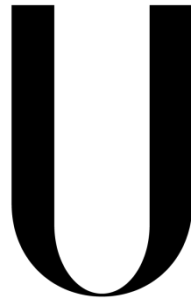


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**Participation of civil society in European Union (EU) decision-making and agenda-setting: role of patient organisations in EU health policy**

**Ana Lúcia Vitorino Cardoso**

Dissertação orientada pelo Prof. Doutor Luís Manuel Costa Moreno e coorientada pela Prof. Doutora Jennifer McGarrigle Montezuma de Carvalho

Mestrado em Políticas Europeias  
Desenvolvimento e Coesão Socioterritorial

2016



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# Abstract

Civil society organisations (CSOs) play a prominent role in influencing national, regional and international policies. They are a key player in democratic societies, have shown to complement (and even replace) governments when it comes to health delivery and provision of services, and have gradually become global players as a result of globalisation. The focus of this study is the policy work of European CSOs representing (directly or indirectly) patients, and which normally act on behalf of national CSOs. The study aims to assess how successful civil society is in representing patients at the EU level and whether this representation has led to policy change. The dissertation explores factors that may influence the success of CSOs when advocating for EU health policies.

A two-fold method has been adopted. The first element includes a review of scientific (28 articles were fully read and others consulted). The second element includes 14 semi-structured interviews conducted with high level stakeholders, 12 with representatives from CSOs working at the European policy level and two with officials working for institutions that develop and implement policies (i.e. policy-makers).

Findings suggest that it is difficult to measure the influence of CSOs in EU health due to the abstract nature of policy work and the policy process, which is not linear. Moreover, the number of interactions and collaborations that exist are complex in nature hence difficult to map and analyse. Although there are challenges that both CSOs and policy-makers face in relation to patient participation in the development and implementation of policy, a number of success stories were provided showing that CSOs play an instrumental role in EU and national health policy. Although the complexity of EU advocacy makes generalisations difficult, patterns were found in interviews such as the way partnerships and coalitions are built, the way challenges are addressed and the way CSOs adapt to policy change. Future research is needed to explore in-depth formal and informal relationships and confounding factors to provide a clearer link between CSO advocacy work and policy outcomes.

**Keywords:** *European Union; health policy; civil society organisations; patient organisations; patient advocacy*



## Resumo

As Organizações da Sociedade Civil (OSC) desempenham um papel importante na sociedade e no contributo para a saúde global. A proliferação e os esforços das OSC na área das políticas de saúde europeias e globais são fenómenos recentes que se devem em grande parte à dimensão global da saúde e à necessidade de respostas internacionais coordenadas face a questões de políticas de saúde. A globalização aproximou as pessoas, mas as populações tornaram-se mais vulneráveis à propagação de doenças. Questões e decisões relacionadas com políticas de saúde tornaram-se rapidamente um assunto global, de onde emergiram, em grande número, novos atores e instituições. Sendo este um fenómeno recente, há necessidade de aprofundar o conhecimento nesta área.

Este estudo tem como objetivo compreender se as OSC europeias que representam pacientes (direta ou indiretamente) contribuem e influenciam a formulação e implementação de políticas de saúde da União Europeia (UE). De forma a responder a esta questão tornou-se necessário analisar fatores que possam influenciar o sucesso das OSC no seu trabalho de advocacia junto das instituições da UE. Analisaram-se também as relações entre as OSC e as instituições Europeias e, mais especificamente, o funcionamento de mecanismos, muitas vezes coordenados por instituições da UE, que permitem o diálogo entre a sociedade civil e decisores políticos sobre políticas de saúde. Considerou-se também fundamental explorar como é que o envolvimento e participação da sociedade civil em questões de política europeia acontece na prática e quais as estratégias utilizadas para influenciar políticas de saúde europeias, tendo em conta o princípio da subsidiariedade e a competência dos Estados-Membros na área da saúde pública.

A metodologia envolveu principalmente duas fases do trabalho. Na primeira, realizou-se uma revisão de literatura científica (28 referências) e na segunda efetuaram-se entrevistas semi-estruturadas a 12 representantes da sociedade civil que trabalham na área de advocacia e políticas de saúde junto das instituições europeias, bem como a dois decisores políticos, um que trabalha na Comissão Europeia e outro na Organização Mundial de Saúde. Foi então desenvolvida uma análise com base nos dados recolhidos durante a revisão bibliográfica e entrevistas.

Num primeiro capítulo descreve-se o processo de tomada de decisão na UE e o papel das diferentes instituições Europeias no processo de formulação e implementação de políticas de saúde. Um exemplo de como um ato legislativo da União Europeia em matéria de saúde é debatido e aprovado demonstra as várias fases do processo político, nas quais a sociedade civil participa de diversas formas, nem sempre documentadas. Neste capítulo também se problematiza a estratégia da UE *'Juntos para a saúde'* que se apoia na estratégia de crescimento *'Europa 2020'*, e se apresenta os principais programas europeus de saúde de modo a demonstrar a forma como a UE apoia projetos focados na saúde e o papel da sociedade civil. O segundo capítulo analisa conceitos essenciais de saúde pública, nomeadamente as desigualdades na saúde e os seus determinantes sociais, um dos maiores focos de políticas de saúde Europeias, e como tal um importante indicador da coerência de políticas de saúde.

A revisão bibliográfica demonstrou que a compreensão da participação pública na área da saúde aparece cada vez mais em discussões teóricas, onde se defende a participação como elemento fundamental da sociedade democrática, e o acesso à saúde e a redução de desigualdades como um direito de cidadania. Apesar de se terem encontrado definições de sociedade civil diversas, parece existir consenso de que a sociedade civil é diferente do Estado e da economia, e de que se relaciona com princípios de democracia e liberdade. Em linhas gerais, a revisão bibliográfica mostra que a investigação nesta área debruça-se sobre: os diferentes papéis e mandatos das OSC; diferenças entre as OSC nacionais, europeias, internacionais e globais; diferenças entre países desenvolvidos e países em desenvolvimento; a importância de recursos que permitam uma advocacia eficaz e planeada da parte das OSC; e a necessidade de indicadores de avaliação que permitam avaliar a influência política das OSC. A noção de *'governança global para a saúde'* foi também encontrada na literatura. Processos políticos ocorrem normalmente num ambiente onde existem regras (Estado), mas quando se trata de governança global as *'regras do jogo'* não são fáceis de definir, e surgem, portanto, questões relacionadas com legitimidade, transparência ou responsabilização.



Representantes de OSC entrevistados destacaram assuntos relacionados, e muitas das vezes semelhantes, aos principais temas de investigação que se encontraram durante a revisão bibliográfica. Os temas mais salientes relevaram a importância de parcerias entre OSC; de recursos que permitam o desenvolvimento de capacidades, o acesso a competências, o acesso a decisores políticos; e a necessidade de mecanismos que assegurem a transparência do processo político. Obstáculos para a participação da sociedade civil foram também encontrados e são apresentados em quatro grupos: 1) obstáculos relacionados com a falta de recursos humanos e financeiros, onde se inclui a necessidade de desenvolvimento de capacidades, a barreira da língua, a falta de recursos financeiros que possibilitem representação perto das instituições Europeias (em Bruxelas) e a impossibilidade de participação devido aos sintomas da doença; 2) obstáculos relacionados com questões de legitimidade e responsabilidade, incluindo a necessidade de boa governança e de uma representação de interesses mais transparente, incluindo no seio das OSC, assim como o problema da dependência financeira e das relações com a indústria farmacêutica; 3) obstáculos relacionados com a falta de coordenação e alinhamento, e a importância de desenvolvimento de estratégias conjuntas; 4) obstáculos relacionados com mudanças nas agendas e interesses políticos que requerem uma rápida adaptação por parte das OSC. Demonstrou-se, através das entrevistas, que ultrapassar os obstáculos requer o recurso a parcerias e a proatividade da parte da sociedade civil, e que a adaptação de estratégias de advocacia é necessária face a mudanças políticas, o que pode resultar em novas oportunidades para as OSC.

A noção de ‘participação significativa’ também foi destacada, e estudos de caso e histórias de sucesso foram partilhadas pelos representantes das OSC e das instituições Europeias e internacionais. A maior parte das OSC consideram desempenhar um papel fundamental, não apenas na adoção de políticas e iniciativas de saúde da UE, mas na avaliação da implementação de políticas nos Estados-membros, mesmo que seja quase impossível estabelecer uma relação entre ações específicas por parte das OSC e resultados políticos.

**Palavras-chave:** União Europeia; políticas de saúde; Organizações da Sociedade Civil; organizações de pacientes; advocacia do paciente.

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## Acronyms and abbreviations

AMR	Antimicrobial resistance
CAN	Active Citizenship Network
CHAFEA	Consumers, Health and Food Executive Agency
CIC	Community-Interest Company
CMR	Child Mortality Rate
COD	Ordinary legislative procedure
Coreper	Committee of Permanent Representatives in the EU
CSDH	Commission on the Social Determinants of Health
CSI	Civil Society Initiative
CSO	Civil society organisation
DEVCO	DG International Cooperation and Development
DEVCO	Directorate-General for International Cooperation and Development
DG	Directorate-Generals
EASME	Executive Agency for SMEs
EC	European Commission
ECR	European Conservatives and Reformists
EEC	European Economic Community
ELF	European Lung Foundation
EMA	European Medicines Agency
ENVI	Environment, Public Health and Food Safety Committee
EP	European Parliament
EPAP	European Patient Ambassador Programme
EPF	European Patients' Forum
EPHA	European Public Health Alliance
EPP	European People's Party
EPSCO	Employment, Social Policy, Health and Consumer Affairs Council
ERCEA	European Research Council Executive Agency
ERS	European Respiratory Society
ESIF	European Structural and Investment Funds
EU	European Union
FBO	Faith-based organisation

FCA	Framework Convention Alliance
FCTC	Framework Convention on Tobacco Control
FP	Framework Programme
GFATM	Global Fund to to Fight AIDS, Tuberculosis and Malaria
GHG	Global health governance
GHI	Global health initiatives
GUE/NGL	European United Left/Nordic Green Left
HiAP	Health in All Policies
HPF	Health Policy Forum
HPP	Health Policy Platform
HTA	Health Technology Assessment
IA	Impact Assessment
IMR	Infant Mortality Rate
INI	Own Initiate Reports
IP	Implementation Plan
ISSG	Inter-Service Steering Group
JURI	Legal Affairs Committee at the European Parliament
LIBE	Civil Liberties, Justice and Home Affairs Committee
LMIC	Low- and middle-income country
M&E	Monitoring and evaluation
MDG	Millennium Development Goals
MEP	Member of the European Parliament
MoU	Memoranda of Understanding
MS	Member State
NGO	Non-governmental organisations
PCWP	Patient and Consumer Working Party
PHA	People's Health Assembly
R&I	Research and Innovation
REA	Research Executive Agency
RSB	Regulatory Scrutiny Board
RTD	DG Research and Innovation
SANTE	DG Health and Food Safety
SDG	Strategic Development Goals

SDM	Shared decision-making
TAC	Treatment Action Campaign
TASO	The AIDS Support Organization
TFEU	Treaty on the Functioning of the European Union
UK	United Kingdom
UN	United Nations
WHO	World Health Organization





# Introduction

Civil Society Organisations (CSOs) have been contributing to public health for centuries but it was only recently that their participation and influence has become more accentuated in the global health arena due in larger part to the global dimension of health and the need for coordinated international responses to health policy issues. Globalisation made the world more connected, but populations became more vulnerable to the fast spread of disease. CSOs stepped up to support governments and international organisations with fast responses and are now closely involved in decision and policy-making. *'Nothing about us without us'* is a well-known slogan that the most affected populations used to demand involvement in the policies that affect them. But how does this involvement and participation happen in practice? What are the strategies used to influence policy? How is the relationship between NGOs and policy-makers governed? Which mechanisms are in place by European organisations that allow for a dialogue?

Although there is a wealth of academic and grey literature on the growing role of civil society, research is lacking on civil society's strategies to influence, and ways to measure their ability to influence policy, particularly at the EU level (Pollard & Court, 2005). Indeed, a number of scholars consider that more research is needed on particular aspects related to CSO participation (Boaz et al., 2016; Beinare & McCarthy, 2012; Lee, 2010; Olafsdottir et al., 2014), including for example a need for primary data on CSOs' involvement in global health governance (GHG) and systematic analysis of CSOs' functions in global health governance (Lee, 2010), as well as *'empirical research to examine the effect of civil society in health outcomes'* (Olafsdottir et al., 2014: 176). The collection of data through this thesis aims to contribute to this and provide empirical evidence to shed light on key issues around patient participation in health policy. This thesis aims to understand how successful patient groups are in contributing to and influencing the development and implementation of European Union (EU) health policy. It is expected that the empirical findings, in particular, will contribute to new knowledge in this field of study.

In order to answer the research question: how successful are patient groups in contributing to and influencing the development and implementation of EU health policy, a qualitative methodology was adopted. This was considered to be the most appropriate method given that policy-making and civil society participation are phenomena that encompass processes, interactions and collaborations, and are therefore difficult to measure quantitatively. A qualitative analysis allows for personal and unique insights to be shared, the characterisation of organisational processes and dynamics, the understanding of changes over time and description of social interactions (Haq, 2014), which would not have been possible to capture otherwise. An interpretative model, with humans in the center of the scientific explanation, and where the importance of 'human experiences' and 'empathetic understanding' are key features (Holloway & Wheeler, 2002: 7) was considered to be the most relevant model for this study, which explores in detail the actions of human actors.

A mapping of key organisations working at EU policy level was conducted and purposive sampling was used. The sample was established using principles of qualitative sampling as defined by Curtis et al. (2000). The sample is relatively small but was studied intensively providing a large amount of information, selection has been sequential and there has been a 'rolling process' with coding and analysis taking place in an iterative fashion. Once the sample was identified, expert interviews were conducted, interviews were fully transcribed, narratives were read and the coding process took place using the transcripts of the interviews as a basis. The analysis used open coding (line-by-line) at first to identify generic concepts; secondly, these codes were grouped in categories around phenomena that were relevant to the research question and thirdly, these categories have been analysed to find relations (axial coding, followed by selective coding) (Flick, 1998).

An inductive approach was taken in the first place as 'knowledge was developed inductively through the accumulation of verified facts' (Ritchie & Lewis, 2003: 6) and concepts and ideas emerged from the results of the semi-structured interviews. This method was adopted to ensure that any pre-conceptions from personal experience did not interfere with data collection and analysis. However, a deductive approach was adopted at a later stage when concepts identified in the literature were

compared with the main themes and concepts arising from interviews. There was therefore a back and forth between an inductive and deductive approach.

### ***Structure***

In order to provide background information and context to the research topic, a first chapter describes the EU decision-making process and the role of different EU institutions in health policy development and implementation. An example of how an EU health-related directive has been discussed and approved is included to provide an understanding of the different phases of the EU policy process. Empirical findings demonstrate that CSOs participate at different stages of the process, although information about this participation is not always included in publicly available documents and other materials. This chapter also discusses the EU Health Strategy, presenting the main EU programmes for financing health, and the role of different EC Directorate-Generals (DG) and EU agencies coordinating health programmes. This overview is included to show how the EU specifically supports health. The qualitative data shows that CSOs participate, and sometimes, coordinate projects funded under these programmes.

A second chapter discusses key public health and global health concepts that provide context to the research topic, including health inequities, health inequalities and social determinants of health. The concept of health inequity is presented as being particularly relevant for health policy as it relates to unavoidable, unfair and unjust health inequalities. Examples of metrics used to measure health equity are provided and the importance of evidence-based policies is highlighted.

The third chapter includes the main issues found in the scientific literature. A specific literature search using key terms yielded a total of 28 scientific publications that provided insight into the research topic. Despite the redefinition of search terms, only a very limited number of publications address the ways that civil society influence health policy, which may show the lack of research in this particular area. Besides the 28 publications mentioned previously, a further 31 publications were left out after the initial search as they focused on patient participation in healthcare (e.g., shared decision-making (SDM)) or health research rather than policy work. In other cases,

there was a focus on health policy but not enough elements about civil society or patient participation. In several cases, publications fully read focused on other (i.e., non-EU) regions such as Africa or Australia but it was considered that the case studies could provide relevant examples or best practices. Of note is that in addition to the 28 articles that resulted from this specific search aimed at identifying the main research in the field, other scientific publications and grey literature found through search engines when looking for a particular topic were consulted and therefore included in the bibliography.

Issues identified in the literature included the different roles and mandates of CSOs; the need for indicators that enable the measure of the extent and the influence of patient participation; differences between national, European, international and global CSOs; the different role of CSOs in developed and developing countries; the importance of resources that enable CSOs to pursue their advocacy work effectively; and issues of legitimacy and accountability. The concept of 'global health governance' (GHG) also emerged during the literature review; GHG is seen as the opposite of government activities that take place at national level. More specifically, politics normally take place in a setting where rules exist (State level) but when it comes to the global level of governance the 'rules of the game' are not very easy to define, and this is the reason why 'mandates' and questions of legitimacy, transparency and accountability emerge.

The fourth chapter describes in more detail the research methodology adopted. The method used included a combination of a literature review and semi-structured interviews. A total of 59 abstracts were read, following which 28 articles considered relevant were fully read. In addition to the literature review, as evident in chapter one and two, an extensive analysis of reports, policy documents and information on official websites of EU institutions was conducted. In parallel, 14 semi-structured interviews were conducted with relevant stakeholders from CSOs, the European Commission (EC) and the World Health Organization (WHO).

The fifth chapter includes the qualitative data analysis and the main issues identified through expert interviews, which included, amongst others, the importance of resources, partnerships and transparency. In addition, key barriers for participation

and a number of challenges were identified, which have an impact on CSOs' ability to influence EU policy. The notion of 'meaningful involvement' was also highlighted as a key issue, i.e. influence can only be effective if participation is meaningful and is not the result of a tokenistic approach.

Finally, a conclusion chapter is provided where main issues highlighted from the literature review are compared with key issues from interviews. Aspects that were found in the literature review but not mentioned during the interviews are also described in this section to highlight divergences between the current study and others. Although the themes that emerged in the literature are very similar to the themes mentioned by respondents, in particular when it comes to challenges faced, a number of success stories were shared showing that respondents consider that they have played an instrumental role in the adoption of EU health policies and initiatives, despite the difficulty of establishing a link between CSOs' efforts and a given policy outcome. This, as well as explanation of interactions between actors, would be unlikely to emerge in such detail in the scientific literature.

### ***Key terms***

Both the literature review and the empirical data show that there are a multitude of terms that are used to refer to the organised civil society (e.g., '*user groups*', '*community groups*', '*grass-root organisations*', '*patients-based organisation*', '*interest groups*', '*Non-State actors*'). Despite the existence of many definitions of civil society there is some consensus that civil society is different from the state and the market, and that it relates to principles of democracy and freedom. For the purpose of this study, CSO is the term used to refer to European civic, patient or public health organisations that influence EU policy. The 'EU level' in this study refers to 'European institutions' such as the EC, the European Parliament (EP), the European Council or agencies like the European Medicines Agency (EMA), whereas 'international level' refers to international organisations such as the United Nations (UN) or the World Health Organization (WHO).

### ***Research limitations***

There are some research limitations that are important to highlight. Firstly, the field of patient representation is vast and there are major differences between groups that cannot all be captured and analysed. Although the number of organisations that participated in the study was relatively small (14), the sample was purposive and includes the main groups representing patients at the EU level, with several of them having '*official relationships*' with the EU institutions. Of note is that only one member per organisation was interviewed. In some cases, this was someone with a full overview of the different activities of the organisation such as the CEO, Director or Secretary General; in other cases, a policy officer or adviser in charge of a specific policy portfolio, with a deep understanding of a certain policy topic. This means that some interviews were more focused on a certain disease or policy objective than others. It is also important to note that the literature review was not exhaustive and therefore only a sample of research issues relating to this topic has been collected.

When it comes to empirical data collection and analysis, it is important to note that coding processes have some limitations. As cautioned by Flick (1998), one of the problems faced was the potential endless possibilities for interpretation that coding offered. All categories could have been further elaborated as new ideas kept emerging but it was considered that a point of theoretical saturation was reached when categories seemed to be fully explained and relationships between them were clear. At that stage, although data were still providing insight into the matter (e.g., importance of civil society participation for society in general), an attempt was made to focus on the importance of civil society participation not only in policy, but in health policy, and specifically at the EU level.

# 1. A policy roadmap: the role of EU institutions in the development and implementation of health policy

In order to analyse how CSOs exert influence at the EU policy level it is important to contextualise the mandate of European institutions and their decision-making role. The standard EU legislative procedure is the ‘Ordinary Legislative Procedure’<sup>1</sup>, also known as ‘co-decision’, which means that European legislation is approved by two of the European institutions: the European Parliament (EP) and the Council of the European Union. This is the legislative procedure most widely used in the EU and it became common law procedure, including for public health<sup>2</sup>. Adoption of EU legislation is a lengthy and complex process, normally initiated by the European Commission (EC), with involvement of a number of actors, inside and outside European institutions, each one playing a specific role, with some being more influential – or able to contribute more - than others.

## 1.1. The EU decision-making process

The three main European institutions are the European Commission (EC), the European Parliament (EP) and the Council of the European Union. Each of these institutions plays a key role in EU health decision-making. As the executive body of the EU, the EC issues proposals and is in charge of policy implementation; each Member State (MS) has a Commissioner focusing on a specific area of work. Commissioner Andriukaitis is responsible for Health and Food Safety until 2019 although with a limited mandate given the principles of subsidiarity and proportionality<sup>3</sup>. All Commissioners are supported by officials working in a number of different Directorate-Generals (DGs). Many health issues are cross-cutting and

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<sup>1</sup> Article 289 of the Treaty of the Functioning of the EU (TFEU)

<sup>2</sup> Consent Procedure and Consultation Procedure are the two other legislative procedures adopted in special cases

<sup>3</sup> This was specifically noted in Jean-Claude Juncker’s, President of the European Commission, letter to Commissioner Vytenis P. Andriukaitis dated 1 November 2014 where the Health and Food Safety portfolio were described. More information at: [http://ec.europa.eu/commission/sites/cwt/files/commissioner\\_mission\\_letters/andriukaitis\\_en.pdf](http://ec.europa.eu/commission/sites/cwt/files/commissioner_mission_letters/andriukaitis_en.pdf) (Accessed 18 August 2016)

several DGs deal with health-related issues, including DG Health and Food Safety (SANTE), International Cooperation and Development (DEVCO) and Research and Innovation (RTD).

The EP adopts legislation and budget, and its work takes place within committees. Health is mainly dealt by the ENVI (Environment, Public Health and Food Safety) committee. The Council sets political guidelines and represents the MSs, with health issues being discussed by the 28 Health Ministers at the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO). Each MS holds the Presidency of the European Council for one semester, and depending on the priorities of the country holding the Presidency, there may be less or more discussions on health-related matters.

The policy process normally starts with action from the EC, the institution with the right of initiative according to the Treaty of Lisbon, and the one in charge of policy conception and execution. Further to the EC's right of initiative, the Treaty of Lisbon also gives the EP the right to request proposals from the EC (legislative initiative)<sup>4</sup>, and the Council the possibility to request specific studies. Scholars have different opinions about the mandate and power of different institutions to initiate (or request) legislative proposals but there is some consensus that the EC's right of initiative has been limited or undermined (Dimitrakopoulos, 2004; Brunmayr, 2008; Kassim et al., 2013), with a number of authors noting that the EP's rise in power has been achieved in EC's detriment (Dehousse, 2011; Kassim et al., 2013), which has implications on the EC's capacity to influence legislation (Brown, 2016).

Decisions about proposals that should be developed are taken on the basis of political priorities of the Commission President and the Commission's Work Programme. Examples of issues included in the Work Programme are cross-border health threats such as the Ebola epidemic, the danger of antimicrobial resistance (AMR) and endocrine disruptors<sup>5</sup>. When a new initiative is proposed, there is a

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<sup>4</sup> Article 225 of the Treaty of the Functioning of the EU (TFEU)

<sup>5</sup> [http://ec.europa.eu/priorities/publications/president-junckers-political-guidelines\\_en](http://ec.europa.eu/priorities/publications/president-junckers-political-guidelines_en) (Accessed 18 June 2016)



process of political validation whereby the lead DG encodes the new initiative in an 'Agenda Planning' and seeks validation by the relevant Commissioner<sup>6</sup>.

In most cases, an Impact Assessment (IA) is required to inform the policy process. Evidence is collected on a particular proposal as part of the IA, the problem is stated and the causes identified, an analysis of social, economic and environmental elements is conducted and an overall assessment determines whether action by the EC is needed, what are the different solutions available to address the problem and potential consequences<sup>7</sup>. A public consultation is part of the IA process to ensure that views of the wider community and of any interested parties are incorporated in the proposal. As the consultation is open to the public, any citizen can provide feedback, although NGOs or other interested organisations normally provide a coordinated response. An 'Inter-service Consultation' is also launched among different EC units to ensure that all aspects related to a particular topic are taken into consideration. The 2013 EC's 'Communication for Strengthening the Foundations of Smart Regulation' calls for a closer link between evaluation and IAs and for the 'Evaluate First' principle to be applied to ensure that any policy decisions take into consideration lessons from past EU efforts. The concept of smart regulation originates from the need to ensure quality of regulation throughout the policy cycle, both by European institutions and MSs with the premise of simplification and high quality of EU legislation and its implementation. Consulting citizens and stakeholders is considered an essential element of smart regulation<sup>8</sup>.

In addition to the smart regulation principle, mechanisms have been established to ensure quality of proposals before these are taken forward by other institutions. Review by a Regulatory Scrutiny Board (RSB) and an Explanatory Memorandum describing how the proposal conforms to principles of subsidiarity, proportionality and smart regulation are normally required. As for more complex directives and

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<sup>6</sup> [http://ec.europa.eu/smart-regulation/guidelines/docs/swd\\_br\\_guidelines\\_en.pdf](http://ec.europa.eu/smart-regulation/guidelines/docs/swd_br_guidelines_en.pdf) (Accessed 18 June 2016)

<sup>7</sup> [http://ec.europa.eu/smart-regulation/guidelines/docs/swd\\_br\\_guidelines\\_en.pdf](http://ec.europa.eu/smart-regulation/guidelines/docs/swd_br_guidelines_en.pdf) (Accessed 3 September 2016)

<sup>8</sup> [http://ec.europa.eu/smart-regulation/docs/com\\_2013\\_686\\_en.pdf](http://ec.europa.eu/smart-regulation/docs/com_2013_686_en.pdf) (Accessed 3 September 2016)

regulations, the EC develops implementation plans (IPs) to support MSs with the potential application of the law<sup>9</sup>.

The legal basis adopted by the EC and the topic of the proposal normally defines the legislative process but in the majority of the cases the ordinary legislative procedure ('co-decision') applies. The procedure starts when the proposal is sent to the EP and the Council, once the initiative has been approved by the EC. The proposal is also sent to all EU MSs Parliaments, which have a strengthened role in the legislative process since the Treaty of Lisbon. National governments have eight weeks to review proposals and decide whether they are in compliance with the principle of subsidiarity. If this is not the case, the EC may be required to re-examine or abandon the proposal. At this stage, the Economic and Social Committee and the Committee of the Regions might be consulted.

The work is continued by a committee within the EP, with a rapporteur being appointed to prepare a position on the proposal (first reading). Members from other political groups appoint a shadow rapporteur who prepares the position of the group and follows the work of the main rapporteur, following which the proposal is debated in plenary: the proposal may follow a simplified procedure (Rule 50 of the Rules of Procedure of the European Parliament) and may be approved without or with some amendments<sup>10</sup>. Rarely, the EP requests the EC to withdraw the proposal. The first reading position is sent to the Council and the discussions by MSs representatives take place within working groups, which report to the Committee of Permanent Representatives in the EU (Coreper), responsible for preparing each Council decision. The technical scrutiny of each proposal is done at working party, Coreper and Council configuration levels. If there is an agreement by both institutions, the legislation may be adopted at first reading; alternatively, there is a second reading or discussion at a Conciliation Committee. Since 1999, 67% of ordinary legislative

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<sup>9</sup> [http://ec.europa.eu/smart-regulation/guidelines/docs/swd\\_br\\_guidelines\\_en.pdf](http://ec.europa.eu/smart-regulation/guidelines/docs/swd_br_guidelines_en.pdf) (Accessed 3 September 2016)

<sup>10</sup> <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+RULES-EP+20091201+RULE-046+DOC+XML+V0//EN&language=EN&navigationBar=YES> (Accessed 19 August 2016)

procedure files were concluded during the first reading, 24% during the second reading and 9% through conciliation<sup>11</sup>.

## 1.2. EU health policy development and implementation

The EU policy competence in the field of public health was first introduced by Article 129 of the Treaty of Maastricht<sup>12</sup>. Although there was no clear basis for EU activities in the field of public health in early days of the European Economic Community (EEC) health was mentioned in the founding treaties<sup>13</sup> to a limited extent and topics that required common action such as HIV/AIDS were discussed. The formal competence of the EU in the health field has increased in recent years and while there is no such thing as *European health law*, EU law may have an impact in national health policies (Hervey & McHale, 2004).

Article 168 and 169 of the Treaty on the Functioning of the European Union (TFEU)<sup>14</sup> applies to public health. The EU's role is to ensure higher level of human health protection through EU policies and activities but in complementarity with the MSs and in cross-border areas. As the EU should respect the responsibilities of the MSs in relation to their health policy and delivery, the focus is to support MSs to achieve their objectives, pool resources and tackle common challenges (for example, in the case of outbreaks or pandemics). Certain measures, for example in the areas of quality and safety of organs or medicinal products and devices for medical use, may be adopted by the EP and the Council through the co-decision procedure. As a way to promote coordination amongst MSs, the EU also develops proposals aiming at the establishment of guidelines and indicators, exchange of best practices, and monitor and evaluation. Moreover, cooperation in the area of public health with countries outside the EU is sought<sup>15</sup>.

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<sup>11</sup> <http://www.consilium.europa.eu/en/council-eu/decision-making/> (Accessed 19 August 2016)

<sup>12</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12002E152:EN:HTML> (Accessed 19 August 2016)

<sup>13</sup> 'Fundamental needs of health' was included in Article 69 of the European Coal and Steel Treaty; Article 36 of the Treaty of Rome (1957) permitted restrictions on imports and exports to protect human health.

<sup>14</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:12012E/TXT&from=EN> (Accessed 8 June 2016)

### 1.3. Approval of EU health-related directives

The example below illustrates how a health-related directive is discussed and adopted at the EU level, which was possible through a desk review of official documents available in the websites of the EC, EP and Council. The example below shows that a number of steps are required before approval, each one involving different institutions and players. In this case, there were official opportunities for involvement of civil society: a public consultation, a stakeholder group, and face-to-face meetings. A number of less formal discussions with interest groups or CSOs are likely to have happened and influenced decisions, also before the initiative was formally taken on board by the EC, but such interactions are seldom documented. For this reason, interviewing key respondents that provide first-hand information was crucial for this study.

#### ***Proposal for a Directive on standards of quality and safety of human organs intended for transplantation (Directive 2010/53/EU)***

The legal basis for the proposal is Article 168 paragraph 4 of the TFEU where it is stated that the EP and the Council, acting in accordance with the ordinary legislature procedure and after consultation with the Economic and Social Committee and the Committee of the Regions, may adopt measures that aim to tackle common concerns such as the quality and safety of organs<sup>16</sup>. DG SANCO led by Commissioner Dalli at the time initiated the proposal.

A public consultation to support the preparation of the proposal and to determine the extent to which measures should be taken at the EU level was open from June to September 2006. According to the consultation report, 73 contributions were received from patient or donor associations (15), transplantation professionals and scientific associations (26), governments, ministries, national agencies or

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<sup>16</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12008E168:EN:HTML> (Accessed 8 June 2016)

international institutions (24), individuals (4) and other (4)<sup>17</sup>. These have been published on the website of DG SANCO.

The results of the consultation contributed to the development of the EC proposal (COM(2008) 819), which was validated and accepted for inclusion in the EC Agenda Planning in 2007. As part of this process, DG SANCO set up an Inter-Service Steering Group (ISSG) composed by different EC staff and an IA<sup>18</sup> was prepared, providing four policy options to policy-makers in the EP and Council: 1) EC continues its activities in the field of organ donation and transplantation, involving primarily support to research and programmes in this field 2) a non-regulatory approach is taken and a European Action Plan is adopted for the period 2009-2015 3) An Action Plan is adopted and combined with a 'flexible' directive that supports key elements of the Action Plan, namely in the area of safety and quality 4) An Action Plan is developed and combined with a 'stringent' directive, which would contain detailed regulation about the quality and safety systems that MSs have to put in place. Option 1 did not involve adoption of legislation whereas Option 4 involved adoption of stringent legislation. At the same time that the Directive was proposed, the EC also recommended an Action Plan on Organ Donation and Transplantation for the period 2009-2015.

Part of the preparatory process also included discussions within a stakeholder group, which met in February 2008 and was composed by 16 European organisations representing professionals, hospitals, patients, donors, organ exchange organisations and industry. A one-day workshop to discuss the impact of the different policy options with stakeholders was organised in May 2008. In addition, the EC organised 20 face-to-face meetings with key actors and at least four meetings with national experts of NGOs working in the field, Eurotransplant and ScandiTransplant. As a result of the IA and consultations, a dual mechanism of action was recommended by the EC: an Action plan plus a 'flexible' Directive (option 3).

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<sup>17</sup> [http://ec.europa.eu/health/ph\\_threats/human\\_substance/oc\\_organs/docs/oc\\_organs\\_frep\\_en.pdf](http://ec.europa.eu/health/ph_threats/human_substance/oc_organs/docs/oc_organs_frep_en.pdf) (Accessed 8 June 2016)

<sup>18</sup> [http://ec.europa.eu/smart-regulation/impact/ia\\_carried\\_out/docs/ia\\_2008/sec\\_2008\\_2956\\_en.pdf](http://ec.europa.eu/smart-regulation/impact/ia_carried_out/docs/ia_2008/sec_2008_2956_en.pdf) (Accessed 8 June 2016)

The proposal was assigned to the ENVI Committee in the EP and a Member of the European Parliament (MEP) from the European People's Party (EPP) was appointed rapporteur in September 2009. Other committees, Legal Affairs (JURI) and Civil Liberties, Justice and Home Affairs (LIBE) were also involved and provided opinions. When the rapporteur's report on the proposal was discussed by the ENVI committee in March 2010, it was decided to amend some parts of the text<sup>19</sup>. The debate in the plenary took place in May 2010 where several MEPs supported the proposal and raised their voices about the need of legislation on organ donation<sup>20</sup>. One MEP from the European United Left/Nordic Green Left (GUE/NGL) strongly supported the proposal but stressed that the reports did not reflect the problem of health inequalities. Another MEP representing the European Conservatives and Reformists (ECR) political group said that *'if there is one area in health care and public health that is genuinely European, then it is surely transplants. This standard is a logical and very welcomed step. I would also like to applaud the rapporteurs for leaving out the ethical element, which will naturally fall within the scope of the Member States'*, providing a concrete example of an issue of European dimension that includes elements that remain in the remit of MSs<sup>21</sup>.

The EP 'Resolution on the Commission Communication: Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States' was adopted on 19 May 2010 when the vote in the EP took place, 643 votes were in favour, 16 against and 8 abstentions. The procedure ended in Parliament at this stage. The act was then adopted by the Council on 29 June 2010, signature took place on 7 July 2010 and the act was published in the Official Journal on 6 August 2010<sup>22</sup>.

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<sup>19</sup> <http://www.europarl.europa.eu/oeil/popups/summary.do?id=1086596&t=e&l=en> (Accessed 8 June 2016)

<sup>20</sup> MEP Marisa Matias on behalf of the GUE/NGL Group. More information at: <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+CRE+20100518+ITEM-012+DOC+XML+V0//EN&language=EN> (Accessed 8 June 2016)

<sup>21</sup> MEP Miroslav Ouzký, on behalf of the ECR Group. More information at: <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+CRE+20100518+ITEM-012+DOC+XML+V0//EN&language=EN> (Accessed 8 June 2016)

<sup>22</sup> [http://www.europarl.europa.eu/oeil/popups/ficheprocedure.do?lang=en&reference=2008/0238\(COD\)#tab-0](http://www.europarl.europa.eu/oeil/popups/ficheprocedure.do?lang=en&reference=2008/0238(COD)#tab-0) (Accessed 8 June 2016)

The EC proposal led to a Directive, which is a binding legislative act that sets out a goal that all EU countries must achieve, and that was adopted to support the implementation of ten priority actions set out in the EC's Action Plan, including the adoption of minimum standards in relation to organ donation and transplantation by MSs. MSs had to incorporate the decision into national legislation by 27 August 2012. A mid-term review of the Action Plan showed that since its launch donor transplant programmes have been set up across EU and efforts of MSs led to an increase in deceased donation rates<sup>23</sup>. The final review has been commissioned in 2015 and is currently taking place<sup>24</sup>.

#### 1.4. EU Health Strategy and Programmes

The EU Health Strategy *Together for Health* was adopted in 2007 to support the overall Europe 2020 strategy, which aims to achieve a 'smart, sustainable and inclusive economy', an objective that can only be achieved through policy coordination, and most importantly, if population is in good health. The strategy strengthens coordination and cooperation across the EU and promotes health as the greatest wealth and the *health in all policies* principle (HiAP), an '*approach to public policies across sectors that systematically takes into consideration the health and health systems implications of decisions, seeks synergies and avoids harmful health impacts, in order to improve population health and health equity*'<sup>25</sup> (Ollila et al., 2013:3).

Figure 1 provides an overview of the EU programmes that support the implementation of the EU Health Strategy and ultimately of the EU growth strategy Europe 2020. The EU Health Programme, coordinated by the Consumers, Health and Food Executive Agency (CHAFEA) is the main financial instrument used by the EC to implement the EU Health Strategy. DG Health and Food Safety is responsible for seeking input and agreement from MSs, define priorities through the preparation

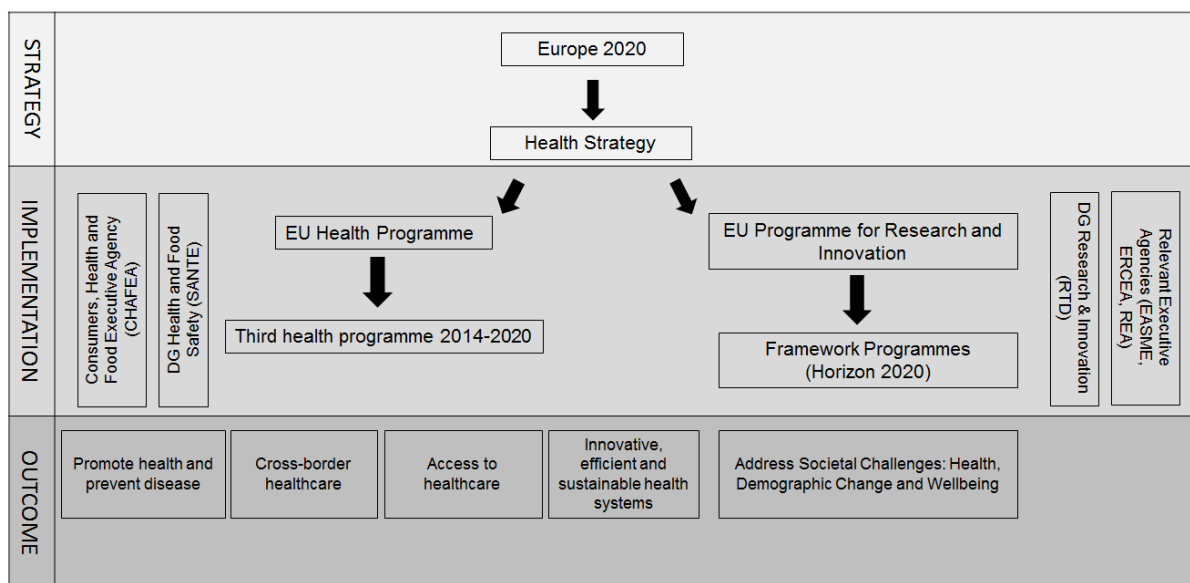
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<sup>23</sup> [https://www.era-edta.org/ekha/Mid-Term\\_Review\\_of\\_the\\_EU\\_Action\\_Plan-on\\_Organ\\_Donation\\_&\\_Transplantation.html](https://www.era-edta.org/ekha/Mid-Term_Review_of_the_EU_Action_Plan-on_Organ_Donation_&_Transplantation.html) (Accessed 3 September 2016)

<sup>24</sup> [http://ec.europa.eu/health/blood\\_tissues\\_organ/docs/ev\\_20160317\\_mi\\_en.pdf](http://ec.europa.eu/health/blood_tissues_organ/docs/ev_20160317_mi_en.pdf) (Accessed 3 September 2016)

<sup>25</sup> [http://www.euro.who.int/\\_data/assets/pdf\\_file/0007/188809/Health-in-All-Policies-final.pdf](http://www.euro.who.int/_data/assets/pdf_file/0007/188809/Health-in-All-Policies-final.pdf) (Accessed 3 September 2016)

and adoption of annual work programmes, report and evaluation. The main objectives of the third Health Programme are to promote health and an environment that supports healthy lifestyles, prevent disease, protect citizens from cross-border health threats, support health systems and facilitate access to healthcare in the EU. This Health Programme allocates funding through grants and tenders with a budget of approximately € 450 million for the period 2014-2020. Since 2003, funding has been allocated to more than 750 individual projects and operating grants, including to NGOs and CSOs. A legislative process was necessary for the programme to come into existence: on 9 November 2011, a proposal for the third Health Programme was adopted by the EC and prior to that an IA was developed which accompanied the proposal<sup>26</sup>. A consultation focusing on national and NGO representatives was launched and one of the recommendations was that the programme should be focused, cost efficient and support actions with added value. The EC proposal was adopted by the EP on 26 February 2016<sup>27</sup>.



Source: Own construction

Figure 1. EU Health Strategy and Programmes

<sup>26</sup> [http://ec.europa.eu/health/programme/docs/ia\\_progr2014\\_en.pdf](http://ec.europa.eu/health/programme/docs/ia_progr2014_en.pdf) (Accessed 3 September 2016)

<sup>27</sup> [http://europa.eu/rapid/press-release\\_STATEMENT-14-31\\_en.htm](http://europa.eu/rapid/press-release_STATEMENT-14-31_en.htm) (Accessed 3 September 2016)



Another EU instrument that supports the implementation of the EU Health Strategy is the Framework Programme (FP) for Research and Technological Development (FP1 to FP8, known by Horizon 2020). Health research is only a part of the programme but it is seen as an investment that will contribute towards achieving the objectives of Europe 2020. Horizon 2020 is the largest EU research and innovation programme ever with nearly € 80 billion of funding for the period 2014-2020. The programme is managed by DG Research and Innovation (R&I) and a number of executive agencies, including the Executive Agency for SMEs (EASME), the European Research Council Executive Agency (ERCEA) and the Research Executive Agency (REA). The qualitative data shows that CSOs are involved in research projects funded by Horizon 2020 but in the majority of the cases they receive funding through the EU Health Programme.

The 2014-2020 European Structural and Investment Funds (ESIF) also contribute to addressing EU health priorities and in particular health inequalities by supporting regions in developing their health, research and innovation capacity. ESIFs are distributed according to the capacity of the country, in some cases investments in health are mainly funded through national resources and Structural Funds cover a small part of the costs, contributing for example to R&D projects (e.g., UK or Belgium). In other cases, they are mainly used for the modernisation of the health infrastructure (e.g., Poland and Bulgaria). Development funds managed by the Directorate-General for International Cooperation and Development (DG DEVCO) also support health in developing countries.

In summary, this chapter shows that despite health being in the core of the welfare state, the landscape of EU programmes that focus on health is vast. This information was collected through a desk review of relevant EU institutions' websites and shows the different institutions deal with health issues, their strategies and programmes as a means to demonstrate the EU health processes where civil society participates. This 'health Europeanization', was explored by Greer (2009) who argues that the interest of policy advocates in health is either in response to EC's efforts to '*win allies in new policy ventures*', in particular in public health or a '*defensive reaction to the increasingly complex and important EU judicial and legislative agenda in health services*' (Greer, 2009: 189).

## 2. Health inequalities and inequity in the EU: the causes of the causes

Health inequalities are discrepancies in health that appear to be more prevalent in one individual or group than another. When these inequalities are avoidable, unfair, unjust and unnecessary they are termed health inequities (Whitehead, 1992). Both terms are often used interchangeably but they are not the same. The concept of health equity is of particular relevance for health policy as it relates to an unfair distribution of resources and processes that lead to different levels of social advantages. The notion of social justice is therefore closely linked to health equity. John Rawls through his pivotal work 'Theory of Justice' (1971) claimed that social and economic inequalities had to be addressed for everyone to benefit from equality of opportunities. This theory is relevant in health where social and economic aspects need to be addressed for everyone to have equal access to health care.

### 2.1. Measuring health equity for evidence-based policy

Measuring health equity is a core aspect of health policy that can be challenging in a Europe with 28 MSs. Better health outcomes do not necessarily reflect better equity and at European and international levels evidence can be difficult to collect and compare due to weak health information systems, and lack of available and quality data. Some health indicators such as child or infant mortality rate (CMR/IMR) have been used to gauge population health and set policy goals. Other metrics include disability-adjusted life year (DALY) used for the Global Burden of Disease report or quality-adjusted life year (QALY), which has been used to assess cost-effectiveness of policies as it takes into account the quality of years lived. The WHO Task Force on Research Priorities for Equity in Health also considered that a measure of equity is *'the extent to which public policy and authority are structured to serve public interests and justice, as reflected in part by the degree to which non-élite groups can influence the allocation of resources for health'* (WHO Task Force on Research Priorities for Equity in Health & the WHO Equity Team, 2005: 949)<sup>28</sup>.

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<sup>28</sup> <http://www.who.int/bulletin/volumes/83/12/948.pdf> (Accessed 3 September 2016)

## 2.2. Social determinants of health

According to WHO, social determinants of health are *'the conditions in which people are born, grow, work, live, and age, and the wider set of forces and systems shaping the conditions of daily life. These forces and systems include economic policies and systems, development agendas, social norms, social policies and political systems'*<sup>29</sup>. The Whitehall study of British civil servants led by Michael Marmot showed the close relation between these social determinants and mortality, and the importance of addressing the 'causes of the causes' (Marmot, 2005). The WHO Commission on Social Determinants of Health later emphasised why social aspects should be taken into consideration by policy makers and that policy action should go beyond addressing only health<sup>30</sup>. The WHO's definition of health is consistent with this approach as health is seen as *'a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity'*<sup>31</sup>.

## 2.3. EU and health inequalities

Different rates of mortality and morbidity across EU MSs show that inequalities are not confined to a country's border and that the EU has a role to play. The White Paper published by the EC *'Together for health: a strategic approach for the EU 2008–13'*<sup>32</sup> states that health inequalities should be at the core of the EU response. Other policy documents focusing on health inequalities include the *2009 EC's Communication on Health Inequalities*<sup>33</sup>; the *EP Resolution of 8 March 2011 on reducing EU health inequalities*<sup>34</sup>; *Council Conclusions on 'Equity and health in all policies: solidarity in health'*<sup>35</sup>; and *Council Conclusions on closing health gaps within*

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<sup>29</sup> [http://www.who.int/social\\_determinants/en/](http://www.who.int/social_determinants/en/) (Accessed 10 August 2016)

<sup>30</sup> [http://www.who.int/social\\_determinants/thecommission/finalreport/en/](http://www.who.int/social_determinants/thecommission/finalreport/en/) (Accessed 10 August 2016)

<sup>31</sup> <http://www.who.int/about/definition/en/print.html> (Accessed 3 September 2016)

<sup>32</sup> [http://ec.europa.eu/health/ph\\_overview/Documents/strategy\\_wp\\_en.pdf](http://ec.europa.eu/health/ph_overview/Documents/strategy_wp_en.pdf) (Accessed 3 September 2016)

<sup>33</sup> [http://ec.europa.eu/health/ph\\_determinants/socio\\_economics/documents/com2009\\_en.pdf](http://ec.europa.eu/health/ph_determinants/socio_economics/documents/com2009_en.pdf) (Accessed 3 September 2016)

<sup>34</sup> <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2011-0081+0+DOC+XML+V0//EN> (Accessed 3 September 2016)

<sup>35</sup> [http://www.consilium.europa.eu/uedocs/cms\\_data/docs/pressdata/en/lisa/114994.pdf](http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lisa/114994.pdf) (Accessed 3 September 2016)

the EU through concerted action on unhealthy lifestyle behaviours<sup>36</sup>. Furthermore, there are policy initiatives that target specific lifestyles or diseases that contribute to inequalities such as the *Council Recommendation on the prevention of smoking and on initiatives to improve tobacco control*<sup>37</sup> or the *European Pact for mental health and well-being*<sup>38</sup>. These policy documents and initiatives were backed by evidence published in a number of studies, including *'The health status of the European Union — Narrowing the health gap'*<sup>39</sup>, published in 2003 or *'Health inequalities: Europe in profile'*<sup>40</sup> published in 2006. The evidence presented in this report shows again that socioeconomic inequalities are the root of the problem and that people in lower socio-economic positions die earlier and spend a larger number of years in ill-health. For example, the report showed that life expectancy at age 25 for men with tertiary education in Estonia was 17.8 years longer than life expectancy for men who did not complete secondary education.

A population's health status influences productivity and the European strategy for growth (Europe 2020) explicitly recognises the need to reduce health inequalities in order to achieve the set objectives. The inclusion of health inequalities in the EU strategy makes health inequalities a cross-cutting theme in EU policy-making. Although there is no dedicated funding stream at the EU level focusing on health inequalities, there have been projects funded by the Framework Programmes and the EU Health Programme, some of them focusing on improving baseline data and developing indicators. Examples include the promotion of the European Community Health indicators (ECHI) shortlist or the project 'Determine - an EU Consortium for Action on the Socio-Economic Determinants of Health'<sup>41</sup>. Other projects aimed specifically at reducing inequalities among the most vulnerable groups in Europe (e.g., Correlation Network II — European network for social inclusion and health).

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<sup>36</sup> [http://www.consilium.europa.eu/uedocs/cms\\_data/docs/pressdata/en/lsa/126524.pdf](http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/126524.pdf) (Accessed 3 September 2016)

<sup>37</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32003H0054> (Accessed 3 September 2016)

<sup>38</sup> [http://ec.europa.eu/health/ph\\_determinants/life\\_style/mental/docs/pact\\_en.pdf](http://ec.europa.eu/health/ph_determinants/life_style/mental/docs/pact_en.pdf) (Accessed 3 September 2016)

<sup>39</sup> [http://ec.europa.eu/health/ph\\_information/documents/health\\_status\\_en.pdf](http://ec.europa.eu/health/ph_information/documents/health_status_en.pdf) (Accessed 3 September 2016)

<sup>40</sup> [http://www.who.int/social\\_determinants/resources/european\\_inequalities.pdf](http://www.who.int/social_determinants/resources/european_inequalities.pdf) (Accessed 3 September 2016)

<sup>41</sup> <http://www.health-inequalities.eu/> (Accessed 3 September 2016)

In summary, this chapter shows that health inequality is a cross-cutting theme in EU strategies, and that health inequality and health inequity are different concepts, with the latter being closely linked to the notion of social justice explored by John Rawls and particularly important in health policy as it relates to an unfair distribution of resources, which result in a discrepancy in social advantages. Measuring health equity is therefore a necessary element of evidence-based health policies.

### **3. A scholars' perspective: civil society and patient empowerment**

#### **3.1. Definition and role of civil society**

There is some consensus that civil society is composed by the State/government, market/economy and civil society (Olafsdottir et al., 2014) and that this is a sphere fundamentally different from the state and the market (Filc, 2014; Lee, 2010). At the basis of civil society are relationships among adults that form the foundation of social networks hence providing an informal structure upon which formal citizenship and civic engagement is built (Gillies, 1998). Giarelli et al. (2014) see civil society as a tool for 'social conversation'; hence, a strong and vibrant civil society should be a policy objective (Anheier, 2013) and a key feature of any democratic society (Battams, 2014).

Two different schools of thought have been highlighted by scholars: one sees civil society as a 'representative' body, where many NGOs advocate and represent constituencies in a governance environment; another sees civil society in the realm of 'social interaction', a different place from the political sphere (Battams, 2014). Although some theories consider civil society as a part of and regulated by the State (liberal egalitarians), the majority of contemporary approaches to political and social theory consider that civil society is a 'positive' sphere different from the state, emanating from freedom (Filc, 2014) and part of modern democracy (Battams, 2014).

CSOs represent civil society (or 'organised civil society') but the term in itself is more complex than that as there is often confusion with associated terms like "voluntary sector", 'non-profit sector', non-governmental organisations', 'social economy' or 'third sector' (Giarelli et al., 2014:163). Furthermore, when it comes to civil society in health, there are a number of related concepts that are often used, including those of patient engagement and participation, which are not new and are often used interchangeably (Clayman et al., 2015). Some authors also consider that it would be impossible to fully understand civil society without understanding the notion of social

capital, a process that according to Gillies (1998) enables people and organisations to work together in trust for mutual benefit.

CSOs are distinct from organisations and institutions of the market (Lee, 2010). CSOs not only contribute to correcting any shortcomings of democracy and strengthening it (Filc, 2014), but also to revitalise and strengthen communities (Giarelli et al., 2014) and scrutinise the operations of international organisations (Doyle & Patel, 2008). In particular, they play an important watchdog role ensuring that formally mandated governmental organisations fulfil their responsibilities, and that corporations do not engage in health harming activities (Lee, 2010).

Definitions of civil society found in the literature included, amongst others, those of the EC, the Dictionary of Civil Society, the Centre for Civil Society at the London School of Economics, the World Bank and the Cato Institute:

*'CSOs are non-governmental, non-profit organisations that do not represent commercial interests, and pursue a common purpose in the public interest'* (EC definition in Beinare & McCarthy, 2012: 889).

*'The set of institutions, organisations and behaviours situated between the state, the business world and the family. This would include voluntary organisations of many different kinds, philanthropic institutions, social, cultural and political movements and dimensions of the public sphere, forms of social capital, political participation and social engagement, and the values and behavioural patterns associated with them. In its transnational dimension, the term goes beyond the notion of both nation state and national society'* (Dictionary of Civil Society in Filc, 2014: 168).

*'The wide array of non-governmental and not-for-profit organisations that have a presence in public life, expressing the interests and values of their members or others, based on ethical, cultural, political, scientific, religious or philanthropic considerations. Civil Society Organizations (CSOs) therefore refer to a wide of array of organizations: community groups, non-governmental organizations (NGOs), labor unions, indigenous groups,*

*charitable organizations, faith-based organizations, professional associations, and foundations*' (World Bank definition in Lee, 2010: 1).

*'Civil society means fundamentally reducing the role of politics in society by expanding free markets and individual liberty'* (Cato Institute definition in Filc, 2014: 169).

*'Group of organisations and institutions that share a common interest that is neither driven exclusively by state or market mandate'* (Centre for Civil Society used by Cohn et al., 2011: 688).

The definitions by the Dictionary of Civil Society and the Centre for Civil Society are consistent with the notion of a tripartite society mentioned by Olafsdottir et al. (2014), Filc (2014) and Lee (2010), amongst others. Other definitions include the concepts of public interest, expression of common interests and values, and individual liberty. Political theorists tend to see civil society in the context of normative theories of democracy while the EU provides a definition in the context of EU governance (Kohler-Koch & Quittkat, 2009).

NGOs and CSOs are not different type of organisations and as seen in the EC and World Bank definitions, CSOs can be considered but are not exclusively NGOs. These may also include labour unions, charitable organisations, foundations, etc. Beinare & McCarthy (2012) investigated the features of NGOs and CSOs and interviewed health CSOs as part of a study funded by the EC to strengthen engagement in public health research<sup>42</sup>. They provide a comparison of features between CSOs and NGOs and one of the key features presented is that the term CSO normally relates to the constituency while NGO defines the legal status.

<b>Civil society organisation (CSO)</b>	<b>Non-governmental organisation (NGO)</b>
Name implies to its constituency and aim	Name defines legal status

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<sup>42</sup> STEPS – Strengthening Engagement in Public Health Research



Always not-for-profit	May link to for-profit organisations
May be led by civil citizens, most of the work done by volunteers	Work usually led by paid professionals
Not representing political interests	More to do with policy or politics, might be interested in economic issues, frequently have a political point of view
Refers to a wide of array of organisations community groups, NGOs, labour unions, charitable organizations, professional associations and foundations	Can have service agreements with the federal government

Source: Beinare & McCarthy (2011)

Table 1. Comparison of features between CSOs and NGOs

Research about different CSOs structures was also observed in the literature with Giarelli et al. (2014) explaining that some CSOs are more institutionalised and others work with a more activist base. When it comes to geographical focus, patient organisations are present at national, European and international levels (Ayme et al., 2008) but national organisations may lobby national actors who then may raise the association's interests next to European institutions (Dür & Mateo, 2012).

### 3.2. CSOs increasing role in the health field

As explained by Gillies (1998: 100) '*connections, networks and associations within societies are important mechanisms for the promotion of social cohesion and health and for the prevention of disease*'. The importance of organised social action in health is recognised in the 1978 Alma Ata declaration<sup>43</sup>, in the 1980s with the publication of the Ottawa Charter for Health Promotion<sup>44</sup> in 1986 and with the development of the WHO Healthy Cities Programme<sup>45</sup> in the 1980s. The Healthy

<sup>43</sup> [http://www.who.int/publications/almaata\\_declaration\\_en.pdf](http://www.who.int/publications/almaata_declaration_en.pdf) (Accessed 28 June 2016)

<sup>44</sup> <http://www.who.int/healthpromotion/conferences/previous/ottawa/en/> (Accessed 28 June 2016)

<sup>45</sup> [http://www.who.int/healthy\\_settings/about/en/](http://www.who.int/healthy_settings/about/en/) (Accessed 28 June 2016)

Settings movement was a result of the WHO strategy of Health for All and the approach is defined in the Ottawa Charter, which was the result of a conference organised as a response to growing expectations for a new health movement around the world, and which includes statements about the importance of having communities at the heart of the health promotion process. Concepts such as community empowerment and ownership have been included in the Charter.

The importance of civil society for health outcomes has increased over the last decades as CSOs involvement started to bring new institutional, technical, political and financial resources to health (Loewenson, 2003). According to the literature, CSOs contribute both in terms of service provision and patient advocacy (Giarelli et al., 2014). This dual mandate, which was also demonstrated through the expert interviews, is also noted by Doyle & Patel (2008) who argue that CSOs typically involved in global health include organisations that either deliver health interventions or lobby for change in policy to tackle global health problems. According to Lee (2010), CSOs have first focused on service delivery, but stepped in when governments did not deliver basic health services; when populations were neglected, they tried to influence policy and priority setting; when there was a lack of funding, they mobilised resources, and in cases of inappropriate corporate conduct they advocated for adequate regulation. The increasing role of CSOs in delivering health services and interventions on the ground is in great part to circumvent governments' corruption or inefficiencies. As explained by Cohn et al. (2011: 688), *'nearly 20% of grants for the seventh funding round of the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) were channelled through NGOs. According to PEPFAR data from 2005, over 40% of PEPFAR funding for prime partners and almost 70% of funding for sub-partners was granted to NGOs or faith-based organisations (FBOs).'*

CSOs also play a more prominent role in research as these organisations have shown concern when research does not respect the real needs of intended users, but is driven by the ambition of researchers, or industry pushing for certain technology and treatments for market reasons (Beinare & McCarthy, 2012). This concern was also observed in the qualitative data. Inclusion of CSOs in global health governance organisations is usually justified either because their involvement enhances democracy or because they have a comparative advantage in delivering

health interventions. Lack of engagement in some regions is considered to be *'the missing link in building resilience against growing transnational threats such as HIV/AIDS'* (Hsu, 2004: 3).

CSOs also play a role in demanding accountability (Battams, 2014) or in holding health officials accountable at national and international levels (Blas et al., 2008), however, this can sometimes be challenging given the undemocratic nature of some of the structures (Doyle & Patel, 2008). As a way to address this, policy-makers and policy institutions can exchange information and learn best practices related to stakeholder engagement from each other (Battam, 2014).

Two examples of civil society empowerment and achievements found in the scientific literature review included the HIV/AIDS movement and efforts from organised civil society in the context of the Framework Convention on Tobacco Control (FCTC). The HIV/AIDS movement was presented as one of the most important examples of the rise of civil society groups. Groups like Treatment Action Campaign (TAC), which had to work in the complex environment of South Africa where for many years President Mbeki was in denial of the existence of HIV; or The AIDS Support Organization (TASO) that has grown to be one of the largest NGOs in the world are two of many CSOs that helped narrowing the gap between civil society and policy-makers (Seckinelgin, 2002; Kapstein & Busby, 2010; Galjour, 2012). Seckinelgin (2002) notes that patient empowerment in the AIDS field changed the relationship between patients and the politics of health, and that this led to changes in other advocacy areas. Similarly, Galjour (2012: 352) notes that the *'AIDS community established an important set of best practices on civil society shaping and evaluating health policy'* and that there is a *'vibrant civil society sector increasingly engaged even in issues that go beyond HIV'*. AIDS activists also played a crucial role in lowering prices of medicines (Kapstein & Busby, 2010) and in the establishment of new global health initiatives such as the Global Fund and PEPFAR (Cohn et al., 2011). In relation to tobacco control efforts, the mobilisation of civil society groups has been highlighted as unusual (Collin et al., 2002) and the establishment of a Framework Convention Alliance (FCA) where a great number of public health advocates actively participated in order to contribute to the FCTC was

provided as an example of a unique structure that allowed to exert unprecedented policy influence.

Some authors emphasise that CSOs complement and replace governments (Pollard & Court, 2005; Doyle & Patel, 2008; Lee, 2010). An example that illustrates how civil society may replace the State or international organisations is the response to the High Level Political Declaration on Ending AIDS, which was adopted on 8 June 2016 and was highly criticised by civil society for excluding language recognising the importance of key populations such as sex workers, people who use drugs and men who have sex with men (Alcorn, 2016). As a result, the following could be read on social media after the closing of the 2016 AIDS conference, which took place approximately one month after the Political Declaration was adopted:

*'I politely interrupted an AIDS 2016 session today (as they wouldn't let us ask questions) to let people know that civil society, scientists, policy makers and others announced in Durban today at AIDS 2016 that they will pool existing evidence and rights based comprehensive strategies into a new, ambitious, evidence and human rights based Global Plan to end HIV within our lifetimes. Why are we doing this? We regret that neither June's High Level Political Declaration nor the UN's revised downwards investment estimates didn't come close to recognising the enormity of the long-term prevention, testing, stigma, treatment and research needs we urgently face. In fact, the complacency they engender, threaten the progress we have made to date. We are therefore today launching a new inclusive and multisectoral coalition to collate existing peer-reviewed and respected strategies, such as the Lancet UNAIDS Commission Report, Civil Society's own response to the tepid final High Level Political Declaration and other evidence and rights based strategies. This informal coalition will commence work immediately.'*

This shows that a strategy that may support civil society in replacing the government or international organisations is the formation of coalitions with policy members and researchers as was also demonstrated by the empirical data (e.g., European Health Forum, a platform for policy-makers to develop joint strategies with civil society).

Another research area that has captured scholars' attention is the difference between CSO participation in developed countries vs developing countries as well as in countries with stronger vs weaker welfare systems (Doyle & Patel, 2008; Giarelli et al., 2014; Olafsdottir et al., 2014). The role and ability of CSOs to influence seems to vary substantially from one to the other. While in parts of Western Europe there is a tradition of partnership between governments and civil society that has arisen from historical ties between the church and state, *'in many African countries private philanthropy often fills the gap left by lower levels of public sector funding'* (Olafsdottir, 2014: 176). This discrepancy was not mentioned during expert interviews. However, if, as Gillies (1998) observes, globalisation and the development of new technologies contribute to the participatory process, one can assume that in developed countries there are higher levels of participation than in less developed countries. These differences are further explored by Doyle & Patel (2008) who conducted research about unequal power relations between CSOs in developing countries and CSOs in developed countries, and who argue that due to competition there is a tendency for CSOs to concentrate their work in areas where it is easier to achieve results.

Moreover, Olafsdottir et al. (2014) tested health implications of different configurations of welfare state and civil society relationships and demonstrated that civil society and welfare states are interrelated, and that civil society positively influences the political and economic dimensions of a community's social welfare. As such, and given that civil society can be often seen as replacing the welfare state (Olafsdottir et al., 2014), it is not surprising to read in one of the publications that *'civil society involvement matters more in societies with weaker welfare states (transitional/developing countries), while it is less clear how its involvement impacts health in advanced industrialised countries with stronger welfare states'* (Giarelli et al., 2014: 165).

### 3.3. Global health governance: civil society, international institutions and the global dimension of health

The important and growing role of CSOs in health policy-making is due in larger part to globalisation, which made the world more connected and offered increased

opportunities for communication and networking, which has facilitated the recognition of common issues and main interests in tackling disease. According to Doyle and Patel (2008: 1930) this provides a *'foundation for trust and solidarity between citizens in different countries and sows the seeds for an emerging global civil society determined to address health problems'*.

Although some scholars question the existence of a 'global civil society' as presented by political theorists (Doyle & Patel, 2008), it is crucial to mention global health governance (GHG), a concept that emerges from new patterns of collective action and increased prominence from civil society (Stoeva et al., 2015), and led to new dynamics that allowed civil society to engage in global policy-making.

Nowadays, the importance of civil society is widely recognised at the global level by international organisations. For example, UNAIDS considers that CSOs are *'at the forefront of prevention, care and support programmes, particularly among the most vulnerable and hard-to-reach populations'* (Lee, 2010: 3); WHO notes that they set *'new, complex relations between the state and society'*, where aspects like *'participation and accountability become engines for innovation'* (Giarelli et al., 2014: 161); while GFATM wrote that *'the foundation upon which effective responses to the three diseases of AIDS, tuberculosis and malaria are being built. CSOs are the advocates who in many countries stimulated the first recognition and response to HIV and AIDS. It is Civil Society who is the critical implementers of support, prevention and care programmes particularly to the most vulnerable and hard to reach communities.'* (The Global Fund to Fight AIDS, 2006b in Doyle & Patel, 2008: 1931).

CSOs have also been considered privileged partners of the EC for many years, with the first NGOs being supported in 1976<sup>46</sup>; and they have been the main actors of thematic programmes delivered by the EU. The programme *'Non-State Actors and Local Authorities in Development'* or the *HIV/AIDS Civil Society Forum* are examples of platforms specifically initiated and coordinated by the EU for CSOs. In its

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<sup>46</sup> [https://webgate.ec.europa.eu/fpfis/mwikis/aidco/index.php/Thematic\\_programme\\_NSA\\_LA](https://webgate.ec.europa.eu/fpfis/mwikis/aidco/index.php/Thematic_programme_NSA_LA) (Accessed 28 June 2016)

communication '*A Stronger European-based Pharmaceutical Industry for the Benefit of the Patient*' the EC puts patients at the centre of the agenda and specifically highlights the importance of strengthening the role of patients in public health decision-making (Liikanen, 2003). Shortly after this communication was published, the EC nominated three patient organisations<sup>47</sup> to become members of the Committee for Orphan Medicinal Products (COMP), a committee from the European Medicines Agency (EMA) responsible for reviewing applications from people or companies seeking '*orphan-medicinal-product designation*'. Qualitative data shows that two of the organisations interviewed participate in these committees.

### 3.4. Access to policy-makers and meaningful participation

Patients can only participate and influence if they have access to policy-makers. Bouwen (2002) examines the interaction of private and public organisations and develops a framework to test the access of business interests to European institutions. Bouwen's 'theory of access' might be relevant not only in the context of business interests but also civil society interests: according to him, the highest degree of access to policy-makers is provided if private actors can provide access goods demanded by institutions. These access goods concern information that is crucial for the EU policy-making process and include for example expert knowledge. This model could potentially be tested with CSOs as Dür and Mateo (2012) also argue that the European institutions need expertise in order to develop proposals and explain that there is an exchange whereby CSOs provide technical expertise and in return they are able to influence.

The concept of meaningful participation was also found in the literature and Battams (2014: 812) highlights that 'the extent to which civil society engagement within processes represents "elite pluralism" rather than genuine engagement and "active citizenship" is also a consideration'. The literature shows that civil society's opportunities to participate meaningfully are limited (Cohn et al., 2011), which was confirmed by the qualitative data. Despite this, examples of initiatives that allowed for

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[http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/2010/02/people\\_listing\\_000005.jsp&mid=WC0b01ac0580028e76](http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/2010/02/people_listing_000005.jsp&mid=WC0b01ac0580028e76) (Accessed 28 June 2016)

progress in this area to be made were provided in some of the papers, such as the WHO Commission on the Social Determinants of Health, which adopted a strategy on meaningful involvement in 2005 (Lee, 2010).

A section with prerequisites for meaningful civil participation has been included in the drafting guidelines on civil society participation in political decision-making being drafted by the Council of Europe<sup>48</sup>. It refers, amongst others, to the importance of genuine exchange of opinions; transparent procedures; the adoption of a legal or regulatory framework that allows meaningful participation with laws being adopted only if participation has taken place in line with this framework; the allocation of the necessary resources and services by public authorities, and access by civil society to all stages of the decision-making process.

In relation to the notion of meaningful participation, there was also research on the reasons that make patients want to participate. For example, one of the articles reviewed by McDermott & Pedersen (2016) found that age, education status, disease severity, ethnic and cultural factors influence the desire for participation. Additional factors may include '*health literacy, knowledge, experience, personality and trust*' (McDermott & Pedersen, 2016:4 citing Thompson, 2007).

### 3.5. Challenges

The main challenge identified in the literature was legitimacy but there were others such as the lack of resources and the need for capacity building. Dür & Mateo (2012: 4) explain that '*financial means, legitimacy, representativeness, knowledge, expertise and information are necessary for influencing policy outcomes*' and that '*resources allow CSOs to be well informed about policy developments and procedures, organise lobbying activities such as campaigning and demonstrations, as well as to exchange resources like expertise or information in exchange of access and influence towards policy-makers*'. More specifically, proper expertise needs to

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<sup>48</sup> [http://www.coe.int/t/dgap/localdemocracy/CDDG/Guidelines-civil-society-consultation\\_en.pdf](http://www.coe.int/t/dgap/localdemocracy/CDDG/Guidelines-civil-society-consultation_en.pdf) (Accessed 6 September 2016)



be ensured through public support for CSOs to be effectively involved in decision-making (Giarelli et al., 2014).

CSOs are often seen as a means to achieve transparency (Giarelli et al., 2014) but due to their prominent role (Lee, 2010), the level of funding that has been channelled directly to them (Doyle & Patel, 2008) as well as the nature of their lobbying activities there is a call for close scrutiny of their effectiveness. CSOs should ensure the legitimacy of their actions, i.e., the validity or justification of an organisation's claim to represent the interests of a group of people (Doyle & Patel, 2008). They also need to work based on principles of good governance (Lee, 2010) and make sure that their actions and work with European and international institutions is done in a transparent manner. As an example, Lee (2010: 4) notes that a review found 482 'relationships' between CSOs and WHO headquarters, of which '56% were official relations'. No evidence was found in the literature on whether CSOs that undertake the 'official route' and are formally registered as interest groups trying to influence policy institutions are more successful than others.

The following research questions related to legitimacy and accountability were found in the publications read: what does it mean for CSOs to be accountable, what precisely they are accountable for and, how (or by what mechanism) they make themselves accountable? (Doyle & Patel, 2008); and to what extent is there sufficient evaluation of their activities? (Lee, 2010). Moreover, an important finding was that trust and solidarity have emerged as the most important lobbying currency in Brussels (Coen & Richardson, 2009), which shows the importance of exploring trust issues in the empirical data and prove any links between trust and results.

Reference to CSOs relationships with the pharmaceutical industry was found in several publications. In some cases, public health interests align with private interests, but research shows that this is not always the case (Brezis, 2008) and overall, there seems to be a general lack of trust towards groups supported by the pharmaceutical industry (Beinare & McCarthy, 2012). Many entities registered at the UN are affiliated with businesses and have extensive relationships with representatives from private companies. For this reason, it is important to differentiate between CSOs and private-interest organisations (Doyle & Patel, 2008).

Initiatives that support the transparency process include the Alliance for Lobbying Transparency and Ethics Regulation (ALTER-EU) that calls for stronger EU regulations on engagement in lobbying activities (Battams, 2014) or the INGO Accountability Charter by the International Civil Society Centre<sup>49</sup>. Furthermore, authors like Kickbusch (2000) provide proposals on how to achieve greater accountability in international health policy.

Governance is defined as *'the actions and means adopted by a society to promote collective action and deliver collective solutions in pursuit of common goals'* (Dodgson et al., 2002: 6). Governance is different from government; within governments, the actions and means within which common goals are pursued are backed by a formal authority, the State (Rosenau, 1992). This means that there is a formal system of rules where any conflicting interests or power struggle can be regulated. Such a formal authority does not exist at the level of global governance, where European and international CSOs sit. National CSOs are normally given a mandate by the citizens of their country (Doyle & Patel, 2008) but there are no popular elections for CSO representatives and no clear mandate is normally given by citizens to transnational CSOs. This might lead to a lack of trust that needs to be addressed by CSOs and policy-makers alike.

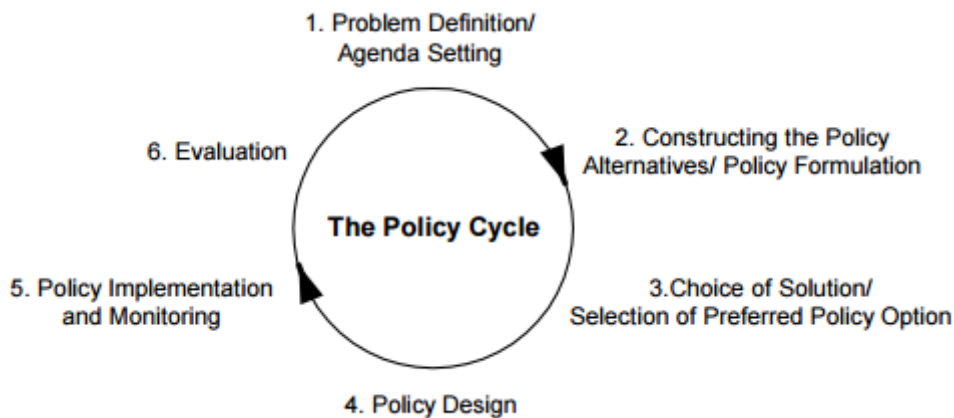
Examples of tensions and competing interests between CSOs and policy institutions were also found in the literature, for example, Lee (2010) notes that ongoing tensions between WHO and CSOs over access to medicines and the organisation's publications policy have created some degree of uncertainty over relations. Furthermore, Doyle & Patel (2008) explain that CSOs that compete with national and international agencies to influence policy have been side-lined.

### 3.6. Measuring policy influence and success

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<sup>49</sup> <https://icscentre.org/area/ingo-accountability-charter> (Accessed 5 July 2016)

One of the publications focused on the policy process and highlighted it as complex, given that it is shaped by a multitude of interacting forces and actors (Jones, 2011). Limited research was found on measurement of health policy influence but Lasswell's (1977) pivotal work contributed towards an understanding of the policy cycle as it breaks it down into a number of components, which are mapped in Figure 2 below.



Source: Young & Quinn (2002) in Pollard & Court (2005: 12)

Figure 2. Policy cycle

Monitoring and evaluation (M&E) is an important part of this process which allows *'to make a judgement about the merit, worth or performance of a programme or intervention'* (Tsui et al., 2014: 3). A policy goal can only be achieved if that policy is implemented and evaluated, which means that CSOs' efforts continue after legislation has been approved. The lack of resources faced by organisations that influence (in this case, CSOs) is limited and in many cases does not allow the implementation of robust M&E programmes, resulting in unclearly defined objectives and goals from the outset (Jones, 2011). Research shows that the 'theory of change' is essential for studying policy influence (Bouwen; 2002; Jones, 2011) and that some scholars applied exchange theories to measure influence based on exchange processes and networks analysis (Pappi & Henning, 1999).

### 3.7. Research limitations

Research limitations on patient participation and the need of indicators that enable the measurement and evaluation of this was one of the main issues identified in the literature. Gillies (1998: 114) asserts that *'it is largely accepted by those engaged in health promotion that a new package of indicators to measure the effects of community-based health promotion is needed'*. Due to the abstract nature of some policy approaches there is a lack of systematic empirical analysis, which could be supported through an information and reporting system as suggested by Anheier (2013).

Other research limitations were highlighted in several publications: Boaz et al. (2016: 2) consider that *'the potential for including patients in implementation processes and evaluating their impact on quality improvement has received limited attention'*, Giarelli et al. (2014: 165) state that only further research can unravel *'how civil society's involvement impacts health in advanced industrialised countries'* while Doyle and Patel (2008) call for additional research to analyse legitimacy claims of CSOs.

## 4. Research methodology

This study aims to answer the question: *'How successful is civil society, through patient organisations, in influencing EU health policies?'* Curtis et al. (2000: 1001) observe that *'qualitative research methods are increasingly recognised for their importance in the geography of health and healthcare'*. As this dissertation focuses on health policy-making and the involvement of civil society in EU policy, a phenomenon that is difficult to measure quantitatively, it was considered that a qualitative analysis would allow data collection necessary to understand the research problem. A qualitative analysis allows for personal and unique insights to be shared, the characterisation of organisational processes and dynamics, the understanding of changes over time and description of social interactions (Haq, 2014), which would not have been possible to capture otherwise.

### 4.1. Literature review

The objective of the review of scientific articles was twofold: provide context to the main research question and gain a thorough understanding of the research issues at hand. The review allowed for a classification of essential concepts related to civil society involvement in health policy, and supported the interview process by providing background and contextual information to the formulation of key questions. The literature review started before the interviews but some of the reading and analysis took place in parallel or shortly after the interviews, especially if clarification was needed when a specific issue raised during the interviews was unclear.

The following methods were used for selection of the literature: a search was done in Papers using a combination of the following keywords: 'patient involvement', 'civil society', 'health inequalities', 'community participation', 'European Union health policy' and 'participatory approaches'. From this first search, 58 papers were identified that seemed relevant from the title. Both the title and abstracts for all articles were read and inclusion/exclusion criteria were then applied, namely, if the topic of research did not seem relevant vis-à-vis the research question the article was excluded. 19 papers were fully read at this stage, and the sample was then

complemented by 9 papers (total - 28 papers) in an effort to collect additional data that would provide answers to the research question. These additional papers were found through references of the first sample and after a more detailed search in Google Scholars using a combination of the following key words: 'civil society influence policy'; 'evaluate policy influence'; 'measure civil society impact'; 'civil society assess to policy-makers'. Despite the redefinition of search terms, only a very limited number of publications address the ways that civil society influence health policy. 31 publications were left out after the initial search as they focus on patient participation in healthcare (e.g., shared decision-making (SDM)) or health research rather than policy work. In other cases, there was a focus on health policy but not enough elements about civil society or patient participation. In several cases, publications fully read focused on other (i.e., non-EU) regions such as Africa or Australia but it was considered that the case studies could provide relevant examples or best practices. The articles selected were published between 1992 and 2016.

In addition to the 28 scientific publications fully read, a desk review of grey literature including reports, policy documents and information in official websites of EU institutions was conducted to complement findings of the scientific literature. The desk review was particularly important for the development of the first and second chapters.

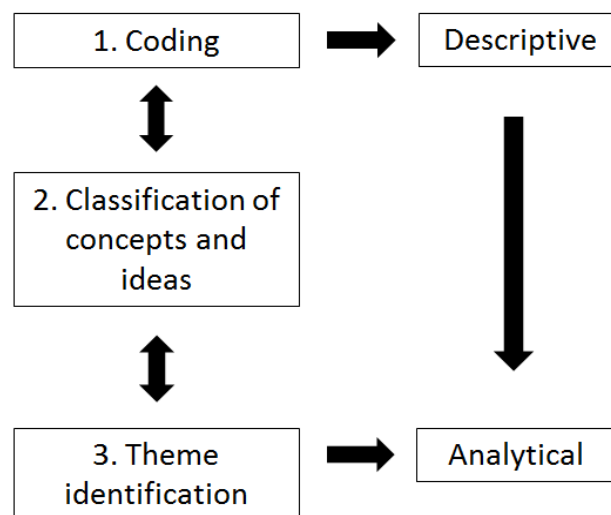
#### 4.2. Semi-structured interviews

In order to collect real-world evidence not fully captured in the literature, semi-structured one-to-one interviews were conducted with experts. The approach taken when analysing data from the interviews was an inductive one as concepts and ideas emerged from the results of the semi-structured interviews. This method was adopted to ensure that any pre-conceptions from personal experience did not interfere with data collection and analysis. A deductive approach was adopted at a later stage when concepts identified in the literature were compared with the main themes and concepts arising from interviews.

In preparation for the interviews, a discussion guide in the form of a matrix was developed (Annex I), which allowed for flexibility in the way the interview was run hence exploring individual experiences and perceptions in detail. Flexible conversations allowed for a two-way communication as well as for some concepts to be identified that were not considered when preparing the interview.

Interviews lasted between 20 minutes and 1 hour and were conducted in English. Interviews were recorded and fully transcribed.

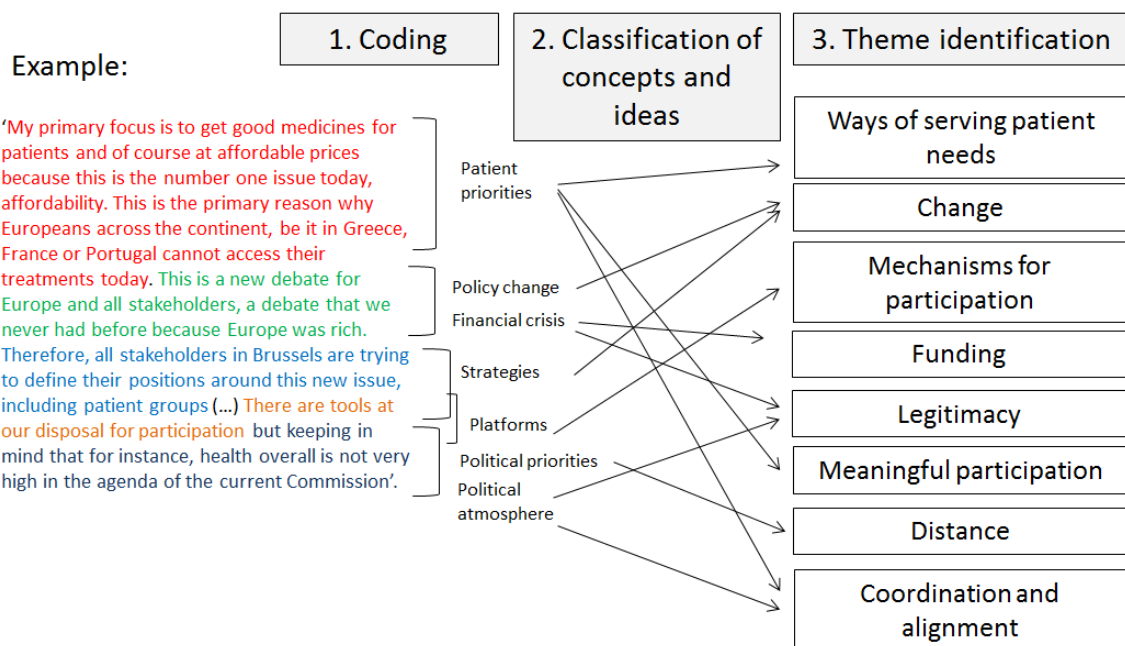
Interview data collection and analysis took place through coding and definition of themes where main concepts were grouped (Annex IV). First, the transcripts and notes of the interviews were coded to identify concepts and ideas that were relevant to the study; secondly, examples of these concepts have been collected; and thirdly, these concepts have been analysed to find commonalities or differences and grouped under themes. As demonstrated in figure 3, concepts were descriptive at first but gradually became analytical once common themes have been identified (Thomas & Harden, 2008).



Source: Own construction based on Gibbs (2011)

Figure 3. Coding process for analysis of interview data

The study by Ryan & Bernard (2003) on techniques to identify themes provided guidance to the data analysis process. Ryan & Bernard (2003: 87) consider that *‘themes are abstract (and often fuzzy) constructs that link not only expressions found in texts but also expressions found in images, sounds and objects (...) themes come in all shapes and sizes. Some themes are broad and sweeping constructs that link many different kinds of expressions. Other themes are more focused and link very specific kinds of expressions’*. Figure 4 provides an example of how themes have been identified.



Source: Own construction based on Gibbs (2011)

Figure 4. Examples of coding, classification and theme identification process

These themes are interrelated and are not mutually exclusive. For example, the idea that there is a financial crisis in Europe will be relevant to the theme ‘change’, as several respondents explained that they have to change their policy strategies and adapt, but also to the theme ‘funding’, as this financial crisis has an impact on the way CSOs are funded. A summary of the main themes and sub-themes identified is provided in Annex IV.

#### 4.3. Study sample



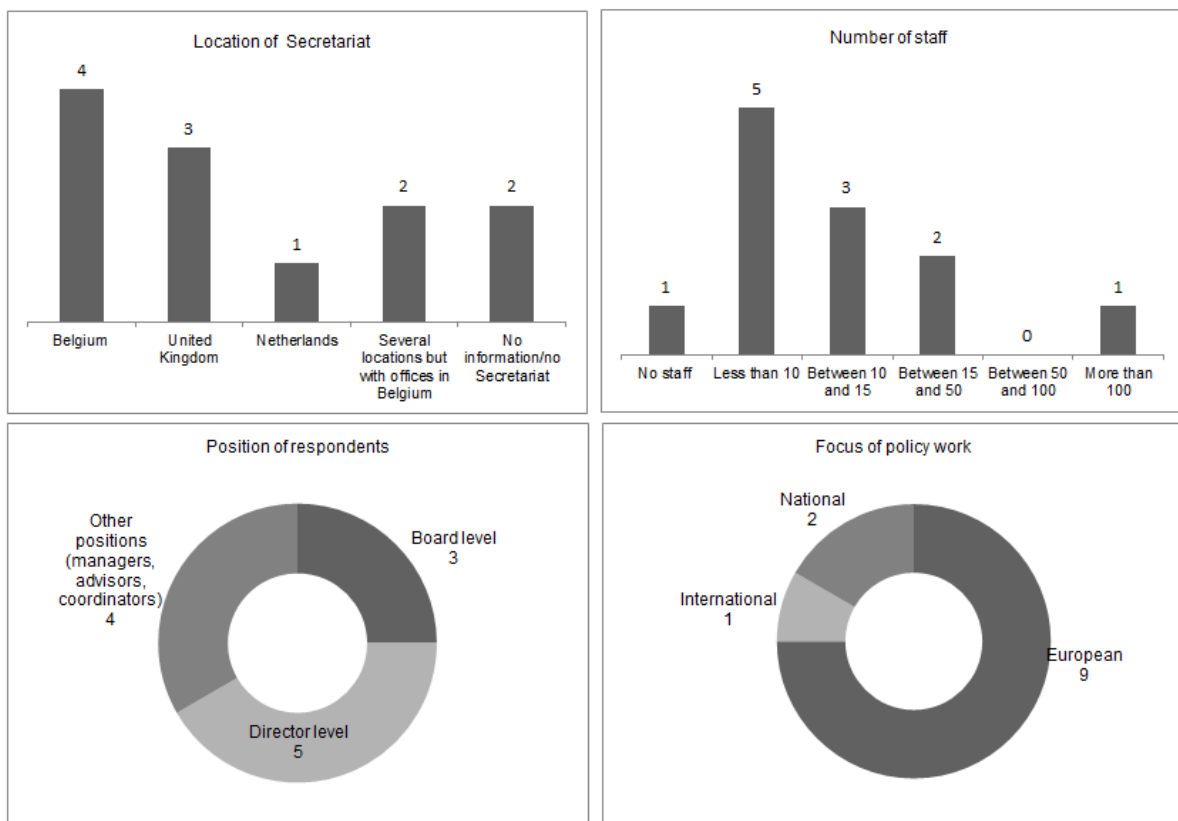
The sample was established using principles of qualitative sampling as defined by Curtis et al. (2000). The sample is relatively small but was studied intensively providing a large amount of information; selection has been sequential and there has been a 'rolling process' with coding and analysis taking place in an iterative fashion. In April 2016, a standardised email was sent to 20 CSOs and policy-makers introducing the research study and requesting participation (Annex III), 12 accepted to be interviewed and three rejected (two due to capacity issues and one without providing a reason). Others did not reply to the request or replied too late. In addition, three representatives in European institutions, one at the EC and two at the EP were contacted. The person at the EC accepted the invitation and provided contacts of another person in WHO who also accepted the invitation. One person at the EP (one MEP) accepted the invitation for a face-to-face meeting, which was not possible to organise; a request was sent for a phone interview but there was no response. The second person contacted at the EP (another MEP via assistants) did not reply.

A profile of respondents is provided in Annex II. There were 12 respondents from patient organisations/CSOs/NGOs (defined as CSOs in this study), one respondent that works for DG SANTE at the European Commission and one for WHO (both considered 'policy-makers' in this study). From the 12 organisations considered CSOs, it is important to note that one organisation is not a patient organisation (respondent 3) but rather a civic organisation representing patients amongst other groups (e.g., consumers); also, respondent 8 represents elderly and not necessarily patients but as there is a huge overlap between both groups it was considered important to include them. In total, 14 interviews were conducted between April and June 2016.

Patient representatives used different terms to present themselves and their organisations during interviews, some terms that are commonly used include advocate or advocacy organisation, community-based organisation, umbrella organisation, charity, NGO or CSO. The oldest organisation was founded in 1969 while the most recently established was founded in 2011.

All organisations are based in Europe, four in Belgium (three in Brussels, one in Diegem); three in the UK (two in London and one in Sheffield); one in Utrecht, Netherlands; two in several locations (one with an office in Rome, Italy and a second office in Brussels, Belgium; and one with a main office in Paris, France, and offices in Brussels, Belgium and Barcelona, Spain). Two provide no information about the location of the Secretariat in their website, possibly because they are volunteer-based and have no offices. 50% of the respondents have offices in Brussels.

Most of the organisations have a professional structure but one has no staff and two only have one staff member. The majority of the organisations employ less than 10 staff members and only a few of them are dedicated to policy work. One organisation has more than 400 employees. Three respondents were members of the Board of the organisation; five were considered to be in a Director’s level position (i.e. Executive Director, CEO, Secretary-General) and four held other positions, (i.e. managers, advisers and coordinators) but all of them with experience in EU health policy. Figure 5 provides an overview of the organisations interviewed (i.e. their location, number of staff and geographical remit) and of the position of respondents within the organisation.



## Figure 5. Profile of CSOs interviewed

When it comes to membership, most of the organisations interviewed (8) represent other organisations, with one representing individuals and organisations, one representing individuals only, one not being members-based and one presenting itself as a 'flexible network'. Several organisations that have other organisations as members highlighted in their website or during the interviews that they represent thousands of patients via their network. For example, respondent 4 considers representing the interests of 150 million patients across Europe, respondent 8 over 40 million people through their member organisations and respondent 5 about 50,000 individual patients. This demonstrates a potential 'cascade effect' whereby citizens are represented by national associations, and national associations are represented by European or international organisations. Such geographical patterns were also explored in the literature by Dür & Mateo (2012) who observed that national actors, influenced by national organisations, raise the association's interests close to European institutions. Most organisations (9) do policy work at the European level, with one focusing rather on the international level and two on national level with some European or international work.

## 5. An expert perspective: understanding the role of patient organisations in EU health policy

This section presents the analysis of the qualitative data collected through interviews with experts. The following issues have been explored through the expert interviews: the importance of patient empowerment and participation, how CSOs influence EU policies for health, which strategies and mechanisms are in place that allow for participation, which channels and initiatives are provided by EU institutions to facilitate participation, which forms of governance allow citizens to be represented at the EU level, what are the main challenges and gaps that hinder participation, and how CSOs measure whether they were successful in influencing EU policy. Examples and success stories have also been provided by the respondents.

This session is structured according to the main categories identified during the qualitative data analysis. The main themes identified include 1) the importance of patient participation and different ways of serving patient needs 2) access to policy-makers and mechanisms that allow for participation 3) importance of meaningful participation 4) challenges including funding issues, issues related to legitimacy and accountability, the importance of coordination and alignment, and the need for adaptation as a result of policy and priorities' change.

As previously discussed in the literature review, definitions of civil society and civil society organisations are complex. In light of this, one of the first objectives of the interview was to ask participants to describe their organisation, who they represent, their mission and objectives, and their geographical remit. In the interviews conducted, respondents used several terms to describe their organisations with both 'CSO' and 'NGO' often being used. Other terms used included 'patients' advocacy group', 'umbrella organisation', 'user' or 'community' groups, 'grassroot organisations', although the latter normally to define organisations working at national level closer to citizens rather than with European policy-makers. The literature showed that there is some confusion associated to the term civil society, which is sometimes mixed with associated terms (Clayman et al., 2015) and that these terms are often used interchangeably (Giarelli, 2004), which has also been proven to be the case in the expert interviews.

In terms of recognition from policy-makers and the formal channels to influence policy, there does not seem to be a specific status for patient organisations working with institutions such as WHO. One of the respondents working for WHO explained that these organisations are considered NGOs and that there is no specific categorisation for patient groups but he highlighted that the process by which these groups are recognised is a very important one. He said:

*'We always have to be very careful about the representativeness of these groups, their status, the way they are recognised by WHO, so it is quite a serious process'.*

It was confirmed in the desk review, conducted for the current thesis, which included the review of the websites of organisations that participated in the interviews, that organisations working at international level are more often called 'alliances' and focus more on policy and advocacy (e.g., respondent 1 or 2) while national organisations tend to offer services, share information, build capacity and deliver health interventions (e.g., respondent 7).

Some of the organisations interviewed work at both national and European while others focus on transnational issues such as the Sustainable Development Goals (SDGs). One of the organisations working at international level (respondent 2) said that they respect the principle of sovereignty and that internal matters are for the Member States to deal with. He noted, however, that the SDGs offer an opportunity to bring both spheres together.

*'We focus on the global and regional levels as we expect local member organisations to act within their borders because we respect the sovereignty principle. I would say that internal matters are matters for the member countries and the member organisations. Having said that, with the SDGs, there is a golden opportunity to actually merge the two, to have national and global act as one. For instance, if I produce a leaflet to improve access to care, that leaflet and the text, if it is clearly evidence based, could help a*

*country headaches if I make it available to local organisations free of charge. They can translate it into local languages and use it for their advocacy.'*

Similar feedback was received from respondent 4 who explained that it is difficult for her organisation to advocate at national level and that they want to avoid a top-down approach. She provided the example of the directive on cross-border healthcare<sup>50</sup>, in which they worked to ensure that certain elements were introduced, but highlighted that implementation of this directive is something important that requires monitoring and that there is groundwork to be done at national level. This shows that even if work is initiated at the European level, continued efforts are needed at the national level. Moreover, it was noted that this is the reason why capacity building of national organisations (i.e. their members) is a priority.

*'We have 17 members that form our National Patient Platform. We do not have them in every country, but sometimes, and this is what has happened in Italy and Portugal, when there is a willingness for organisations to come together, we try to support that process as much as we can. (...) For us it is difficult to advocate at national level and that is why we are focusing on capacity building of national organisations. They can do the work, they know the local situation, and they can report back to us. We have worked quite a lot on the follow up of the cross-border healthcare directive. For us the implementation is really important because there are some good things in the legislation itself but there has to be some groundwork at national level so that it is done the best way for patient organisations. We have developed a lot of guidelines, recommendations and organised events with local patients' representatives'.*

Despite this need to work with national actors and this close link with national organisations, the interviews showed that many of the issues that patient organisations work on are transnational in nature and as such cannot be solved at national level. Some of the respondents said that policy areas they work on include crossborder healthcare, transatlantic agreements or antimicrobial resistance, which

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<sup>50</sup> More information at: [http://ec.europa.eu/health/cross\\_border\\_care/policy/index\\_en.htm](http://ec.europa.eu/health/cross_border_care/policy/index_en.htm) (Accessed 3 July 2016)

has undoubtedly become a global issue. As demonstrated in the literature, the concept of global health governance has recently emerged (Stoeva et al., 2015), and this transnationality of health issues is also the reason why international actors such as WHO exist, and why European institutions have a responsibility in health, not aiming to duplicate what is being done by States but to address global issues such as emergencies, and to add value to the work that is already being done at country level. At the same time, the qualitative data shows that supranational organisations work with States to ensure that they deliver on health commitments. Respondent 2 from an international organisation representing patients highlighted the importance of States ratifying global documents such as declarations by WHO or the UN as this provides a mechanism for NGOs to exert pressure on countries to ensure that commitments are met. He particularly mentioned the work of his organisation to advocate for the inclusion of target 3.8<sup>51</sup> in the SDGs<sup>52</sup> and said:

*'We know very well that when countries signed up to WHO's Constitution, they also signed up to the right to health. The right to health is a recognised and an enforceable legal right in international law because it appears on an international ratified treaty. How does SDG 3.8 influence the right to health? It creates a bigger obligation from States to enact. That gives us more leverage and more power to go back to each MS and ask them to start honouring their commitments'.*

The influence that this organisation might exert shows the role that CSOs have in demanding the accountability of health officials at the national and international level as Battams (2014) and Bas et al. (2008) have previously argued.

As was verified in the interviews, the membership of European and international organisations is normally composed of other organisations while the membership of national organisations is normally composed of individuals, consumers or patients,

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<sup>51</sup> Development goal 3.8: 'Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all'. More information at: <https://sustainabledevelopment.un.org/sdg3> (Accessed 2 July 2016)

<sup>52</sup> SDGs are an intergovernmental set of Goals with 169 targets contained in paragraph 54 of the United Nations Resolution A/RES/70/1 of 25 September 2015. More information at: <https://sustainabledevelopment.un.org/sdgs> (Accessed 2 July 2016)

also known as end-users. Some organisations may also have a mixed membership structure as explained by Respondent 9 who said that in some cases patients suffering with a rare disease do not have a national organisation to represent them given that the disease is so rare. In these situations, individuals are accepted as members. This shows that different factors influence the structure of CSOs and their constituencies, which will ultimately influence how they are defined and presented.

### 5.1. Importance of patient participation and the different ways of serving patient needs

The policy-makers that have been interviewed highlighted the importance of civil society in health with one of the participants saying:

*'Policy-makers look at things from a rather top level perspective and they may have a tendency to see things in a traditional way, related to how they have acted on this theme also in the past. Patients bring a bottom up perspective, experience and a real-life experience of health problems and bringing the two perspectives together clearly offers better insights into the problem and also into the solutions'.*

This narrative highlights the value of combining the policy level with the lived experience of patients in offering more holistic solutions. CSOs considered that policy-makers are cooperative and hear their voice but as explained later in this section there is sometimes a 'feeling of obligation'.

Respondent 3, an organisation that promotes civic participation at national, and more recently, at the European level highlighted the importance of participation and said:

*'The point is: are you interested just to vote in elections and pay taxes or as a citizen are you interested in being involved, in improving the quality of life in the neighbourhood where you live, school, health services, etc.? Our idea is that citizens have a role in society that is not only to vote or pay taxes each year, they have a role in the daily life and should be involved so that quality of*



*life improves. We strongly believe that citizens have to take an active role in the protection of common goods'.*

Respondent 10 representing an organisation focusing on respiratory diseases provided a comprehensive view of why patient participation is important. She highlighted different aspects, one is rather fundamental and ethical, '*we should not be talking about treatment without involving patients, it is just ethically wrong doing so*', she said, but another aspect was a rather practical one, when, for example, healthcare practitioners miss important practical points that only patients understand. For example, in one of the projects where her organisation participated patients enrolled in a clinical trial were requested by practitioners to visit the hospital three times, with separate visits, which was quickly raised as an issue by the patients, as these were individuals with respiratory difficulties. This led to a protocol change and the recruitment rate increased. This shows how very simple and practical feedback from patients can influence a clinical trial protocol in a way that will lead to higher recruitment rates. The importance of civil society participation was also confirmed by the literature review (e.g., Lee, 2010; Anheier, 2013; Battams, 2014; Giarelli et al., 2014; Filc, 2014) and several authors provide examples of success (e.g., Seckinelgin, 2002; Kapstein & Busby, 2010; Galjour, 2012).

The interviews demonstrate, confirming past studies (e.g., Doyle & Patel, 2008; Giarelli et al., 2014), that there is a dual mandate of health CSOs, in cases where organisations do policy work but also provide services to the patient community, for example, through information sharing and capacity building. The discussions with representatives from CSOs showed that there are different ways of serving patient needs and the CSOs interviewed seemed to focus on 'niches', possibly to avoid duplication of efforts and ensure complementarity. Respondents 1 and 4, for example, mentioned that a priority area is affordability, quality and access to medicines; respondent 2 is focusing on ensuring that MSs commitments to SDGs are met; respondent 8 is making efforts to ensure that legislation for equal treatment of people irrespective of age but also religion, belief, disability and sexual orientation is approved by the European Council; respondent 3 as a civic organisation focuses on the protection of citizen rights; and respondent 7 said that research and in particular patient data is where they pitched their involvement at the EU level.

## 5.2. Access and mechanisms for participation

Respondents mentioned a number of mechanisms that allow them to participate and access policy-makers. The platform that was most often mentioned was the EU Health Policy Forum (HPF), established in 2001 to provide a communication channel between the EC and NGOs, and to allow stakeholders to identify issues and propose policy options.

The HPF brings together 52 umbrella organisations<sup>53</sup> representing European health stakeholders, including patients, and specific working groups to discuss pressing issues and develop and present recommendations to the EC during meetings. One of the policy-makers working for the European Commission referred to it as an important instrument for the mental health community, he explained that a thematic network had been established, which should lead to a joint statement by the NGOs that participate. He said that this is an instrument that brings NGOs together and in this particular case he noted the importance of decreasing the isolation of mental health NGOs. As he elaborates in his own words:

*'The objective is to have something more representative including all the relevant NGOs in the mental health field, hopefully also with NGOs from other areas because this separation and isolation of mental health NGOs in the public health community is a disadvantage'.*

These discussions within working groups are complemented by feedback received during an annual major event, the 'EU Open Health Forum', which allows for the participation of a larger number of health representatives, including some of the respondents, in the policy debate<sup>54</sup>.

Although the Forum is considered a collaborative, transparent and inclusive platform as found through desk review conducted as part of this study, a renewed format was proposed in 2015, which allows for more openness and a revamped EU HPF, called

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<sup>53</sup> [http://ec.europa.eu/health/archive/ph\\_overview/health\\_forum/docs/members.pdf](http://ec.europa.eu/health/archive/ph_overview/health_forum/docs/members.pdf) (Accessed 28 June 2016)

<sup>54</sup> [http://ec.europa.eu/health/interest\\_groups/eu\\_health\\_forum/policy\\_forum/index\\_en.htm](http://ec.europa.eu/health/interest_groups/eu_health_forum/policy_forum/index_en.htm) (Accessed 28 June 2016)

EU Health Policy Platform (HPP) was presented in April 2016 in Brussels to health stakeholders. Several respondents mentioned the HPF as an important platform where they participate and said that they are looking forward to see if the new platform will provide the same (or improved) opportunities for dialogue with the EC.

The interviews demonstrate that CSO form coalitions and strategise when needed as was specifically noted by respondent 12 who said that civil society missed the HPF during the transition period and explained that CSOs continued to meet to discuss issues of common interest while the revamped platform was not yet up and running. Although the link with the EU institutions was missing, CSOs filled the gap of the platform, working as an alliance at the transnational level without the EU instigating it directly.

The desk review conducted as part of this study showed that the criticism of the EU's democratic deficit and calls for more citizen participation resulted in the launch of the European Citizens Initiative (ECI), which was created to allow EU citizens to make proposals to the EC. At least 1 million signatures from at least 7 of the 28 EU countries are required for the process to initiate.<sup>55</sup> This is a specific tool for participatory and direct democracy and one of the respondents highlighted that they were closely involved in two ECIs, one on stem cell research and one aimed at defending the use of animals in research.

Another platform mentioned by several respondents is the Patient and Consumer Working Party (PCWP) of the European Medicines Agency (EMA). This was considered an important place to be represented in by several organisations that were interviewed, including by respondents 4, 8 and 9. Indeed, respondent 9 from an European organisation representing rare diseases focused on the importance of working with the EMA, where they participate in three committees, which was not the case for other CSOs interviewed. The members of this organisation are selected to participate in these committees depending on their expertise, and occasionally, if the organisation is asked to work on a dossier on certain medicinal drugs and there is no expertise 'in-house', they reach out to experts outside their network. This shows that

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<sup>55</sup>: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV:ai0044> (Accessed 10 June 2016)

'patient experts' provide feedback to EMA and that CSOs play a role in facilitating the process (i.e. selection of experts, ensuring feedback from other patients is collected, etc.).

At the EP, the mechanisms seem to be more 'fluid', with conversations taking place *'behind closed doors'* although there are some opportunities for participation through Interest Groups normally founded and composed by MEPs who work closely with NGOs, established to influence policy on specific themes. Some of the Interest Groups mentioned by respondents included the Rights' and Cross-border Healthcare Interest Group where respondent 3 plays an active role or the Brain, Mind and Pain Interest Group launched by the organisations of respondents 5 and 6. In the case of these respondents, the launching, coordination or holding the Secretariat of such groups seemed to be their core business. In other cases, CSOs interviewed were well aware of these groups and participated in meetings at the EP but did not play such an active role.

The opportunities to work with the European Council seem to be narrower according to our research. However, two of the organisations in our study, respondents 1 and 4 mentioned that they work with the Council and also with health attachés of Permanent Representations in Brussels in an advocate's capacity. Respondent 8 also noted that they organise an event with the European Council on the needs of elderly people on an annual basis, which helps raising awareness and mobilise political support. The Presidency of the European Council also seems to offer opportunities for engagement, depending on the priorities of the Member State holding the Presidency in a given semester. For example, respondent 4 said that they were closely involved with the Luxembourg Presidency on personalised medicines, and respondent 3, who represents an Italian organisation noted that the Italian Presidency in the second half of 2014 supported the inclusion of issues like chronic pain and palliative care in the European agenda. In this case, it is likely that this organisation worked closely with the Italian Presidency given that they were founded and are established in Italy. This does not preclude work with other Presidencies as demonstrated by respondent 4, an European organisation with offices in Belgium working closely with the Luxembourg Presidency.

It also became apparent during interviews that some CSOs consider that they have an *'official relationship'* with the UN or EU institutions. As in the literature review, no evidence was found on whether CSOs that undertake the 'official route' and have more formalised relationship with institutions are more successful than others. One organisation said that they have an *'official and recognised relationship with the WHO and that they support all of their policies'*, and other that they are officially recognised as an official stakeholder by DG SANTE. When this respondent was asked what the definition of 'official' was, membership and participation in meetings at the HPP and other EU-coordinated platforms were given as an example. This respondent's understanding of an 'official' relationship does not correspond with the definition in a discussion paper (2010) on building partnerships between the EC and NGOs<sup>56</sup>.

Most of the organisations provided examples of meetings that they normally attend or expert groups where they normally sit. When asked about access to EU institutions, however, one of the respondents noted the difficulty in access for those who were not already privileged members or for newcomers:

*'There are mechanisms but in theory... in practice, they are more likely to look at people they know, and they are going to ask them first to participate. It is very difficult to get in the circle where they ask for advice. A lot of lobbying is needed before you get into that circle.'*

Another element related to access that was highlight by several respondents was the idea that geographic proximity influences the level of access to policy-makers. Organisations that do not have an office in Brussels showed that they need to form alliances or second Brussels-based partners for policy work.

In summary, platforms exist that allow for participation of civil society but the degree of proximity and the possibility to influence depends on the European institution. There is also evidence that shows that there are obstacles in gaining access to EU

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<sup>56</sup> [http://ec.europa.eu/transparency/civil\\_society/ngo/docs/communication\\_en.pdf](http://ec.europa.eu/transparency/civil_society/ngo/docs/communication_en.pdf) (Accessed 13 July 2016). The paper contends that an 'official relationship' relates to a structured dialogue and co-operation as well as formalised consultations that the EC aims to have with NGOs, rather than ad-hoc meetings.

institutions which are based on familiar pre-established working relationships and geographical proximity. Overall, findings from interviews with CSOs show that there is an uneven level of access granted to the CSOs we studied by EU policy-makers. Some organisations had more access than others, and reliance on coalitions, and delegation of work and responsibilities to organisations that are closer to policy-makers was shown as an important feature of the CSO participation process.

### 5.3. Meaningful participation

The establishment of platforms and fora by European institutions that facilitate patient participation demonstrate that civil society is seen as an important partner, however, in order to fully address the research question, it was considered important to investigate if patients that participate in EU committees, expert groups or taskforces feel that their voice is heard and if their recommendations are being taken into policy and practice. This relates to the concept of meaningful participation discussed in the literature review (e.g., Lee, 2010; Cohn et al., 2011; Battams, 2014).

Respondent 4 coordinated a project funded by the EC, which aimed at defining meaningful patient involvement. According to this study, meaningful involvement means that *'patients take an active role in activities or decisions that will have consequences for the patient community, because of their specific knowledge and relevant experience as patients. The involvement must be planned, appropriately resourced, carried out, and evaluated, according to the values and purposes of the participating patients or patient organisations; other participating organisations and funding bodies and the quality of their experiences during the involvement activity<sup>57</sup>'*.

Respondent 4 also added:

*'What we say is that meaningful patient involvement means that the involvement is done according to the priority of the patient. Sometimes there is a tokenistic approach to patient involvement, and the idea that the patient has to be around the table to tick a box. Other times projects come last minute*

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<sup>57</sup> <http://www.eu-patient.eu/globalassets/projects/valueplus/value-toolkit.pdf> (Accessed 3 July 2016)

*to patient organisations because this looks good. We are trying to fight against this approach’.*

Some respondents felt that their voice was heard but there was a recurring sentiment that there is a ‘feeling of obligation’ when it comes to patient participation rather than a genuine desire to hear the patient’s experience. An informant working for a pan-European alliance said:

*‘There are enough mechanisms but the problem is that a lot of these channels are in some cases just for superficial reasons or for the EC to tick the box and show stakeholder engagement. What I am trying to say is that indeed there are these tools that are at our disposal but we should also keep in mind that health is not very high in the agenda of the current Commission’.*

One of the respondents representing patients living with Parkinson’s disease emphasised the importance of meaningful patient involvement in the research field as well as the importance of results:

*‘The Brain, Mind and Pain interest group is having a session in the European Parliament about patient involvement in research. I suppose the thing for us is it has to be true. It has to be meaningful involvement and people have to also see that once their views have been taken on board, things have changed’.*

One of the policy-makers working for the European Commission also referred to meaningful involvement and said:

*‘Patient organisations and patients have expressed through surveys that what they need is a sense of meaningfulness...’.*

The idea that policy trends have an impact in the level of access was also brought up by another respondent who said that the possibility for participation depends on the policy area:

*'There are mechanisms but the involvement is not always systematic. For example, at the moment I am working very much on medical devices, and the involvement is not at all comparable as to medicines'.*

A respondent working in the UK said that true and meaningful involvement means that there is change once patient views are taken on board. In some cases, there are consultations but it is difficult to understand if there was a change, or what the change means in practice given the abstract nature of directives and regulations, in particular if there is a feeling that consultation is tokenistic.

Another idea that emerged was that more official representation is needed in lieu of participation in advisory roles and taskforces. One of the patient organisations working at the supranational level said that they would welcome patients '*employed by the structures*' and plans to start a project to know how many employees of European institutions are patients, and in which positions. He said:

*'We find that the EU has improved tremendously over some of the engagement rules but there is still room for more. We need more representation of patients officially and not as advisors or as task-forces, but actually employed directly, meaning, we want to see patients employed by the structures. Even with the European Council, we would like to ask them to do an internal audit and find out how many patients are there employed officially, and at what stage of decision-making are they. Are they placed at directorship level? What kind of jobs are they doing? Those are the kind of things we are looking for, real engagement, and not just having a task-force or something like that.'*

In contrast with the opinions of the respondents from the CSOs earlier in this section, policy-makers tended to present a much more positive and uncritical discourse regarding meaningful participation. One of the policy-makers working for WHO noted that their voice is heard because they are seen as a very important constituency while the policy-maker working at the European Commission emphasised patients' activism and motivation:



*'They are sitting around the table and have equal status and are listened to. They are even listened to sometimes more than just on an equal basis because they are often seen as representing a very important constituency. They are taken very seriously (...) It is crucial to hear their voices and that has to be taken seriously. If we want to have effective, safe services, we need to know what this means to the people using these services'*

*'Their voice is really heard because they are very active and motivated. In fact, we also have indirect collaboration with the patient organisations through the activities that they do together with the European Parliament. One of the patient organisations is the Secretary of an MEP (Members of the European Parliament) Interest Group on Mental Health. You should also note that people who are themselves experiencing mental health problems have been regularly invited as speakers for meetings in the European Parliament'*

The notion of meaningful participation cannot be fully explored without investigating the reasons that make patients want to participate. Some of the factors that influence the desire, need and willingness to participate were explored in the literature review and included age, education status, disease severity, ethnic, cultural factors (McDermott & Pederson, 2016) as well as health literacy, knowledge, experience, personality and trust (Thompson, 2007 as cited by McDermott & Pederson, 2016). Disease awareness was mentioned in the interviews whilst it was not mentioned in the literature, as it seems that patients that suffer with diseases less known may need to engage more than others; at the same time as patients affected by diseases that get more media and political attention may be more interested in becoming involved, as they may find it easier to influence. As in the literature, knowledge was also mentioned as one of the factors by respondent 10 who explained that some diseases are less understood than others, and in these cases raising awareness is needed. One of the examples given by this respondent was the campaign 'Healthy Lungs' launched by the European Lung Foundation (ELF) to create awareness about respiratory diseases which are often undervalued and not well understood.

Findings of the interviews also demonstrate that some communities are more active than others. For example, the policy-maker working for the European Commission said:

*'The mental health community is quite present but it is not as powerful as the activists in other areas like AIDS or the lesbian, gay, bisexual, trans, and/or intersex (LGBTI) community. Why is that? Probably because mental health is such a wide field and there is usual a distinction between people with common and severe mental disorders or mild to moderate and severe mental disorders. That creates some vagueness which is difficult to address.'*

One of the aspects that might explain different levels of involvement could be stigma and discrimination, i.e. patients that are discriminated because of their disease might refrain from participating. As disease is linked with social determinants, patients normally face a 'double vulnerability', which means that in addition to suffering from illness, they face social and economic challenges. A policy-maker highlighted:

*'Some groups are clearly vulnerable and that is one of the key challenges (...) the social exclusion that they are facing. They are part of social and economic vulnerable groups themselves. It's a double vulnerability and that is a problem in this context.'*

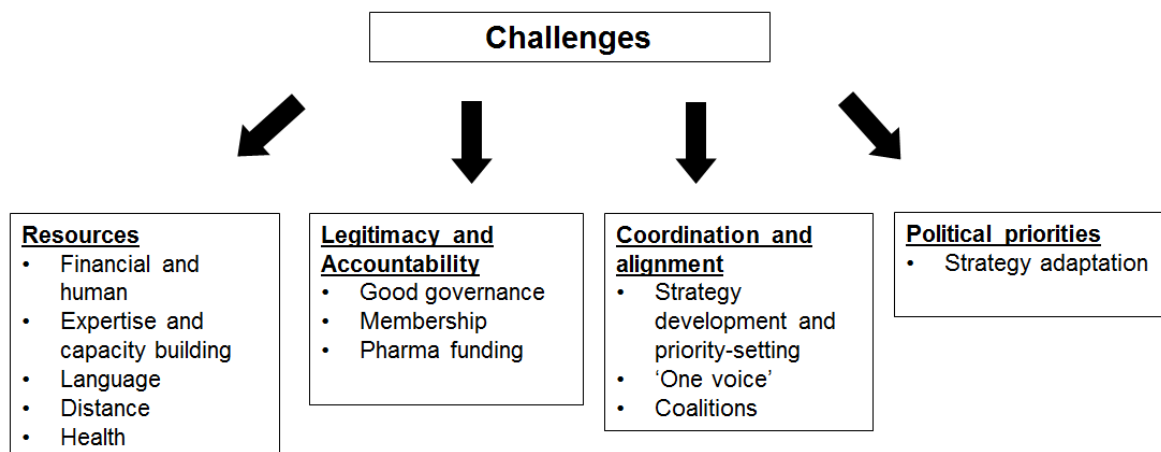
Another aspect that was not found in the scientific literature but was observed during the qualitative data analysis is that health in itself (i.e. being healthy) also influences participation. The fact that patients suffer from conditions that may affect their ability to be active, travel and overall engage in policy was raised by respondents 2 and 10. For example, respondent 2 noted, *'we need to recognise that disease and its symptoms can be very exhausting, and that very often there is no energy left for anything else'*.

In summary, the importance of meaningful participation was specifically mentioned at least by half of the civil society organisations that participated in this study. Furthermore, the idea that change should be an observable result from the patients' input into a given discussion was mentioned by at least one respondent. One of the

organisations coordinated a project funded by the EC aimed at defining ‘meaningful participation’, which shows that this is a theme that interests policy-makers. Although respondents from civil society expressed some concerns about what motivates institutions to capture patients’ views, policy-makers in this study considered that patients’ real life experiences provide valuable insights into problems and that their voice is heard.

#### 5.4. Challenges

Another important emergent theme of this investigation was challenges that patient organisations or the wider civil society face when trying to influence policy. A summary of the challenges found through interview data analysis are provided in Figure 6 and each will be discussed in turn.



Source: Own construction

Figure 6. Summary of challenges identified through the qualitative data analysis

## **Resources**

The limitation that was most frequently mentioned by respondents was the need for financial resources, followed by expertise and capacity building, as these were considered to be valuable resources that determine the ability that organisations have to pursue and achieve their objectives. At least 8 organisations considered that financial resources are the main challenge faced by patient groups (respondents 1, 3, 5, 6, 8, 9, 11, 12), and other organisations mentioned challenges that would only be possible to tackle if financial resources are available (e.g., need for human resources or no representation or offices in Brussels, which creates a certain distance to policy-makers; a need for translated materials, etc.). The lack of financial resources was also confirmed by both policy-makers that participated in this study, with one of them specifically mentioning the importance of commitment from both sides:

*'There is always something that could be improved, but that is both ways. We are busy, they are busy and we try hard. It is possible to engage even more in everything, but there is also a funding issue and a time issue. In the end, it all depends on commitment from both sides.'*

The number of funding sources was said to be limited by the respondents and more project funding - in most cases through funds from the EC - is being sought. Funding can be restricted or unrestricted. Restricted funding is normally linked to projects with clear deliverables and milestones. Respondent 4 said that this can be challenging given that it is not possible to know years in advance, at the proposal writing stage, which consultations or legislations they will be working on. It was also highlighted that in some cases patients attend meetings as volunteers without any form of compensation for their time, and that they are willing to pay in advance for their travel expenses and get reimbursed afterwards. These are practical aspects that seem to influence the capacity for participation. One of the policy-makers highlighted commonly shared sentiments:

*'One obstacle which the NGOs themselves would always highlight are financial limitations. We are inviting NGOs to contribute to our work but they have to find the resources in order to be able to do the intelligence work and provide us with this input. That can be very difficult. This also represents a huge conflict. Some of them receive funding from industry, others refuse such funding. Then they can be even more dependent on EU funding which is given only over a period of time. They then need to find other funding sources. Funding is certainly the biggest obstacle'.*

At least three of the organisations interviewed provided similar feedback to the one given by this policy-maker. One of the respondents working at national and European level explained their funding sources and noted the following:

*'It is not easy to find the economic resources that we need... and we find funds from public and private sources as well as donations directly given by citizens. At national level, our source of funding is both public and private. We also receive European funds, and by private sources I mean foundations, companies, etc. Donations from citizens only happen at the national level, not at the European level'.*

Human resources are linked to the need for financial resources and another respondent representing patients at European level said:

*'There are many topics on which we could participate but there is sometimes a human resource challenge that does not allow us to participate. Also, the fact that our involvement cannot be very well planned is a challenge. In some projects, we are involved in advisory boards without any compensation for our time. This is not the kind of involvement that we want and it is not the kind of involvement that produces results'.*

Another organisation highlighted how financial resources would allow them to travel and produce materials in additional languages:

*'Travel is also required as not everything happens in Brussels. Language is a major issue and with budget cuts the possibilities for translation are limited. There is a feeling that the EU is getting more and more apart from its citizens and has everything in English, which does not always help.'*

One of the European alliances specifically explained how the financial crisis has changed the way that patient organisations advocate at the EU level.

*'My primary objective is to get good medicines to patients and of course at affordable prices because this is the number one issue today, affordability. The fact that we have insane prices for medicines has become an issue in Europe. This is the primary reason why Europeans across the continent, be it in Greece, France or Portugal, cannot access their treatments today. This is a new debate for Europe and all stakeholders, a debate that we never had before in Europe because we were rich. Now we are not rich anymore. Countries are facing this new challenge, which has also been translated into a very heated political debate. All stakeholders in Brussels are trying to define their positions around this new issue, including patient groups. It is important to keep in mind that this is a new debate related to one of the most profitable sectors in the World so it is very politically sensitive, and it has to do with the different levels of interaction, influence and stakeholder engagement in the EU Brussels 'bubble'.'*

In terms of human capacity and expertise, patients need to have the necessary know how in order to influence policy. CSOs tend to have this expertise in their membership (often, 'expert patients') but the feedback received by the majority of the organisations interviewed also points to a lack of expertise and the need for more information sharing and capacity building:

*'Patients can only be empowered if they have timely, accurate and relevant information. Unless we have information solidly in our hands, we do not have true empowerment'.*

There was also the idea that confidence and self-belief are key elements of empowerment; respondent 2 stated that *'a lot of patient groups become uncertain of what they should do'*, and respondent 7 emphasised that the time given by policy-makers for patients to provide feedback on complex matters is limited:

*'Quite a lot of times questions are asked that are very difficult for people to answer simply, we find ourselves translating things into plain English, and then approaching people to ask what they think about particular things'.*

Respondent 7 who is working in the UK said that it can be very difficult to understand which mechanisms exist, and how to participate and exert influence:

*'It is quite difficult to explain why you want people in the UK to work with MEPs. MEPs are almost these mythical creatures... everything is really abstract. Pretty much what most people will think of in terms of Europe are bureaucracy, immigration and sending money to Europe. People do not know who their MEPs are so I think it is really difficult for us to try and engage our supporters in activities that focus on Europe. Whenever we do a campaign and try to engage our supporters, it is trying to think actually what would make a difference for Mr. Brown in Scarborough or Mrs. Smith in Bristol. Things are really abstract in Europe. It is difficult to understand how you influence and obviously because the Parliament is very much made up of Interest Groups and party groups, it is difficult to understand exactly how you get in and influence those. I have just started getting the daily digest about what is coming out from the EP and that was really helpful but you do not necessarily get information about exactly what an organisation like Parkinson's UK or what an individual citizen could do. Possibly there is a little bit of resource or investment in communicating some of those things. Maybe it is for the patient organisations to work together in a more collaborative and better way to drill down into some of those things. It is a combination of both the EP and the EC, and also patient organisations needing to do a little bit more work to understand exactly how patients can contribute'.*

This statement shows how Europe is being perceived as undemocratic and bureaucratic, and it highlights the importance of making European processes more engaging and understandable. Moreover, there seems to be a lack of information on citizenship participation that could be addressed, according to several respondents, through production of materials into different languages, as well as through sharing of information and expertise.

Feedback from respondent 9 also included some concerns about bureaucracy at the EU level: *'sometimes there are bureaucratic issues before patients can participate, mostly related to confidentiality and conflict of interest'*. This informant explained that the organisation where she works helps patients to deal with this bureaucracy, showing that one of the roles of CSOs might be to bridge the gap that exists between patients and policy-makers, and facilitate the involvement of the patients or citizens in the policy process. This was not specifically mentioned as one of the roles of civil society in the scientific literature.

The need for capacity building was found both in the literature and through the qualitative data analysis. But whose responsibility is it to invest in building civil society capacity? The literature has shown that capacity building should be ensured through public support for CSOs (e.g., Giarelli et al., 2014) and this was consistent with the views shared by respondent 3 who highlighted the responsibility of the public sector in funding health. Examples of public support have been shared during the interviews and one of the policy-makers considered that MSs have this responsibility and said that Action Plans developed by WHO state that countries should provide funding towards development and support of patient organisations.

*'I do think this is the responsibility of the countries. We have included it in the Action Plan as well, i.e., the European Action Plan does say that countries should provide funding towards the development and support of patient groups. We haven't got the funding for that and I also do not think it is our role. I think it is very much the role of the countries they come from.'*



An example of a capacity building programme being supported by a national government is the Expert Patient Program, which started in 2002 as a research project by the UK Department of Health and became a community-interest company (CIC) in 2007. The programme aims to give patients ‘more control’<sup>58</sup> by providing cognitive therapy courses for people with long-term illnesses, such as diabetes, arthritis or respiratory problems. Respondent 2 said:

*‘What comes up majorly following that empowerment is the development of expert patients, capacity building within the patients... Expert patients are patients that are trained, know their condition well, the health system well, have been trained in negotiation skills and therefore can stand on their own two feet and seek health from the system. We do need programmes like the Expert Patient Programme to help developing that capacity’.*

The feedback provided through the interviews show that CSOs also consider having a role to play, and a number of capacity building initiatives led, funded and supported by these organisations were mentioned. For example, when the European Respiratory Society (ERS) published a book on lung disease, respondent 10 made it more readable and accessible, not only to patients but also to policy-makers. They also developed the European Patient Ambassador Programme<sup>59</sup> (EPAP), a free tool translated into several languages that can be used by any patient organisation to train patients, which shows that these efforts are made for the entire community rather than for a specific group of patients.

Respondent 9 has set up a training programme aimed at empowering patients to advocate directly at EU and national levels. The training is focused on aspects of clinical research, health technology assessment (HAT), pricing, etc. Respondent 3 provides free information and guidance to citizens (including patients) through their Citizen Advisory Service while respondent 4 supports national organisations in developing their Strategic Plans and with the organisation of local events.

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<sup>58</sup> <https://www.gov.uk/government/case-studies/the-expert-patients-programme> (Accessed 3 July 2016)

<sup>59</sup> More information at: [http://www.europeanlung.org/en/projects-and-research/projects/european-patient-ambassador-programme-\(epap\)/home](http://www.europeanlung.org/en/projects-and-research/projects/european-patient-ambassador-programme-(epap)/home) (Accessed 5 July 2016)

## ***Legitimacy and accountability***

The literature shows how issues related to legitimacy and accountability are closely linked to civil society participation in policy-making processes (e.g., Doyle & Patel, 2008; Lee, 2010), and the qualitative data analysis corroborates this. The majority of the respondents mentioned legitimacy issues around patient participation and demonstrated to be well aware that this is a research topic that captures the interest of academia.

One of the policy-makers highlighted representativeness as a key challenge and said:

*'I am not always sure who they represent and how these patient groups have been formed. That is quite critical because they can say that they are patient groups but this doesn't mean that they necessarily represent the voice of the people out there. The other issue is that sometimes the person being nominated to participate in certain meetings or initiatives does not always provide feedback back to the organisations and I am not always sure that they really talk on behalf of these organisations very well. That can be a real problem'.*

Another policy-maker said:

*'On the one hand, there is the legitimacy gap, but on the other hand, there is also a gap which these organisations are filling. That is why we have to work together with them. Only when they act with legitimacy, credibility and quality, only then they will also achieve the impact that they are seeking and will be heard'.*

This statement shows that policy institutions may work with patient organisations to address legitimacy issues. Indeed, respondents 4, 5 and 6 mentioned the work of the EU institutions to ensure transparency in the policy process with the Transparency

Register operated jointly by the EC and the EP being given as an example. The objective of the Register (and a Code of Conduct that was developed to govern relations) is to answer questions related to transparency at the EU policy level and ensure that EU decisions are taken in a transparent and open manner.<sup>60</sup>

When asked about legitimacy, the majority of the respondents referred to their membership. More specifically, it was considered that their members and the way they participate in the organisation's activities contributes to the legitimacy of these organisations. Respondent 4 said:

*'Our Board is composed of patients and our staff members are professionals, but we are only a means to an end, we are not the ones deciding. Of course we have reflected on this issue, and that is why we have more and more working groups where our members can provide feedback. It is important to have strong membership, and that is why we spend a lot of time focused on building capacity of national and some European patient organisations'.*

Several organisations explained the process for involving members in decision-making: for example, respondent 8 has a number of task-forces where members nominate experts to ensure that there is the expertise required to discuss a certain topic. Respondent 10 said her organisation's positions are developed through advisory or steering groups composed by partners from their network or individual patients and respondent 7 works with policy panels where their supporters (i.e. people living with Parkinson's, their families or carers) participate.

Although the importance of assessing CSOs' membership was considered important in the scientific literature (Lee, 2010), none of the respondents specifically explained which mechanisms they have in place to assess their membership.

After membership, the most common issue highlighted during the interviews in the context of legitimacy was sources of funding. Respondent 2 noted that *'legitimacy*

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<sup>60</sup> [http://ec.europa.eu/transparencyregister/public/staticPage/displayStaticPage.do;TRPUBLICID-prod=WWaDaNCgBqzFloj-ydKMSRnFf4ehx8zrUaiWzfPP5bnyCY1veBZ!!-590538967?locale=en&reference=WHY\\_TRANSPARENCY\\_REGISTER](http://ec.europa.eu/transparencyregister/public/staticPage/displayStaticPage.do;TRPUBLICID-prod=WWaDaNCgBqzFloj-ydKMSRnFf4ehx8zrUaiWzfPP5bnyCY1veBZ!!-590538967?locale=en&reference=WHY_TRANSPARENCY_REGISTER) (Accessed 9 January 2017)

*affects one issue only: the pharma funding of patient groups*'. The existence of a close link between CSOs and the pharmaceutical industry was also observed through the review of publications (Beinare & McCarthy, 2012).

CSOs are very often dependent on donor funding and have to adapt their strategy to meet donor's needs but when funding is provided by pharmaceutical companies, until what extent do they influence the policy work of these CSOs? This was considered by one of the respondents representing patients at the international level to be *'the bone of contention'* and the results of the qualitative data analysis did not show a consensus from patient organisations that participated in this study on whether it is acceptable to receive funding from industry and on which conditions. Respondent 1 said:

*'The links between industry and a lot of the Brussels-based patient groups and at the national level are very, very strong (...) this is concerning and alarming. I'm fully aware of the reality, that unfortunately there are not many other sources of financing and that there is no public funding going to patient groups. This [legitimacy] is an extremely valid point and it is also why sometimes here in Brussels, especially in my field, in pharma, we forget that we are supposed to be representing the public interest. This is why I stress again the issue of transparency. You need to make sure that you are forthcoming about who you represent and how you represent your constituency.'*

One organisation considered that diversifying funding sources is key to ensure independence while two others considered that receiving funding from industry is not a problem as long as the process for engagement is transparent, which can be supported for example through the adoption of NGO Codes of Conduct or other transparency or ethical guidelines. Respondent 3 highlighted the importance of partnerships with private sector actors and said:

*'The point is not who the companies are but what the relationship is. Our objective while working with private companies is not only to be sponsored but to build a partnership. The difference is that a partnership is not only linked*

*with money but also with a common goal and an active role that has to be played by both parties in order to achieve this goal. When I said before that we have worked to put some health topics in the European agenda to avoid unnecessary suffering and pain, we have worked three years with both private and public funds to achieve a common goal, not just for us, not just for them, for all patients’.*

One of the respondents who works for an organisation that is not considered to be attractive to receive funding from industry given that there is no medicine for the patients they represent said:

*‘The financial capacity of any European organisation is limited because of the way that you can get funded. To be involved in European policy-making, you have to follow some guidelines, and that means that you cannot only be funded by pharmaceutical companies. It is very difficult to get money outside of the pharmaceutical world. That is a limitation; those limitations are made up by politicians, who have no real belief in patient associations. That is very strange, because they do not think that patient associations, which are sponsored by pharmaceutical companies, are doing the best for their patients but doing the best for the pharmaceutical companies. That is ridiculous, of course, but that is maybe the way they are working for themselves (...) Our biggest problem is that there is no medication for this disease. No official or recognised medication so there are no pharmaceutical companies supporting patient organisations in this area. Pharmaceutical companies are not sponsoring associations working on areas where they do not have any medication for. It is very difficult for us to get money from pharmaceutical companies, sometimes we manage, but it is a very little amount’.*

In one case, the respondent said that her organisation mainly receives funds from the EU, which for some might be seen as problematic given that they can be perceived as an instrument of the EU. This raises the question of funding dependency and whether being dependent on EU funds is better than being dependent on industry funds. No findings were found in the literature on this matter.

## **Coordination and alignment**

Findings from the qualitative data suggest that there is some lack of coordination and misalignment between CSOs and policy-makers, or between CSOs themselves due to different priorities. An informant working for an international alliance said:

*'I have been in events in the EP where they discuss things and afterwards you are more confused than you were before because there are so many different schools and approaches. This is natural because patient organisations have different priorities and themes, so they also have different ideas (...) but sometimes I think this is where the worst comes out, when the EU used to have these huge public grants. When there is money on the table it is the best time to see organisations revealing their true nature. You find that these letters were being sent... that internal conflict within the groups. Firstly, that confuses policy-makers. I always say that we must be helping them out to make a decision. We must help those policy-makers to come up with a definitive decision by burying our differences. When you come to the table make sure you speak with one voice. That helps policy to be instituted quickly. Secondly, it also helps the other party using this disunion to do nothing. My experience with the Department of Health in the UK is that if we went in there with one voice then we quickly got things done. If we went with any faction of opinion, what the civil servants will do is to use that and pitch it against us. They say for example, 'The reason why we have not done this, that, the other, is because group A and B say the opposite of what you are proposing'. They say, 'Go and undertake some more policy research and come back with evidence'.*

This statement shows that relationships between CSOs and their level of coordination is important and that such dynamics might play a role in influencing policy. Another respondent said:

*'We need one patient voice. I think that what is happening at the moment is one of the critical weaknesses. Any time we meet with the health policy-*

*makers, especially at the European level (not so much in low- and middle-income countries (LMICs) where there are fewer groups and they fall in line with each other), the competing interests that they face, we do not have an EU with a single voice sometimes in one single room. This is my last experience at another event where we had the room split up into six different opinions on one single issue. That patient voice is not in unison or harmony. This is a challenge’.*

One of the policy-makers, when asked if there is alignment between CSOs considered that it depends on the topic and said:

*‘That depends on how global you want to take it. If you talk about work towards better health services, yes they do. If you talk about issues like legislation, not necessarily. In this case, there are sometimes very fundamental differences. The more precise you look at it, the bigger the differences will become’.*

None of the policy-makers mentioned specific tensions between civil society and their organisations although examples were found in the literature (Lee, 2010). One of the policy-makers said that there were no obstacles from his institution in relation to his relationship with patients, on the contrary, this seemed to be encouraged and a core part of his role.

The majority of the respondents noted the importance of collaboration with other NGOs, especially on cross-cutting issues, although smaller organisations, or organisations that do not have offices in Brussels mentioned more often the importance of collaboration with larger organisations, or with organisations that have representation in Brussels. Respondent 5 said:

*‘We work very closely with other organisations... If they can help us to raise more political awareness on chronic diseases, for instance, on unemployment, the healthcare system, or on research, then in the end, our*

*patients will also benefit, of course. When it comes to specific issues, we do it on our own but for the broader issues we work on coalition'.*

It was possible to identify patterns of collaboration through the qualitative data analysis. For example, pan-European alliances represent a variety of diseases and patients while others work on a specific disease area and group of patients. These tend to work with the larger alliances, which have a more direct relationship with EU institutions. Furthermore, organisations with no representation in Brussels tend to delegate some of the policy work to organisations based in Brussels, which are closer to the EU institutions. Sometimes, Memoranda of Understanding (MoUs) are signed describing these collaborations but this is not always the case.

In relation to representativeness, one of the policy-makers said:

*'It is not for me to judge what the position of a patient group is but what is important for me is to be able to judge who it stands for, how its opinions are being formed and how much that represents the larger user movements. That can be very sensitive, particularly in the fields where there is more than one group. For example, I invited three patient groups. Now, they don't always agree on something. What do you do? That can be an issue'.*

The issue of coordination is closely linked with strategy development and priority setting. One of the questions asked to interviewees addressed the process for priority setting, and in particular, which efforts are taken to ensure that there is no duplication of efforts. The importance of partnership and information sharing was again stressed. One of the representatives said *'we prefer to concentrate our efforts on areas that we know best and where we are the only players'* and another said that they look out for the 'Gates effect', which means that what large players such as Bill & Melinda Gates Foundation focus on influence strategies and priorities of CSOs:

*'Periodically we look out for the 'Gates effect'; I don't know whether you have read about that, what Bill & Melinda Gates focus on, that becomes the driving force of change. Currently they are concentrating on primary healthcare; we*



*then have to follow that. To a larger degree we try to follow the current trends’.*

### **Policy change and shifting policy priorities**

Respondents 1 and 4 emphasised that they had to change their strategy in order to adapt to policy change. Respondent 1 said that they are changing the way they work because there is *‘not much happening’* in the EP and because not only is the mandate of the EC to work on health issues limited but health is not a high priority of the current Commission. Some of the words used were that the EP has been *‘side-lined or marginalised’*, which means that they have to work more closely with MSs or on other instruments such as EP’s Own Initiative Reports (INI), which do not have the same gravitas as legislation.

*‘The entry points in order to influence policy-making are becoming rather limited. The game changed in Brussels and that is why we need to work more with the traditionally, most secretive of all institutions, which is the Council. This illustrates the tough times that we face in Europe where we need to go back to basics and call for transparency and access to information (...) many organisations are also going through the sides trying to influence MSs and take part in closed-door discussions, etc.’.*

Respondent 4 also alluded to policy change and said:

*‘I have really seen a trend in my work, in the first two years there were a lot of proposals that were important for the patient community, like the Patients’ Rights and Crossborder Healthcare Directive, pharmacovigilance and clinical trials’ legislation. Suddenly, there is a bit of a step back on health. There are a lot less proposals these days, but in a way this makes us being more proactive on the topics that are important to us so in the end this can be good for our activities. Also, there is another problem, even if the EC would like to do something, let’s say in access to healthcare or health inequalities, MSs sometimes raise the issues of competencies and subsidiarity’.*

This shows that a strategy shift was required due to policy change, including a change in policy actors, however, this might have had a positive impact in CSOs, which had to become more proactive to ensure a focus on the most important policy issues.

In summary, there are a number of challenges faced by CSOs that seem to impact their ability to influence EU health policy. The main challenge is a lack of financial or human resources and expertise, followed by a need for transparency to tackle issues around legitimacy, a lack of coordination between CSOs that should be united in one voice. Policy change, shifting of priorities and the reduced mandate of some of the EU institutions and actors in health influence the number of debates and legislation being discussed, which requires CSOs to adapt their policy and advocacy strategies.

## 5.5. Selected success stories and monitoring results

Two main examples of patient empowerment and civil society achievements were found in the review of the scientific literature: the HIV/AIDS movement and efforts in the context of tobacco control (Seckinelgin, 2002; Collin et al., 2002; Kapstein & Busby, 2010; Galjour, 2012). However, qualitative data collection allowed for a number of other success stories to be shared. This included for example how patient groups influenced important aspects of the Cross-border Healthcare Directive<sup>61</sup>, the pharmacovigilance legislation<sup>62</sup>, the Falsified Medicines Directive<sup>63</sup> and the Clinical Trial Regulation<sup>64</sup>; advocacy for the creation of European Days that became part of the EU or international agenda (e.g., European Patients' Rights Day<sup>65</sup> or the International Elder Abuse Awareness Day<sup>66</sup>); the establishment of a number of Interest Groups in the EP; the development and launch of the European

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<sup>61</sup> [http://ec.europa.eu/health/cross\\_border\\_care/policy/index\\_en.htm](http://ec.europa.eu/health/cross_border_care/policy/index_en.htm) (Accessed 3 July 2016)

<sup>62</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:348:0074:0099:EN:PDF> (Accessed 3 July 2016)

<sup>63</sup> [http://ec.europa.eu/health/human-use/falsified\\_medicines/index\\_en.htm](http://ec.europa.eu/health/human-use/falsified_medicines/index_en.htm) (Accessed 3 July 2016)

<sup>64</sup> [http://ec.europa.eu/health/human-use/clinical-trials/regulation/index\\_en.htm](http://ec.europa.eu/health/human-use/clinical-trials/regulation/index_en.htm) (Accessed 3 July 2016)

<sup>65</sup> <http://www.activecitizenship.net/patients-rights/projects/201-european-patients-rights-day-2016.html> (Accessed 3 July 2016)

<sup>66</sup> <http://www.un.org/en/events/elderabuse/> (Accessed 3 July 2016)

Charter of Patients' Rights<sup>67</sup>, and advocacy work in the framework of SDGs and the subsequent inclusion of target 3.8 to achieve universal health coverage in the SDGs.

As seen in the scientific literature the policy process does not end once a given result has been achieved, and monitor & evaluation is an important part of the process as demonstrated by Lasswell (1977), Young & Quinn (2002), Pollard & Court (2005) and Tsui et al. (2014) Respondent 2 alluded to the importance of monitoring the implementation of policies:

*'We were so glad when we got SDG 3.8, the work was thanks to all patient organisations, including us, we all lobbied for that. With that comes a responsibility to make sure that in 15 years we got it implemented. It is a double-edged sword, you get it, and then you have to make sure that it happens. It is eight months on and we are already panicking because we want to make sure these things happen.'*

When CSOs were asked how successful they were in influencing their policy work and how they measure such results, respondents tended to provide examples of achievements and explaining how their work has been instrumental with little mention of processes that supports them in measuring and evaluating their policy work. This is consistent with the limited information found in the scientific literature on methods and strategies to influence policy.

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<sup>67</sup> The European Charter of Patients' Rights was drafted in 2002 by Active Citizenship Network in collaboration with patient organisations. More information at: [http://ec.europa.eu/health/ph\\_overview/co\\_operation/mobility/docs/health\\_services\\_co108\\_en.pdf](http://ec.europa.eu/health/ph_overview/co_operation/mobility/docs/health_services_co108_en.pdf) (Accessed 3 July 2017)

## Discussion and Conclusion

This thesis explored the role of patient organisations in EU health policy. Indeed, despite the fact that health is at the core of national welfare states, there is an 'Europeanization of health'. This was observed both in the literature and qualitative data, and is evidenced by the landscape of EU institutions and agencies that deal with health matters. The overview of the EU health policy process, presented in chapter one, shows how the adoption of EU legislation is a lengthy and complex process, where a number of actors participate, inside and outside European institutions, and with some being able to be more influential – or contribute more – than others. The example of the proposal for a directive on standards of quality and safety of human organs intended for transplantation (Directive 2010/53.EU) show how a health-related directive is discussed and adopted at the EU level. Although it is possible through a desk review of official EU documents to understand the different steps and actors involved, information about less formal discussions between policy-makers and interest groups or CSOs are seldom documented. For this reason, and given some of the research limitations found in the literature in regards to the 'need for more empirical research to examine the effect of civil society in health outcomes' (Olafsdottir et al., 2014: 176) it was considered necessary to conduct expert interviews with stakeholders working to influence EU health policy. The conduct of semi-structured expert interviews allowed for personnel perceptions, organisational dynamics and social interactions to be shared. It was considered that a point of data saturation was reached when it was no longer possible to collect data that provided additional information and that contributed to answering the research question at hand.

Both the literature review and the qualitative data analysis show that definitions of civil society and civil society organisations are complex. The literature showed that there is some confusion associated to the term civil society, which is sometimes mixed with associated terms (Clayman et al., 2015) and that these terms are often used interchangeably (Giarelli, 2004), which has also been proven to be the case in the interviews, where experts used a number of different terms to define CSOs and patient groups, sometimes also interchangeably. Some terms, however, seem to be associated more with national activities and service delivery (e.g. user or community

groups, grassroots organisations, end users) rather than European policy-making (i.e. advocacy groups, umbrella organisations, alliances).

It was observed in the literature that globalisation led to the proliferation of CSOs and that patient organisations are present at different geographical levels (Doyle & Patel, 2008; Stoeva et al., 2015), and this was also demonstrated through the qualitative data analysis, with some of the CSOs participating in this study working at the national level, others at the European, others at international and others at different levels. The dual mandate of CSOs highlighted by Doyle and Patel (2008) in the literature was also mentioned by respondents that provide services and develop capacities in addition to conducting their policy and advocacy work. The discussions with CSO representatives showed that patient organisations serve patient needs in different ways and although they work towards the same goal, they tend to identify their specific priority areas in order to avoid duplication of efforts and competition. Moreover, the prominent role of CSOs in health research noted in the literature and the concern that research does not respect the real need of end users (Beinare & McCarthy, 2012) was also shared during the expert interviews, with some of the respondents highlighting the importance of their involvement in research.

Most of the issues identified through this study were found both in the literature and through the qualitative data analysis. For example, the literature shows that NGOs provide coordinated responses to EC consultations and this was also demonstrated through the analysis of collaboration patterns between CSOs, where it was observed that coalitions and alliances are formed to respond to pressing issues. The literature shows that consulting citizens and stakeholders is an essential element of the EU smart regulation and that scholars believe that civil society involvement is a key element of democratic societies (Battams, 2014). Policy-makers that were interviewed as part of this study confirmed this importance, however, both the literature (e.g., Cohn et al., 2011) and qualitative data analysis show that opportunities for CSOs to participate meaningfully are limited. The importance of meaningful participation was noted by CSOs and policy-makers alike. Examples of projects funded by the EC aimed at defining 'meaningful participation' were given, which shows that this is a theme that interests policy-makers. Although respondents from civil society expressed some concerns about what motivates institutions to

capture patients' views, policy-makers in this study considered that patients' real life experiences provide valuable insights into problems and that their voice is heard.

In line with this, the literature demonstrates how trust and solidarity have emerged as the most important lobbying currency in Brussels (Coen & Richardson, 2009), which is consistent with the feedback received by respondents who called for transparency. The undemocratic nature of some of the structures was mentioned by scholars (Doyle & Patel, 2008) but also by respondents who alluded to the fact that the EU is seen as undemocratic and that patients consider the policy process abstract and that they are not sure how to participate, which highlights the importance of making European processes more engaging and understandable. There were a number of publications focused on legitimacy and accountability issues and these were also some of the key issues that were mentioned during the interviews. The notion that legitimacy is closely linked with membership and representativeness, as well as to funding sources and the dependency on EU or pharma funding was observed in the qualitative data but not in the literature. The legitimacy of representatives of European organisations in the design of policies was raised in particular by policy-makers who considered it important to know who the individuals influencing policies represent. Knowing whether the individual who sits in a specific EU committee represents a group of citizens and issues that affect individuals in a given EU member country is key. The process for citizens across the EU to provide input to representatives that then act at the EU level was explained by some of the interviewees, i.e., European organisations normally have national organisations as members, which in turn normally have individuals as members; decisions are always taken by an organisation's members, which suggests that the citizen of a given country who is a member in a local or national organisation can ultimately influence issues at the European level. Additional research to specifically evaluate these processes could provide valuable insights on the role that EU citizens play, even when physically distant from the EU institutions, at the EU level.

Other findings also provided new insights into processes that have not been studied or referred to in the scientific literature. Examples include how CSOs might play a role in bridging the gap between patients as individuals and policy-makers. The notion that some communities are more active than others, and the symptoms of

disease and vulnerability of certain groups or individuals may influence participation was also observed in the empirical data. Empirical data also shows that some groups have more access than others, and that resources and lobbying are required for privileged access, which was not covered by the selected literature.

Moreover, the analysed qualitative data shows that although platforms exist that allow for participation of civil society, the degree of proximity and the possibility to influence depends on the European institution. There is also evidence that shows that there are obstacles in gaining access to EU institutions which are based on familiar pre-established working relationships and geographical proximity. Overall, findings from interviews with CSOs show that there is an uneven level of access granted to the CSOs we studied by EU policy-makers. As some organisations had less access than others, reliance on coalitions, and delegation of work and responsibilities to organisations that are closer to policy-makers was shown as an important feature of the CSO participation process.

There are a number of challenges faced by CSOs that seem to impact their ability to influence EU health policy. The main challenge is a lack of financial or human resources and expertise, followed by a need for transparency to tackle issues around legitimacy, and a lack of coordination between CSOs that should be united in one voice. Policy change, shifting of priorities and the reduced mandate of some of the EU institutions and actors in health influence the number of debates and legislation being discussed, which requires CSOs to adapt their policy and advocacy strategies.

The research has shown that European CSOs play an important role in global and EU health policy and findings suggest that CSOs have been successful in influencing EU health policy. Their expertise is valued by policy-makers, and mechanisms have been created such as the Health Policy Platform that facilitate exchange between policy-makers and CSOs. Support from policy-makers is not only evidenced through the existence of these platforms and fora, but also through the European Citizens' Initiative, which allows citizens to suggest proposals to the EC, and through project funding by EU health, research and development programmes. Some of the projects supported in the past focused specifically on patient participation research. Moreover, EU's legislative proposals result from a lengthy consultative process

involving impact assessments, evaluations and public consultations. Research also shows that when institutionalised support is lacking communities mobilise themselves, form coalitions and powerful alliances, including policy-makers.

Measuring influence has proven to be a difficult exercise and the extent to which CSOs succeeded in influencing EU health policy is difficult to establish mainly because it is almost impossible to establish a clear link between a certain action or effort and policy outcome. In other words, there are a multitude of actors and relationships that are difficult to map, some of these interactions take place within formal settings, but others are rather informal and very rarely documented. CSO information and evaluation systems, including the use of indicators that allow evaluation of influence processes are necessary and would strengthen the role of CSOs and confidence of patients to participate in the political debate. The theory of access and network analysis might provide insights into this complex interplay, and revisiting this question in separate research through a multidisciplinary approach and more in-depth analysis of networks and exchanges might yield interesting results. In order to investigate more precisely whether CSOs have influenced EU health policy a larger number of policy-makers could be interviewed as only they would be able to say if they were directly or indirectly influenced by civil society (hence, influencing certain policy outcomes).

Due to the abstract nature of some policy approaches this study found that there is a lack of systematic empirical analysis, which could be supported through information and reporting system as suggested by Anheier (2013). A number of research limitations were also highlighted in several publications: Boaz et al. (2016) considers that *'the potential for including patients in implementation processes and evaluating their impact on quality improvement has received limited attention'*, Giarelli et al. (2014: 166) state that only further research can unravel *'how civil society's involvement impacts health in advanced industrialised countries'*, and Gillies (1998: 114) asserts that *'it is largely accepted by those engaged in health promotion that a new package of indicators to measure the effects of community-based health promotion is needed'*. An aspect that seems to have received the attention of scholars is the difference between CSO participation in developed countries versus developing countries as well as in countries with stronger versus weaker Welfare



systems (Giarelli, Annandale and Ruzza, C., 2014; Olafsdottir et al., 2014) but such discrepancy was not discussed during expert interviews.

There were a large number of success stories and achievements shared by respondents, showing that they consider having played an instrumental role in the adoption of EU health policies and initiatives. Cases of non-success shared by respondents were very limited, possibly because it was preferred to highlight successes, but they are likely to exist given the number of challenges shared. The qualitative data analysis shows that challenges may have created opportunities (e.g., new alliances and working methods) and it would be useful to understand what the lessons learnt are from stories of non-success. The lack of evaluation programmes may explain the absence of processes to systematically compare stories of success/non-success.

A set of recommendations for civil society and policy-makers are provided below based on the main findings of the literature review and interviews:

1. Investment in patient-centred capacity building programmes, and sharing resources and information amongst NGOs in order to address the lack of resources and expertise
2. Adoption of Codes of Conduct or transparency guidelines that provide a framework for engagement with funders both from the private and public sector to address lack of trust and funding dependence
3. Information sharing at all stages of the policy process, not only between policy-makers and CSOs, but also between and within CSOs (i.e. including between members and working groups within a given CSO) to ensure transparency and encourage collaboration
4. Monitor policy trends and have mechanisms in place that facilitate quick establishment of coalitions to deal with pressing issues that are high in the agenda as a way to address (inevitable) changes in policy priorities
5. Setting up consultations between CSOs working in the same field for joint strategic assessments and priority-setting. These consultations would also ensure a coordinated response ('one voice') to requests by policy-makers

6. Policy documents and information related to the policy process (i.e. how to contribute, what the policy will change, etc.) to be published in clear and plain language.

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# Annexes

## Annex I: Interview guide

Interview guide				
Research question: How successful is civil society, through patient organisations representing the most vulnerable groups in Europe, in influencing EU health policies				
Data collection	1. General information about organisation <ul style="list-style-type: none"> <li>- Try to capture information that is not easily accessible via website or published documents</li> <li>- Governance: how is the organisation structured; how are decisions taken and who makes decisions</li> <li>- Membership: how members provide input</li> <li>- Strategy: how are priorities defined</li> <li>- Collection of success stories and failures in relation to policy work</li> </ul>	2. Relationship with EU institutions <ul style="list-style-type: none"> <li>- Extent to which organisations works with them</li> <li>- Openness from EU institutions for a dialogue with civil society</li> <li>- Mechanisms that allow for participation</li> <li>- How influencing policy happens in practice, collect strategies, examples, etc.</li> </ul>	3. <ul style="list-style-type: none"> <li>3.1. Challenges faced               <ul style="list-style-type: none"> <li>- What are the main challenges, gaps or limitations that prevent participation</li> <li>- What are the main obstacles when it comes to influencing EU policy</li> <li>- Is there any particular challenges faced when it comes to policies on health inequalities</li> </ul> </li> <li>3.2. Opportunities               <ul style="list-style-type: none"> <li>- What are the main opportunities for CSOs advocating for EU health policy change?</li> </ul> </li> </ul>	4. Measure success <ul style="list-style-type: none"> <li>- How are the CSO activities evaluated are there any tools to measure success</li> <li>- Collect examples</li> </ul>

**Interview guide**

Research question: How successful is civil society, through patient organisations representing the most vulnerable groups in Europe, in influencing EU health policies

<p>Relevance in relation to research question</p>	<ul style="list-style-type: none"> <li>- Provide context</li> <li>- Have a thorough understanding of the study sample</li> <li>- Understand if organisation represents patients as individuals or a network of patient organisations</li> <li>- Understand if organisation represents vulnerable groups and works on health inequalities</li> <li>- Success stories may help understand if the organisation has been successful in influencing policy when compared to failures</li> <li>- How priorities are defined and strategy developed might help understand if NGOs work on the most pressing issues and if these are the issues that policy-makers also focus on</li> <li>- Information about membership will allow understanding how the process of influencing policy happens in practice as it is assumed that members, in collaboration with staff, are the ones doing so</li> </ul>	<ul style="list-style-type: none"> <li>- Understand the building blocks for policy making and how things happen in practice</li> <li>- Understand what are the channels of communication and levels of 'openness' and willingness from policy-makers</li> </ul>	<ul style="list-style-type: none"> <li>- Understand the factors that may influence success</li> </ul>	<ul style="list-style-type: none"> <li>- Understand if CSOs consider having been successful in influencing policy, understand how they evaluate results</li> </ul>
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## Annex II: Profile of respondents

Respondent	Type of organisation*	Year of establishment	Secretariat location	No. staff**	Position respondent	Membership	Geographical focus**	Disease area
1 - EPHA	NGO; member-led organisation	1993	Brussels, Belgium	Between 10-15 (policy: 6)	Coordinator	+100 Organisations- public health NGOs, patient groups, health professionals and disease groups (Pan-European; national and non-EU)	Europe	Various
2 - IAPO	Not-for-profit foundation; global alliance; UK-registered charity	1999	London, UK	Less than 10 (policy: 2)	CEO	276 member organisations from 71 countries representing 50 disease areas	International	Various
3 - ACN	Network of European civic organisations	2001	Headquarters in Rome, Italy with a EU Representative in Brussels, Belgium	40 among Rome and Brussels	Director	Open and flexible network - no formal membership	National/ Europe	Various: the starting point are patients' rights rather than patients' diseases

Respondent	Type of organisation*	Year of establishment	Secretariat location	No. staff**	Position respondent	Membership	Geographical focus**	Disease area
4 - EPF	Umbrella organisation	2003	Brussels, Belgium	Between 10-15 (policy: 2)	Adviser	67 members, which are pan-European patient organisations and national platforms of patient organisations	Europe	Chronic disease
5 - ENFA****	Non-profit making association	2008	n/a	No staff	Treasurer	17 official national or regional fibromyalgia associations	Europe/International	Fibromyalgia
6 - PAE****	Pan-European umbrella organisation	2011	Diegem, Belgium	1 (policy: 1)	President	33 national associations in 16 Member States	Europe	Diseases causing chronic pain
7 - Parkinson's UK	Charity registered in England, Wales and Scotland; company, limited by guarantee	1969 as Parkinson's Disease Society	London, UK	Approx. 400 (policy: 9)	Manager	Individuals - open to anyone	National (some work at European/international level)	Parkinson's disease

Respondent	Type of organisation*	Year of establishment	Secretariat location	No. staff**	Position respondent	Membership	Geographical focus**	Disease area
8 - AGE Europe	European network	2001	Brussels, Belgium	Between 10-15 (policy: 7)	Secretary General	More than 150 organisations	Europe	Various
9- EURORDIS	Non-governmental patient driven alliance of patient organisations	1997	Paris, France; Brussels; Belgium; Barcelona, Spain	37 (public affairs: 3)	Manager	716 rare disease patient organisations in 63 countries	Europe	Rare diseases
10 - ELF	Non-profit organisation registered as a UK company and charity	2000	Sheffield, UK	Less than 10 (policy: 0 but a working group being established)	Director	n/a	Europe	Respiratory diseases
11 - SMA Europe	Non-profit organisation; umbrella organisation	2006	n/a	1 (policy: 1)	Board member	13 SMA patient and research organisations from 11 countries across Europe	Europe	Spinal Muscular Atrophy

Respondent	Type of organisation*	Year of establishment	Secretariat location	No. staff**	Position respondent	Membership	Geographical focus**	Disease area
12 - EUPHA	Umbrella organisation	1992	Utrecht, Netherlands	4 (policy: 2)	Director	15 members in 12 countries. Members are both organisations and individuals	Europe	Various
13 - EC****	European institution	1958	Luxembourg	643 in DG SANTE; 32966 in EC	Officer	College of Commissioners of 28 members	Europe	n/a
14 - WHO****	Specialised agency of the United Nations	1948	Geneva, Switzerland	8500	Manager	194 Member States	International	n/a

\*Combination of terms as presented in organisation's website and during interviews

\*\*As of 1/1/2016

\*\*\*Main geographical focuses; does not preclude work in other regions

\*\*\*\*Same respondent for ENFA and PAE; the person is holding different positions within each organisation

\*\*\*\*\*For the purpose of this study, this respondent is considered a 'policy-maker'

## Annex III: Samples of emails sent to potential respondents and respondents

### 1. Policy-makers

----- Forwarded message -----  
From: **Ana Lúcia Cardoso** <[REDACTED]>  
Date: 29 April 2016 at 14:24  
Subject: Request for interview - patient/CS involvement in EU health policies  
To: [REDACTED]@europarl.europa.eu

Dear Assistant(s) of MEP [REDACTED]

My name is Ana Cardoso and I'm currently conducting research about patient involvement in the development/implementation of EU health policies as part of a Master's degree with the University of Lisbon. I'm particularly interested in the role of vulnerable groups in the development of EU policies for the reduction of health inequalities.

I am currently conducting a number of interviews with Civil Society Organisations (CSOs)/Non-Governmental Organisations (NGOs) working at EU level but I would also like to capture the views of policy-makers. I am well aware of the work of MEP [REDACTED] great supporter of the Interest Group on "European Patients' Rights and Cross-border Healthcare" and for this reason, I would be most grateful if I could speak with someone from Mr [REDACTED] team on this topic. My questions would be mainly focusing on the importance of civil society participation at EU level and the main mechanisms that the EP offers for patient involvement. I would also like to understand more about the establishment and objectives of this particular Interest Group.

Given that I am working towards a deadline in June, I would greatly appreciate it if I could speak with you or someone from your team before the 13<sup>th</sup> May. If preferable, I am also happy to send you additional information about the project prior to the teleconference.

Many thanks in advance for your support and cooperation. I look forward to hearing from you.

Kind regards,  
Ana

### 2. Civil society organisations

----- Forwarded message -----  
From: **Ana Lúcia Cardoso** <[REDACTED]>  
Date: 26 April 2016 at 20:46  
Subject: Request for interview - research project on patient/CS participation at EU level  
To: [REDACTED]

Dear Dr [REDACTED]

My name is Ana Cardoso and I'm currently conducting research about patient involvement in the development/implementation of EU health policies as part of a Master's dissertation with the University of Lisbon. I'm particularly interested in the role of vulnerable groups in the development of EU policies for the reduction of health inequalities.

I am currently conducting a number of interviews with Civil Society Organisations (CSOs)/Non-Governmental Organisations (NGOs) working at EU level and given your expertise, and the focus and mission of your organisation, I would be most grateful if we could schedule a one-hour teleconference for an interview. The questions will be focusing on how your organisation contributes to patient participation at EU level, and the strategies/mechanisms that you use to influence EU policy. I would also like to understand what the main gaps are in terms of patient participation as well as any success stories (e.g., a specific EU regulation or initiative that you have – directly or indirectly – influenced).

Given that I am working towards a deadline in June, I would greatly appreciate it if I could speak with you or someone from your team before the 13<sup>th</sup> May. If preferable, I am also happy to send you additional information about the project prior to the teleconference.

Many thanks in advance for your support and cooperation. I look forward to hearing from you.

Kind regards,  
Ana



## Annex IV: Qualitative data analysis: summary of main concepts and themes identified

Main concepts	Respondents	Theme
Medicines affordability, quality and access	1	Importance of patient participation and different ways of serving patient needs
Ensuring that MS commit to SDGs	2	
Avoid discrimination, ensure employment, insurances, benefits, etc.	8	
Working on horizontal and vertical issues (i.e. diagonal approaches)	2	
Health literacy and capacity building	2, 4, 7, 8, 10, 11	
Focus on problems of the entire community rather than individual	3	
Seeing patients as one body/one voice	2	
Protection and promotion of citizen rights	3	
Consultations & expert groups such as the e-health stakeholder group	4, 8	Access to policy-makers and mechanisms for participation
Interest Groups at the EP	3, 5, 6, 7	
Contribute to international legal statements like SDGs	2	
Official EU channels (HPP/EMA PWCP)	3, 4, 8, 9, 12	
Influence national Constitution	3	
Engagement in EU Joint Actions	4	
Awareness days	3, 8	
Difficult to understand how to engage; distant EU	7, 10	
Official representation	2, 3	Meaningful participation
FENSA & WHO	2	
Patients employed by policy institutions rather than only sitting in advisory groups or taskforces	2	
National CSOs provide input to European CSOs	1, 2, 4, 7, 10	
Need for systematic involvement (e.g. medical devices vs medicines)	4	
Definition of meaningful participation	4	
Closeness to citizens	7	
Participation in health research	7, 9, 10	
Civic participation and role in society	3	

<b>Main concepts</b>	<b>Respondents</b>	<b>Theme</b>
Strong links with pharma are alarming because of their power	1	Challenges – resources – funding
Not many other sources of funding in addition to industry	5, 6	
Importance of defining partnerships: not who funds but what the relationship is	3	
Responsibility of the public sector	3	
Funding patient education and literacy – invest in 'expert patients'	2, 4	
Funding for translation	8	
Travel – distance to Brussels	5, 6, 12	
Importance of having offices in Brussels, or hire staff to be based in Brussels	3, 5, 6, 12	
Tensions related to funding	2	
EU funding dependency	10, 13	
Links with pharma: different views	1, 2, 3, 4, 5, 6	
Importance of transparency	1	
Membership	4, 8, 9	
Representativeness: Be forthcoming about who you represent and how you represent your constituency	1, 14	
EU's role – Transparency Registry	4, 5, 6	
Adoption of Codes of Conduct and ethical frameworks	3	
Transparency and level playing field needed	1	Challenges – policy change and shifting priorities
New debates in Europe due to financial crisis	1	
Increased work with the European Council: need for lobbying close to MSs and take part in closed door discussions	1	
Difficulty in becoming involved in EU Joint Actions	4	
Lack of legislation and work at the EP	1, 4	
Dependency on pharma funding	1, 2, 5, 6	
Proactivity as a result of policy change	4	
Less health in Juncker's Commission	1, 4	
Limited mandate of EC in health matters	1, 4	
Changes that result from legal and binding statements such as SDGs	2	
Transition period trying to define new policy as a result of recently established SDGs	2	

<b>Main concepts</b>	<b>Respondents</b>	<b>Theme</b>
Change in EU rules (impact in funding and partnerships)	4	
CSOs working towards same goal but defining specific priorities	5, 6, 8	Challenges – coordination and alignment
Importance of partnerships and coalitions	2, 3, 4, 5, 6, 7, 8, 12	
Important to second work to organisations in Brussels	2	
Memorandum of Understanding	2	
The Gates effect	2	
High expectations	3	Challenges - Other
Impossible to plan policy work	4	
Illness and disease symptoms, lack of energy	2, 5, 6	
Avoid patient apathy	2	
Build confidence and self believe of patients	2	