of taxable person, shall be obliged to make a notification to the competent VAT office. This notification must be made within the month following the beginning of such activities. In addition, the group must also submit to the office a list of its members, as well as the nature of their activities. This must happen within the same period. In addition, the group is also obliged, by the entry or departure of a member, by modification of the activity of the group or any of its members or termination of the activity, to inform the VAT office of this within the month following the aforementioned event. Although the group exclusively performs services which are exempt from VAT or for which it does not have the status of taxable person, based on art. 44 §2bis, second paragraph of the Code of the VAT, a notification and an information obligation is imposed on the group. Of note is that such a group does not fall within the scope of art. 53 of the Code of the VAT.

An independent group that has mixed VAT rate obligations is obliged to report, based on art. 53 of the VAT. The new regime imposes an additional notification obligation and information obligation based on art. 44 §2bis third paragraph of the Code of the VAT, to submit a list of its members at the start

of its operations, as well as the nature of their activity. In addition, this group must inform the supervising office of any entry or departure of a member.

Moreover, this requirement applies for groups that already existed on 1 July 2016, when the Act came into force. Therefore groups are obliged to be transparent about their members and the nature of the activity of their members. The King will determine the further practical formalities for the notification and information obligation.

4.2.9 Compliance with competition law by the group

Agreements of undertakings, like hospitals and decisions of associations, networks or groups of hospitals must not hinder competition in the healthcare market. An entity that practices an economic activity, whatever legal form it has and however it is financed, can be considered as an undertaking.

Where a group brings together numerous hospitals and possibly other institutions and becomes a significant major player, the question arises if there will be no abuse of dominant position on the Belgian market or on a substantial part of this market. Art. IV.2 of the Code of Economic Act stipulates that 'without the need for a prior decision to that effect, the abuse by one or more undertakings of a dominant position on the Belgian market concerned or a substantial part thereof is prohibited'.

Such abuse may, in particular, consist of:

1. directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions;
2. limiting production, markets or technical developments to the detriment of consumers;
3. applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;
4. making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.

Not only may a group not abuse a dominant position, it is necessary to seek intervention of the competition authority prior to the creation of group.

According to art. IV.6, §1 of the Code of Economic Law a 'concentration' shall be deemed to arise where a change of control on a lasting basis results from:

1. the merger of two or more previously independent undertakings or parts of undertakings; or
2. the acquisition, by one or more persons already controlling at least one undertaking, or by one or more undertakings, whether by purchase of securities or assets, by contract or by any other means, of direct or indirect control of the whole or parts of one or more other undertakings.

Where the undertakings of the group in Belgium surpass a turnover of more than 100 million euro and at least two of the undertakings in Belgium surpass a turnover of at least 40 million euro, notification of the concentration will be mandatory. Prior authorisation of the concentration by the Belgian Competition Authority will be necessary. This authority determines whether or not the concentration will be allowed (art. IV.9 §1). The decision will take into account:

1. the need to maintain and to develop an effective competition in the national market, especially taking into account the structure of all the relevant markets and the actual or potential competition from companies based in or outside Belgium;
2. the market position of the undertakings and their economic and financial power, the alternatives available to suppliers and users, their access to supplies or markets, any legal or factual barriers to market access, the development of demand and supply of the products and services, the interests of the intermediate and ultimate consumers and the development of technical and economic progress, to the extent that it is to consumers' advantage and does not hinder competition.

Concentrations which do not result in a significant impediment of the effective competition in the Belgian market or in a substantial part of it, including by the creation or strengthening of a dominant position, shall be declared admissible (art. IV.9. § 3).

Concentrations have to be notified to the Competition Prosecutor general before their implementation and after the conclusion of the agreement, publication of the take-over bid or public offer of exchange, or of the acquisition of a controlling interest. The parties may however notify a proposed agreement provided that they declare explicitly that they intend to conclude an agreement which does not differ significantly from the notified proposal as regards all the relevant points of the competition act. The notification can be made in Dutch or French. As long as the Competition College does not pronounce its decision on the permissibility of the concentration, the undertakings concerned may not implement the concentration.

The application of the aforementioned competition rules with respect to a health system that has a large market share are important. In case of abuse of this power there could be distortion of competition, higher prices and/or lower quality of care for patients. This may be the case if the group can behave differently from its competitors by virtue of its position. In order to verify that there is no question of a dominant position in the relevant Belgian market or in a substantial part of it, a product market and a geographic market will have to be defined.[228] It is assumed that it is unlikely that the institution can act independently of others, when an institution has a market share of less than 25%.[229] With a market share between 25% and 40% there may be, under certain circumstances, what is called in the Netherlands substantial market share, for example if that institution has control over essential facilities, if there are long-term non-market prices, or if market share of other market (segments) is used to exercise market power with a small market share.[230] With a market share between 40% and 55%, it is likely that there is a significant market share and with a market share of 55% or more, it is assumed that the institution is able to exercise significant market power.[231]

4.2.10 Evaluation

4.2.10.1 Adjustment objective and legal form

A legal entity may operate several institutions. If the health system wants to operate, besides hospitals, also residential care centres and nurseries, an amendment of certain acts will be required. Certain legal texts describe in a strict manner the aim that the legal entity is entitled to pursue, so that it is not possible to run hospitals and residential care centres. Some acts provide a specific company form, while this is not the case in other acts. However, European legislation already allows that a government reserves the right to perform certain services, for example, for not-for-profit organisations. With regard to general services of economic interest, art. 49 and 56 TFEU (concerning freedom of establishment and free movement of services) should be respected. The restriction must be justified. According to the jurisprudence of the Court of Justice, such restrictions may be justified, particularly if this restriction is necessary and proportionate in order to achieve certain national social security objectives (GIDS).

228 D. Fornaciari, S. Callens en E. Schokkaert, *Ziekenhuizen, mededingingsrecht en recht op kwaliteitsvolle zorg*, Antwerp, Intersentia, 2010, 107.

229 Andersson, Elffers enFelix, *Ordening en toezicht in de zorg*, 2015, p. 72

230 Andersson, Elffers en Felix, *Ordening en toezicht in de zorg*, 215, p. 73

231 Andersson, Elffers enFelix, *Ordening en toezicht in de zorg*, 215, p. 73

4.2.10.2 Need of legal authorisation

The authorisation of an institution belongs to the administrator

In Belgium authorisation is granted to the legal person, even though it is related to the concrete institution.

Financing for one institution of the health system must be used for that institution.

Funding by the government to one institution of a health system cannot be used for another institution of the health system. The legal entity can receive various forms of compensation per institution, but must also have a separate accounting, so that it can be clearly demonstrated which government funding covers which costs. It will for example not be possible to use compensation for hospital A to cover costs at hospital B.

Specific legal rules for the health system might be needed

Specific authorisation rules for a health system itself, as described in this first model, are lacking. There are rules concerning authorisation for a group of hospitals, but not for the health system as described in this report. If the legislator wants to make such rules, it will be necessary to do this with the conclusion of collaboration agreements between the federal government and the communities. Through these new rules, it should be for example possible to avoid the abuse of a dominant position, that the establishment of the health system does not benefit the quality of care or that the establishment of the health system is not supported by patients, physicians, employees (see below).

4.2.10.3 Modifications of the Royal Decree of 30 January 1989

If a health system wants to create a collaboration between the hospitals of the health system, it may be possible to create a group of hospitals as defined in the Royal Decree of 30 January 1989. Nevertheless, this Royal Decree limits the distance of a group of hospitals to 25 km. Given this, hospitals cannot be located more than 25 km from each other. This may hinder the creation of health systems with hospitals located in different regions.

Moreover, the Royal Decree of 30 January 1989 does not regulate collaboration amongst hospitals and other care institutions, e.g. the homes for the elderly.

4.2.10.4 Collaboration between hospitals within the health system

General

The health system model does not lead to collaboration; it only allows one legal person to run several institutions (hospitals, nursing homes etc.). In reality true collaboration between institutions within the health system can only exist, if consultations are held at many levels and participation/involvement of numerous employees of the health system and users of the services of the health system occurs. It is appropriate that the legislation is adjusted so that it provides not only the conditions for the establishment of the health system, but also rules which facilitate collaboration between institutions of the same health system. It would be preferable to avoid a setup whereby for each function in each hospital within a health system (e.g. CMO, CEO, etc.) or for each committee or council a different person or committee or council is chosen as if the institutions are run by separate legal entities (see below).

Joint committees / councils / functions

Medical council

It is possible under the existing legislation, to create a common medical committee if two hospitals that are not yet merged. If hospitals work closely together, e.g. in a ‘group’ as in the meaning of the Royal Decree of 30 January 1989, there is the possibility to create one medical council for the two hospitals. Model 1 as such does not lead immediately to the creation of a common medical committee for all hospitals involved. This will only be the case if the hospitals of the health system collaborate or do enter into an agreement regarding a group as defined in the Royal Decree of 30 January 1989. Art. 5, § 6 of the Royal Decree of 10 August 1987 provides that in case of different collaborating hospitals, the board and the medical staff may send a common and concurrent request at the Joint Committee Hospital Administrators and Hospital Physicians (‘Nationale Paritaire Commissie

geneesheren-ziekenhuizen'/'Commission paritaire nationale médecins-hôpitaux') at the Federal Public Service of Health to organise elections for one single medical council. In deciding whether to consent to this request the Commission will look at the integration of governance structures and of the medical activities in the hospitals.

The problem is, however, that the rules of voting for a medical council, do not really take into account the fact that a physician may work in several hospitals of the health system. Physicians working in various hospitals of the health system will have their voting power for the election to the medical board limited, especially if each hospital has its own medical board.

If two hospitals A and B decide to cooperate and, as part of this collaboration, organise services on different hospital sites so that physicians of hospital A will also work in hospital B, it will be no longer possible for this physician – if he/she works fulltime – to have the maximum of 4 votes. Instead, he/she will have only maximum 3 votes. Moreover, if he/she works at least two half days in the other hospital, he/she will have to decide where he/she will vote for the elections of the medical council. If he/she wants to vote in both hospitals, he/she will have only 2 votes divided over the two hospitals. It is only in case of activities in hospitals which were regrouped in a **hospital merger**, that the activities are counted together in order to determine the total activity (and the total number of votes). The above mentioned rules are not applicable to a health system where each hospital has its own medical council, CMO and general CEO and does not take initiatives to merge the hospitals.

CMOs and heads of medical services working in different hospitals of the health system

CMOs and heads of medical services can under certain conditions work in different hospitals of the collaboration. The CMO and the head of a medical department have to work normally exclusively in the hospital. However, this rule does not apply if they work in several hospitals in a group of hospitals according to the Royal Decree of 30 January 1989. In that case, the CMO can practice his function as a fulltime role or as a part-time role together with other functions in the hospitals of the group. However, as was described above, the health system as mentioned in this model 1 does not necessarily imply a group of hospitals in the meaning of the Royal Decree of 30 January 1989. It is only if the health system has also been authorised as a group in the meaning of the Royal Decree of 30 January 1989 that a CMO or the head of a medical department can also work in another hospital (of the health system) with which a contract of a group was drafted.

Ethics committee

Each hospital must have a local ethics committee. In the case of an authorised hospital group in the meaning of the Royal Decree of 30 January 1989, a common ethics committee can be created for all hospitals of the group, or separate ethics committees can be created for each hospital. For the same rule to apply to a health system in the meaning of model 1, new legislation is needed.

A common ombudsfunction for collaborating hospitals

Art. 71 of the Hospital Act provides that to be authorised, every hospital must have a mediation function. Such a function can be shared between hospitals under the conditions described by the King.

Art. 1 §2 of the Royal Decree on the conditions to be fulfilled by an 'ombudsfunction' in hospitals provides that such collaboration can take place through the conclusion of a written collaboration agreement between the hospitals. It seems that this rule would allow a health system to have only one common 'ombudsfunction'. Moreover, it is provided in art. 1, § 3 of the Royal Decree of 8 July 2003 that psychiatric hospitals can comply with art. 11 of the Act on patient rights (i.e. the right of a patient to file a complaint related to his rights before a competent ombudsman) through the 'ombudsfunction' of a collaboration of psychiatric institutions and services as consultation platform as mentioned in the Royal Decree of 10 July 1990.

Medical-Pharmaceutical Committee and Health Committee

Each hospital of the group is expected to continue to meet the authorisation standards that apply to it. Each hospital therefore has to continue to have a medico- pharmaceutical committee and a health committee. However, the possibility exists for hospitals of a group to organise some unique committees. This is particularly the case for local ethics committees (art. N1, A, III, 9° d of the Royal Decree of 23 October 1964 cited above) or hospital transfusion committees (art. N1, A, III, 9° d of the Royal decree of 23 October

1964 cited above). Such a possibility is not expressly provided for hospital hygiene committees or for medico-pharmaceutical committees.

4.2.10.5 Competition and authority

It is not appropriate in case of a health system to limit the collaboration with other institutions. This does not benefit the free movement of services and may lead to infringements of competition law. Based on the above legal analysis, it seems appropriate that prior to the establishment of a health system, the government must give its approval. In case of a merger in principle a notification to the Competition Authority will be required. The Competition Authority can also become involved if there is for example an abuse of a dominant position by the health system. It could also be argued that it is appropriate, following the example of the Netherlands, to provide, in addition to the Competition Authority, a specific healthcare institution to monitor mergers or, as is the case in this model, a health system.

The Netherlands has opted to allow the Dutch Healthcare Authority ('Nederlandse Zorgautoriteit', NZa) to act in a more preventive way where there is no market failure. This surveillance by the Dutch Healthcare Authority is not based on competition law, but is a specific care control.[232] An institution that offers professional or commercial care with more than 50 healthcare providers and has the intention to concentrate, cannot proceed to concentration without the approval of the NZa. Healthcare providers must, under art. 49b of the Act on regulating the market of healthcare ('Wet Markt Ordening Gezondheidszorg'), include with their request a report on the expected impact of the proposed concentration. The report should at least provide clarification of the objectives of the concentration, the reasons for concentration, the structure of the proposed organisation of healthcare or healthcare providers, the financial impact of the concentration on the healthcare provider or healthcare providers, the impact of the concentration on the provision of care to the patient, the risks of the concentration on the quality and accessibility of care and how these risks are set off. The report also should include the findings and recommendations of clients, staff and other stakeholders about the intention to concentrate and how they have been able to express, as well as a justification for the way the judgment or the recommendations are taken into account in the intention to concentrate. Finally, the report has to indicate how and in what time frame the concentration will be realised.

1. Within four weeks, the Dutch Healthcare Authority will take a decision. It may withhold its consent to the concentration if:
2. clients, staff and other stakeholders who are not closely involved in the preparation of the concentration are not informed at least in a timely and understandable manner about the content of the concentration plan and the way in which judgments or recommendations may be disclosed;
3. the findings and recommendations of clients, staff and other stakeholders are not convincingly argued and included in the decision to concentration;
4. as a result of the concentration, the continuity of through general administrative measures designated types of care are jeopardized;
5. the applicant's report does not provide sufficient insight into the expected effects of the proposed concentration on the basis of the requirements specified in art. 49b, second and third paragraphs (art. 49c WMO).

NZa may impose conditions, regulations or restrictions to be met in order to gain approval. If it approves the concentration, it shall make the report public (as referred to in art. 49b). Data that is categorical as 'not for distribution', under art. 10 of the Freedom of Information Act, is not made public.

The care authority clarifies to the Competition Authority the impact that the concentration will have on the affordability, accessibility and on the quality of care, according to the findings of the officials of the state supervision.

In terms of oversight of the concentration, the NZa does not do the same job as the Competition Authority. In particular, it controls whether the procedural conditions are met and whether crucial care remains available.[233] The advantage of the method in the Netherlands is that in case of a proposed

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[232] Andersson, Elffers en Felix, *Ordening en toezicht in de zorg*, 215, p. 82

[233] Andersson, Elffers en Felix, *Ordening en toezicht in de zorg*, 215, p. 83

merger, the applicants have to be able to have an internal support for the proposed merger.[234]

4.2.11 Conclusion

If the person who operates the hospital receives the authorisation, the funding will be provided to whoever has received the authorisation.

The current funding rules provide the possibility of additional financing in case of a merger or a transfer of activities.

In case of a transfer of an undertaking, the CLA n° 32bis must be applied. In principle there is one competent joint committee for each undertaking and the CLA concluded within the joint committee is applicable. The scope of a joint committee shall be determined by the main activity of the undertaking, unless another criterion is defined in the foundation document.

As soon as a health system exists, i.e. one undertaking with potentially different activities, there are no immediate specific VAT issues. This may be the case prior to the establishment of the health system, if a transfer will take place or if there is a cost-sharing association.

According to art. 11 of the VAT Code, the transfer of all assets or a company division by contribution in partnership or otherwise is not considered as a delivery, when the transferee is a taxpayer who could be able to deduct the tax in whole or in part, if it would be due under the transfer. In that case, the purchaser shall be considered to remain the legal person of the transferor.

Since 1 July 2016, the VAT system of cost-sharing associations has been radically modified by the Act of 2 May 2016. This change applies to associations with legal personality as well as unincorporated associations acting under their own name or as an individual organisation or group to its members and third parties. Under certain circumstances, the services provided by independent groups of persons to their members are exempt from VAT. It is possible that the group also carries out activities for non-members but the activities carried out for the members must represent a predominant part of the activity of the group.

A not-for-profit organisation, or even a for-profit company may be a member of another coordinating not-for-profit organisation. In a not-for-profit organisation, decisions can be delegated but this mainly concerns the daily management. For for-profit companies, the Act on Corporate Governance has provided the possibility of setting up a management committee.

A health system is not allowed to abuse its position, when it has a dominant position on the relevant market or in a relevant part of it. Prior to the establishment of a health system notification to the Competition Authority will be required.

The not-for-profit organisation structure is not a must for operating hospitals, unless the hospital wants to obtain infrastructure grants.

European State aid rules do not impose specific criteria for the selection of a legal form. The Public Procurement Directive of 2014 does allow a Member State to reserve tendering procedures for services in the field of health to organisations with employee share or active board participation of employees and where profits are reinvested with the aim of fulfilling the purpose of the organisation.

It is also possible to restrain, for specific activities and in exceptional circumstances, access to certain services for not-for-profit organisations, but it must then be justified in the light of art. 49 and 56 TFEU (freedom of establishment / free movement of services).

Some legislation may sometimes limit the statutory purpose of a healthcare institution (see e.g. art. 15 of the Hospital Act). Modification of such legislation is needed if the legislator would allow that the health system runs e.g. also homes for the elderly, homes for young people etc.

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234 Andersson, Elffers en Felix, *Ordening en toezicht in de zorg*, 215, p. 84

It is the legal entity responsible for the exploitation that receives authorisation. It is also the administrator who requests the authorisation. Where an organisation is the registered holder for hospital A and hospital B is, it can receive several authorisations, e.g. for hospital A and for hospital B. The authorisation will then be provided to a hospital, but such an authorisation shall belong to the legal entity that operates the hospital.

The establishment itself of a health system will not necessarily lead to collaboration among hospitals. Each hospital will remain separate, unless a group as described in the Royal Decree of 30 January 1989 or an association is established, for example between hospitals. It is appropriate to ensure that various committees / functions can be set up for the health system without the need for them to be present in each hospital of the health system. At present, regulation has only been provided for medical councils, the ombudsman, ethics committees established for a group of hospitals within the health system.

Concerning collaboration of a health system with other hospitals, it is difficult to limit such collaboration in view of competition law.

It is recommended (following the Dutch example) to subject the establishment of a health system, prior to notification of the Competition Authority, to a healthcare specific study. Such a study would examine the impact of the concentration on the provision of care to the client, the risks of the concentration on the quality and the accessibility of care. It would also examine whether the clients, physicians, employees, etc. had been able to express their views on the potential concentration and whether such views played a role to the intention to create a concentration.

4.3 Legal feasibility of a health network

4.3.1 In general

The collaboration within model 2 is through the formation of a network. The characteristic of this type of collaboration is that decision making and authorisation remain at the level of the participating hospitals and are not transferred to the network. Nevertheless, there is permanent concertation with persons representing different actors, such as hospital physicians and administrators. The network may serve different purposes and may include not only hospitals, but also homes for the elderly, GPs, etc. The question is whether a network should take care of one or several services or all services carried out by hospitals.

A network as described in this chapter will leave many issues related to the decision making regarding hospital services and authorisation mainly at the level of the participating hospitals. Consequently, the network itself will neither run the hospital services nor will it be officially authorised as a hospital.

Collaboration between hospitals and other health actors of a network can be based solely on a contract without the network itself taking the form of a legal person. Nevertheless, the network can also operate through the creation of a legal person.

This subchapter analyses the legal feasibility of such arrangements without focusing on existing, specific networks. This chapter also takes into account the need to look for a network that is not limited to hospitals, although the main focus is related to the impact of the hospital legislation.

4.3.2 Financing and networks

The current rules on financing regulate the funding of the legal person operating a hospital. The creation of a network will not lead as such to a specific budget for a network. As already discussed above, a hospital can, on the basis of art. 109 of the Hospital Act, receive a specific compensation to ameliorate the internal functioning of the institution if this is the result of a collaboration agreement with one or more hospitals, which leads to a specialisation or a greater concentration of hospital activities. The rules and conditions which are applicable to the grant of the amount are determined in art. 91 quarter to 91 sexiesdecies of the Royal Decree of 25 April 2002. It is the administrator who must submit a request for getting the special fee and who must show that there is an effective structural reduction of the budget of the hospital within one or more of the sections A1, A3, B1, B2, B3 or B5, which is the result of an internal restructuring of the institution or the result of a collaboration agreement with one or more hospitals leading to a specialisation or a greater concentration of hospital activities (art. 91 quinquies and art. 91 septies KB 25 April 2002).

For this purpose, the administrator must include the following with its application:

1. the nature and the extent of the measures which lead to the structural reduction;
2. the precise list of each of the measures and their impact on the BFM.

Then the application will be examined and if the conditions are met, a contract will be drawn up between the Minister of Health and the administrator(s). This agreement shall contain at least the following elements:

1. the measures which the administrator will put in place in accordance with the request and the purpose for which the amount was intended, and in particular the arrangements for the benefit of personnel affected by the internal restructuring measures or those taken in the context of the collaboration agreement between the hospitals;
2. the mutual obligations to which the hospitals will adhere to in a collaboration agreement in order to retain the advantage of the particular amount in the future (art. 91nonies, § 1 KB April 25, 2002).

Upon agreement of all parties, the terms of the agreement can be revised at the request of a concerned administrator.

Art. 107 of the Hospital Act provides that the King may make specific financing arrangements to allow, on an experimental basis and for a limited time, a prospective financing of care circuits and collaborations, focusing on care programmes. This possibility allows a reallocation of existing financial resources to develop care circuits and networks. It is a financial technique that allows the reallocation of part of the BFM so that resources and manpower can be devoted to a specific area of work in order to adapt the current supply of care.[235]

Based on this article, many projects have been established in psychiatric care. Art. 63 §2 of the Royal Decree of 25 April 2002 on the fixing and the liquidation of the BFM allows the conclusion of agreements within the framework of pilot projects with psychiatric hospitals in particular to allow the implementation of art. 107 of the Hospital Act.

4.3.3 Governing the network

As explained above, the parties of a network may only have a contract as a basis for the network. They can also write articles and create a legal person, separate from the parties that are members of the network. The question then is under which conditions hospital administrators can start becoming members of a network and how decisions will be taken at the level of the network once a network operates.

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235 http://www.psy107.be/files/Vlaanderen.pdf, p. 4.

4.3.3.1 The role of medical council

Before a hospital administrator can join a network, the hospital will need to consider whether the general regulation of the hospital contains specific provisions concerning such a collaboration. In principle, these provisions will have to be respected. It is also important to verify what is stipulated in the general regulation of the hospital concerning a collaboration with another hospital. The general regulation of a particular hospital will likely stipulate that an advice of the medical council is required. In such cases a hospital administrator will therefore have to ask the opinion of the medical council before the hospital can join a network. If the general regulation refers only to the Hospital Act or, if nothing is provided in the general regulation regarding the creation of a network, then art. 137, 12° of the Consolidated Hospital Act of 10 July 2008 has to be complied with. It follows from art. 137, 12° of the Hospital Act that medical councils should give an opinion when its hospital enters into an agreement with another party that may have an impact on medical activities. Unless otherwise provided in the General Rules of Rights and Obligations of Hospital Administrators and Hospital Physicians, the opinion is not reinforced upon the hospital administrator. It is therefore up to the hospital administrator to verify whether the applicable general rules do not provide for a reinforced opinion before a hospital can become party to a network.

4.3.3.2 Permanent Consultation Committee - Role and Composition

The network committee at the level of a hospital

A PCC can be set up at the level of a network. Art. 142 of the Hospital Act[236] defines the notion of a 'PCC' as a committee composed of a mandated delegation of the administrator and a mandated delegation of the medical council. Within this PCC, direct consultation between the administrator and the medical council will lead to a consensus. The medical council must, in written form, have agreed with this procedure of direct consultation, after the administrator has proposed this procedure. This procedure of direct consultation replaces the procedures specified in the art. 137 to 140 of the Hospital Act,[237] namely the procedure whereby the hospital administrator asks to give an advice at the medical council before he takes a policy decision. If a consensus is reached, the members of the PCC are obliged to defend this decision, namely the administrator and the medical council at hospital level. A characteristic of the current procedure is that the PCC cannot bind the hospital administrator or medical council.

The above mentioned PCC can serve as a model for the network committee that will be established in the context of a network collaboration. This will, however, not have the same objectives as the PCC, as defined in art. 142 of the Hospital Act.[238]

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236 Coordinated Act 10 July 2008 op de ziekenhuizen en andere verzorgingsinrichtingen, *BS* 7 Nowember 2008.

237 Coordinated Act 10 July 2008 op de ziekenhuizen en andere verzorgingsinrichtingen, *BS* 7 November 2008.

238 Coordinated Act 10 July 2008 op de ziekenhuizen en andere verzorgingsinrichtingen, *BS* 7 November 2008.

Decision-making rights of the network committee

In order to decide whether the decision making can take place at the level of the network committee one has to make a distinction between two types of decisions. Decisions related to the operation of a hospital, its services, programmes etc., cannot be taken by the network committee if the authorisation of the hospital or of its services, programmes etc. is the role of the hospital administrator and not the network. By contrast, decisions concerning the network can be taken at the level of the network committee by representatives of the participating members. With regard to this aspect, no formal feedback or decision of the participating institutions will be necessary, although it is likely that the members of the network committee consult in advance their hospitals to know their opinion. Decisions concerning the rights and obligations related to a network itself, can therefore be taken at the level of the network by the network committee, provided that this type of decision is written down in the contract creating the network (or in the articles of the legal person). If the contract describes how the network will be run and provides that a network committee can decide on certain issues and if it is described how all the parties to the network are represented in the network committee, a network committee can take a binding decision. If the network would be run by a legal person and each partner to the network has an administrator, it is obvious that the decisions of board of the network will also be binding for the members of the network. Where the network operates as a legal person, it is recommended that physicians are also members of the network and are represented at the level of the board. The board could be composed as a sort of network committee and the decisions of the network committee would then be binding on the members of the network, as long as the decisions are solely related to the purposes of the network.

If a network will not have the role of authorisation of hospitals, services etc. it is not logical to transfer competence of the board running the hospital, to the board or the network committee. This may lead to problems with competition rules if the network would be vested with control over the legal persons running the hospital(s). If one wants more control over the different hospitals of a network it is recommended to work directly with the health system framework of model 1.

Composition of the network committee

The network committee must be composed of members of all participating institutions, so that all participating institutions are represented. It is important to determine in advance how the network committee can legitimately assemble, specifically how many members of each institution must be present. If other parties beside hospitals belong to the network, it is obvious that these parties are also members of the network and are represented at the level of the network committee or board.

It is also important to consider who the participants are and who can be designated as a representative on behalf of the participants. For participating hospitals this may be the administrator, the general manager, the CMO, the chairman of the medical council. The medical staff/councils of each hospital should also be represented in the network committee and be a member of the network. This may require the creation of a legal person representing the hospital physicians. In a network it seems important to provide for equality between the different participating members. The articles can provide this or clarify this if the legislator would not regulate this issue.

4.3.4 The network vis-à-vis a group or association of hospitals

Since the objective of a network (see below) may not include running hospitals or services solely by hospitals, use of the existing rules on hospital groups, as well as the rules on hospital associations is still required. The objectives of a network as well as of the parties in the network will often be different from the one of a group or an association. Moreover, continuity in the organisation of healthcare is important. This is why the existing rules of a group or an association should not immediately be replaced by concepts of a network.

4.3.5 Objectives of the network

A network can have multiple objectives. This might include, for example, a clinical workstation, the organisation of a guard function, the replacement of certain physicians, the use of specialised material or – and this is close to the aim of an association – the operation of a specific service.

It is recommended, in the context of the collaboration in a network, to underline that the main objective will be to promote the quality of healthcare by the joint optimisation of the quality of care within the area of the network. The network itself however cannot have the entire control over the hospital and its activities will be related to the specific purposes of the network itself. Hospitals belonging to a network cannot use it to by-pass or abuse competition rules to affect competition in a substantial part of the Belgian market. That is why it is so important to clearly define the objectives of a network. In that respect, it will be important for a network, if it becomes an important market player, not to exclude parties that are willing to participate in the network.

The goal of a network can be high-quality care within a particular area and taking into account the local expertise and capabilities of the parties.

Other healthcare providers can be involved in the development of the network, e.g. GPs, home care organisations, patient associations, etc.

A network can lead to the optimisation of the accessibility and the continuity of care for the patient. This occurs if the purpose of a network relates to exchange of medical information and/or medical knowledge, the use of physicians trained for specific activities (including guard functions), the use of specific, cost consuming devices etc.

4.3.6 Competition and the network

Sensitive data

In case of the launch of a network, it is important to take into account the competition rules. Concerning the information sharing, it is not permitted for example to share sensitive information. The exchange of information concerning sensitive data is anti-competitive. Sensitive data are data related to essential elements of commercial policy: prices, discounts, price lists, rate and date of rate changes, special abnormalities, overdraft facilities, credit, delivery, service, etc. These data may provide network information on sales volumes and provide market share that indirectly gives indications about the 'commercial' policies of competitors. The same applies where such data concerns industrial information such as production volumes, costs or decisions about investments.[239]

Concentration

In addition, the regulation concerning concentrations should be taken into account. According to art. IV.6, §1 of the Code of Economic Law a concentration shall be deemed to arise where a change of control on a lasting basis results from:

1. the merger of two or more previously independent undertakings or parts of undertakings; or
2. the acquisition, by one or more persons already controlling at least one undertaking, or by one or more undertakings, whether by purchase of securities or assets, by contract or by any other means, of direct or indirect control of the whole or parts of one or more other undertakings.

Art. IV.6, § 2 of the Code of Economic Law adds that 'the creation of a common undertaking hat on a lasting basis fulfils all the functions of an autonomous economic entity shall constitute a concentration within the meaning of paragraph 1, 2.' The control is based on rights, contracts or any other means which separately or jointly taking into account all the factual

[239] VBO, *Informatie-uitwisseling en de mededingingsregels*, Luik, VBO, 2011, 9.

and legal circumstances, make it possible to influence significantly the activities of an undertaking, in particular: 1°ownership or the right to use all assets of a company or parts thereof; 2°rights or contracts which confer a significant influence on the composition, voting or decisions of the company organs. This is determined by art. IV.6, § 3 of the Code of economic Act.

The term 'control' was clarified in the European consolidated communication on merger control.[240] Below some of the provisions of the Commission's Communication are cited.

Control is defined by art. 3 of the Merger Regulation as the possibility of exercising decisive influence on an undertaking. It is therefore not necessary to show that the decisive influence is or will actually be exercised. However, the possibility of exercising that influence must be effective.[241] Art. 3 further provides that the possibility of exercising decisive influence on an undertaking can exist on the basis of rights, contracts or any other means, either separately or in combination, and having regard to the considerations of fact and law involved. A concentration therefore may occur on a legal or a *de facto* basis, may take the form of sole or joint control, and extend to the whole or parts of one or more undertakings (cf. art. 3(1)(b)).

Whether an operation gives rise to an acquisition of control therefore depends on a number of legal and/or factual elements. Control can also be acquired on a contractual basis. In order to confer control, the contract must lead to a similar control of the management and the resources of the other undertaking as in the case of acquisition of shares or assets. In addition to transferring control over the management and resources, such contracts must be characterized by a very long duration (ordinarily without a possibility of early termination for the party granting the contractual rights). Only such contracts can result in a structural change in the market.[242] Examples of such contracts are organisational contracts under national company law [243] or other types of contracts, *e.g*. in the form of agreements for the lease of the business, giving the acquirer control over the management and the resources despite the fact that property rights or shares are not transferred. In this respect, art. 3 specifies that control may also be constituted by a right to use the assets of an undertaking.[244] Such contracts may also lead to a situation of joint control if both the owner of the assets as well as the undertaking controlling the management enjoy veto rights over strategic business decisions. [245]

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240 Consolidated Communication of the Commission on division of competences on the basis of the Regulation (EC) nr. 139/2004 of 20 January 2004 on the control of concentrations between undertakings , *Pb.C.* 95.1.

241 Judgment in Case T-282/02 Cementbouw v Commission, paragraph 58, [2006] ECR II-319

242 Consolidated Communication of the Commission on division of competences on the basis of the Regulation (EC) n° 139/2004 of 20 January 2004 on the control of concentrations between undertakings , *Pb.C.* 95.1.; In Case COMP/M.3858 — Lehman Brothers/SCG/Starwood/Le Meridien of 20 July 2005 the management agreements had a duration of 10-15 years; in Case COMP/M.2632 — Deutsche Bahn/ECT International/United Depots/JV of 11 February 2002 the contract had a duration of 8 years.

243 Examples of such specific contracts under national company law are the 'Beherrschungsvertrag' in German law or the '*Contrato de subordinação*' in Portuguese law; such contracts do not exist in all Member States.

244 See Case COMP/M.2060 — Bosch/Rexroth of 12 January 2001 concerning a control contract (Beherrschungsvertrag) in combination with a business lease; Case COMP/M.3136 — GE/Agfa NDT of 5 December 2003 concerning a specific contract to transfer control over entrepreneurial resources, management and risks; Case COMP/M.2632 — Deutsche Bahn/ECT International/United Depots/JV of 11 February 2002 concerning a business lease.

245 Consolidated Communication of the Commission on division of competences on the basis of the Regulation (EC) n) 139/2004 of 20 January 2004 on the control of concentrations between undertakings, *Pb.C.* 95.1; Case COMP/M.3858 — Lehman Brothers/SCG/Starwood/Le Meridien of 20 July 2005; see also case IV/M.126 — Accor/Wagon-Lits of 28 April 1992 in the context of art. 5(4)(b) of the Merger Regulation.

The object of control can be one or more, or also parts of, undertakings that constitute legal entities, or the assets of such entities, or only some of these assets.[246]

The concept of a concentration will be defined in such a manner as to cover operations only if they bring about a lasting change in the control of the undertakings concerned and, in the structure of the market.[247]

Where the undertakings of the network will together reach a turnover of more than 100 million euro in Belgium and at least two of the undertakings will reach each in Belgium a turnover of at least 40 million euro the notification of the concentration will be mandatory.[248]

Prior notification of the concentration by the Belgian Competition Authority will be necessary. This authority determines whether or not the concentration will be allowed (art. IV.9 §1).

Because a network must avoid having control over other undertakings, it will be difficult to argue that the general rights and duties of physicians and hospitals administrators of the network must be (to a large extent) identical.

4.3.7 The network and VAT

Since 1 July 2016, the VAT regime of cost-sharing associations has been adapted in way that will be of importance for networks. The Act of May 26, 2016 'amending the Code of the VAT regarding the exemption of services provided to their members by independent groups of persons' inserted in art. 44 of the 'Code of the VAT' a paragraph 2a. As the title suggests, it is a modification of the exemption of services that independent groups of persons provide to their members. This exemption regime applies to 'independent groups of persons'.

The notion 'independent group of persons 'means: an organisation with legal personality (such as a not-for-profit association) and organisations without legal personality, acting under its own name as a separate organisation or group towards its members and third parties. The group can legally exist separately of its members, but this is not a requirement. If the group has no legal existence distinct from its members, the group needs to operate under its own name towards its members and third parties as a separate entity.

It should be noted that the Belgian administrative practice refers to an independent group usually with the notion 'cost-sharing association'. A cost-sharing association is a permanent community of interest founded by physical persons or legal entities in order to rationalize and reduce their administrative and operating costs. Typically, the expenditure of its members occurs on a communal basis. The objective of cost-sharing associations is to save the costs associated with exempted or non-taxable activities of their members.

The Act of 26 May 2016 is a partial transposition of Directive 2006/112 / EC of 28 November 2006 on the common system of VAT. By inserting paragraph §2bis in art. 44 of the Code of the VAT, Belgium has fulfilled the request of the European Commission to comply with art. 132, paragraph 1(f) of the European directive 2006/112 / EC which provides that: services supplied by independent groups of persons whose activities are exempt from or are not subject to tax, in order to provide services to their members which are directly necessary for the exercise of their activity, where these groups of their members only claim reimbursement of their share of the joint expenses, provided that such exemption is not likely to cause distortion of competition.'

246 Consolidated Communication of the Commission on division of competences on the basis of the Regulation (EC) n° 139/2004 of 20 January 2004 on the control of concentrations between undertakings, *Pb.C.* 95.1., 24.

247 Recital 20 of Consolidated Communication of the Commission on division of competences on the basis of the Regulation (EC) n° 139/2004 of 20 January 2004 on the control of concentrations between undertakings , *Pb.C.* 95.1, 28.

248 Art. IV.7 Code Economic Act.

The conditions under which the services provided by independent groups of persons to their members are exempted are listed under paragraph 2bis of art. 44 of the Code of the VAT. These four conditions must be met cumulatively:

- members of the group exercise, on a regular basis, an activity that, under art. 44 of the Code of the VAT, is exempted or is not taxable. The exempted activities or activities for which the members do not pay tax, represent a major part of the activity of the members;
- the activities of the group consist of the provision of services to its members which are directly necessary for their exempt activity or their activity for which they are not taxable. If the group also carries out activities for non-members, the activities carried out for its members represent the majority of the activity of the group;
- the fee charged to each member only represents the reimbursement of its share of the joint expenses incurred by the group;
- the exemption does not lead to distortion of competition.

The cost-sharing association has a notification and information obligation. At the beginning of its activity, the independent group of persons, who carries out only services which are exempt or for which it has not the status of taxable person, shall be obliged to make a notification to the competent VAT office. This notification must be made within the month following the beginning of these activities. In addition, the group must also submit (to the same office) a list of its members, as well as the nature of their activity. This happens within the same aforementioned period. In addition, a group is also obliged, by the entry or departure of a member, by modification of the activity of the group or any of its members or termination of the activity, to inform the VAT office of this within the month following the aforementioned event. Although the group only provides services which are exempt from VAT or for which it does not have the status of taxable person, based on art. 44 §2bis, second paragraph of the Code of the VAT, a notification and an information obligation is imposed on the group. It is noteworthy that such a group does not fall within the scope of art. 53 of the Code of the VAT.

An independent group that has VAT obligations at different rates is obliged to report, based on art. 53 of the Code of VAT. The new regime imposes an additional notification obligation and an information obligation based on art. 44 §2bis third paragraph of the Code of the VAT. This requires the submission of a list of its members at the start of its operations, as well as the nature of their activity. In addition, this group must inform the supervising office of any entry or departure of a member.

Moreover, this requirement applies for groups that already existed on 1 July 2016, when the Act came into force. Therefore, the groups are imposed to be transparent about their members and the nature of the activity of their members. The King will determine the further practical formalities for the notification and information obligation.

4.3.8 *Transparency and network: a network as a legal person or not and its consequences*

It will be important for users of the network to be aware of its legal status (i.e. whether it is a legal person or not), its members and its objectives.

If the members of the network only conclude contractual agreements, they should be aware of the legal risks regarding liability of the members of the network if activities are carried out by the network.

The collaboration may or may not have legal personality. A not-for-profit association is an organisation with a legal personality. An organisation without legal personality is called an incorporated association or a factual association (*'feitelijke vereniging'/'association de fait'*). The factual association is considered to be a collection of its members.[249] The Supreme Court ruled that a claim set against an association without legal personality must be considered as a claim set against its members.[250] This means that, in case of a liability claim, members shall be held liable. Since its members

[249] M. Denef, M. Wauters en J. Vananroye, 'Situering en algemene kenmerken van de vzw', in M. DENEF *et al.* (ed.), *De VZW*, Brugge, die Keure, 2015, 55.

[250] Cass. 20 June1988.

unite on the basis of a contract and not many legal rules are provided related to a factual association, the principle of the autonomy of the free will plays an important role. The contract may contain further clarifications. Third parties have a direct claim against the members of the association, only if there is proceeded in the name of the members together and within the scope of the competence of representation.[251] Members are unlimitedly liable for equal parts.[252] The members of the association can be held personally liable for the debts of the association.[253] The property that arises within the association is the collective property: the property which is jointly held by the members to achieve the common purpose.[254] The common purpose determines how the collective property is managed.[255]

4.3.9 Conclusion

In case of a network, the funding remains at the level of the hospitals. Also under the current law, the network will in principle not receive any funding, if the network itself has no authorisation number.

The cases demonstrate that collaboration with the medical council certainly may lead to many conflicts. To achieve a real collaboration, the statutes of the physicians must be conformable to each other. This implies often a rather reinforced opinion of the medical councils. If a physician is working in several hospitals, the opinion of the medical council will be necessary for an appointment. This often makes the procedure very complex.

If a network wants more impact, control and supervision on the way hospitals are operating in the network, and thus on the legal persons who are members of the network, then competition rules become important. If there is a concentration, the network will have to be reported to the Competition Authority.

If the network wants to exercise a significant degree of control of the institutions, it will then be appropriate to transfer to a health system as in model 1.

A network will have to take account of the new regulation about cost-sharing associations and VAT.

It is possible (legally speaking) to provide what type of health actor is included in a network committee. If the legislator does not provide this, it can also be contractually determined by the members of the network. It should be kept in mind however, that the network committee can only take binding decisions for the purposes of the network. It cannot decide how the hospitals organise themselves, the steps they will take etc. If a network, for example, concerns an ICT collaboration then the network committee cannot decide about other care issues in hospitals.

The network model can be complementary to a group (as described in the Royal Decree of 30 January 1989) or association, but cannot replace them. A network closely resembles an association, except that non-hospitals can be part of it.

Optimisation of a patient pathway may be a target, but the network will also continue to be supportive unless it switches to a health system (model 1) or a new organisation (model 3). Other objectives of a network may be related to the on duty service / ICT collaboration, etc.

Whether there will be an added value in terms of quality will depend on the objective and the realisation of it. The impact of a network on individual institutions is likely to be limited, meaning that the impact on quality is also likely to remain limited. Communication with patients about the role and responsibility of the network is crucial. This communication will be easier in case of models 1 or 3. The impact on funding will be limited, given the limited role of the network. Whether there is over-consumption will depend on the

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251 M. Denef, M. Wauters en J. Vananroye, 'Situering en algemene kenmerken van de vzw', in M. DENEF *et al.* (ed.), *De VZW*, Bruges, die Keure, 2015, 57.

252 M. Denef, M. Wauters en J. Vananroye, 'Situering en algemene kenmerken van de vzw', in M. DENEF *et al.* (ed.), *De VZW*, Bruges, die Keure, 2015, 57.

253 D. Van Gerven, *Handboek Verenigingen*, Kalmthout, Biblo, 2002, 41.

254 H. De Page en R. Dekkers, *Traité élémentaire de droit civil belge*, Bruylant, Brussels, 1975, V, 1018-1019.

255 D. Van Gerven, *Handboek Verenigingen*, Kalmthout, Biblo, 2002, 42.

purpose of the network. Over-consumption is seemingly better addressed through models 1 or 3.

4.4 Legal feasibility of a new organisation

4.4.1 General

Model 3 creates a new structure that aims to provide specialised care for a certain category of pathologies (hereinafter the new organisation). Hence, the hospital landscape is adapted in such a way that centres specialised either in pathology, or in a certain category of patients (orthopaedics, ophthalmology, paediatrics, etc.) - operate next to hospitals providing general care. The direction taken by model 3 is to go further than what is currently proposed for healthcare programmes by proposing the creation of a new structure of independent health facilities that offer specialised care for a limited number of diseases - some of which are not necessarily covered by care programmes - and/or for certain categories of patients.

In today's hospital landscape, specialised healthcare structures which were either created between already existing hospitals[256] or on the basis of the Hospital Act[257]already exist. Certain hospitals work together to share both their know-how and materials/infrastructure by means of these specialised structures. An 'association of hospitals', as described in the Royal Decree of 25 April 1997,[258] is the preferred method of collaboration to develop these specialised structures.

As was discussed in Chapter 2, it appears that the existing forms of collaboration do not always provide the ideal solution. A specialised healthcare structure built on the aforementioned model of association can currently not exist independently of the hospitals that created it. Art. 67, al. 2 of the Hospital Act prescribes that '*only the legal persons who operate the hospitals that are part of the association, as well as the natural or legal persons nominated by the legal person in question, may be a member of or be associated with the legal person who operates this association*'.

Moreover, every institution that meets the concept of being a 'hospital', as defined by the Hospital Act[259], must be approved[260] as being such and, as a consequence, must meet all the authorisation standards, drafted for the operation of hospitals. [261] It is therefore not possible for a healthcare institution '*where specific, specialised medical examinations and/or treatments, related to medicine, surgery and possibly obstetrics, can be carried out or applied at any time in a multidisciplinary context, in terms of medical, medical-technical, paramedical and logistics required and appropriate for patients who are admitted and can stay there, because their condition requires this care package to treat or alleviate disease, restore or improve the health status or to stabilize the injury as soon as possible*'[262] to function without authorisation and without integrating into national planning (or programmes). This implies, therefore, that a specialised healthcare structure such as proposed in model 3 can currently solely function through the pre-existing hospitals. Likewise, the current legislation seems to oppose hospital services that function independently from hospitals.[263] Art. 72 of the Hospital Act prescribes that a hospital service can only be approved when it is organised within the hospital itself. Such a restriction also exists for care

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256 See for example the Iridium Kankernetwerk vzw

257 Centre hospitalier universitaire Jules Bordet – Hôpital universitaires des enfants Reine Fabiola – different geriatric hospitals or for rehabilitation

258 Royal Decree of 25 April 1997 houdende nadere omschrijving van de associatie van ziekenhuizen en van de bijzondere normen waaraan deze moet voldoen, B.S. 18 June 1997 (hereinafter referred to as 'Royal Decree of 25 April 1997')

259 See art. 2 Hospital Act

260 Art. 69 Hospital Act

261 See in particular Royal Decree of 23 October 1964 tot bepaling van de normen die door de ziekenhuizen en hun diensten moeten worden nageleefd, B.S. 7 November 1964 (hereinafter referred to as 'Royal Decree of 23 October 1964')

262 Art 2 Hospital Act

263 Except for the isolated services (see below)

programmes that may be authorised only if they are part of a hospital. Moreover, a hospital requires in principle minimum 150 beds, which may not be the case for a specialised organisation. It also needs to be noted that the current funding provided by hospital legislation can only be granted through the hospital as an intermediary (or more specifically the legal person running the hospital). Indeed, the BFM is set per hospital[264] and the legislation does not permit separate financing per healthcare service.[265] The BFM can only be given to a hospital. It is therefore up to the participating hospitals to agree upon the financing of these specialised healthcare structures. Such a structure can therefore not have financial independence.

Finally, it is important to note that the current rules on billing activities to the RIZIV – INAMI (the National Institute for Health and Disability Insurance) include specific requirements that must be met for an intervention to be reimbursed.[266] It is generally accepted that certain activities can only be performed within an authorised hospital, for example surgery in order to receive a reimbursement of the costs. It will therefore also be necessary to modify this regulation in order to develop model 3.

It would therefore appear that the current legislation does not permit the creation of a specialised healthcare institution which coexists independently alongside current hospitals and which is financed distinctly.

The question then arises which modifications will be necessary in order to permit the development of a structure such as proposed in model 3. Two hypotheses present themselves. The first one would adjust the current legislative framework in order to permit such specialised healthcare structures to be integrated in the current legislation on hospitals and other healthcare establishments. The second one would be to create new specific legislation for these specialised structures. For both possibilities, it will be necessary to analyse what the specific conditions for creating such a structure are (e.g. governing bodies, the decision-making process, the employees, VAT). But first of all, before explaining these different options more in detail, it is important to indicate the general rules which need to be applied to create such a new organisation.

4.4.2 Rules to be taken into account for the creation of the new organisation

The creation of a new healthcare structure demands an analysis of which aspects of the legislation need to be taken into account in order to assure the compatibility of the structure with the law. This is why, for example, the right of competition and the rules concerning the free market in regulating the possibility of collaboration between medical institutions require certain provisions to be respected. In the same way, the legislation concerning State aid prescribes that the financing of a public healthcare structure is subject to certain provisions. It also needs to be noted that the principle of free movement of services prohibits the limitation of economic development without a legitimate reason. Finally, it will be necessary to revise the division of competences between the federal state and the communities concerning the healthcare organisation to analyse on which level of power it is necessary to place the development of a new organisation.

4.4.2.1 Competition law

Competition law subjects the collaboration between companies to strict conditions in order not to disrupt the market. The question then arises whether such rules should be followed by creating and operating as a new organisation.

As explained in 4.2.9 competition rules must be complied with. This means that rules concerning the formation of cartels, the abuse of dominant position must be complied with. In addition, where the creation of a new organisation

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264 Art. 95 Hospital Act, art. 4 Royal Decree 25 April 2002 betreffende de vaststelling en de vereffening van het budget van financiële middelen van de ziekenhuizen, *B.S*. 30 May 2002 (hereinafter referred to as 'Royal Decree of 25 April 2002')

265 Except for the isolated services (see below)

266 Royal Decree of 14 September 1984 tot vaststelling van de nomenclatuur van de geneeskundige verstrekkingen inzake verplichte verzekering voor geneeskundige verzorging en uitkeringen, *B.S.* 29 September 1984

leads to a concentration, the concentration rules of the competition law has to be complied with.

4.4.2.2 Public procurement rules

The legislation on public procurement subjects the conclusion of a contract by a contracting authority to strict rules in order to assure the principles of equality, non-discrimination and transparency are respected. The question arises whether these rules need to be respected when creating the new organisation. A particularly important question is whether the organisation of a company between contracting authorities (i.e. legal entities operating hospitals) is in compliance with the rules on the free market in the selection of a partner. Take the example of a hospital A that wishes to collaborate with others in order to create a structure such as the one represented by model 3. Is the choice of the other hospitals, subjected to the rules on public procurement? What if the collaboration is concluded with private partners?

4.4.2.3 A preliminary remark concerning the organisation of healthcare and public procurement

Before analysing whether public procurement legislation has to be complied with when several legal persons operating hospitals want to create a new organisation, one must ask whether the Member State has to comply with public procurement legislation when it grants an authorisation to a new organisation and gives subsidies to this new organisation. Healthcare is often provided as a SGEI. The TFEU has declared the importance of such SGEIs. Art. 14 TFEU states that without prejudice to art. 4 TFEU or to art. 93, 106 and 107 of this Treaty, and given the place occupied by SGEIs in the shared values of the Union as well as their role in promoting social and territorial cohesion, the Union and the Member States, each within their respective powers and within the scope of application of the Treaties, shall ensure that such services operate on the basis of principles and conditions, particularly economic and financial conditions, which enable them to fulfil their missions. In Protocol n° 26 on services of general interest it is stated that the shared values of the Union in respect of SGEIs include in particular:

- the essential role and the wide discretion of national, regional and local authorities in providing, commissioning and organising SGEIs as close as possible to the needs of the users;
- the diversity between various SGEIs and the differences in the needs and preferences of users that may result from different geographical, social or cultural situations;
- high level of quality, safety and affordability, the equal treatment and the promotion of universal access and of user rights.

Art. 2 of the Protocol n° 26 states also that the provisions of the Treaties do not affect in any way the competence of Member States to provide, commission and organise non-economic services of general interest.

Directive 2014/24 on public procurement is without prejudice to the freedom of national, regional and local authorities to define, in conformity with Union law, SGEIs, their scope and the characteristics of the service to be provided, including any conditions regarding the quality of the service, in order to pursue their public policy objectives.[267] The Directive is also without prejudice to the power of national, regional and local authorities to provide, commission and finance SGEIs in accordance with art. 14 TFEU and Protocol No 26 on Services of General Interest annexed to the TFEU and to the Treaty on European Union (TEU). In addition, this Directive does not deal with the funding of SGEIs or with systems of aid granted by Member States, in particular in the social field, in accordance with Union rules on competition.[268] So Member States and public authorities remain free to provide those services themselves or to organise social services in a way that does not entail the conclusion of public contracts, for example through the mere financing of such services or by granting or authorisations to all economic operators meeting the conditions established beforehand by the contracting authority, without any limits or quotas, provided that such a

[267] Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (hereinafter referred to as 'Directive 2014/24/EU'), recital n° 7.

[268] Directive 2014/24/EU, recital 7.

system ensures sufficient advertising and complies with the principles of transparency and non-discrimination.[269] Therefore, art. 1, point 4 of the Directive 2014/24 states very clearly that the Directive does not affect the freedom of Member States to define, in conformity with Union law, what they consider to be SGEIs, how those services should be organised and financed, in compliance with the State aid rules, and what specific obligations they should be subject to. Equally, the Directive does not affect the decision of public authorities of whether, how and to what extent they wish to perform public functions themselves pursuant to art. 14 TFEU and Protocol No 26. In point 5 of art. 1 it is stated that the Directive does not affect the way in which the Member States organise their social security systems.

Moreover, agreements, decisions or other legal instruments that organise the transfer of powers and responsibilities for the performance of public tasks between contracting authorities or groupings of contracting authorities and do not provide for remuneration to be given for contractual performance, are considered to be a matter of internal organisation of the Member State concerned and, as such, are not affected in any way by this Directive on public procurement (art. 1.6).

It follows from the above that a Member State who wishes to create a new organisation that will be entrusted with a SGEI will not necessarily be forced to apply the public procurement legislation. So it is possible for the Member State or the competent public authority to establish in advance the conditions for provision of a social service and, after sufficient advertising and in accordance with the principles of transparency and non-discrimination, grant authorisations to all providers meeting these conditions.[270] Such a system does not specify any limits or quotas concerning the number of service providers; all those meeting the conditions can participate. Providers which have obtained an authorisation must provide the service at the request of the user, who will thus have the choice of several providers, at a price set beforehand by the public authority.

Vertical and horizontal collaboration

Collaboration between public authorities is not in principal exempt from the application of provisions concerning public procurement. Thus, every form of collaboration which has as its object activities, supplies or services, at the expense of a contracting authority for the benefit of another, supported by consideration – (even as incurred costs) constitutes a public procurement.

The Court of Justice has however expressed two hypotheses concerning activities that are exempted from the application of provisions of public procurements.[271] On the one hand, there is an 'in house' exception (also known as vertical collaboration); on the other hand, more recently, there is a 'collaboration contract' exception (also known as horizontal collaboration). These two exceptions aim at two different situations. Where vertical collaboration implies the control of one or more contracting authorities over another separate legal entity, horizontal collaboration does not necessarily imply a contracting authority having control over another, allowing thus collaboration on a contractual basis.

These two exceptions were included in the new European directives concerning public procurement. Directive of 2014/24/EU defines for the first time explicit rules to establish which procurements can be concluded between entities of the public sector without the use of award of contract.

If the conditions to qualify for an exemption from the rules on public procurement are not met, the collaboration between the contracting authorities will have to respect the aforementioned rules.

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269 Directive 2014/24/EU, recital 114.

270 Commission staff working document of 29 April 2013, entitled 'Guide to the application of the EU rules on State aid, public procurement and the internal market to services of general economic interest, and in particular to social services of general interest', Brussels, SWD(2013) 53 final/2, 100

271 Court of Justice of the EU (CJEU), decision of 18 November 1999, C-107/98, Teckal, Rec. 1999 I-08121; CJEU, 9 June 2009, C-480/06, Commission v. Federal Republic of Germany, Rec 2009 I-04747

Vertical collaboration

The objective of a 'vertical collaboration' is to create a separate legal entity which will be controlled by one or more contracting authorities. This exception is prescribed by art. 12 of the Directive, which states:

'A public contract awarded by a contracting authority to a legal person governed by private or public law shall fall outside the scope of this Directive where all of the following conditions are fulfilled:

1. the contracting authority exercises a level of control over the legal person concerned which is similar to that which it exercises over its own departments;
2. more than 80% of the activities of the controlled legal person are carried out in the performance of tasks entrusted to it by the controlling contracting authority or by other legal persons controlled by that contracting authority; and
3. there is no direct participation of private capital in the controlled legal person with the exception of non-controlling and non-blocking forms of private capital participation required by national legislative provisions, in conformity with the Treaties, which do not exert a decisive influence on the controlled legal person'.

The European legislator has therefore considered that public contracts awarded to controlled legal persons should not be subject to the procedures provided by the Directive if the contracting authority exercises over the legal person concerned a control which is similar to that which it exercises over its own departments. This means that the contracting authority exercises a decisive influence over both strategic objectives and significant decisions of the controlled legal person.

The control can be exercised by one or more contracting authorities that exercise in this case a jointly control. When a contracting authority exercises jointly with other contracting authorities a control over that legal person which is similar to the control they exercise over their own departments, the following conditions must be fulfilled:

1. the decision-making bodies of the controlled legal person are composed of representatives of all participating contracting authorities. Individual representatives may represent several or all of the participating contracting authorities;
2. those contracting authorities are able to jointly exert decisive influence over the strategic objectives and significant decisions of the controlled legal person; and
3. the controlled legal person does not pursue any interests which are contrary to those of the controlling contracting authorities.[272]

Public contracts awarded to controlled legal persons should not be subject to the application of the procedures provided for by the Directive if the contracting authority exercises a control over the legal person concerned which is similar to that which it exercises over its own departments, provided that the controlled legal person carries out more than 80% of its activities in the performance of tasks entrusted to it by the controlling contracting authority or by other legal persons controlled by that contracting authority, regardless of the beneficiary of the contract performance.[273]

For the determination of this percentage of activities the average total turnover, or an appropriate alternative activity-based measure such as costs incurred by the relevant legal person or contracting authority with respect to services, supplies and works for the three years preceding the award of contract shall be taken into consideration.[274]

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[272] Art. 12, paragraph 3 of the Directive 2014/24/EU

[273] Directive 2014/24/EU recital 32

[274] Art. 12, paragraph 5 of the directive 2014/24/EU

The European legislator decided not to extend the exemption to situations where there is direct participation by a private economic operator in the capital of the controlled legal person since, in such circumstances, the award of a public contract without a competitive procedure would provide the private economic operator with a capital participation in the controlled legal person an undue advantage over its competitors. [275]

This exception was implemented in the Belgian legislation through the new Act on public procurement of 17 June 2016 (art. 30).[276]

Horizontal collaboration

Next to the situation where multiple contracting authorities decide to create a new separate legal entity which they control, the directive also provides the possibility for contracting authorities to jointly choose to provide their public services by way of a collaboration without being obliged to use any particular legal form.[277] In this case, the services provided by the different participating contracting authorities need not necessarily be identical; they might also be complementary.

A contract concluded exclusively between two or more contracting authorities shall fall outside the scope of this Directive where all of the following conditions are fulfilled:[278]

1. the contract establishes or implements a collaboration between the participating contracting authorities with the aim of ensuring that public services they have to perform are provided with a view to achieving objectives they have in common;
2. the implementation of that collaboration is governed solely by considerations relating to the public interest; and
3. the participating contracting authorities perform on the open market less than 20% of the activities[279] concerned by the collaboration.

In order to fulfil those conditions, the collaboration should be based on a cooperative concept. Such collaboration does not require all participating authorities to assume the performance of the main contractual obligations, as long as there are commitments to contribute towards the cooperative performance of the public service in question. In addition, the implementation of the collaboration, including any financial transfers between the participating contracting authorities, should be governed solely by considerations relating to the public interest.[280]

This exception was implemented in Belgian law through the new Act on public procurement of 17 June 2016 (art. 31).[281]

Application of the rules on public procurement to the new organisation

A Member State can limit the form of a new organisation to a not-for-profit organisation

As stated already in the foregoing analysis of model 1, it is possible for a Member State, under certain conditions, to limit the form of the new organisation to a specific type of legal person, e.g. a not-for-profit organisation. The Court of Justice has held that, according to the scale of values held by each of the Member States and, having regard to the discretion available to them, a Member State may restrict the operation of certain activities by entrusting them to public or charitable bodies. Any

275 Directive 2014/24/EU recital 32

276 *BS* 14 July 2016

277 Directive 2014/24/EU recital 33

278 Art. 12, paragraph 4 of the directive 2014/24/EU

279 For the determination of this percentage of activities, the average total turnover, or an appropriate alternative activity-based measure such as costs incurred by the relevant legal person or contracting authority with respect to services, supplies and works for the three years preceding the contract award is taken into consideration (art. 12, paragraph 5, of the Directive 2014/24/EU)

280 Directive 2014/24/EU recital 33

281 *BS* 14 July 2016

measure of this kind must, however, be suitable for guaranteeing the achievement of one or more legitimate objectives invoked by that Member State and must not go beyond what is necessary to achieve those objectives. National legislation is suitable for ensuring attainment of the objective pursued only if it genuinely reflects a need to attain it in a consistent and systematic manner. In any event, such restrictions must be applied without discrimination.

The Public Procurement rules do not necessarily apply if a Member State provides an authorisation to a new organisation

As written above, Member States and public authorities remain free to provide those services themselves or to organise social services in a way that does not entail the conclusion of public contracts, for example through the mere financing of such services or by granting authorisations to all economic operators meeting the conditions established beforehand by the contracting authority, without any limits or quotas, provided that such a system ensures sufficient advertising and complies with the principles of transparency and non-discrimination.[282]

Do the Public Procurement rules apply if several legal persons want to create a new organisation?

Depending on how the new organisation will be created, it will be important to discern whether the rules on public procurement are applicable as it is clear from the definition of contracting authority that a hospital must apply the legislation on public procurement when it concludes an onerous contract concerning activities, supplies or services.

Indeed, next to the State, local authorities and public bodies, the legislation on public procurement is also applicable to others, '*whatever their form, their nature, that at the date of the decision to launch the public procurement* ', that:

- 'were created specifically to meet needs of general interest, not having an industrial or commercial character;
- come with a legal personality;
  - for whom the activity is mainly financed by the authorities or bodies mentioned in 1 °, a, b or c; or
  - their management is subject to supervision of those authorities or agencies; or
  - more than half of the members of the administrative body, the management or supervisory body are designated by such authorities or bodies.'[283][284]

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282 Directive 2014/24/EU, recital 114.

283 Art. 2, 1°, d) of the Act of 15 June 2006 overheidsopdrachten en bepaalde opdrachten voor werken, leveringen en diensten, *B.S.* 15 February 2007

284 L'art. 2 de la nouvelle loi du 17 juin 2016 relative aux marchés publics indique :
« Pour l'application de la présente loi, on entend par :
1° pouvoir adjudicateur :
c) les organismes de droit public et personnes, quelles que soient leur forme et leur nature qui, à la date de la décision de lancer un marché :
i ont été créés pour satisfaire spécifiquement des besoins d'intérêt général ayant un caractère autre qu'industriel ou commercial, et;
ii sont dotés d'une personnalité juridique, et;
iii dépendent de l'Etat, des Régions, des Communautés, des autorités locales ou d'autres organismes ou personnes relevant du présent point c), de l'une des manières suivantes :
1. soit leurs activités sont financées majoritairement par l'Etat, les Régions, les Communautés, les autorités locales ou d'autres organismes ou personnes relevant du présent point c);

By this definition, a private law status does not constitute a criterion for precluding the qualification of a person as a contracting authority.[285] This means that a private person satisfying these three conditions will be required to comply with rules on public procurement.

A hospital responds thereby to the concept of contracting authority within the meaning of the legislation on public procurement.[286] Hospitals fulfil a mission of general interest[287] and receive funding that primarily comes from public sources given that their funding comes primarily from the BFM, the payment of a number of fees by RIZIV – INAMI, refunds from insurances or from the receipt of grants for certain investments such as real estate construction.[288]

The question then arises whether the collaboration between hospitals for the creation of a new organisation may benefit from the exemptions provided by public procurement legislation.

On the basis of analysis of exemptions related to horizontal collaboration, it can be concluded that the choice of partner hospitals to create a new organisation can be made without following public procurement regulations.

It would, on the other hand, be different if a private partner was involved in such a collaboration concerning what would in effect be a public-private partnership. In this case, the selection process would eventually have to comply with legislation on public procurement.

It has been assumed for a long time that a partnership agreement and its creation were not subject to the application of regulations on public procurement. The correctness of this assumption has been discussed following a judgement of the State Council of 30 May 2005.[289] In this regard, the European Commission states in a Communication of 5 February 2008 on the application of Community law on Public Procurement and Concessions to IPPP that if public bodies decide to involve third parties in economic activities and if this involvement qualifies as a public contract or a concession, the Community provisions for public procurement and concessions must be complied with. If the task assigned to the public-private entity is a public contract fully covered by the Public Procurement Directives, the procedure for selecting the private partner is determined by these Directives. If it is a service concession or a public contract not covered by the Directives, the selection of the private partner has to comply with the principles of the EC Treaty.

This insight allows us to distinguish two situations. When the social purpose of a company of mixed nature is of a general scope, the selection of a private partner does not come within the scope of the public procurement rules. In other words, this choice should not result in a situation of competition which has to comply with the Public Procurement Act. This does not mean however that the choice is free. Indeed, as stated by the Court of Justice in the case of Coname (275/98 18 November 1999), it is necessary to ensure that the procedure achieves a sufficient degree of publicity in compliance with Art 49

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2. soit leur gestion est soumise à un contrôle de l'Etat, des Régions, des Communautés, des autorités locales ou d'autres organismes ou personnes relevant du présent point c);

3. soit plus de la moitié des membres de l'organe d'administration, de direction ou de surveillance sont désignés par l'Etat, les Régions, les Communautés, les autorités locales ou d'autres organismes ou personnes relevant du présent point c)

285 CJUE, 15 May 2003, C-214/00, Commission v Spain, Rec. 2003 I-04667 , 54-57

286 Callens, S., Coëffé, M., en Van Leuven, L., 'Mededinging, overheidsopdrachten en gezondheidszorg', in *Organisatie van de gezondheidszorg*, Intersentia, Antwerpen-Cambridge, 2015, p. 703

287 Art. 2, paragraph 2 Hospital Act

288 Bosquet, J., en Lafaut, L., Flexibel aanbesteden in de gezondheidszorg. De toepassing van de wetgeving overheidsopdrachten – De rol en de beperkingen van de raamovereenkomst en de onderhandelingsprocedure voor de verzorgingsinstellingen, MCP 2014, liv. 2, 138

289 Cabuy, Y., « Le cadre général de la loi du 15 juin 2006 et ses grands principes », in *Le nouveau droit des marchés publics en Belgique. De l'art. à la pratique*, Larcier, Bruxelles, 2013, p. 46

and 56 of the TFEU for the purposes of respecting the principles of non-discrimination, equality and transparency.

On the other hand, when a company's purpose is precise and the choice of the private partner is integrated in the project which is to be carried out or, in other words, the private partner is selected depending on the proposed project, the procedure comes, in principle, within the scope of the public procurement rules. The operation of creating a public company of a mixed nature is in this case a 'means' to conclude an onerous contract which has, as its object, the realisation of a work corresponding to the requirements specified by the contracting authority. The European Commission strongly recommends the application of the regulations on public procurement in the establishment stage of the mixed company or the opening of its capital to economic operators (Commission Interpretative Communication on the application of Community law on public contracts and concessions to public-private partnerships institutionalized - 5 February 2008).

The Council of State has stated in a Judgement of 19 June 2009 that although it recognizes that the choice of a partner to form a company falls in principle outside of the scope of the regulation on public procurement, that *' when it comes to entrusting a partner with services under section 5 of the Act of 24 December 1993, with contractual arrangements following the path of the partnership agreement, the transaction must be considered a public procurement and be subject to Belgian regulations.* It is therefore not enough, according to the State Council, *'to carry out activities, supply products or provide services through a special purpose company, formed by the contracting authority and a private operator to escape public procurement rules.*'

Finally, it must be stated that the Directive 2014/24/EU remains very flexible in cases where certain public authorities want to organise certain healthcare services. In the recitals to the directive it is stated that certain categories of services continue by their very nature to have a limited cross-border dimension, namely such services that are known as services to the person, such as certain social, health and educational services. Those services are provided within a particular context that varies widely amongst Member States, due to different cultural traditions. Given the importance of the cultural context and the sensitivity of these services, Member States should be given wide discretion to organise its choice of service providers in the way considered most appropriate (Recital 114). In art. 76 of Directive 2014/24/EU it is provided that Member States shall put in place national rules concerning the awarding of contracts subject to this Chapter in order to ensure contracting authorities comply with the principles of transparency and equal treatment of economic operators and that Member States are free to determine the procedural rules applicable as long as such rules allow contracting authorities to take into account the specificities of the services in question. Art. 76 provides also that Member States shall ensure that contracting authorities may take into account the need to ensure quality, continuity, accessibility, affordability, availability and comprehensiveness of the services, the specific needs of different categories of users, including disadvantaged and vulnerable groups and the involvement and empowerment of users and innovation. Member States may also require that the choice of the service provider shall be made on the basis of the tender presenting the best price-quality ratio, taking into account quality and sustainability criteria for social services.

4.4.2.4 Rules related to State aid

Above we analysed the impact of public procurement rules on the creation of the new organisation. The question then is whether European State aid rules apply if public authorities give subsidies to the new organisation. The question is important concerning the new organisation if this organisation does not receive a public funding as is foreseen for hospitals. If a financing method was granted to the new organisation which differs from the one applied to hospitals, one would have to clarify the public services performed in hospitals in order to justify the aid granted in relation to the new organisation which does not deal with such tasks and which could explain the non-funding of the new organisation or the different funding.

The European rules on State aid determine the possibilities in terms of public funding in compliance with certain rules. The State aid rules and the rules on public contracts and concessions have different aims and scope.[290] The State aid rules relate to the conditions for financing Social services of general interest (SGEIs) and consequently economic SSGIs and are aimed at preventing distortions of competition caused by financing or similar benefits granted by the State and its emanations. The rules on public contracts and concessions, on the other hand, concern the conditions for awarding these services to operators. One of their main aims is to ensure equal treatment and transparency in addition to preventing distortions of competition that may arise from the management of public funds by the contracting authorities when awarding these services.[291] Public authorities wishing to set up an SGEI must therefore comply not only with State aid rules but also with the rules on the award of public contracts or concessions.

The question then arises as to whether the public financing of a healthcare structure (as proposed by model 3) is compatible with the rules on State aid matters. It is not because the public procurement principles do not apply, that the Member State organizing and financing a new organisation does not have to comply with State aid rules when financing the new organisation.

Principle

Art. 107 paragraph 1 of the Treaty of Rome states that: '*Save as otherwise provided in the Treaties, any aid granted by a Member State or through State resources in any form whatsoever which distorts or threatens to distort competition by favouring certain undertakings or the production of certain goods shall, in so far as it affects trade between Member States, be incompatible with the internal market.*'

Incompatible State aid can thus be defined as any selective advantage that the State, sensu lato, grants to an (or several) undertaking(s) that may alter the conditions of competition and affect trade within the Union.[292]

The concept of State aid

Since its 1961 'Gezamenlijke Steenkoolmijnen'-judgment, the Court has considered that the concept of *'State aid is broader than the concept of subsidy because it includes not only positive benefits such as subsidies themselves, but also measures which, in various forms, mitigate the normal burdens on the budget of an undertaking and which thus, without being subsidies in the strict sense of the word, are similar in character and have the same effect.'*[293] This definition has subsequently been confirmed consistently in case law.

Several conditions have to be met before one can speak of incompatible State aid.[294] According to the case law of the Court of Justice, State aid consists of various constitutive elements under the TFEU, namely the existence of an undertaking, the accountability of the measure taken to the State, its funding through State resources, the granting of an advantage, the

290 Commission staff working document of 29 April 2013, entitled 'Guide to the application of the EU rules on State aid, public procurement and the internal market to services of general economic interest, and in particular to social services of general interest', Brussels, SWD(2013) 53 final/2, 101

291 Commission staff working document of 29 April 2013, entitled 'Guide to the application of the EU rules on State aid, public procurement and the internal market to services of general economic interest, and in particular to social services of general interest', Brussels, SWD(2013) 53 final/2, 101

292 Sabbadini, P-M, *Les aides d'Etat. Aspects juridiques et économiques*, Bruxelles, Larcier, 2015, p. 29

293 CJEU., decision of 23 February1961, C- 30/59, Rec., 1 p. 39

294 Sabbadini, P-M, *Les aides d'Etat. Aspects juridiques et économiques*, Bruxelles, Larcier, 2015, p. 35

selectivity of the measure and its potential effects on competition and trade within the Union.[295] These are cumulative conditions.[296]

- The concept of 'an undertaking' and 'an economic activity'

The rules on State aid will generally only be applicable when the beneficiary of the aid is an undertaking. An undertaking is defined by the Court as any entity engaged in an economic activity, regardless of the legal status of the entity or the way in which it is financed.[297] It is therefore the nature of the entity's operations that is decisive for the qualification of the entity as an undertaking or not. In discerning the difference between economic and non-economic activities, the Court has consistently held that an economic activity is any activity consisting of offering goods or services on a given market.[298]

Regarding healthcare, the Court found that hospitals were not acting as an undertaking where public hospitals are an integral part of a national health service and their operation almost entirely based on the principle of solidarity. These hospitals are financed directly by social security contributions and other State resources and provide their services free on the basis of universal coverage. If the hospital or other healthcare providers offer their services against a remuneration received either directly from patients or from their insurance, it must be considered that a degree of competition exists between hospitals and that the activity can therefore be classified as economic. The Court has already considered the medical services that self-employed physicians and other private practitioners provide against remuneration at their own risk as economic activity.[299]

Whether hospitals can be considered as undertakings may differ from country to country. In some Member States, public hospitals represent an integral part of a national health service and are almost entirely based on the principle of solidarity.[300]

In the cases *Poucet* and *Pistre*, the Court argued already that organisations involved in the management of the public social security system, that fulfil an exclusively social function and that have an activity based on the principle of national solidarity, that are entirely not-for-profit-making and where the benefits paid are statutory benefits bearing no relation to the amount of the contributions, do carry out an activity that is not an economic activity. Such organisations are therefore not undertakings.[301] In the case *Fenin* it was not disputed that the Spanish national health system (Sistema Nacional de Salud) ('the SNS') managed by ministries and other organisations, is operated according to the principle of solidarity, in that it is funded from social security contributions and other State funding and in that it provides services free of charge to its members on the basis of universal cover. In managing the SNS, the organisations were not therefore considered to be acting as undertakings. [302] In many other Member States, hospitals and other healthcare providers offer their services for remuneration, be it directly

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295 Draft Commission Notice on the notion of State aid pursuant to art. 107(1) TFEU, 5

296 CJEU, 21 March 1990, C 142-87 Belgium v Commission, *Rec.* 1990 I-00959, 25

297 CJEU, 12 September 2000, C-180/98 - C-184/98, Pavel Pavlov and Others, *Rec.* 2000 I-6451, 74

298 CJEU, 16 June 1987, C 118-85, Commission v Italian Republic, Rec.1987 I2599, 7 ; CJEU, 18 June 1998, C-35/96, Commission v Italian Republic, Rec. 1998 I-3851, 36 ; CJEU, 12 September 2000, C-180/98 - C-184/98, Pavel Pavlov and Others, *Rec*. 2000 I-6451, 74

299 CJEU, 12 September 2000, C-180/98 - C-184/98, Pavel Pavlov and Others, *Rec.* 2000 I-6451, 75-77

300 Communication from the Commission on the application of the EU State aid rules to compensation granted for the provision of services of general economic interest, 22

301 Court of Justice, 17 February 1993. Joined cases C-159/91 and C-160/91, recitals 18 – 19

302 Court of First Instance 4 March 2003, T-319/99, FENIN, *Rec.* 2003II-357, 39; CJUE 11 July 2006, C-205/03, *Rec.* 2006 I-6295, 25 -28

from patients or from their insurance.[303] In such systems, there is a certain degree of competition between hospitals concerning the provision of healthcare services. The Court of Justice and the General Court have also clarified that healthcare services in which independent doctors and other private practitioners provide for remuneration at their own risk are to be regarded as an economic activity.[304]

- Origin of the measures financed through State resources

The granting of an advantage, directly or indirectly, through state resources in addition to the State's accountability for such a measure are two separate and cumulative conditions for establishing the existence of State aid.[305]

- Advantage

The concept of advantage that determines the existence of aid, must be defined in the light of normal market conditions. In order to determine whether a particular State measure constitutes aid, it is necessary to establish whether the recipient undertaking receives an economic advantage which it would not have obtained under normal market conditions.[306] One must therefore compare the financial situation of the company once it has benefited from the measure with the situation that would have prevailed in the absence of the measure being granted.

- Selectivity

In addition to being a benefit to the company that receives it, State aid within the meaning of the TFEU must be selective, that is to say, it must favour certain undertakings or certain products.[307] Therefore, not all measures that promote economic operators necessarily fall within the concept of State aid. Only those that confer a selective advantage to certain companies or categories of companies or certain economic sectors are concerned.[308] It is thus important to verify whether the aid leads to an advantage for the exclusive benefit of certain undertakings or certain sectors,[309] in which case the aid would fulfil the condition of selectivity and could therefore be considered incompatible, assuming the other criteria are also fulfilled.

- Effect on trade and competition

Finally, aid will only be incompatible if it is likely to distort competition and affect trade between Member States of the Union. Regarding the impact of the advantage on Community trade, the Court considers that when aid granted by the State strengthens the position of an undertaking compared to other competing companies in intra-community trade, the latter must be regarded as affected by the aid, even if the beneficiary undertaking is not engaged in export.[310] Indeed, when a Member State grants aid to an undertaking, domestic production may for that reason be maintained or increased with the consequence that the opportunities for undertakings established in other Member States to export their products to the market of

303 Communication from the Commission on the application of the EU State aid rules to compensation granted for the provision of services of general economic interest, Brussel, *OJ* C 8, 11.1.2012, 24**.**

304 Communication from the Commission on the application of the EU State aid rules to compensation granted for the provision of services of general economic interest, Brussel, *OJ* C 8, 11.1.2012, 25.

305 Draft Commission Notice on the notion of State aid pursuant to art. 107(1) TFEU Projet de communication de la Commission relative à la notion d'aide d'Etat au sens de l'art. 107, paragraphe 1, du TFUE, pt 41

306 CJEU, 11 July 1996, C-39/94, Syndicat français de l'Express international (SFEI) and others, *Rec.* 1996 I-03547 pt 60 et CJEU, 29 April 1999, C-342/96, Spain v Commission, *Rec.* 1999 I-02459, 41

307 CJEU, 26 september1996, c-241/94, French Republic v. Commission, Rec. 1996 I-04551, 24, CJEU, 1 December 1998, C-200/97, Ecotrade, *Rec.* 1998 I-07907, 40

308 Draft Commission Notice on the notion of State aid pursuant to art. 107(1) TFEU, 118

309 CJEU, 17 June 1999, C-75/87, Maribel, *Rec.* 1999 I-03671, 26

310 CJEU, 17 June 1999, C-75/87, Maribel, *Rec.* 1999 I-03671

that Member State are reduced.[311] The case law of the Court reflects the fact that the Commission has not the task to establish the need to show a real effect on trade between Member States or an actual distortion of competition. In reality showing a priori control of State aid is sufficient.[312]

In practice, the existence of a distortion of competition will be presumed given that state intervention targets a liberalized sector where competition could exist. [313] Assistance will be likely to affect trade between Member States when it strengthens the position of an undertaking compared with competitors in the context of intra-community trade.[314]

The Commission has in several cases concluded that activities had a purely local character and did not affect trade between Member States, e.g. local hospitals aimed exclusively at the local population.[315]

Analysis of the compatibility of State aid – the concept of general interest services

When it appears from the analysis conducted by the Commission that a selective advantage granted by the State, *sensu lato*, to an (or several) undertaking(s) is likely to alter the conditions of competition and affect trade within the Union, such State aid will be incompatible with the Treaty and thus illegal. It is worth mentioning that some measures are considered, by the Commission, as not fulfilling the condition of effect on trade and competition, which are prerequisites for the existence of State aid. These measures, called '*de* minimis aid', should therefore not be notified to the Commission. This treatment applies to measures which are awarded to single enterprises over a given period (a maximum of three fiscal years) and whose fixed amount does not exceed, in principle, 200 000 euros.[316]

Art. 107(1) TFEU states that '*Save as otherwise provided in the Treaties, any aid granted by a Member State or through State resources in any form whatsoever which distorts or threatens to distort competition by favouring certain undertakings or the production of certain goods shall, in so far as it affects trade between Member States, be incompatible with the internal market*'. The State aid rules therefore only apply in general where the recipient is an 'undertaking'. Whether or not the provider of a service of general interest is to be regarded as an undertaking is therefore fundamental for the application of the State aid rules.[317]

In practice, the analysis will be distinct if the aid takes the form of public service compensation granted to certain undertakings entrusted with the operation of SGEIs (see below).

- The concept of SGEI

Europe has gradually authorised the need for services of general interest in order to provide better social cohesion and security for citizens. These services, of which the fundamental role is now well authorised within the EU (see above), concern different fields such as social welfare, transportation or, for example, healthcare.

311 CJEU, 14 September1994, C-278/92 -C-280/92Spain v. Commission, , *Rec.* 1994 I-04103, 40

312 Sabbadini, P-M, *Les aides d'Etat. Aspects juridiques et économiques*, Bruxelles, Larcier, 2015, p. 52

313 Court of First Instance, 4 September 2009, T 211-05, Italian Republic v Commission, *Rec.* 2009 II-02777, 157-160

314 CJEU, 12 May 2005, C-347/03, Fiulia venzia Giulia, Rec. 2005 I-03785, 41

315 Communication from the Commission on the application of the EU State aid rules to compensation granted for the provision of services of general economic interest, Brussel, OJ C 8, 11.1.2012, 40 ; see Commission Decision in Case N 543/01 — Ireland — Capital allowances for hospitals, OJ C 154, 28.6.2002, p. 4.

316 Commission Regulation (EU) n° 1407/2013 of 18 December 2013 on the application of art. 107 and 108 of the Treaty on the Functioning of the EU to de *minimis* aid, *OJ L 352, 24.12.2013*, 1-8

317 Communication from the Commission on the application of the EU State aid rules to compensation granted for the provision of services of general economic interest, Brussel, OJ C 8, 11.1.2012, 8.

Services of general interest (SGI) can consist of economic services or non-economic services (depending on which activities public authorities class as being of general interest and therefore submit them to the rules applicable to public services).[318] Companies responsible for the management of this service of general interest may be private or public in nature.[319] The concept of 'general interest' is not one that is clearly defined and Europe leaves a wide margin of discretion to Member States in the definition of services that could be classified as being services of general (economic) interest.[320] Authorisation of what constitutes a service of general interest therefore lies with the Member States and the European Commission merely has a monitoring role in the event of a manifest error as regards the definition of services of general (economic) interest.

In the general category of services of general interest, there is a more specific sub-category which comprises SGEI. These services involve economic activities, namely the sale of goods or services, that fulfil tasks of general interest that would, in the absence of State intervention, be performed by the market (albeit under different conditions in terms of quality, safety, accessibility, equal treatment or universal access). [321]

Art. 106 TFEU[322] represents a clear authorisation of the special role of SGEI and the need (given the type of general interest for which they are responsible), for derogations to some extent from the European rules. Therefore, while they are in principle subject to competition rules, SGEIs may derogate from them when necessary to fulfil their public interest role.[323] To be able to derogate from certain European rules, the company must have been specifically entrusted by the Member State with the operation of a particular SGEI.[324] The Commission specified in a decision of 20 December 2011[325] the conditions that must be met in order to enjoy protection of this derogation. The public service obligations entrusted to the undertaking concerned must be clearly indicated in one or more documents issued by the competent public authorities of the Member State concerned. The form of the instrument may vary from one Member State to another, but the act must specify at least the identity of the undertakings concerned, the precise content and duration and, where appropriate, the territory concerned by the

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318 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions of 12 May 2004 entitled 'White Paper on services of general interest' [COM(2004) 374 final]

319 In accordance with art. 345 of the Treaty, as interpreted by the Court of Justice of the EU (see Commission Decision of 20 December 2011 on the application of art. 106(2) of the Treaty on the Functioning of the EU to State aid in the form of public service compensation granted to certain undertakings entrusted with the operation of services of general economic interest (notified under document C(2011) 9380), OJ L 7, 11.1.2012, 2

320 Commission Decision of 20 December 2011 on the application of art. 106 of the Treaty on the Functioning of the EU to State aid in the form of public service compensation granted to certain undertakings entrusted with the operation of services of general economic interest (notified under document C(2011) 9380), OJ L 7, 11.1.2012, 8

321 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions of 20 December 2011 entitled 'A Quality Framework for Services of General Interest in Europe' [COM(2011) 900 final]

322 D. Fornaciari, S. Callens en E. Schokkaert, *Ziekenhuizen, mededingingsrecht en recht op kwaliteitsvolle zorg*, Antwerp, Intersentia, 2010

323 Callens, S., Coëffé, M., en Van Leuven, L., 'Mededinging, overheidsopdrachten en gezondheidszorg', in *Organisatie van de gezondheidszorg*, Intersentia, Antwerpen-Cambridge, 2015

324 Commission Decision of 20 December 2011 on the application of art. 106 of the Treaty on the Functioning of the EU to State aid in the form of public service compensation granted to certain undertakings entrusted with the operation of services of general economic interest (notified under document C(2011) 9380), OJ L 7, 11.1.2012, 13

325 Commission Decision of 20 December 2011 on the application of art. 106 of the Treaty on the Functioning of the EU to State aid in the form of public service compensation granted to certain undertakings entrusted with the operation of services of general economic interest (notified under document C(2011) 9380), OJ L 7, 11.1.2012

public service obligations, any exclusive or special rights that are granted and the description of the compensation mechanism and the parameters for determining compensation and avoiding and recovering any possible over-compensation.[326] In the interest of transparency regarding the implementation of the Commission's decision of 20 December 2011, it is also stated that the act of entrustment should also include a reference to it.[327]

Companies that are engaged in exploiting a SGEI may, because of the public service obligations entrusted to them and under certain conditions, benefit from financial compensation of public origin.

- Compatibility of public service compensation granted to certain undertakings entrusted with the operation of SGEI

The Court of Justice clarified in the Altmark judgment that the qualification of granting an advantage for SGEIs can be ruled out if four cumulative conditions are met.[328]

First, the recipient undertaking must actually be entrusted with the implementation of public service obligations and those obligations must be clearly defined. Second, the parameters on the basis of which the compensation is calculated must be established beforehand in an objective and transparent manner. Third, the compensation cannot exceed the amount necessary to cover all or part of the costs incurred in performing the public service task, taking into account related revenues and reasonable profit. Fourth, where the choice of the undertaking which is to perform the public service tasks, is not done within the framework of a public procurement procedure to select the candidate able to provide these services at the lowest possible cost to the community, the level of compensation must be determined on the basis of an analysis of the costs which a typical undertaking, well run and adequately equipped in order to meet the public service requirements, would have incurred in performing those obligations, taking into account the related revenues and what would constitute a reasonable profit. The Commission has described these conditions in its communication on the application of the rules of the EU regarding State aid rules for compensation granted for the provision of SGEIs. [329]

If follows from what is written above that if there no economic activity, if the measure has no effect on trade between Member States or on competition or if one of the four conditions of the *Altmark* judgment are met, there will be no State aid within the meaning of art. 107 TFEU.[330]

If this is not the case, there is e.g. an economic activity, then one must examine the total amount of compensation. The SGEIs analysis tree provided by the Commission (Figure 5) is useful for such purposes:

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326 Commission Decision of 20 December 2011 on the application of art. 106 of the Treaty on the Functioning of the EU to State aid in the form of public service compensation granted to certain undertakings entrusted with the operation of services of general economic interest (notified under document C(2011) 9380), OJ L 7, 11.1.2012 ,14

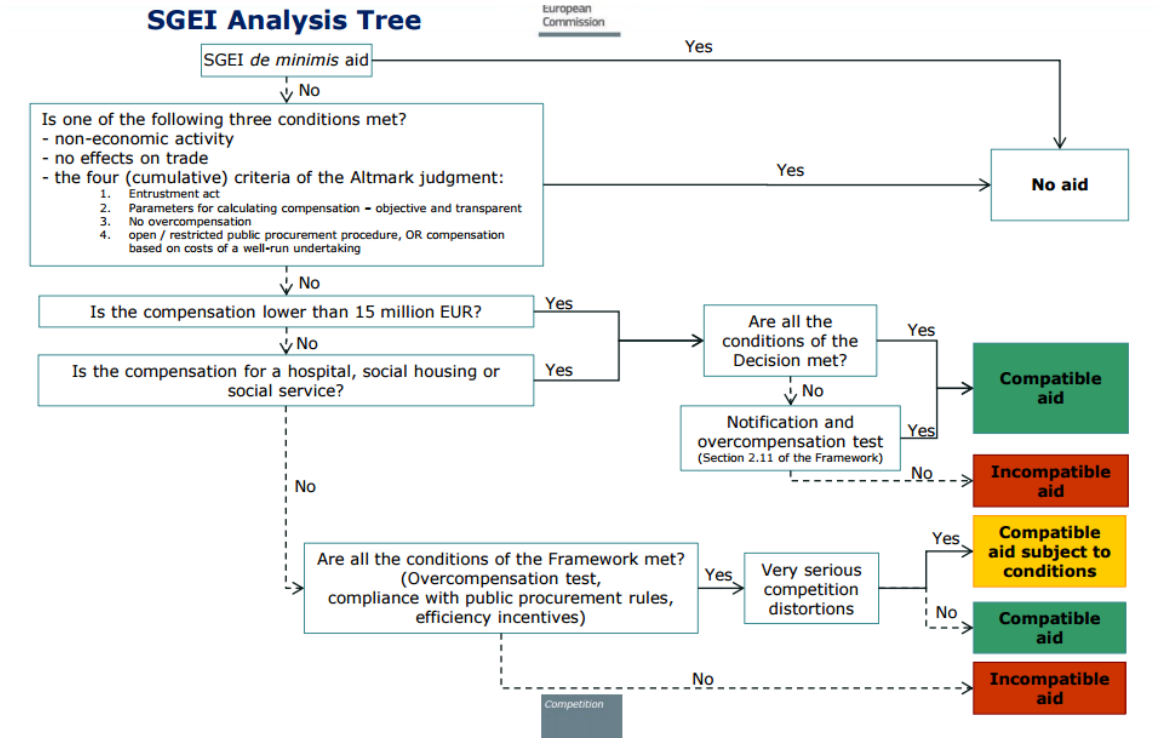
327 See for a Belgian example: art. 172 of the Act of 10 April 2014 houdende diverse bepalingen inzake gezondheid, *BS* 10 May 2014, has modified art. 108 Hospital Act to foreseen a reference to the decision of the European commission of 20 December 2011 within the communication of the BFM for hospitals

328 CJEU, 24 July 2003, C-280/00, Altmark Trans, Rec.2003 I-7747, 87-95

329 Communication from the Commission on the application of the EU State aid rules to compensation granted for the provision of services of general economic interest, Brussel, OJ C 8, 11.1.2012, p.4

330 Commission staff working document of 29 April 2013, entitled 'Guide to the application of the EU rules on State aid, public procurement and the internal market to services of general economic interest, and in particular to social services of general interest', Brussels, SWD(2013) 53 final/2

Figure 5 – SGEI Analysis Tree



Source: Commission staff working document of 29 April 2013, entitled « Guide to the application of the European Union rules on State aid, public procurement and the internal market to services of general economic interest, and in particular to social services of general interest, Brussels, SWD(2013) 53 final/2, p. 28

If the compensation does not exceed 500 000 euros spread over three years, the measure will not be considered State aid under art. 107 TFEU.[331] If the amount of compensation is higher, one must examine whether it is less than 15 million euro or if the compensation relates to a hospital or social service. If the latter is the case, the State aid will be compatible if the conditions laid down in the Commission Decision of 20 December 2011 are met.[332] If these conditions are not met, the measure must be notified to the Commission which will then analyse whether the aid is compatible. If the compensation exceeds 15 million euro or it does not concern a hospital or a social service, one has to examine if the conditions of the Framework[333] are met and if there is no serious distortion of competition.

Application of State aid rules to the new organisation

Below we analyse whether the funding of the new structure is compatible with the rules on State aid. We also verify whether it is possible to give public financing to hospitals and to decide not to fund the new organisation.

If the latter option were withheld or if a different financing method was granted to the new organisation compared to hospitals, one would have to clarify the public services performed in hospitals in order to justify the aid granted in relation to the new organisation which does not deal with such tasks what could explain the non-funding of the new organisation or a different funding.

Currently, the Hospital Act provides that hospitals are entrusted with tasks of general interest without precisely defining the tasks involved. It is possible to refer to the definition of a hospital which includes some indicator elements such as emergency services, continuity of care, multidisciplinarity, overnight beds, and numerous other analogous aspects.[334] If such missions were also entrusted to the new organisation, it would be difficult to grant public funding only to hospitals and to refuse it to a new organisation. Similarly, if the financing method were different, the additional funding granted to authorised hospitals would risk being qualified as illegal State aid.

With regard to this, it is interesting to refer to the recently issued decision of the European Commission through which it authorised public compensation to IRIS Brussels hospitals.[335] In that case complaints were filed by two associations representing private hospitals in Brussels that claimed that the IRIS public hospitals were receiving illegal State aid. Since 1996, these hospitals have received funds from various municipalities in the Brussels region as compensation for registered deficits that were brought about by the delivery of health services and social welfare of general economic interest. By contrast, private hospitals in Brussels do not benefit from this type of compensation. In October 2014, the Commission opened a detailed investigation regarding public compensation granted to five public hospitals in Brussels, following the decision of the Court of First Instance of the European Union which annulled the decision of the Commission on 7 November 2012. The Court of First Instance had ruled that the Commission should collect further information given the doubts expressed by the complainants as to the compatibility with the internal market of the compensation granted in the form of deficit financing resulting from additional obligations performed by IRIS hospitals.

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331 Commission Regulation (EU) No 360/2012, of 25 April 2012 on the application of art. 107 and 108 of the Treaty on the Functioning of the EU to de minimis aid granted to undertakings providing services of general economic interest, OJ L 114/8 26.4.2012

332 Commission Decision of 20 December 2011 on the application of art. 106 of the Treaty on the Functioning of the EU to State aid in the form of public service compensation granted to certain undertakings entrusted with the operation of services of general economic interest (notified under document C(2011) 9380), OJ L 7, 11.1.2012

333 Communication from the Commission entitled 'EU framework for State aid in the form of public service compensation', OJ C 8/15 11.1.2012

334 KCE Reports 225Bs, Correction of refractive errors of the eye in adults – Part 3: Organisation and legal framework of extramural surgery centres, Synthesis, p 12,

335 Commission decision of 5 July 2016 on State aid, SA.19864- 2014/C, C(2016) 4051 final

After a thorough investigation, the Commission found that the IRIS public hospitals had to perform a certain number of tasks in addition to the minimum obligations imposed on all Belgian hospitals. These additional tasks include, for example, the requirement to treat all patients in all circumstances (including situations outside of emergency situations), regardless of their ability to pay the corresponding fees. They aim to ensure that the most disadvantaged inhabitants of Brussels also have access to the hospital services they need and to ensure access for all to high-quality hospital care. Since the common sources of funding for hospitals, both the public and the private sectors, are insufficient to cover the costs of these additional obligations, IRIS public hospitals ran up deficits. Through compensating these deficits, the Brussels based municipalities allowed the concerned hospitals to continue to perform their public service obligations.

During its investigation, the Commission also found that, in accordance with rules on State aid for SGEIs, the IRIS hospitals had not received excess compensation, as the funds paid by the municipalities never exceeded the actual amount of losses they have registered due to their public service obligations. On this basis, the Commission concluded that the funding provided since 1996 by the Brussels municipalities to the IRIS hospitals in order to cover these deficits was in line with EU rules on State aid.

If different financing (compared to hospitals) was therefore granted to a new organisation, it would be necessary to justify this difference on the basis of the specific tasks of general interest with which only hospitals were charged.

It will also be necessary to analyse whether the new organisation can receive funding compared with private initiatives that could be developed and do not necessarily receive funding. In this case, one would have to justify why the public service tasks that the new organisation fulfils, had not been entrusted to private initiatives.

As the Commission rightly stated in its Guide, Member States have a wide margin of discretion when it comes to organizing and financing what they regard as a SGEI. The Decision of 2011 allows Member States to finance in full the net costs incurred in providing SGEIs by their providers, but does not oblige them to do so (Guide 61). Member States can, if they wish, decide to pay an equal flat-rate compensation to all providers, as long as such compensation does not give rise to excess compensation for the operators concerned. They are also free to under-compensate, or not compensate at all, SGEI providers. In as much as public service compensation granted to SGEI providers is calculated on the basis of their effective costs and relevant revenues and thus does not exceed what is necessary for discharging the SGEI, such compensation can be viewed as compatible within the meaning of the state aid rules (Guide 61). When the compatibility of the aid is assessed on the basis of the Framework, the method of calculating the compensation must be the same for all undertakings entrusted with the same SGEI (Guide 62).

4.4.2.5 The concept of the free movement of services

TFEU provides that restrictions on the freedom to provide services are, in principle, prohibited.[336] As a fundamental principle of the Treaty, the freedom to provide services may only be restricted by rules justified by the public interest and applicable to all persons and undertakings operating in the territory of the host Member State.[337] Thus, national measures likely to hinder or render the exercise of fundamental freedoms guaranteed by the Treaty less attractive, must meet four conditions: they must apply without discrimination, they must be justified by compelling reasons of general interest, they are suitable for securing the attainment of the objective they pursue and do not go beyond what is necessary to achieve it.[338] Indeed, any restriction on the freedom to provide services must be appropriate, proportionate, necessary and indispensable.

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336 Art. 56 du TFEU

337 CJEU, 9 March 2000, C-355/98, Commission v Belgium, Rec. 2000 I-01221, 37

338 CJEU, 4 July 2000, C 424/97, Haim, Rec. 2000 I-05123, 57 ; CJEU, 30 November 1995, C-55/94 Gebhard, Rec. 1995 I-04165, 39

According to Van Den Bossche, access to a service activity may be subject to authorisation by the competent authorities as complying with the principles of non-discrimination, necessity and proportionality. [339]

When a state considers the possibility of creating an institution of specialised care needs to comply with its obligation to integrate it in national planning it must respect the principles of the Treaty (equality, non-discrimination, etc.) and cannot refuse without good reason to issue an authorisation to an institution even if it is for example majority owned by private equity. It must be noted that this principle does not prevent the possibility for a Member State to decide to allow financial means only to certain entities with a specific legal form. The Court of Justice considered that such a restriction could be justified, in particular, if it is necessary and proportionate in view of the attainment of certain social objectives pursued by the national social welfare system.[340] Therefore a particular activity might, in exceptional cases, provide for restricted access to certain services to the advantage of not-for-profit organisations.

The Court of Justice has recognised that requiring authorisation to exercise an economic activity constitutes a restriction on the freedom to provide services.[341] Such a restriction may nevertheless be justified if it is an indispensable condition for achieving the objective in question.

Regarding the programming, where a State subjects the granting of an authorisation to the integration of activities in national planning (programming), the principle of freedom to provide services authorised by art. 56 TFEU must be respected.

It may be possible to argue that the programme creates a measure having the equivalent effect of a purely quantitative restriction which is prohibited under the articles discussed here, unless it can be justified. According to European case law,[342] such a restriction on freedom of provision of goods and services can be justified only if:

- the measure is prescribed by law;
- the interference is necessary for the protection of the general interest;
- the interference is proportionate to the advantage created by the limitation. This means that the authority must maintain a balance between the general interest affected by this limitation and the interests at stake

In the Directive of 9 March 2011 on the application of patients' rights in cross-border healthcare,[343] it has been pointed out that the Court of Justice has found that a planning seeks to ensure that there is sufficient and permanent access to a balanced range of high-quality hospital treatment in the Member State concerned. In addition, it assists in meeting a desire to control costs and to prevent, as far as possible, any wastage of financial, technical and human resources. According to the Court of Justice, such wastage would be all the more damaging because it is generally recognised that the hospital sector generates considerable costs and must satisfy increasing needs, while the financial resources made available for healthcare are not unlimited, whatever mode of funding is applied.

It is therefore important to respect these principles when defining the operating framework for the new structure of model 3.

Based on this analysis, it is assessed that it will be increasingly difficult to deny private (profitable) companies to have the chance to take on such care tasks if they meet all conditions to ensure the safety and the quality of care.

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339 Van Den Bossche, A.M., 'Vestiging en overname van zieken- en rusthuizen in de interne markt', *T.Gez/Rev.dr.santé*, 2008-2009, liv. 4, 282

340 CJEU, 17 June 1997, -C-70/95, Sodemare SA, Anni Azzurri Holding SpA en Anni Azzurri Rezzato Srl/ Regione Lombardia, Rec. 1997 I-3395

341 CJEU, 9 July1997, C-222/95, Parodi, Rec. 1997 I-03899, 31

342 CJEU, 8 May 2003, C-14/02,Atral, Rec. 2003 I-04431; CJEU, 7 June 2007, C-254/05, Commission v Belgium, Rec. 2007 I-04269; CJEU, 13 March2008, Commission v Belgium, C 227/06, Rec. 2008 I-00046

343 OJ 4.4.2011, L 88/45, recital 40

4.4.2.6 *The Competence of the Communities and of the Federal state concerning healthcare institutions*

If one opts for the development of entities as provided by model 3, the question arises whether it is the federal legislator and / or the Community legislator who has the power to participate in the legislative framework for these new structures.

The sixth reform of the state has further modified the distribution of powers between the federal state and the Communities concerning health matters. The federal state remains competent in particular to 'organic legislation' ('organieke wetgeving/'legislation organique').[344] The concept of 'organic legislation' covers in particular the basic rules and guidelines of the hospital policy, as contained in the Hospital Act.

One of the objectives of the sixth reform of the state was to enable communities to effectively exercise the powers transferred to them. Whilst the funding and programming remain a federal competence, the competence to grant authorisations and the policy concerning specialised care provision or care for specific populations belong to the community level.

When drafting the amendment text for the special Act of 8 Augustus 1980 on institutional reform under the sixth reform of the state, it has been pointed out that the term 'organic legislation' should be refined. The concept of the 'organic legislation' now covers the basic rules and guidelines of a hospital's policy, as they are enshrined in the Hospital Act, and aims to ensure the minimal coherence that is needed between programming, authorisation and financing, when implementing a policy at various levels in a workable way. These three policies are, according to the authors of the proposal, to a certain extent complementary.[345] Funding should be based upon authorisation within the scheduled programming.

According to the Explanatory Memorandum accompanying the special Act concerning the sixth reform of the state the following elements are 'organic':

1. the basic characteristics[346] of the:
   a. hospitals (including *inter alia* the provision of hospitals care, split over several sites, minimum activity level), psychiatric hospitals, university hospitals;
   b. hospital services, wards, hospital functions, medical and medico-technical services, care programmes, heavy medical equipment, networks and care circuits. Basic characteristics can be identified as characteristics which have a direct link with the programming and / or funding and exhibit a structural nature (e.g. the necessary equipment, the nature of the care provided in a hospital or hospital service or the target, the minimum personnel framework).
   c. collaboration between hospitals[347];
2. the rules regarding the management and decision-making in hospitals, including internal advisory organs;
3. the status of the hospital physicians and involvement in the decision-making of hospital physicians and other healthcare professions;
4. the general rules relating to the structuring of nursing and medical activities;
5. the rules for accounting, financial control and reporting of the data;

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344 Art. 5 Special Act of 8 August 1980 tot hervorming der instellingen, *BS* 15 August 1980

345 Explanatory Statement of the proposal of bijzondere wet met betrekking tot de Zesde Staatshervorming, *Parl.St.*Senate 2012-13, nr. 5-2232/1, 35.

346 What should be considered as 'basic characteristics' is unclear. Depending on the interpretation of the 'characteristics' , the reserved power in favour of the federal authority will have a greater or lesser impact (J. Van Nieuwenhove, 'De bevoegdheidsoverdrachten inzake gezondheidszorg' in A. Alen, B. Dalle, K. Muylle, W. Pas, J. Van Nieuwenhove en W. Verrijdt (eds.), *Het federale België na de zesde staatshervorming*, Brugge, die Keure, 2014, 394).

347 Explanatory Statement of the proposal of bijzondere wet met betrekking tot de Zesde Staatshervorming, *Parl.St.*Senate 2012-13, nr. 5-2232/1, 36.

6. the implications of compliance (or non-compliance) with the basic rules for programming or concerning the maximum number of services, functions, etc., or with the provisions of the organic legislation;
7. the general rules concerning the consequences of compliance or (non-compliance) with the authorisation standards of services, functions, etc., or the authorisation to set up heavy medical equipment (this concerns for example the rule that 'no authorisation equates to no funding').

The explanatory memorandum of the special Act also enumerates what is not 'organic' and thus what is under the control of the Communities:[348]

1. the establishment of conditions that must be met or the determination of matters to which the minimum standards should cover (this falls under the authorisation standards), including rules relating to the quality of hospital service, institutions or organisation;
2. the procedures and implementing decisions with respect to the powers that do not belong to the federal government (e.g. authorisation procedures (provisional authorisation, suspensive appeal, etc.));
3. in terms of delegated powers, the regulations related to quality assessment and developing the quality evaluation (this interferes with the authorisation standards). Care characteristics related to the process and the result (outcome) should - if necessary - be embedded in the authorisation standards;
4. the provision of medical and social establishments, places of sheltered living, transit shelters and categorical (Sp and G) hospitals.

The federated entities have therefore received all powers related to the Sp services and isolated geriatric services (see below for more information regarding these services).

If one considers the objective of model 3 is to move towards the development of a specialised care structure which fulfils the definition of a hospital under the Hospital Act, it seems obvious that this concerns also (at least) partially the competence of the federated entities.

Similarly, if the development of a new organisation will be situated outside the notion of a hospital, it seems also that the federal government should be involved (at least in part), although according to the Council of State ('Raad van State'/'Conseil d'Etat') regulating extramural institutions cannot be considered as an application of the exception provided by art. 5, § 1er, I, 1º, *a)*, of the special Act of 8 Augustus 1980 on institutional reform (Advice 49,795 / VR / 3 of 28 June 2011 Parl.St. Senate 2010-2011 5-62 / 2).[349]

In general, it seems that an analysis of the hospital landscape and the hospital care provision in Belgium with regard to the new organisation can only properly be performed if all levels of government are considered. This is what has been decided in the framework of the joint declaration signed by nine ministers and members of the federal, community and regional governments on 29 June 2015 in order to implement all necessary reforms in the Belgian hospital landscape. Through this joint declaration, the nine ministers underlined the importance of a shared vision and consensus to achieve the necessary changes in the hospital sector. All levels of power start with the same vision in order to maintain a logical coherence between the powers of the different authorities. The different levels of power have, inter alia, also pledged to reach agreements on the distribution of tasks within the hospital landscape when necessary.

348 Explanatory Statement of the proposal of bijzondere wet met betrekking tot de Zesde Staatshervorming, *Parl.St.*Senate 2012-13, nr. 5-2232/1, 36.

349 KCE Reports 225Bs, Correction of refractive errors of the eye in adults – Part 3: Organisation and legal framework of extramural surgery centres, Synthesis p. 11-12

4.4.3 Must the new organisation comply with the hospital legislation?

With regard to the way the new organisation will be regulated, the legislator must make a choice. Two hypotheses emerge. The first would be to work with the existing legislative framework of hospitals in order to enable the new organisation to be integrated in the current Hospital Act and therefore meet, after the changes made by the legislator, the concept of a 'hospital' within the meaning of the Hospital Act. The second hypothesis would be to provide new specific legislation for a new organisation. Below we briefly describe the impact of the two hypotheses.

4.4.3.1 Scenario 1: Use of the current legislative framework - amendment of the Hospital Act

The purpose of this section is to analyse the possibilities that can be used by the Belgian legislator if it decides to use the current legislative framework to develop a new organisation. If this option is chosen, this means that a new organisation will be considered as a hospital under the Hospital Act and must therefore comply with this legislation.

It is for the legislator to decide what is meant by a 'hospital under the Hospital Act'. When analysing the current Hospital Act, it appears that the legislator has already provided specific provisions for small hospitals or for so-called *categorical hospitals*. One possibility would therefore be to use these concepts to develop a new organisation. The idea is to enable services or care programmes to operate in an isolated manner, respecting the applicable authorisation standards and by establishing a functional link with one or more of the nearest hospital(s).

After analysing the current categorical hospitals and the specific provisions applicable to them, we assess which the benefits the use of such a system could offer. In a final section we emphasize the importance of analysing the issues posed by existing hospitals where part of their activity must be withdrawn in favour of a new organisation.

Concept of categorical hospitals

Categorical or specialised hospitals

Categorical or specialised hospitals are smaller hospitals that provide specific care to a specific target group: they focus on functional rehabilitation (hospital with isolated Sp services) or care for the elderly (hospitals with isolated G services). The Royal Decree of 23 October 1964 laying down the standards hospitals and their services must meet[350] determines specific standards for the authorised categorical hospitals.

The current regulation also provides for the existence of hospitals that perform both surgical and medical activities exclusively for children or for the treatment of tumours.[351]
Here it is useful to indicate that currently a maternity ward cannot be isolated and must always be part of a hospital including at least one service where there is both surgical activity and activity related to the practice of internal medicine (C and D services).[352]

The geriatric hospitals or isolated geriatric services

Annex 20[353] of the Royal Decree of 23 October 1964 provides for special standards for geriatric services. In addition to the authorised geriatric service in a general hospital, there are isolated geriatric services outside a hospital. This isolated service must have a functional link with the geriatric service of the nearest hospital.

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350 *B.S.* 7 November 1964

351 Art. 2, § 1erbis of the Royal Decree of 23 October 1964

352 Art. 2, §4, Royal Decree 30 January 1989 houdende vaststelling van aanvullende normen voor de erkenning van ziekenhuizen en ziekenhuisdiensten alsmede tot nadere omschrijving van de ziekenhuisgroeperingen en van de bijzondere normen waaraan deze moeten voldoen, *BS* 21 February 1989

353 Art. N20 of the Royal Decree of 23 October 1964

Unless the two services concerned belong to the same organizing authority,[354] the functional link is subject to a written agreement that specifies the terms:

- of the collaboration between the geriatric services, particularly with regard to the policy of admission and transfer of geriatric patients;
- the use of medical-technical services;
- the medical, nurse and paramedic collaboration, in particular in a concertation policy and a continuing education.

The authorisation standards for the isolated service are the same as for the authorised geriatric service in a general hospital. The only difference concerns the need for the establishment of a functional link.

It is also provided that an isolated geriatric service can or cannot be associated with a specialised service for treatment and rehabilitation (Sp index).

Rehabilitation hospitals or isolated Sp services

The specialised service for treatment and rehabilitation is for patients with cardiopulmonary diseases, neurological diseases, locomotive diseases, psycho-geriatric and chronic diseases, chronic illnesses and multiple pathologies requiring curative care and rehabilitation. The affected patients require specialised medical treatment, nursing, functional rehabilitation and reactivation in a hospital and require active and prolonged support for a limited duration. Additionally, this service can be intended for patients suffering from an incurable disease that is in a terminal phase and who require palliative care.[355]
The service Sp is focused on a unit of 20 beds, dedicated to a same specialty mentioned in the authorisation decision, except for units dedicated to patients requiring palliative care that will have at least 6 beds and a maximum of 12 beds.[356]

Annex 11[357] of the Royal Decree of 23 October 1964 provides that Sp services may be located outside a general hospital. If the Sp service is implanted outside a hospital, it must have a functional link with a general hospital that has at least the services referred to in art. 2 of the Royal Decree of 30 January 1989,[358] namely:

1. 'a service where both surgical activity and internal medicine are practiced (C-D service);
2. a geriatric service (index G) or a neuropsychiatry service for observation and treatment (index A) or a maternity (index M) or a paediatric service (index E).'

The functional link must be provided in a written agreement.[359] This agreement will organise the working arrangements, including the operating rules in case of emergencies and transfer of patients.

An isolated Sp service must meet the same standards as the Sp service organised in a hospital.[360]

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354 Art. N20, 1, paragraph 3, of the Royal Decree of 23 October 1964

355 Art. N11, 1, of the Royal Decree of 23 October 1964

356 Art. N11, 3, of the Royal Decree of 23 October 1964

357 Art. N11, 7, of the Royal Decree of 23 October 1964

358 Royal Decree 30 January 1989 houdende vaststelling van aanvullende normen voor de erkenning van ziekenhuizen en ziekenhuisdiensten alsmede tot nadere omschrijving van de ziekenhuisgroeperingen en van de bijzondere normen waaraan deze moeten voldoen, *BS* 21 February 1989

359 Art. N11, 8 of the Royal Decree of 23 October 1964

360 Art. N11, 9 of the Royal Decree of 23 October 1964

Hospitals that perform both surgical and medical services exclusively for children or related to tumours

The Royal Decree of 30 January 1989 provides for the possibility to create specific hospitals for children or related to the treatment of tumours.[361] For these hospitals, the Minister responsible for the authorisation of hospitals may grant a derogation in art. 2, § 1, 1°, 2° and 3° of the Royal Decree of 30 January 1989 setting additional standards concerning the authorisation of hospitals and hospital services.[362]

Specific provisions applicable to categorical hospitals

The Hospital Act provides a number of specific provisions applicable to *categorical hospitals* or smaller hospitals that could be applied to a new organisation if the new organisations were considered as hospitals as defined in the Hospital Act.

Funding of categorical hospitals

Art. 96 of the Hospital Act provides that the Minister responsible for public health may determine a separate budget, for one or more hospital services, hospital sections, hospital functions or hospital care programmes. Such a provision could therefore be used by the competent authority to allocate separate funding for a new organisation.

With regards to G- and Sp- isolated services, the King has set specific rules for funding in the Royal Decree of 25 April 2002 on the fixing and the liquidation of the budget relating to the BFM for hospitals.[363] This concerns in particular the calculation of subparts A1, B1, B2, B4 and B5 of the applicable budget.

In a similar manner, the King has set specific rules for specific hospitals for children or related to the treatment of tumours.[364] Thus, while the costs covered by subpart B1 of the BFM are normally financed by means of a lump sum budget, the King has decided that these hospitals are excluded from it.

The operation of categorical hospitals

In addition to the specific standards which have to be met in order to create a categorical hospital, the Hospital Act also provides specific provisions for the operation of these hospitals. Art. 7 of the Hospital Act states that the King may, in the case of small hospitals, remove (whole or in part) the application of Chapters III and IV of Title I, art. 68 and Title IV of the Hospital Act. This concerns hospitals

1. which have a very limited number of services and/or beds; or
2. where a very limited number of hospital physicians work.

For such circumstances specific rules have been provided for the medical councils of these small hospitals. The Royal Decree of 10 August 1987 laying down the rules on the composition and functioning of the Medical Council pursuant to art. 24, 25 and 26 of the Act of 23 December 1963 on hospitals provides that when a hospital has less than six physicians who can vote, these physicians are part of the medical council. Their number, where applicable, is completed to a maximum of five members to the Medical Council by physicians who cannot vote.[365] If the hospital has less than six

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361 Art. 2, §1bis, Royal Decree 30 January 1989 houdende vaststelling van aanvullende normen voor de erkenning van ziekenhuizen en ziekenhuisdiensten alsmede tot nadere omschrijving van de ziekenhuisgroeperingen en van de bijzondere normen waaraan deze moeten voldoen, *BS* 21 February 1989

362 Royal Decree 30 January 1989 houdende vaststelling van aanvullende normen voor de erkenning van ziekenhuizen en ziekenhuisdiensten alsmede tot nadere omschrijving van de ziekenhuisgroeperingen en van de bijzondere normen waaraan deze moeten voldoen, *BS* 21 February 1989

363 See art. 15, 29°; 29, §4, 1°; 43; 47; 56, §1erbis; 65, b) ; 74ter; 75, §2, b) ; 75, §5, §6 ; 91; 99 *in fine* and 100 of the Royal Decree of 25 April 2002

364 Art. 33, §1, of the Royal Decree of 25 April 2002

365 Art. 5, §4 of the Royal Decree of 10 August 1987 tot vaststelling van de regels met betrekking tot de samenstelling en de werking van de medische raad in uitvoering van de artikelen 24, 25 en 26 van de wet van 23 December 1963 op de ziekenhuizen, *BS* 18 August 1987

hospital physicians, they constitute the Medical Council without further formalities.[366]

Advantage of this scenario

The use of this concept of categorical hospital would have the advantage of keeping the supply of specialised care within the notion of a hospital. Furthermore, under this hypothesis the necessary legislative amendments are limited and would mainly delegate the task of specifying specific standards applicable for such categorical hospitals that would operate independently of existing hospitals to the competent legislator. In this regard, it could provide specific exemptions for certain hospitals.

Under these specific authorisation standards, the competent legislator should for example provide that these hospitals are required to conclude an agreement with the nearest hospital to provide a specific support patients in case of emergency. It is desirable that the regulation explicitly states the need to conclude such an agreement with the nearest hospital in order to avoid future discussions during which conflicts of interest could be involved. This will avoid that hospitals refuse to sign such agreements.

Such a scenario could also for example permit new organisations to benefit from a hospital pharmacy.

Implications for existing hospitals

It will also be important to analyse the situation of existing hospitals if, with the creation of a new organisation, the purpose is to remove a part of their activity. In such cases it will be necessary to ask whether they still meet current standards for authorisation.

4.4.3.2 Scenario 2: Creation of a new legislative framework alongside the Hospital Act

A second scenario would be to allow the development of certain hospital activities outside a hospital under the Hospital Act. Art. 81 of the Hospital Act provides in this respect that '*the King may provide rules concerning medical procedures that have to be carried out inside or outside a hospital*.'

On the basis of this article, it would be possible - taken into account the rules on the competence of the federated entities related to healthcare - to provide a list of activities that may be organised outside a hospital, subject for example to compliance with a number of authorisation standards. Through such regulation, it would be possible to formalize the creation of a new organisation. In such a situation, a new organisation would not meet the definition of a hospital under the Hospital Act.

The development of such a structure outside the current hospital framework would also require the amendment of the regulations on compulsory health insurance in order to provide the reimbursement of services provided within such new organisations. It is, in this respect, interesting to examine the eye clinics that have been developed in recent years. In addition, the different legislative aspects that should be specified in the new framework to allow proper operation of these new organisations will be analysed. Finally, the advantages of this hypothesis are assessed.

Example of extramural clinic: eye clinic

The example of eye clinics is interesting because their development has emerged in recent years from a change in the nomenclature of healthcare which has expanded reimbursement for acts relating to ophthalmic surgery outside an authorised hospital setting.

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366 Art. 5, §5 of the Royal Decree of 10 August 1987 tot vaststelling van de regels met betrekking tot de samenstelling en de werking van de medische raad in uitvoering van de artikelen 24, 25 en 26 van de wet van 23 December 1963 op de ziekenhuizen, *BS* 18 August1987

In principle, the nomenclature provides that surgery provisions must, except in cases of *force majeure*, be performed in a hospital authorised by the competent authority and which comprises at least one C or D service if it concerns a surgical intervention equal to or greater than K 120 or N 200 or I 200. [367]

Since the Royal Decree of 16 February 2009,[368] it is provided that this rule no longer applies to the interventions listed in art. 14 h) of the nomenclature (ophthalmology), if these interventions are performed in an ambulatory manner in an extramural environment (that meets the architectural standards of a surgical day hospital as described in art. 2 to 6 of the Royal decree of 25 November 1997 laying down the standards to be met for the 'surgical day hospitalisation') and that these services are performed under local or topical anaesthesia and do not require patient sedation or direct home or nursing monitoring needs.

So when it concerns a reimbursed intervention in a hospital, it is also possible to use the legislation on compulsory health insurance to frame practices performed outside a hospital.

It should be noted however that these extramural centres (that are not hospitals under the Hospital Act) will not be required to comply with all quality and safety standards laid down by the Hospital Act or other rules applicable to hospitals, which can be disadvantageous for patients. Moreover, these structures can operate without being subject to prior official authorisation.[369] Therefore, if these structures are not integrated into the concept of a hospital, it seems important to create a new legislative framework for these health facilities in order to better supervise them.

The new legislative framework

The organisation of such a framework is needed given that EU legislation requires a regulation concerning quality of health in all healthcare institutions. Certain specific obligations should thus be placed upon healthcare institutions outside hospitals. The purpose of this section is to point out certain standards that should be applied to these new organisations.

The directive of 9 March 2011 on the application of patients' rights in cross-border healthcare[370] requires Member States to establish a minimum framework of quality and safety standards for healthcare provided on their territory. The concept of healthcare providers within the meaning of this Directive is broad and covers all persons or entities providing healthcare. The new organisation created outside the concept of a hospital therefore certainly falls under the concept of a healthcare provider within the meaning of this Directive.

The Directive requires such providers to comply with obligations such as providing relevant information concerning choice, price, the status of authorisation or registration etc.

It is important that this framework specifically states that the organisation defined by the new legislation is excluded from the scope of the Hospital Act in order to avoid any confusion between different institutions. It would be possible within the new law to make some specific provisions of the Hospital Act applicable. This would also make the executed Royal Decree applicable.

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367 Art. 15, §2, of the Annex of the Royal Decree of 14 September 1984 tot vaststelling van de nomenclatuur van de geneeskundige verstrekkingen inzake verplichte verzekering voor geneeskundige verzorging en uitkeringen, *BS* 29 September 1984

368 Royal Decree of 16 February 2009 tot wijziging van het artikel 15, § 2, van de bijlage bij het koninklijk besluit van 14 September 1984 tot vaststelling van de nomenclatuur van de geneeskundige verstrekkingen inzake verplichte verzekering voor geneeskundige verzorging en uitkeringen, *BS* 16 March 2009

369 KCE Reports 225Bs, Correction of refractive errors of the eye in adults – Part 3: Organisation and legal framework of extramural surgery centres, Synthesis p. 7

370 OJ 4.4.2011, L 88/45

Below some elements are pointed out that should be taken into account in the drafting of a new legislative framework in case of the second hypothesis:

Financing

At present, the BFM is liquidated per hospital and cannot therefore be used to finance an organisation that is not considered as a hospital under the Hospital Act. Thus, if the goal is to integrate these new organisations (or some of them) in the calculation of the BFM, the rules concerning funding should be adapted to allow the administrator of another care organisation than a hospital to also receive a part of the budget.

Another possibility would be to finance the new organisation separately from the hospitals and to create a new budget.

The central responsibility of the new organisation

The advantages concerning the central responsibility of hospitals for patients should also be in place for these new organisations. As the Act on patients' rights is applicable to all healthcare professionals, and therefore also to the healthcare professionals working in the new organisations, it is necessary, in order to facilitate the rights of patients, to allow proceedings against a new organisation to be commenced without first determining which professional has committed misconduct connected to the damage that they have incurred.

Patient health records

It should also provide specific standards for the storing and archiving of medical files within these new organisations. Whilst specific legislation in this regard is not available, it is not obvious for the professionals who work in such structures to know whether it is the institution or the healthcare professional that is responsible for keeping and maintaining patient health records. Furthermore, the minimum content of the medical file is only currently defined for hospitals.

Collaboration agreement with a hospital for the transfer of patients

It will be particularly necessary to provide an obligation of collaboration with hospitals, for example to provide certain specific care such as emergency or intensive care. As discussed above, it seems important to determine which hospital will be required to enter into such an agreement in order to avoid situations where conflicts of interest could arise or situations where hospitals could refuse to enter into such agreement.

Similarly, if a new organisation is subsidised and has a mission of general interest, it will also be important to ensure that the new organisation cannot refuse to cooperate with hospitals which are in need of the services of the new organisation.

The provision of medicines and medical devices

For the functioning of these institutions it will be necessary to provide specific rules on the provision of medicines and medical devices. It would, in this regard, be possible to use to a certain extent the legislation concerning the storage of medical products by physicians. Indeed, normally medicines and certain medical devices can only be distributed to patients by public pharmacies or hospital pharmacies if it is intended to be used in the hospital.

The current legislation provides that a physician or a dental practitioner may be authorised to have a place specific for the storage of medicines. In this case, the physician buys medicines and implantable medical devices in a pharmacy open to the public or in a hospital pharmacy. In doing so, the physician makes an agreement with a holder of a pharmacy open to the public or a hospital pharmacy.[371] This place for the storage of medicines is considered as a pharmacy not open to the public. If the agreement has been signed with the owner of a hospital pharmacy, this place will be treated as a hospital pharmacy. Medicines and implantable medical devices can only be delivered in the framework of a medical procedure. The holder of the place for the storage of medicines can either be a physician or a pharmacist-holder

[371] Art. 20 of the Act of 10 May 2015 betreffende de uitoefening van de gezondheidszorgberoepen, *BS* 18 June 2015

appointed by the physician in order to take the responsibility for the pharmacy.

The competent authority will still need to determine the terms and conditions of the procurement of the place in question and the management and control of these deposits, which are separated from the main medical practice or other places where the physician receives and examines patients in order to give advice or to provide healthcare.

Making certain dispositions of the Hospital Act applicable to these structures

As part of the drafting of the legislative framework applicable to new organisations, it is important to analyse what principles of the Hospital Act could be transposed to the new organisation.

Advantage of this scenario

The application of such a hypothesis would be able to regulate private clinics. It would however be necessary to distinguish clinics charged with a mission of general interest from others that do not have such a purpose in order to justify their funding. It would also be necessary to distinguish the structures intended to perform complex care (involving hospitals) from others that could be specialised in simpler care practices (e.g. ophthalmology or cosmetic surgery) for which a simple contractual collaboration with hospitals would be sufficient.

4.4.4 Implementation of a new organisation in practice

4.4.4.1 Important points to consider for the establishment of the new subsidised organisation

Designation by Member States of SGEI but limited review by the European Commission

The competent authority shall, if it wishes so, subsidize the new organisation and describe the services to be provided by the new organisation as a SGEI.

The concept of general interest is not clearly defined and the EU leaves a wide discretion to Member States to define services that could be classified as services of general interest. Authorisation as a service of general interest therefore belongs to Member States and the European Commission only has a role to check for manifest error of assessment in the definition the general interest.

An important question is whether the possibility for a Member State to qualify a service as a SGEI is unlimited. In this respect, the European Commission has outlined in its guide to the application of the European Union rules on State aid, public procurement and the internal market to SGEIs, and in particular to social services of general interest, the possibilities Member States have to qualify a service as a SGEI.

The question thus arises whether a public authority can classify a service as SGEI if a similar service is already provided by other operators in the market that are not entrusted with an SGEI.

The European Commission states that where there are other undertakings operating under normal market conditions, not entrusted with an SGEI, who already provide or can provide a service satisfactorily and under conditions, such as price, objective quality characteristics, continuity and access to the service, consistent with the public interest as defined by the State, it would not be appropriate to attach a public service obligation to such a service. [372]

[372] Commission staff working document of 29 April 2013, entitled 'Guide to the application of the EU rules on State aid, public procurement and the internal market to services of general economic interest, and in particular to social services of general interest', Brussels, SWD(2013) 53 final/2, p. 26

Therefore, the Commission explained that it is even more important that the Member States clearly specify the characteristics of the service in question, in particular the conditions for its provision and its target group. If a service is already provided by the market, albeit under conditions that are considered unsatisfactory by the Member State concerned, for instance because the market cannot provide it at the level of quality or at a price that public authorities might consider as being in the public interest (for example because transport fares are too expensive for low-income families), such a service can qualify as SGEI. This service must be offered on a non-discriminatory basis. When the service is not already provided by the market, the question whether it can be provided by the market is for the Member State to decide, while the Commission can only check for manifest error.[373]

The European Commission has also analysed the question of whether a service can be defined as SGEI in the case that the market would be able to provide it in the near future.

In this case, the Commission considered that where the classification of a service as SGEI is otherwise justified, the mere fact that the market may be able to provide it in the future would in principle not prevent a Member State from defining the service currently as an SGEI. However, in cases where it is clear that the market will be able to provide the service within a short time under the conditions (including price, quality, continuity and access to it) desired by the Member State, the public authorities should reduce the entrustment period accordingly and monitor the evolution of the market in order to be able to decide whether a new entrustment is still needed when the previous one expires. If the market is still failing to provide the service at the end of the entrustment period, and the Member State considers that the service still qualifies as an SGEI, a new entrustment compliant with art. 106 TFEU is possible. As regards the question of whether it is clear that the market will be able to provide a particular service in the foreseeable future, the Commission's task is limited to checking for manifest errors in the Member State's assessment.[374]

Discern whether a cross-border element is present

In principle, it is authorised that personal services (such as healthcare, for example) have few cross-border effects, allowing some flexibility in the rules applied to them. This follows clearly from rules on public procurement and State aid.

In case a new organisation plays an important role in providing healthcare in the Belgian market and if a high amount of subsidy is concerned the cross-border level may be affected.

Give more than just an authorisation: care for a real entrustment

It is important to remember that if the competent authority decides to qualify the services by the new organisation as a SGEI, it is necessary that the public service obligations entrusted to the concerned organisation are clearly indicated in one or more documents issued by the competent public authorities. Approval or authorisation given by a public authority to a service provider, authorizing the provision of certain services, does not correspond to the notion of act of entrustment.[375]

The European Commission states that an entrustment in the sense of art. 106 TFEU and in the sense of the *Altmark* judgment only requires that the act of entrustment takes the form of one or more acts having binding legal force under national law. The specific form of the act (or acts) may be determined by each Member State, depending *inter alia* on its political and/or administrative organisation. According to the basic rules of

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373 Commission staff working document of 29 April 2013, entitled 'Guide to the application of the EU rules on State aid, public procurement and the internal market to services of general economic interest, and in particular to social services of general interest', Brussels, SWD(2013) 53 final/2, p. 26

374 Commission staff working document of 29 April 2013, entitled 'Guide to the application of the EU rules on State aid, public procurement and the internal market to services of general economic interest, and in particular to social services of general interest', Brussels, SWD(2013) 53 final/2, p. 26

375 Commission staff working document of 29 April 2013, entitled 'Guide to the application of the EU rules on State aid, public procurement and the internal market to services of general economic interest, and in particular to social services of general interest', Brussels, SWD(2013) 53 final/2, p. 40

administrative law, every local, regional or central public authority needs a legal basis in order to define a SGEI and finance it. Consequently, the notion of an act of entrustment can largely correspond to the legal basis that the public authority concerned chooses in each case at its own discretion. It is not necessary for this act to bear the title of 'act of entrustment'. It is also not necessary for Member States to establish a special legal framework for adopting so-called 'acts of entrustment'.[376]

There is therefore no standard 'one size fits all' act of entrustment. However, certain elements have to be specified in the entrustment act, such as the content and the duration of the obligation, the parameters for calculating, controlling and reviewing the compensation and arrangements for avoiding and recovering any overcompensation. Where State aid for a SGEI is granted under the Decision or the Framework, the requirements for the entrustment act are set out explicitly and with additional details in art. 4 and paragraph. 16 respectively (i.e. the undertaking and, where applicable, the territory concerned; the nature of any exclusive rights assigned to the undertaking by the granting authority; a description of the compensation mechanisms; reference to the Decision).[377]

Care for an appropriate announcement before giving a compensation

In any procedure used to organise the SGEI, the general principles of transparency and non-discrimination laid down by the TFEU, in accordance with which equal treatment must be given to all the economic operators invited to participate, are applicable to services with a cross-border interest.[378]

The procedure used to organise the SGEI does not necessary need to be organised in accordance with the public procurement regulation: possibility to work with authorization

The competent public authority may, for example, establish in advance the conditions for provision of a social service and, after sufficient advertising and in accordance with the principles of transparency and non-discrimination, grant authorisations to all providers meeting these conditions. Such a system does not specify any limits or quotas concerning the number of service providers; all those meeting the conditions can participate. Providers which have obtained an authorisation must provide the service at the request of the user, who will thus have the choice of several providers, at a price set beforehand by the public authority.[379]

4.4.4.2 How to determine conditions for such collaboration?

If the Belgian legislature decides to opt for the development of a new organisation, one must also analyse the possibilities of creating such an organisation. Who can participate in the creation of such a structure? Is a bed transfer possible? Can there be a transfer of personnel? Does the establishment of such a structure have to go beyond what is provided for network-related care programmes?

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376 Commission staff working document of 29 April 2013, entitled 'Guide to the application of the EU rules on State aid, public procurement and the internal market to services of general economic interest, and in particular to social services of general interest', Brussels, SWD(2013) 53 final/2, p. 40

377 Commission staff working document of 29 April 2013, entitled 'Guide to the application of the EU rules on State aid, public procurement and the internal market to services of general economic interest, and in particular to social services of general interest', Brussels, SWD(2013) 53 final/2, p. 40

378 Commission staff working document of 29 April 2013, entitled 'Guide to the application of the EU rules on State aid, public procurement and the internal market to services of general economic interest, and in particular to social services of general interest', Brussels, SWD(2013) 53 final/2, p. 96

379 Commission staff working document of 29 April 2013, entitled 'Guide to the application of the EU rules on State aid, public procurement and the internal market to services of general economic interest, and in particular to social services of general interest', Brussels, SWD(2013) 53 final/2, p.100

Establishment and management of the new organisation

Whether one opts for the use of the possibilities offered by the current legislation or the creation of a new legislative framework, it will be important to specify for which areas of care such an organisation can be created. Whist it is difficult to list the interventions concerned as medicine evolves very quickly, it could still be advantageous to provide a framework to regulate the areas concerned.

Creation on a collaborative basis

The goal is not to create a parallel healthcare supply circuit, but rather to enable the hospital landscape to retrain. It therefore seems right that existing hospitals should have a role in the creation of the new organisation, in particular if it concerns complex healthcare.

To encourage hospitals to participate in the development of new organisations, incentives will be needed.
Whilst for certain complex forms of healthcare, the use of an existing hospital is necessary, it is at the same time necessary to not restrain the use of such structures only to hospitals. Doing so in situations where it is not justified may infringe the principle of freedom to provide services.
It would therefore be possible to design a system in which the creation of these structures for specified domains could be done without the participation of hospitals. One can imagine for example cosmetic or eye surgery structures that have already developed without hospitals. For other areas, for example for cancer care, it would be necessary to have at least the participation of one or two hospitals.

Besides participating hospitals, it could also be interesting to analyse a possible collaboration with private partners or foreign institutions. It would be essential to introduce safeguards to avoid any conflict of interest. Imagine for example a distributor of medical devices who participates in the creation of a specialised care structure pursuing an activity requiring the use of a medical device equivalent to the one sold by the distributor.

Which legal form should the new structure have?

In principle the new organisation should be able to choose any legal form. As it is nowadays foreseen for hospitals, the legal form has no effect as long as the hospital is authorised. A similar approach could be used for the new organisation. The legislator could choose to limit the possibility to obtain financial means to a certain legal form. We refer in this regard to the analysis done for the health system in model 1. As stated already in the foregoing analysis of model 1, it is possible for a Member State, under certain conditions, to limit the form of the new organisation to a specific type of legal person, e.g. a not-for-profit association. The Court of Justice has held that, according to the scale of values held by each of the Member States and, having regard to the discretion available to them, a Member State may restrict the operation of certain activities by entrusting them to public or charitable bodies. Any measure of this kind must, however, be suitable for guaranteeing the achievement of one or more legitimate objectives invoked by that Member State and must not go beyond what is necessary to achieve those objectives. National legislation is appropriate for ensuring attainment of the objective pursued only if it genuinely reflects a need to attain it in a consistent and systematic manner. In any event, such restrictions must be applied without discrimination.

Independent management

From the moment the aim is to create a totally independent organisation from the entities that collaborate to create it, it is important to provide a management that respects the independence of the new organisation. The new structure must have a management that will serve its own interests and not the interests of those who created it.

When we take the example of organisations that are co-owned by various municipalities in a region (e.g. an intermunicipal company as Vivalia), it appears from analyses performed on their management that conflicts of interest arise.[380] If the role of the general assembly may be to represent the member institutions, it must be ensured that managers are not acting in the

[380] http://www.guberna.be/sites/default/files/general/Gouvernance%20intercommunales%20wallonnes_rapport_0.pdf: p. 14

interest of the institutions they represent, but work well on behalf of the new organisation.

In this respect, it is not necessary that each member is represented in the board. Again, it is clear from the example of an intermunicipal company that a board of managers comprised of too many managers can harm effectiveness by hampering united and effective decision-making. [381]

Staff

As an independent entity, the new organisation will be able to hire staff as an employer. The structure will be able to engage salaried employees as well as self-employed personnel.

Note however that the question of a possible resumption of staff working within the participating hospitals may arise. We refer in this respect to developments that have been made for model 1. If there is no recovery of all staff, whether employee or self-employed, by the new organisation, it will be necessary to observe within each hospital the breaking contract terms as provided if the personnel cannot work anymore in the hospital.

Transfer of beds

To avoid duplication of healthcare provision and stimulate an integrated national planning, it may be useful to analyse the possibility for hospitals to transfer their beds to create a new organisation. Such a transfer could be done via the transfer of a branch of activity (for the legal aspects of transfers, see also model 1).

4.4.5 Evaluation

As long as the King does not provide a specific regulation, a person that is not a hospital cannot receive a BFM.

To the extent that the establishment of the new organisation is not part of the 'organic legislation', the federated entities will also be involved in the regulation of the new organisation.

In addition to procurement legislation, the rules on State aid and abuse of dominant position will also play a role. The government will be able to decide the form of the new organisation. This need not necessarily occur through public procurement legislation at the level of the Member State (or potentially at the level of the organisation between hospitals themselves, although the recent procurement rules provide flexible formulas for the organisation of healthcare services). The State aid rules will however have to be strictly respected. It will be important, if support is given, to outline how it includes SGEIs with a clear allocation decree that establishes which financial aid can be used (and how reimbursement takes place in case of overcompensation).

The establishment of a new organisation can occur either by an amendment of the Hospital Act, or by the establishment of a new legal text. The legislation does not have to be limited to care programmes, but will probably still require the collaboration of the federated entities. So one should make a choice to either adapt the Hospital Act or to adopt new legislation. The legislation concerning a new organisation may be a way to provide a system of private clinics, regardless of whether this is done by an amendment of the Hospital Act (and the extension of the scope) or by a law alongside the Hospital Act, although the new regulation will require the collaboration of the federated entities (for example to determine the content).

This form will also be linked to certain conditions such as the presence of an Intensive care unit (ICU), emergency department, etc. Agreements will have to be concluded with the hospitals that have to work together.

It is important that the legislation provides clearly, if they have public service obligations, an obligation to cooperate with the new organisation. If the new organisation is charged with a SGEI, it will be legally obliged to cooperate with hospitals.

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381 http://www.guberna.be/sites/default/files/general/Gouvernance%20intercommunales%20wallonnes_rapport_0.pdf: page 7

4.5 Conclusion

If the three models (health system, network and new organisation) find a statutory basis, it is appropriate to retain the current legislation on associations and groups and possibly even to apply them within certain models. For example, the rules about groups (see the Royal Decree of 30 January 1989) and associations could be applied to a health system or rules about associations to a network. For continuity of care, it is advisable that the present rules about associations and groups continue to exist and can be used, especially when they also apply within the new models (e.g. model 1 or 2). Note that some changes are still required in the current legislation on groups and associations. For example, the proximity control with pooling should be adjusted or it should be possible that non-hospitals are part of a group/association, etc.

For a variety of legislation concerning the three models support from the federated entities is required.

It is appropriate to ensure, at the level of certain organs where decisions are taken (such as the network committee in the network), a representation of the actors. For medical councils or general meetings this may require that they organise this themselves in the form of a legal person.

Model 3 would best be achieved with a legal person that can recruit its own staff.

Both in a health system (model 1) and in a new organisation (model 3) the composition of the board shall be decided by the person who set up the health system and the new organisation. In a sense, this will also be the case with a network (model 2). However, this network cannot just control the members of the network itself in areas that have nothing to do with the purpose of the network. The network committee can take binding decisions concerning decisions that constitute the subject of the purpose of this network.

A network should avoid market concentration. The exchange of sensitive information that cannot be exchanged in accordance with competition rules should be avoided. If the parties of a network want more control, the establishment of a health system as in model 1 must be chosen.

The legislators can help to develop the model by determining the objectives, conditions for approval, monitoring mechanisms, need for prior consultation of actors, etc. To the extent the government intervenes financially concerning a SGEI which also receives public money, the objective must be regulated clearly and specifically.

It does not seem appropriate in drafting rules for the 3 models, to provide specific rules regarding distance issues.

Model 2 should not be used to gain control over institutions. In that case, there is a concentration and it is advisable to work on the basis of model 1. It is possible, if a hospital wants to join a network, to provide that there must, in advance, be a favourable opinion of the medical councils. Working with one medical council seems only appropriate in case of a group, or in case of a health system (model 1, which may or may not take the form of a group).

In model 1 (health system), it is essential to ensure that, additional to the establishment of the health system, attention is paid to collaboration between the health system institutions. The establishment of a health system alone does not directly imply a true collaboration between the institutions of the health system. Only when such collaboration is effective, it can lead to quality-oriented and cost-effective care. The establishment of the health system should also be discussed in advance with stakeholders. Following the example of the Netherlands and the Supervisory Authority, the legislator may provide that a sponsor that wants to establish a health system must get the approval of the government in advance.

In model 2, collaboration in specific fields can lead to quality-oriented and cost-effective care, e.g. if the collaboration consists of the efficient exchange of medical information, realising the on duty care (e.g. via an association). It will be important to avoid the creation of a concentration and / or to ensure that the roles, liabilities etc. of the network are transparent to other stakeholders.

Model 3 can lead to quality-oriented and cost-effective care if it is clearly indicated what will be the tasks of the new organisation and how such collaboration can/should take place when hospitals want to redirect patients to the new organisation, and when the new organisation wants/needs to rely on those hospitals.

Key points

Three models can be facilitated through the legislation, namely:

A health system:

- **A possible legal form of a health system is a not-for-profit association. This is not a must for operating hospitals, unless they want to obtain infrastructure grants.**
- **In a health system the person who operates the hospital receives the authorisation. Hence, the funding will be provided to whoever has received the authorisation.**
- **The current funding rules in Belgium provide the possibility of additional financing in case of a merger or a transfer of activities.**
- **Modification of the legislation is needed if the legislator wants to allow that the health system runs e.g. also homes for the elderly, homes for young people etc.**
- **As soon as a health system exists, i.e. one undertaking with potentially different activities, there are no immediate specific VAT issues.**

A network:

- **Due to the less integrated structure problems are identified, e.g. financial problems are not solved with this governance structure. The network structure will have to take account of the new regulation about cost-sharing association and VAT.**
- **Under the current legislation, the network will in principle not receive any funding, as the network itself has no authorisation number.**
- **The impact on individual institutions by a network may be limited, meaning that the impact on quality may also remain limited. Communication with patients about the role and responsibility of the network is crucial.**
- **A network committee should be established wherein any type of health actor should be able to participate.**

A new organisation:

- **The establishment of a new organisation can be a problem: as long as the King does not provide a specific regulation, a person that is not a hospital cannot receive funding. The establishment of a new organisation can occur either by an amendment of the Hospital Act, or by the establishment of a new legal text.**
- **The legislation does not have to be limited to care programmes, but will probably still require the cooperation of the federated entities. So the government should make a choice to either adapt the Hospital Act or to adopt a new legislation.**
- **The legislation concerning a new organisation may also be a way to provide a regulatory framework for private clinics, regardless of whether this is done by an amendment of the Hospital Act (and the extension of the scope) or by a law alongside the Hospital Act.**

Overall conclusions

- **To enhance a smooth transition, it is appropriate to retain the current legislation on associations and groups and possibly even to apply them within certain models, such as the rules about groups (see the Royal Decree of 30 January 1989) and associations related to a health system or rules about associations related to a network.**
- **It should be endorsed (following the Dutch example) to subject the establishment of new collaborations, prior to notification to the Competition Authority, to a healthcare specific study.**
- **The new legislation will require the cooperation of the federated entities since also other types of organisations should be facilitated.**

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