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Options and Requirements. A Study of the External Process of Specialized Document Production

Abstract

The process of producing a specialized document can be considered to consist of an internal and an external part. The internal process is the mental or cognitive side, not accessible to direct observation, whilst the external process is all which can be witnessed by an observer. We model the internal part as a process of decision-making which is steered by controlling influences. These originate in the external process. The way in which the task, the agents and the controlling influences interrelate is then elaborated on in an empirical analysis of the production process of Patient Information Leaflets.

1. Focus on the Process

In the present study we look into the process of creating specialized documents. This process has two sides which we call the internal and the external process. The internal process is the mental or cognitive activity required for a person to produce a document. The external process is all which can be noted by an outside observer. It may be roughly equated with the workflow[1].

It is our objective to describe some of the ways in which the two sides of the overall process are interrelated. To this end, we discuss a combination of two models which depict the decision process and the controlling influences between the external and the internal process (section 2). We then elaborate on the models using the document type of the Patient Information Leaflet (PIL) as an example (section 3). In a short conclusion we try to bring the theoretical and practical findings together (section 4).

The present contribution is a short study in which we try to sketch our theoretical viewpoint and to substantiate it with an analysis of a single set of actual materials from professional practice. This article cannot, however, give a comprehensive account of the field. To provide such an account, large-scale further study is required.

Choosing as its object of study the process of producing documents with a specialized content, this study positions itself in specialized communication studies. This is a fairly new discipline which still lacks a consolidated name in English[2]. It came into being when its two precursor strands – the study of languages for special purposes for the monolingual and translation studies for the multilingual perspective – to some extent converged where they both investigate oral and written communication with content from specialized domains. This is an area where it quite fre-

1 Various authors have set off the internal and the external process. In translation studies, Toury (1995: 247) defines the (internal) *translation act* and the (external) *translation event*. In writing process research, van Gemert and Woudstra (1997: 107) point out the different objects studied in research interested in the cognitive aspects and the business communication aspects, respectively. In specialized communication studies, Schubert (2007: 157) and Göpferich (2008: 1) word the distinction as given here.

2 This new discipline is also called *technical communication studies* (cf. Schubert 2009b: 17).

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quently is unclear and very often impossible to establish whether a certain text or document is an original or a translation[3], whether it was created as a coherent workpiece by a single author, by a team of co-operating authors or maybe by a documentation manager who recombined elements of documents from a content management system previously created at different points in time by different authors and as components of different documentations[4]. The latter kind of re-use of components is typical for large sectors of technical documentation, especially where the techniques of single-source publishing and cross-media publishing are applied[5]. In section 3, we analyse pharmaceutical documentation. Given its highly standardized nature, similar techniques of component re-use are applicable in that field as well.

Both forerunner disciplines of specialized communication studies have at some point in their development been mainly concerned with the workpiece, that is, the text or document viewed as a static object, and only later turned their interest towards the activity and the process in which the workpiece is created. One of the common ways of modelling work processes is focusing on the decisions made by the acting person. We adopt this view and try to describe the document production as a decision-making process. This may seem contradictory, since we stated that we are concerned with the external process, whilst decision-making quite obviously is part of the internal process. Yet decisions can be controlled or at least influenced by external factors and an analysis of the external process has to account for the ways in which it exerts this control over the internal.

2. The Process of Specialized Document Production

In specialized communication, authors, technical writers, translators and other specialists carry out work which underlies many conditions, norms, constraints and other factors which we subsume under the notion of controlling influences (Schubert 2007: 136). The controlling influences constitute a major difference between these professional writers and the schoolchildren and essay-writers whose behaviour is often studied in writing process research. To capture this professional work process, we sketch a model of decision-making (2.1.) and a related model of the controlling influences (2.2.).

2.1. A Model of Decision Processes

We have proposed a model of decision processes which takes into account both internal and external influences[6].

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3 Cf. House's well-known concept of *covert translation* (House 1977: 188; 1997: 29). – Cf. Knapp/Knapp-Potthoff (1985: 451), Hatim/Mason (1990: 16-19), "the translator's invisibility" (Venuti 1995).

4 We use the term *workpiece* to reserve the word *product* for the object (engine, software system, drug, procedure...) dealt with in the text or document. – We use the term *recombination* for processes in which previously stored document components are reassembled to form new documents, whereby the reading path may come to differ from the writing path (cf. Schubert 2003: 232 note 8).

5 Single-source publishing and cross-media publishing are techniques commonly used in technical documentation, website management, software localization and other areas of specialized communication. The first basic principle is producing, editing and, where applicable, translating text in small portions, called *contents* or *topics*. These units are normally stored in a database or some other kind of repository from which they can be retrieved, re-used and recombined to make up new texts. The second basic principle is storing the text and its formatting information separately. These two principles allow for the production of different versions of documents, in part or wholly identical in text, but different appearance. For instance, a user's manual can be produced in print, as a PDF document and as a webpage, with essentially the same text but with small differences such as "see chapter 7" in the print version and a hyperlink in the electronic documents. This is the cross-media aspect. Although the eventual documents differ in appearance and, in some parts, in content, each unit of text is stored only a single time. This is the single-source aspect. The techniques are used to reduce labour and production cost and to achieve consistency. Content management systems provide a software environment which can accommodate the entire process of single-source and cross-media publishing. – See for instance Hennig/Tjarks-Sobhani (eds) (1998, s.v. *Produktion, medienneutrale*), Albers (2003), Williams (2003), Closs (2005: 2007), Ferlien (2006).

6 The model was originally published by Schubert (2003b: 637-638; 2007: 244-245). We quote a concise description in English.

> The basic idea of this model is conceiving of the deciding as the process of selecting one out of a given number of possible options. Depending on the task, the number of possible options may be smaller or larger, including the infinite. The set of possible options is called the decision space. Each option has a number of features. It is then assumed that there is a (mental or automated) decision mechanism which consists of rules that comprise criteria. The mechanism will then match the features of the options against the criteria of the rules. If the criteria and the features are sufficiently distinctive, a single option will be selected. If not, arbitrary criteria will be resorted to, such as (in a mental mechanism) the nicest option or (in an automated mechanism) the first-encountered option. (Schubert 2009b: 27-28)

This model may give a rather deterministic impression. However, it is not at all meant to imply any equivalence between human and automated processes. Its main purpose in our present reasoning is to provide some concepts and terms by which to account for the decision process.

In the creation of specialized documents, decisions need to be made at various levels and concerning a number of different features of the workpiece at hand and concerning characteristics of the activity. Decisions are required as to what to say, in which order to say it, what to express by means of language and for what to prefer images, graphics, videos and other forms of illustrations, at which level of speciality to express it, in which language to write the text, by which linguistic means to word it, in which way to arrange the text on the sheet or screen and eventually by which tools to carry out the work and how to organize the process. This list of decisions is based on the finding that specialized communication, and along with it to some extent other types of communication as well, can in a meaningful way be described in terms of four dimensions. These are the dimension of the technical content, the dimension of the linguistic form, the dimension of the technical medium and the dimension of the work processes (Schubert 2007: 248). Obviously the list of decisions is by no means exhaustive. Its length depends on the granularity of analysis applied in a given case.

Using this model given above, the decision-making in the creation of specialized documents can be described roughly as follows.

For each of the decisions to be made in an overall document production process, the model assumes that there is a set of all possible options from which to choose. This set is the decision space. The options contained in the decision space have features. From a systematic point of view it is important to establish whether each option can be uniquely identified by means of its features. Only if this is the case, the features are distinctive and only then a meaningful decision can be achieved by means of the features. If such distinctiveness cannot be ascertained, one either has to refine the set of features or to resort to arbitrary decisions. Both approaches are legitimate and both can be assumed to occur in everyday decision-making.

Decision-making is a two-sided act. On the one side, there is the decision space, made up of the options, which in turn are characterized by their features. On the other side, there is the agent, who is equipped with (explicit or implicit, conscious or unconscious) decision rules which in turn are based on criteria. At the core of the overall decision-making act, the features are matched against the criteria.

With this rather abstract account of the decision process in mind, the production of specialized documents can now be described in a more systematic and at the same time more concrete way.

In the dimension of the technical content, decisions have to be made as to which portions of content to include, in which sequential or networked structure to arrange them and which access structure to provide[7]. The options in this dimension can be described by means of features worded in terms of the macrostructure. The more the description takes into account the microstructure, features can be taken from speech act theory[8] and other models which classify propositions

7 Many, though not all document types in specialized communication are frequently or virtually only used for reference rather than for linear reading from cover to cover. Therefore, larger documentations include tables of contents, indices (if possible hyperlinked), running headers, marginal headings and other means of reader orientation which together make up the access structure (cf. Steehouder 1994).

8 After the standard works by Austin (1962) and Searle (1969), the theory has been elaborated and applied in an

or portions of content at the semantic or pragmatic level. In technical writing, information structuring techniques such as Information Mapping[9] or Funktionsdesign[10] are commonly applied which take their basic concepts explicitly from speech act theory. While the design of these two techniques has its starting point in a semantic and pragmatic approach to communication, the more technically oriented newer techniques and data formats such as the Darwin Information Typing Architecture (DITA)[11] which has been very much en vogue in the technical communication of this decade, are no longer aware of (or do not explicitly acknowledge) their roots in speech act theory, but nevertheless refer to it indirectly by quoting the preceding structured-writing techniques.

In the dimension of the linguistic form, the decisions concern the choice of words, especially the choice between terms and common words, between various degrees of specialization and formality. They further concern the choice of syntactic constructions including syntactic complexity. At the text level, decisions are made as to the use of the instruments of cohesion and coherence, among which are the verbatim repetition of words versus stylistic variation, the use of anaphora, cataphora and other pro-forms, and the arrangement of theme-rheme structures.

In the dimension of the technical medium, the typography and the layout need to be decided upon, along with the general design of the document including, where applicable, the webdesign and the hypertext functionality. This comprises the placement of illustrations, captions and other components which accompany the body of the text.

In the dimension of the work processes, an important set of decisions is concerned with the choice and use of tools. The main tools in specialized document production are software systems such as word processing and desktop publishing systems, XML- and HTML-editors and terminology management, translation memory, authoring memory, machine translation, content management and workflow management systems. This dimension, however, is not only concerned with tools and their impact on the process. It also includes decisions on the specialists to be assigned tasks in the overall process, on the route the workpiece should take from one specialist to the other, on secondary processes to be started and subsequently on the workpieces from these processes to be fed into the primary process etcetera[12].

Above we outlined a model of decision processes in general terms which we then applied to specialized document production. The idea of describing communicative acts in terms of decisi-

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abundance of literature.

9 Information Mapping is a structured-writing technique (*The Top Ten Things* 2008: 9) developed for technical communication by Robert E. Horn. It uses a classification of speech acts derived from classical speech act theory, but restricted to and refined for the speech acts needed in technical documentation. The essential principle is building up complex documents from small, monothematic units, called *blocks*, which are assembled into larger units, *maps*. Information Mapping is a commercially exploited trademark so that most of the publications from its author and his team have a commercial rather than a scholarly tenor. – By the author: Horn (1986, 1989, 1999). Independent publications: Jansen (2002), Information Mapping (2006?), Böhler (2008).

10 Funktionsdesign, too, is a structured-writing technique for technical communication. Its authors are Jürgen Muthig and Robert Schäflein-Armbruster. Their approach is inspired by the speech act theory and controlled languages. The technique analyses documents into four layers of which the *funktionale Einheit* 'functional unit' is a small chunk comparable to the *block* of Information Mapping. These units are arranged in sequences which in turn form documents. Funktionsdesign is a commercially exploited trademark, so that independent publications are scarce. Publications by its authors: Schäflein-Armbruster (2004), Muthig/Schäflein-Armbruster (2008).

11 DITA is a data structure for accomodating the components of documents written in a structured way. In the literature on DITA, which is mainly concerned with the dimension of the technical medium, only a few scattered paragraphs summarize some of the deliberations underlying its design, thereby positioning this technique in the dimensions of the technical content and the linguistic form as well: DITA (2007: 14), Closs (2007: 112). Closs's information concerning the authors of the speech act theory must be a blunder, but she is right in connecting DITA to this theory.

12 A complex work process normally consists of several tasks. We consider these tasks elements of a single process as long as they handle the same workpiece. Tasks and sequences of tasks which have a different workpiece are considered to make up a separate process. If the workpiece or deliverable of one process is used in another process, the former is called secondary to the latter (Schubert 2007: 9). For instance a terminographic process which delivers a set of entries in a termbank can be secondary to a translation process in which these terms are used. The translation process may in turn be secondary to a document production process, in which translations of the original document are ordered and subsequently assembled to make up a single multilingual documentation. The distinction of primary and secondary processes thus is a relative one.

on-making is not new. It has roots in many disciplines of which translation studies is closest to our present discussion. This discipline emerged in the late 1940's and early 1950's primarily in response to machine translation[13] from which it inherited the procedural view on translation. With a view to technical and scientific text types, Jumpelt (1961: 186) notes the desirability of a theory which would describe the aspects steering the translator's decisions. Coming from literary translation, Levý (1967) suggests describing translating as a decision process[14]. His short article is remarkable in several respects. Levý adopts a pragmatic vantage point and speaks of "the working situation of the translator" (Levý 1967: 1171), an unheard-of category in the linguistic discourse of his day. Levý introduces the term of *paradigm* for "the class of possible solutions" (Levý 1967: 1171). This term corresponds to the *decision space* in our model. Levý's model is less clear as to the distinction of what we call *features* and *criteria*. He uses the term *instruction* to denote various functions which both define the features of the possible solutions and the criteria by means of which the translator chooses among them. The decision-making approach catches on in translation studies. It is used, varied and developed.[15] In a much more elaborate form it is continued in the approach advocated by Gerzymisch-Arbogast and Mudersbach (1998). This latter direction is especially relevant to our research interest, since from the methods approach there is a connection to specialized communication research as pursued by Kalverkämper (1998: 1-2)[16].

2.2. Controlling Influences

The description of the specialized document production process sketched in 2.1. in terms of the suggested model, primarily focuses on decision-making and thereby on the internal process. This now allows for an analysis of the ways in which the external process exerts an impact on the internal so that the two eventually form a single whole. The external part of the overall process is that which can be observed by others, that is, all physical rather than mental actions carried out by the document-producing specialist.

Many among the activities in the external process have an effect on the decisions made by the document producer. We call these effects controlling influences (Schubert 2007: 136; 2009b: 23-25). Before we proceed, it may be worth considering the concept of the *controlling influence* which is central to our argument. The concept is taken from the Integrative Model of Specialized Communication suggested by Schubert (2007: 136 et passim: *lenkender Einfluss*). Generalizing what was discussed in the above paragraphs, one can say that the term denotes every kind of stimulus or constraint affecting a document-producing professional's decisions which originates from any other person or group of persons. Influences of this kind can be positive in the sense that they prescribe a certain option and they can be negative in the sense that they forbid a specific option. Maybe the word *constraint* would sound more familiar. However, *constraint* is not as neutral and open as *influence*. A constraint is more on the negative side, often denoting a restriction, whereas *control* and *influence* comprise both positive and negative meanings. Another term to consider in this connection is the *norm*, amply discussed by Chesterman (1997: 54-59). With a reference to Bartsch (1987: 76), Chesterman deliberates the possible prescriptive and descriptive readings of the term and opts for the latter. In his words, the concept of a norm is "descriptive of particular practices within a given community" (Chesterman 1997: 54). Defined in such a way,

13 Fedorov (1953/1968: 6), Kade (1968: 7), Wilss (1988a: 2; 1996: 2), Gerzymisch-Arbogast (2002: 18; 2003: 25), Schubert (2007: 163-173).

14 Levý (1967) is often referred to as being the first to view translation as a form of decision-making. In general translation studies, Levý's work has indeed become seminal. However, the book by Jumpelt (1961) appeared earlier, and to the study of specialized communication it is even more pertinent than Levý's. The importance of Jumpelt's work is emphasized among others by Oettinger (1963), Kade (1968: 7), Stolze (1994: 71-72), Chesterman (1997: 41), Schubert (2007: 176) and Olohan (2009).

15 See for instance Reiß (1976/1993; 1981/2000), Kußmaul (1986/1994). Wilss (1988a: 92-107; 1988b; 1996: 174, 1998/2001), Gerzymisch-Arbogast (1996: 260-263 + 269-272; 1997), cf. Shuttleworth/Cowie (1997/1999, s.v. *Decision Making, Translation as*).

16 Concerning these connections cf. Schubert (2007: 200).

the term is very useful in specialized communication studies[17]. Yet for our present study we need a term which includes all influences which control the professional's decisions: the prescriptive ones (such as standards and legislation) and the habitual ones (such as a specific industry's best practice). For this, we choose the term *controlling influence*.

Most of the controlling influences become relevant for the process when the document producer interacts with other persons. We therefore review some of the major influences by discussing the agents who take part in the process, directly or indirectly and in some cases even unknowingly.

Specialized document production normally is a form of mediated communication (Schubert 2007: 136). The document producer carries out an assignment received from an external customer or a department within the same enterprise or organization. We call this agent the initiator. The main instrument of the controlling influences from the initiator's side is the assignment brief. This can be a letter, a fax, an e-mail message, a telephone call or the like in which the initiator specifies the assignment. Leaving aside the business elements of the brief, such as price and deadline, the main contents is instructions what kind of document to create, about which topic, in which language or languages, for which audience, using which sources of information, applying which resources such as termbanks, authoring memories, content repositories etc. If the instructions for the document producer are more numerous or more detailed and especially if the same set of instructions will be used for many assignments, it is common to compile them into a style guide which then becomes the main instrument of these controlling influences[18].

A second group of agents from whom controlling influences can originate is the recipients or audience. An audience analysis is a common task in the overall process. From this analysis, controlling influences derive which set criteria for the decisions within the dimensions of the technical content and the linguistic form. Comprehensibility requirements may for instance control the choice of common words rather than terms (linguistic form) and if terms are inevitable, they may result in a decision to add explanations (technical content). Whilst it normally is assumed that the audience analysis is the document producer's duty, it is worth noting that Göpferich in her Karlsruhe Comprehensibility Concept lists this among the information the initiator has to provide (Göpferich 2001; 2009: 34 Fig. 1).

A third group of agents to be considered is the team in which the document producer works. In specialized communication, the workpieces are frequently much too large and the deadlines too short for a single person to carry out the entire assignment. Therefore, teams are employed, which leads to consistency requirements in all dimensions and in addition co-ordination requirements in the dimension of the work processes. Another form of team work in a very wide sense is the use of content management systems and similar repositories. In processes supported by such systems, documents may be created by a recombination of previously produced documents or document components which then often originate from various authors who did not know when producing their workpieces, when, by whom and in which assignments these would be re-used.

The fourth important group of agents is the informants. We use this term in a large sense for all persons with whom the document producer is in contact when researching information. This can be experts consulted for content matter clarifications or for information on terms or other questions of the language use in the relevant speciality community. Much of the information research is of course done by searching libraries, archives, the Internet and other sources of printed or written documents, and we count the authors of such documents among the informants. They play a role in the document production process normally without even knowing.

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17 Note the connection between the concepts *norm*, *culture* and *speciality*. According to Chesterman, a norm denotes practices within a community. According to House (1997: 70), the set of habits within a group is this group's culture. And according to Schmitt (1999: 157) the habits within a community of professionals in a particular speciality are a microculture.

18 Concerning style guides in specialized communication see Bright (2005), Schubert (2007: 332-333), Murawski (2009).

The model of decision-making allows analysing the controlling influences more precisely. Take as an example the assignment brief. The more detailed it is and in the more dimensions it gives instructions, the more it controls the document producer's decisions. In the model of decision-making there are two prominent elements where controlling influences can take effect. These are the decision criteria and the decision space. If the decision criteria are influenced, the effect will be that out of a given set of options, some specific options will be preferred and others dispreferred. If an option is dispreferred, it will not be chosen, as long as there are other, preferred options. By contrast, an influence on the decision space will make an option either selectable or unselectable. An option removed from the decision space cannot be chosen, even if there is no other option. In this way, controlling influences which affect the decision space are more rigorous than influences on the criteria.

When the initiator in the assignment brief instructs the document producer to write a package insert of a drug, this restricts the decision space for the choice of content drastically. When the text type in itself involves the use of a prescribed macrostructure or if such a requirement is explicitly worded in the brief, this reduces the decision space for the sequencing and arrangement of the content. Both controlling influences lie in the dimension of the technical content. Other influences in this dimension originate from the use of information structuring techniques such as Information Mapping or Funktionsdesign which recommend or prescribe patterns of content sequencing at the macro- and at the microlevel. Macrolevel influences also derive from standards, manuals and legislation. This can be seen in detail in section 3.

In the dimension of the linguistic form very many different controlling influences of varying degrees of rigour can be observed. Recommendations for preferred wording are often contained in style guides, corporate-identity manuals and similar instruments. They affect the decision criteria. When these instructions are more rigorous and especially when they are enforced by means of software systems which simply do not allow for the dispreferred words and phrases to be used, the influence affects the decision space. A specific and more elaborate form of controlling influences in the dimension of the linguistic form is contained in the use of controlled languages. These are derived from normal ethnic languages by means of lexical and syntactic reductions (Lehrndorfer 1996, Huijsen 1998, Schubert 2008). When prescribed for a document production process, they narrow the decision space.

In the dimension of the technical medium, controlling influences come mainly from the initiator who orders a workpiece to be arranged according to a given model and who prescribes its data format. These influences can restrict the decision space, and they are especially rigorous when they are enforced by means of software templates or the like provided by the initiator.

In the dimension of the work processes, the controlling influences may consist of a prescribed sequence of tasks. This kind of an influence can originate from the initiator, but also from the document producer's own organization. It is most rigorous, when the workflow is steered by means of a software environment which enforces a certain sequence of tasks as is the case in authoring memory and translation memory systems with workflow or team functionality and if possible still more so when content management software is applied in single-source and cross-media publishing processes. These software-based processes affect the decision space.

This short account shows a multitude of controlling influences. An analysis of the purposes and objectives of those who exert the influences is far beyond the scope of this contribution. Many of the controlling influences aim at optimizing the communication (cf. Schubert 2009a).

3. Production of a Patient Information Leaflet as a Specialized Document: an Analysis

To illustrate how the production of specialized documents is affected by controlling influences that determine producer's decision process, we will analyze the production process of a text type within the pharmaceutical documentation, i.e. the Patient Information Leaflet (PIL), also called

Package Information Leaflet or package insert. A thorough empirical study of this text type[19] has been carried out as a preparatory step to the development of a software tool that aims at optimizing this text type with regard to different features of the dimension of the technical content and the dimension of the linguistic form. The tool will help to introduce the prescribed structure (included mandatory headings and sentences), to reduce redundancy, to use common words instead of scientific terminology and to formulate instructions and warnings in an unambiguous way. In developing the software it was necessary to take into account all aspects that influence the production process of this text type: prescriptive influences, constraints and the workflow within a pharmaceutical company[20]. The analysis in this section is based on the insights gained by the many contacts with pharmaceutical companies that have not yet been described systematically in the scientific literature.

This section consists of three subsections. First of all we will define the PIL as a specialized document. Then we will analyze the impact of the controlling influences on each of the four dimensions discussed in section 2.1., and finally, we will study the controlling influences of the agents, their relation to the work process as well as their interrelations.

3.1. The PIL as a Specialized Document

Before analyzing the production process of a PIL, it is important to justify why we consider this text type a specialized document. The PIL is a text with a specific content and with specific objectives: it informs the consumer about a medicine as such and shows the necessary instructions for a proper use. At the same time it aims at ensuring legal coverage and constitutes an integral component in the registration procedure of the medicine. Three characteristics, mentioned in section 1, manifestly apply to the PIL. First of all, it is very difficult to find out whether the text of a PIL is an original text or a translation. On the European level, particularly in the case of the centralized procedure[21], the English version has to be considered as the original one; the versions in other languages as translations. In the case of national procedures, the document is drawn up in the official language or in one of the official languages of the authorities of the country concerned. As the scientific discussion is carried out in English, also these texts that are drawn up in any other language than English will include parts that are translated from English or based on studies written in English. This leads to the second characteristic mentioned in section 1. It is very difficult to discover whether the text is written by one author or by a team of authors. The PIL is a text with a high degree of intertextuality, among other things, because the content has to correspond to that of the Summary of Product Characteristics (SmPC), of which it is an adaptation[22]. Moreover, as

19 For previous empirical research see Van Vaerenbergh (2007a) and (2007b).

20 The software tool has been developed within the framework of the ABOP project funded by IWT Vlaanderen (Agentschap voor Innovatie door Wetenschap en Technologie – Agency for Innovation through Science and Technology), carried out by Artesis University College Antwerp and University College Ghent, with the scientific support of the Research Centre for Pharmaceutical Care and Pharmaco-Economics of the Katholieke Universiteit Leuven and the Computational Linguistics and Psycholinguistics Research Center of the University of Antwerp. The tool developed in 2008/2009 focuses on the optimization of Dutch leaflets; the development of a version for optimizing English leaflets will happen in 2010 within the framework of the OptiPIL project. This new project is funded by the Industrial Research Fund of the Antwerp University and TechTransfer of the University of Ghent. For a first description of the terminology module of the ABOP software see Delaere et al. (2009).

21 On the European level there are three procedures for marketing authorization applications: centralized procedure (CP), mutual recognition procedure (MRP) and decentralized procedure (DCP). Medicines authorized through the centralized procedure are registered for all EU countries. In the case of MRP, the marketing authorization is given by the competent authority of one of the EU Member States (called the reference Member State – RMS) and can be recognized in an abridged procedure by the competent authority of other Member States. In the case of DCP, identical dossiers are submitted in all Member States that want to receive a marketing authorization. A RMS is selected by the applicant. In the case of MRP and DCP, the dossier contains beside the English version of the PIL a version in the language of the RMS as well. (Definitions by the authors of the article)

22 About intertextuality in technical texts: Ostapenko (2007); about intertextuality in European text types: Schippel (2006); about the intertextual and intergeneric relation between the product summary (SmPC), a scientific document composed by experts and meant for other experts, and the PIL, a document meant for laymen: Askehave/Zethsen (2002)

a result of the work process (cf. sections 3.2. and 3.3.) the text will rarely be, if ever so, the work of one single author. A more in-depth analysis will show that the PIL is a highly standardized document, which is its third characteristic. In the next subsection, we deal with a list of documents that contain regulations, requirements (including required headings and standard sentences) and recommendations that control and limit the options during the decision process and that are the same for all PIL texts within the European framework.

3.2. Controlling Influences in the Production Process of the PIL

In each of the four dimensions discussed in section 2.1. the technical content, the linguistic form, the technical medium and the work processes – the decision process is affected by controlling influences. Most of the requirements and recommendations are laid down in a number of documents. The most important of them are: (1) *the Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004* (European Commission 2004)[23]; *The Guideline on the Readability of the labeling and package leaflet of medicinal products for human use* (European Commission 2009)[24]; (3) *the templates provided by the Quality Review of Documents (QRD) working group* (EMEA 2009)[25], together with some other documents listed under the title of "QRD reference documents"[26] and finally (4) circulars with annexes sent by the national authorities. These circulars are intended to draw attention to the valid regulations and to give additional instructions and explanations for the use of the templates. Because these circulars only have an explanatory function and are country bound, they do not introduce new elements regarding the controlling influences. We mentioned them to have a complete overview, but we do not analyze them further.

The *Directive 2004/27/EC* includes a few articles concerning the PIL (European Commission 2004, L 136/48-49). They have an impact on the dimension of the technical content and the dimension of the work processes. Article 59 (1) stipulates which elements a PIL has to include and in which way sections and elements have to be ordered. This means that article 59 (1) particularly determines features of the macrostructure. Furthermore, article 59 (1) starts with the stipulation that the PIL "shall be drawn up in accordance with the summary of product characteristics" (L 136/48). This phrase does not only express a requirement of the technical content, but it also refers to the dimension of the work processes: drawing up the SmPC precedes the writing of the PIL. The dimension of the work processes is also affected by the content of article 59 (3) and article 61 (1):

> The package leaflet shall reflect the results of consultations with target patient groups to ensure that it is legible, clear and easy to use. (Art. 59 (3) L 136/49)

And article 61(1) respectively:

> ... The results of assessments carried out in cooperation with target patient groups shall also be provided to the competent authority. (Art. 61 (1) L 136/49)

Consulting target patient groups in the form of a user testing[27] is a constituent part of the production process of a PIL.

Concrete support for writing the information and performing a user testing is provided by *Guideline on the readability* (European Commission 2009). This guideline is based on the information design concept developed at the Communication Research Institute of Australia (CRIA), particularly on the work of Sless/Wiseman (1997[2]) that gives actual guidelines for people writing Con-

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and *Directive 2004/27/EC Art. 59 1* (European Commission 2004).

23 In the following text abbreviated as *Directive 2004/27/EC*.

24 In the following text abbreviated as *Guideline on the Readability*.

25 In the following text abbreviated as *QRD templates*.

26 http://www.emea.europa.eu/htms/human/qrd/qrdreference.htm

27 Other methods than user testing may be acceptable under the conditions specified in the guideline and they have to be justified by the applicant.

sumer Medicine Information. The principles applied by Sless/Wiseman largely resemble those of the Information Mapping and of the Funktionsdesign[28], but they have been especially designed for application in consumer medicine information. Moreover, the work of Sless/Wiseman does not only include recommendations for writing the information, but also contains a guideline for the performance of diagnostic tests, in the same way the European guideline does.

Chapter 1, section A of the *Guideline on the Readability* (8-10) encompasses recommendations for: (1) type size and font, (2) design and layout, (3) headings, (4) print colour, (5) syntax, (6) style, (7) paper, and (8) use of symbols and pictograms. Most of the recommendations – with the exception of those on syntax and style – have an impact on the dimension of the technical medium. The recommendations with regard to syntax and style influence, on the one hand, the microstructural organization of the technical content. On the other hand, they control the dimension of the linguistic form. Regarding the *syntax*, the *Guideline on the Readability* recommends to split up long paragraphs, to point out the side effects by frequency of occurrence, starting with the highest frequency and to use bullet points for lists (9). However, other recommendations concerning syntax rather belong to the dimension of the linguistic form: it is recommended to use simple words of few syllables and to avoid long sentences (9). On the one hand, paragraph 6 on *style* deals with the structure of directive speech acts:

> When writing, an active style should be used, instead of passive. … Instructions should come first, followed by the reasoning, for example: 'take care with X if you have asthma – it may bring on an attack'. (European Commission 2009: 9)

On the other hand, it deals with the choice of words: instead of repeating the name of the medicine, it is recommended to use "your medicine, this medicine" (9). Uncommon abbreviations and acronyms should be avoided and medical terms should be explained "by giving the lay term with a description" (9-10). Chapter 1, section A ends by referring to the *QRD templates*. These templates have to ensure consistency in the information "across a number of different medicines and across Member States" (11).

Chapter 3 of the *Guideline on the Readability* is linked to article 59 (3) and to article 61 (1) *of the Directive 2004/27/EC* stipulating the requirement of a user testing and it can be considered as a "Guidance concerning consultations with target patient groups for the package leaflet" (19). As an illustration, one possible way of undertaking a user testing is outlined in the annex. Five aspects of the testing are explained: performing the test, recruiting participants, suggested testing procedure, preparing for the test and success criteria (24-27). What is described here is the external work process of a consumer testing that, by itself, is a constituent part of the external process of the PIL production.

Whereas the *Guideline on the Readability* relies on the *Directive 2004/27/EC*, the documents produced by the Quality Review of Documents (*QRD)* working group transpose the requirements and recommendations of the *Directive 2004/27/EC* and the *Guideline on the Readability* into a practical writing help and style guide with a binding effect. The *QRD template* (EMEA 2009: 14-16) provides a model for the PIL and it is available for the producer in an electronic form. It determines the macrostructure of the technical content that must consist of an introduction and six sections with headings, listed in a preceding table of contents. On a microstructural level, the *QRD template* provides standard sentences to be used not only for headings and subheadings, but also for the expression of directives such as instructions and safety warnings such as "Do not <take> <use> X <if …>" or "Take special care with X <if you…> / <when …>" (14). Two other documents published under the heading of *QRD reference documents* have to be considered as additional to the templates. The *Convention to be followed*[29] (EMEA 2007) includes e.g. an explanation of the bracketing convention used in the templates (<…> or {…}) and other instructions with re-

28 This comparison is a very interesting issue to be studied but goes beyond the aim of this article.

29 Full name of the document: *Convention to be followed for the EMEA-QRD templates and the PIM data exchange standard (DES)*.

spect to the technical medium. The *Compilation of QRD decisions on stylistic matters in product information* (EMEA 2008) consists of a list of QRD solutions meant to solve specific problems. These can concern the content as well as the linguistic form or technical aspects. This will be illustrated by an example of each of these three dimensions.

(1) Dimension of the technical content

> Can general information on health or disease be included in the package leaflet in certain justified cases? (EMEA 2008: 2)

(2) Dimension of the linguistic form

> The patient or physician is often referred to as "he". (= problem)
>
> "He/she" should be used if no other neutral gender locution is possible. Patients can be referred to as "he" or "she" when the medicinal product is exclusively for use by males or females. (= so lution suggested) (EMEA 2008: 1)

(3) Dimension of the technical medium

> Different languages use different number separators (a comma or a dot) to distinguish between thousands and decimals. Style of number must correspond to language used. (EMEA 2008: 2)

The controlling influences of the documents discussed in this section do not only affect the decision space and the decision criteria of the producer, but they also have an effect on other agents in the external process of the PIL production, as it will be shown in the next section.

3.3. Controlling Influences and the Agents in the Production Process of the PIL

In section 2.2. we have listed and discussed four agents or groups of agents that have controlling influences: the *initiator*, the *recipients* or *audience*, the *team* and the *informants*. In the case of the PIL, the role of these agents is determined and restricted by the documents dealt with in section 3.2. This can be demonstrated by the role of the *initiator*. When a person or a department of a pharmaceutical company assigns the task to produce a PIL text to a colleague, the assignment brief can be very concise. It suffices to refer to the *Directive 2004/27/EC*, the *Guideline on Readability* and the *QRD reference documents* that contain all requirements, instructions and recommendations necessary for writing a PIL text. Furthermore, these documents introduce a further, fifth agent or group of agents and determine their role. It is the person or the team in a service company assigned by the pharmaceutical company (*initiator*) that performs a consumer testing in accordance with the relevant articles in the *Directive 2004/27/EC* and the recommendations of the *Guideline on the Readability*.

As mentioned at the beginning of section 3, the contacts with pharmaceutical companies, indispensable for the development of the software tool, have contributed to better insights into the production process of the PIL. From these contacts we know that within a pharmaceutical company, the assignment to produce a PIL text originates from a steering committee (*initiator*) and that the work is carried out by somebody of the Regulatory Affairs department. The author knows that, on the basis of the scientific report, i.e. the Summary of Product Characteristics (SmPC), he has to write a comprehensible text for a large *audience* of laymen. This text has to fulfil the requirements of the documents discussed in 3.2. The text produced in the Regulatory Affairs department is read through and revised by several other departments. On the basis of its own specialization, each department pays particular attention to specific parts and elements in the text. The text production is actually a matter of *team* work, not only because it makes use of the content of an already existing document (the SmPC), but also because of staff collaboration. The revised version produced by the pharmaceutical company does not represent the final stage. In many cases the service company, which has performed a consumer testing, and/or the competent authority involved returns the text to the pharmaceutical company asking for further adaptations and corrections. In that way new additional *initiators* appear. Adaptations to the text are often made by the service

companies themselves as well. The concerned adaptations are implemented before the consumer testing is performed and also between the different test rounds[30]. If these adaptations are performed in consulting the original producer[31], the continuity between the text production in the pharmaceutical company and the text production in the service company can also be considered as a kind of *team* work.

The fourth group of agents is the *informants*. Almost all of them have already been mentioned before: the colleagues of the different departments in the pharmaceutical company, the authors of the SMPC, the organizers of the consumer testing, the competent authorities, the authors of the *Directive 2004/27/EC* and the *Guideline on the Readability* and the QRD working group. We only have to add the authors of studies not mentioned before.

The presence of several *initiators* and different forms of *team* work has a considerable impact on the external production process. To some extent, the authorities responsible for the *Directive 2004/27/EC*, the *Guideline on the Readability* and the style prescriptions act as *initiators* and *informants*. They play a decisive role regarding the assignment, in determining the comprehensibility requirements with respect to the audience and in stipulating the requirements for the organizers of the consumer testing. This means that their controlling influences affect to a large degree the external process of the PIL production as well as the role of the other agents. All the agents involved restrict the decision space of the document producer. This is a characteristic that the production of the PIL has in common with the production of other specialized documents. As in the case of other specialized documents, the aim is to optimize the quality of communication by means of controlling influences[32]. Whether these controlling influences do contribute or not to optimization of the communication quality and to which degree they do so, is an interesting and important issue; though not within the scope of this article.

4. Conclusion

In this article, we studied the external process of specialized document production and the internal decision-making process based on four dimensions: technical content, linguistic form, technical medium and work processes as well as on four agents or groups of agents: the initiator(s), the recipients, the team and the informants. We showed the external process as a source of influences controlling the internal process and postulated that the controlling influences affect the decision space as well as the decision criteria.

The analysis of the production process of the text type Patient Information Leaflets showed how external factors have impact on the decision space within each of the four dimensions as well as on the different agents. With the theoretical model it is possible to name the different stages of the workflow and to describe more systematically the decision-making process as well as the actual controlling influences.

It would be very interesting to study for one or more PILs the whole work process from the first draft to the last version after consumer testing. Such an ethnographic study would bring insights into the contribution of each of the text producers and proofreaders, into the collaboration within the team, into the relation between writing and translating, into the nature of the additions and changes i.e. if they concern the technical content, the linguistic form, the technical medium or the work processes.

30 The *Guideline on the Readability* stipulates: "repeat tests until you have satisfactory data from a group of 10 participants". (European Commission 2009: 25)

31 The *Guideline on the Readability* stipulates: "Ideally the person writing the package leaflet should help draw out the questionnaire and occasionally accompany the interviewer during testing, to enable direct transfer of learning." (European Commission 2009: 24)

32 See article 63 §2 of the *Directive 2004/27/EC* (European Commission 2004: 136/49 and *Guideline on the Readability* (European Commission 2009: 6)

To carry out this study the collaboration with one or more pharmaceutical companies is indispensable, because they have to provide the material and to give permission for the research and the publication. Up to now, we did not find companies that have systematically collected the different versions of a PIL with metadata. The point will be to convince them of the importance of an ethnographic study.

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