Cognitive Approaches to Specialist Languages

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PREFACE

Many of the contributions to this volume were originally presented during a theme session "Cognitive Approaches to Specialist Languages" organized at the Polish Cognitive Linguistics Association 2015 Conference in Lublin. Others were invited by the editor especially for this collection and they include contributions written by prominent scholars in the fields of Cognitive Linguistics and Applied Linguistics, among others, Pamela Faber, Barbara Lewandowska-Tomaszczyk, Maria Cornelia Wermuth, José Mateo, Catherine Diederich, Wei-Lun Lu or José Manuel Ureña Gómez-Moreno. The contributors constitute an international team and represent countries as diverse as Poland (five different universities), Ukraine, Czech Republic, Spain, USA, Taiwan, Switzerland, Belgium.

The proposed volume, however, is not a collection of selected proceedings of a theme session but it has a character of a monograph. Its aim is to discuss various ways of approaching the problems associated with a very broad phenomenon of specialist languages by means of the analytical mechanisms and theoretical conceptions developed within the framework of Cognitive Linguistics. Specialist languages (e.g. language of law, language of business, language of aviation, language of football, language of journalism, etc.) can be perceived as highly conventionalized, semi-natural and not fully autonomous communication codes limited to specific, predominantly formal, situations. A large number of them can be best characterized by subject matter and semantic content, but the most important distinctive element in their make-up seems to be the frame of context in which they are embedded.

The subject to be discussed in the volume is innovative as it offers a new way of researching specialist texts – the kind of linguistic output which is especially popular among corpus linguists, translators, lexicographers, dictionary compilers, data-base creators, text analysts. 'Specialist languages', 'special languages', 'specialized languages' or 'languages for special/specific purposes' are terms more widely used among practitioners than theorists and are tightly connected to professional practices. Similarly, Cognitive Linguistics is a usage-based model in which language reality is perceived as inextricably linked to human experience. The proposed volume offers a wide range of perspectives on a well-defined and closely focused question of a possible contribution of Cognitive Linguistics to the study of specialist languages.

PART I.

INTRODUCTION

CHAPTER ONE

SPECIALIST LANGUAGES AND COGNITIVE LINGUISTICS: A MARRIAGE OF CONVENIENCE OR IRRECONCILABLE OPPOSITES?

MARCIN GRYGIEL

Introduction

'Specialist languages', 'special languages', 'specialized languages' (henceforth SL) or 'languages for special/specific purposes' are terms more widely used among practitioners than theorists. Yet, despite their enormous popularity, SL remain a little researched and variously defined area of applied linguistics (Sobkowiak 2008, Grucza 2009, Lewandowski 2013, Wille 2014). SL are mostly characterized by subject-specific terminology or a communication situation with a particular frame of reference and may include specific linguistic means of expression. These mostly cover lexical, semantic, stylistic and syntactic features. SL are traditionally invoked in the contexts of foreign language teaching and translation studies to refer to ergolects of business, medicine, law and other subject areas which are considered vital from the communicative point of view in professional interaction.

The aim of this chapter is to discuss a possible contribution of Cognitive Linguistics (henceforth CL) to the study of SL. CL is a usage-based model in which language reality is perceived as inextricably linked to human experience. Similarly, the concept of SL is both usage-oriented and tightly connected to professional practices. SL seem to constitute an ontologically gradient phenomenon which generates a number of controversies. Some researchers discard SL as a construct for investigation, claiming that instead of languages we are dealing with terminologies or discourses. Others maintain that a specialist language includes "the totality of all linguistic means" and should be investigated at all linguistic levels (Hoffmann 1976: 170). Still in other approaches, SL are treated as semi-autonomous variants, varieties, jargons, technolects or sub-languages

based on expert knowledge. The question arises to what extent these semiotic systems should be considered natural and to what extent artificial languages. What role does cognition play in the emergence and development of SL?

CL promises to be a framework that could offer novel insights into the problem of defining and better understanding of SL. Additionally, CL can serve as an analytical tool in accounting how SL are conceptualized and linked to professional practices. Consequently, the aim of this chapter, as well as the whole volume, is to show the usefulness of cognitive apparatus in the study of SL.

Characteristic features of SL

The present chapter attempts to draw a broad background for the main ideas that will be developed in more detail in the subsequent parts of the volume. One of its focuses is the notion of SL and their characteristic features. SL function in a great variety of types, but they generally share a number of converging areas and common characteristics. These similarities may be centered around language use, topic, audience, communicative goals, production circumstances (Schulze and Römer 2008). We should not forget, however, that SL are themselves very dynamic phenomena that fluctuate in the continuum between specialist and non-specialist communication as well as different levels of granularity. SL are definitely far from being uniform and the notions we associate with them are in fact conventionalized generalizations highlighting the most prototypical cores of stability around which they emerge. Thus, SL in their totality should be treated more like abstractions and conceptual structures rather than physical entities. This is the reason why in Grygiel (this volume – Chapter 6) I approach SL as three dimensional multimodal forms of communication where specialist knowledge, professional practices and modes of linguistic expression are mixed together.[1]

The most important characteristic features of SL, which make them different from more general means of communication, involve primarily the specific language use. This covers – first of all – lexis, morpho-syntax as well as textual patterning. Of all the three categories, lexis has definitely been considered the most prominent area of research and, accordingly,

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[1] Similarly, Gotti (2003: 24) refers to "specialist discourse" as "the specialized use of language in contexts that are typical of a specialized community stretching across the academic, the professional, the technical and the occupational areas of knowledge and practice".

received much more attention in linguistic literature on SL than the two remaining classes. The distinctiveness of lexical items used in specialist texts persuaded many scholars to treat lexis as a separate phenomenon and even, metonymically, equate its applications with the whole concept of SL. Thus, SL are often associated with their most central – lexical – component and, as a result of the *pars pro toto* reasoning, are frequently reduced to the study of terminology.

According to Gotti (2003), the salient lexical characteristics of SL include monoreferentiality and precision. As the major goal of SL is to communicate a precise message, efficiency is a great priority and words with a double meaning in context as well as figures of speech and metaphorical expressions, which are common in literary texts, are generally avoided. Monoreferentiality means that there is one word form used for one referent and its exact sense can be inferred without reference to the context. Consequently, one term signals a concept in a given specialized subject domain and a given term cannot be substituted by a synonym but only by definition or paraphrase. Sinclair (1996: 82) defines this "terminological tendency" within SL as "the tendency for a word to have a fixed meaning in reference to the world, so that anyone wanting to name its referent would have little option but to use it, especially if the relationship works in both directions".

The lack of emotion and lack of ambiguity have been posited as other characteristic traits of SL. The traditionally held view is that SL should be neutral, logical and informative as their main function is purely denotative. Furthermore, they are also described as transparent. The feature of transparency describes the fact that within SL it should be always possible to promptly access the meaning of a term through its surface form and translators should be able to apply literal translation procedures. SL accommodate those values by being as specific, unambiguous and thus as literal or transparent as possible. Consequently, they are often assumed to function as ideally objective containers of scientific knowledge and empirical findings.

However, in practice SL are far from being artificial languages constructed to perform pre-programmed functions. Cases of ambiguity, imprecision and semantic instability have also been detected, especially in social disciplines (economics, and non-exact sciences) and at times also in legal language. Many studies show that SL do not have a different grammar or lexis with respect to common language. The only difference is the frequency of usage of grammar rules and lexis (Chubaryan and Muradyan 2015).

Because the general function of specialist texts is usually the transmission of knowledge, they are characterized by a greater repetition of terms, phrases, sentences, and even full paragraphs. This can also mean that the text shows similarities in the syntactic constructions used. Among the typical linguistic features of academic prose are the frequent use of nouns, adjectives, and prepositions – as well as a comparatively infrequent use of verbs, pronouns, and adverbs (Biber 1988, Biber et al. 1999).

Terms are generally represented by compound nominal forms. They have meanings specific of a given domain. As a result, understanding a terminology-rich text requires knowledge of the domain, the concepts within it, the propositional relations within the text, as well as the conceptual relations between concepts within the domain.[2] This is a key factor in the translation of specialist texts by a translator, who is obliged to acquire the specialist knowledge necessary to understand the entities and processes described in the source text (Faber 2012).

Examples of applying CL analytical tools to SL

According to many SL researchers (e.g. Faber 2012 or Herrmann and Sardinha 2015), CL is an attractive linguistic paradigm for the analysis of SL. For example, Faber (2012: 6) claims that "the emphasis placed by Cognitive Linguistics on conceptual description and structure, category organization, and metaphor coincides to a certain extent with crucial areas of focus in Terminology, such as scientific ontologies, the conceptual reference of terminological units, the structure of scientific and technical domains, and specialized knowledge representation".

On the other hand, however, we should bear in mind that CL is not one, uniform and rigorously defined approach to the study of language. Instead, CL could be treated as an umbrella term which includes not only work on Cognitive Grammar, Conceptual Metaphor Theory, Conceptual Metonymy Theory (Panther and Radden 1999, Barcelona 2000, 2012) and Conceptual Blending Theory, but also other cognitive-oriented theories such as Construction Grammar (Goldberg 1995, 2006), Cognitive Semantics (Talmy 2000), Conceptual Semantics (Jackendoff 1983, 1990, 1997), and Frame Semantics (Fillmore 1975, 1976, 1977, 1978, 1982, 1985, 1991, 2003a, 2003b, 2009).

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[2] In fact, Meyer (1992: 20) notices that terminology is "somewhat of a misnomer: most fundamentally, it is not the study of terms but rather of the knowledge conveyed by the terms".

    Numerous studies carried out within the Conceptual Metaphor Theory
(CMT) paradigm have suggested that metaphorical language use is
pervasive in natural language across many different domains of application
including textual genres, contextual registers, discourses and SL in
general. Thus, the role of metaphors has been studied in the language of
business and economics (Henderson 2000, White 2003, Koller 2004,
Crawford Camiciottoli 2007, Grygiel 2015), technical communication
(Giles 2008), medicine (Salager-Meyer 1990), biosciences (Larson et al.
2005, Hellsten 2008, Nerlich et al. 2009), environmental studies (Larson
2011), physics (Pulaczewska 1999), law (Smith 2007), newspapers
(Krennmayr 2013), football (Lewandowski 2013), politics (Musolff 2004),
academic discourse (Herrmann 2013) and many other varieties of SL.
    As far as academic discourse is concerned, the type of SL used in this
context cannot be confined to a common subject as academic discourse
can be further subdivided into humanities and arts, natural sciences,
politics, law, education, and social sciences. Instead, Herrmann (2013:
127) claims that in the case of academic prose the audience is specialist, its
dialect domain is global and its main communicative purposes are
information, argumentation and explanation. As a result of being grounded
in a distinctive type of SL, metaphors indentified in academic discourse
display a distributional profile of their own. Herrmann's (2013) analysis
suggests that although metaphorical use is relatively stable in terms of
frequency across academic sub-registers, certain features of academic sub-
registers, such as subject matter, stylistic conventions, and typical
communicative goals are likely to influence the distribution of metaphor
types across academic fields and disciplines. All sub-registers rely largely
on indirect metaphor, but implicit and direct metaphor vary across sub-
registers, with natural sciences, humanities and arts showing a higher
proportion of direct metaphors than the other two sub-registers, but
probably for divergent reasons; while natural sciences may use direct
metaphors for pedagogical reasons, humanities and arts may also apply
them to create aesthetically rich prose.
    It seems that all studies where CMT is applied to investigate SL appear
to suggest that metaphorical language use is ubiquitous in SL and may
play a special role in the careful production of the registers associated with
informational exposition, specifically with regard to their focus on
conveying densely packed and highly precise information. Thus,
metaphors are conceptual tools that exploit familiar knowledge to render
possible the creation of abstract SL ideas across a wide range of source
domains. This is compatible with the basic position of CMT (Lakoff,
1987, 1993; Lakoff & Johnson, 1980, 1999) which sees metaphor as an

indispensable phenomenon of natural discourse spread across all domains, and more abstract domains in particular.

CMT seems to be the most popular and widely used CL model applied to the analysis of SL. However, other researchers are more interested in finding a more general cognitive mechanism that would be able to describe both dynamic aspects and multi-level construction of SL. Specialist languages can be thought of as representations of micro-realities which integrate specific linguistic expressions, expert knowledge, special practices and particular socio-cultural settings. All of these elements seem to be amenable to frame-based modeling in the form of dynamic scenarios with their interactional properties. A cognitive frame refers to events, perceived as schematized 'scenes' or 'situations', and has a form of a scenario containing typical roles played by participants, objects manipulated by them and background factors in which the events are anchored. It schematizes connections between experience and language and contains links to more elaborate knowledge structures. As a result, frames have the advantage of making explicit both the potential semantic and syntactic behavior of specialist language units.

Frames are typically activated and indexed by words (or specialist terminology) associated with them. By means of frames, a language-user interprets her/his environment, formulates her/his own messages, understands the messages of others, and accumulates or creates an internal model of her/his world (Fillmore 1976: 23).Thus, frame-based approaches, more than other accounts, allow for the dynamicity, inherent to specialist languages, to be taken into consideration and are able to explain any specialist language in terms of an on-going process rather than to represent it as a ready-made product.

There have been a number of influential applications of Fillmore's Frame Semantics (Fillmore 1976, 1982, 1985; Fillmore and Atkins 1992; Fillmore et al. 2003) and previous frame-based models to the study of specialist languages, specialized discourse, specialized terminology, specialized knowledge and ontology (e.g. Fillmore and Atkins 1992, Kralingen 1995, 1997; Faber 2012, 2014; Faber and León-Araúz 2014; Diederich 2015). For example, in Faber's Frame-Based Terminology approach certain aspects of Frames Semantics are used to structure specialized domains and create non-language-specific representations. Such configurations form the conceptual meaning underlying specialized texts in different languages, and thus facilitate specialized knowledge acquisition. One of the basic premises of this approach is that the description of specialized domains is based on the events that generally take place in them, and can be represented accordingly (Grinev and

Klepalchenko 1999). Each knowledge area thus has its own event template.

Advantages of applying CL to SL

Traditional approaches to SL have been mostly descriptive and comparative – describing differences between specialist language and general language, e.g. Business English and General English or between various types of specialist languages confronted with each other. Figurative language seems to have been officially banished from the realm of scientific and specialist communication. Such analyses, though useful and practical, are merely anecdotic if they are not placed within the richer context of a wider theoretical framework.

Similarly, most studies on SL have been conducted on a small scale or have been limited in their focus, investigating only a small set of linguistic phenomena such as the use of the passive voice and the concentration of semantic information in complex nominal forms. Accordingly, manuals and research in terminology tend to restrict themselves to a description of practical matters regarding database organization, information extraction, term entry design, language planning, etc (Faber 2012). In the same line, broad quantitative studies which utilize a transparent, systematic method that identifies *all* metaphorical language rather than particular subgroups have largely been absent.

Thus, the biggest advantage of applying CL to the study of SL is putting this investigation not only in the context of a comprehensive theory of language use but also in an even wider perspective where language makes part of cognition and is subjected to cognitive processes. As a result, SL can be studied as coherent and uniform semiotic codes without being separated from the specialist knowledge and culture or social setting with which they are closely integrated. We should not forget that SL, when used in an authentic context, are always culture-specific. In fact, they may be global, nationally based or reflect particular corporate cultures.

In comparison to previous approaches, CL offers better models for the theory of SL. Cognitive mechanisms such as metaphor or metonymy are able to explain the construction of SL in terms of conceptual transfers between micro-realities. Thus, CL makes it possible to study linguistically encoded 'SL micro-realities' as systematically motivated metaphorical construals. Conceptual metaphors sanction context-specific practices, procedures, behavior. The idea that meaning is context-dependent and

encyclopedic, on the other hand, is the basis of the notion of frame, which is in consonance with the knowledge-specific approach to meaning in SL.

CL challenges the assumed arbitrariness and objectivity of not only linguistic, but also social and cultural reality. From this perspective, SL can be regarded not as mere mirrors of the reality around us, but also as active participants taking part in the creation of this reality. SL can be perceived as tools for accumulation and transmission of knowledge and experience, but these tools are shaped by cognitive mechanisms and have a human dimension. SL constitute modes of organizing human knowledge, ideas, experiences, practices, conventions. They play a crucial role in the construction of socio-cultural settings encapsulated in language. As a consequence, they are rooted in the specific micro-realities with their concrete contexts and their understanding is only possible in the framework of cognitive processes that make our interaction with the outside world possible.

Conclusions

Specialist vocabulary, and by extension specialist texts as well as specialist languages, are often described as monoreferential, formal, subject-specific, devoid of emotions, non-metaphorical, technical, precise and based on clearly delineated Aristotelian boundaries. Despite the fact, however, that specialist languages are to a large extent a product of artificial processes of language engineering rather than natural language evolution and development, they are a creation of human minds and constitute scientific or quasi-scientific models. On the other hand, cognitive linguistics offers a number of analytical tools which seem to be ideally suited for the study of sociolinguistic, semantic, pragmatic and discursive aspects of specialist languages. As such, they can be equally revealing in cognitive pursuits and provide a good source of information about how specific fragments of reality are shaped, structured and categorized in the form of idealized, mental languages.

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PART II.

LANGUAGE OF DISCOURSE COMMUNITIES

CHAPTER TWO

A COGNITIVE LINGUISTICS APPROACH
TO THE DISCOURSE OF DRUG INFORMATION
FOR EXPERTS AND PATIENTS

MARIA CORNELIA WERMUTH

Introduction

In this chapter, we take a Cognitive Linguistics approach to analyzing the specialized vs. popularized discourse in written drug information. There are two types of audience to which information on a drug's characteristics is to be transmitted: experts (medical doctors, pharmacists) on the one hand, and patients on the other. The discourse in the texts addressing experts is highly technical and terminology-rich, reflecting the ergolect or work language (Pickett 1989: 5) of the medico-pharmaceutical domain.

Patient-oriented texts such as Patient Information Leaflets, by contrast, use a popularized discourse in which the specialist knowledge is reworded and reframed in a format conform to the linguistic and knowledge profile of a non-expert audience. This is not particularly surprising considering the impact of the situational context on communication (Schulze and Römer 2010: 1) and the inherent relationship between discourse domains and specialized language. In the case of drug information this close interrelationship is manifest: Already a cursory glance at specialized medico-pharmaceutical documents shows a number of discourse features on different levels, which reflect the expert's perspective and conceptualization (Cabré 1998). Hereby, terms (or so-called specialized knowledge units; see Faber 2012: 2) play a pivotal role, being the most important vehicles of conceptual meaning in specialized texts. The high frequency of terms in combination with distinctive syntactic constructions (e.g. nominalizations and passive constructions resulting in a de-personalized style) is in sharp contrast to the discourse in Patient Information Leaflets, which has been popularized by a series of "microstrategies" (Zethsen Korning 2009: 800 and Wermuth, forthcoming 2016).

There is already a large body of research into the formal and linguistic features of Patient Information Leaflets and their readability (see, for example, Pander Maat and Lenz 2010; Garner et al. 2012; Clerehan et al. 2005; Clerehan et al. 2009; Clerehan 2014; Fage-Butler 2013a) tackling problems mainly related to comprehensibility and lay out.[1] Important input has, among others, been provided by discourse analytic studies of medical communication and by numerous studies of language use and interactional aspects in medical conversation analysis, which has become an established field of research in the medical domain (for a detailed review see Ong et al. 1995; Stewart et al. 2003). In a recent study Fage-Butler (2013b) explored Patient Information Leaflets in a novel way using perspectivist theory (Alrøe and Noe 2011). According to this theory, knowledge is inherently associated with some disciplinary, professional and/or personal "locus of observation" (Fage-Butler 2013b: 144). Starting from the general consensus that patients' perspectives should be included in Patient Information Leaflets, the author examines the appropriateness of perspectivist theory as a means of conceptualizing the neglect of the non-expert viewpoint in this text genre. Her analysis highlights the relevance of a polyocular approach in order to optimize "communication across perspectival asymmetries" (Fage-Butler 2013b: 140).

At the same time, the results point to the urgent need for more research on the topic from other disciplines as well. This finding is the starting point for the present investigation: So far there are indeed no detailed investigations into the linguistic implications associated with the reconceptualization and reframing of medico-pharmaceutical expert knowledge from a patient's perspective. Though a recent study on the linguistic localization of Patient Information Leaflets (Wermuth, forthcoming 2016) describes a number of linguistic modifications that point to different viewpoints from which the described reality is perceived (i.e. expert vs. patient), the underlying cognitive mechanisms and interrelationships between conceptual structures on the one hand, and linguistic expressions on the other still require further studies. The aim of the present chapter therefore is to explore in closer detail the linguistic repercussions of the expert's vs. patient's perspective using a cognitively inspired approach.

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[1] As the genre has been judged as being 'dysfunctional' (Askehave/Zethsen 2008: 171) many efforts have been undertaken to improve the reader-friendliness of patient leaflets. For example, more patient-friendly elements have been introduced, the side effects section has been improved, and sections on benefits and on other sources of information have been added.

The chapter is elaborated as follows. In Section 2 we introduce the European Medicines Agency and describe our corpus in greater detail. In section 3 we describe the theoretical framework of our analysis and the relevant apparatus developed within Cognitive Linguistics used for the analysis. In Section 4 we present and discuss the analysis results. In section 5 we provide some conclusions that must confirm the usefulness of the proposed cognitive approach.

Corpus description

The present study is based on the manual analysis of two English language documents accompanying the blood pressure lowering medicine *Telmisartan* (Teva Pharma).[2] The documents are issued by the European Medicines Agency and revised according to the most recent guidelines (European Medicines Agency 2009). The first document is the so-called Summary of Product Characteristics addressing medical experts, the second document is the Patient Information Leaflet, in which the specialized knowledge is 'translated' and reframed in a format conform to the patients' linguistic skills and background knowledge.

The European Medicines Agency

The European Medicines Agency (henceforth: EMA) is substantially involved in the authorization process of pharmaceuticals in the European Union (for a detailed description, see Wermuth, forthcoming 2016). During this process many different kinds of documents are to be submitted, among which the so-called Product Information Document, in three parts: the Summary of Product Characteristics, the Labeling,[3] and the Patient Information Leaflet. The documents are drafted and submitted in English and (after revision and approval by EMA) translated by pharmacists and/or translators into the languages of the EU countries where the product will be marketed (see Nisbeth Jensen 2012; Nisbeth Jensen and K.K. Zethsen 2012, for a detailed description). In this translation process also the mono- or *intralingual* translation of the Summary of Product Characteristics into the Patient Information Leaflet plays an important role besides translation proper. Before we are more explicit about this type of translation, we first will describe in greater detail the two text types under investigation.

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[2] The documents are accessible via the EMA website http://www.ema.europa.eu/.
[3] The labeling shall not be considered here.

Summary of Product Characteristics

The Summary of Product Characteristics (henceforth: SmPC) is the most important regulatory document on a medicinal product in the EU as it is a substantial part of the marketing authorization. As already indicated by the name, the document provides the product description in terms of its chemical, pharmacological, and pharmaceutical properties, and clinical or industrial use. The document is issued by the manufacturing pharmaceutical company as the result of a lengthy development process with numerous preclinical trials (see Figure 1). industrial use. The document is issued by the manufacturing pharmaceutical company as the result of a lengthy development process with numerous preclinical trials (see Figure 1).

SmPCs are scientific texts with a high information density that is related to the needs of the expert reader (medical doctors, pharmacists) to obtain as much information as possible as quickly on how the product is to be used for a specific treatment. The document uses a specialized discourse and represents the information in a specific sequential order at different levels of analysis (see Figure 2).

Important to the present study is the fact that the SmPC is the reference document for preparing the Patient Information Leaflet (henceforth: PIL). The latter can be characterized as popularized and simplified summary designed by the manufacturing pharmaceutical company for patient use. This transformation represents a specific form of mono- or intralingual translation that will be detailed in section 3. The main objective of PILs is to enable patients to take their medication on their own and in the right way. This is achieved by using everyday language and by reframing the specialized information according to the viewpoint of the non-expert target audience (Table 1).
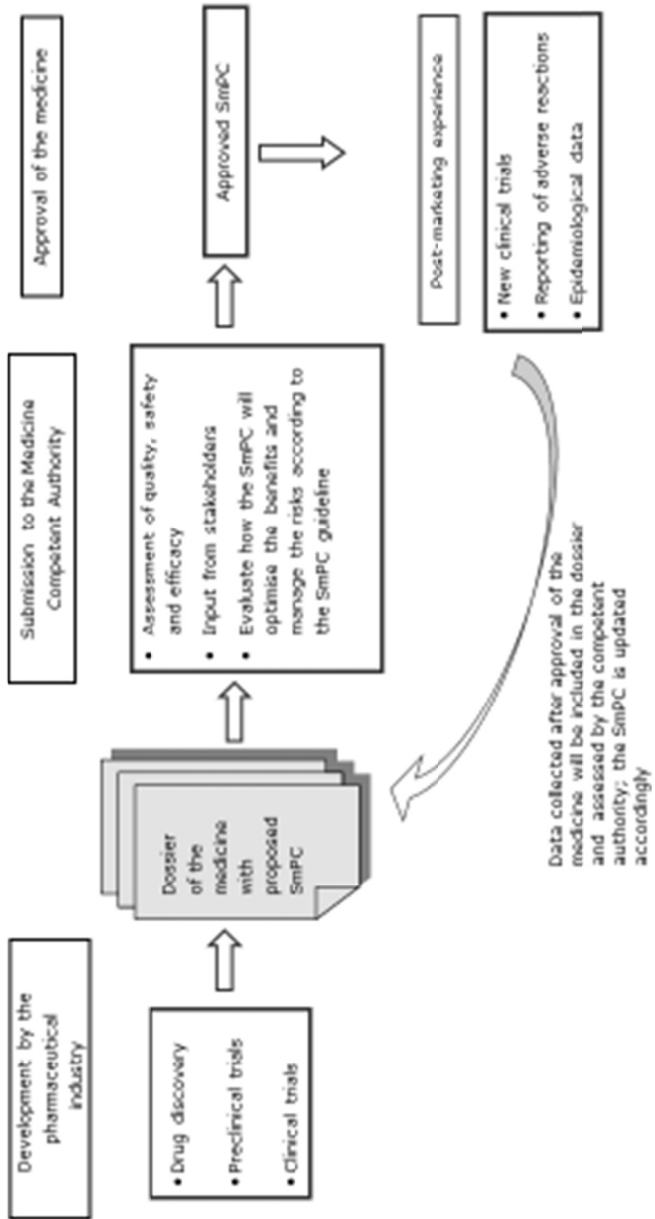
Figure 1. Preparation of the Summary of Product Characteristics.
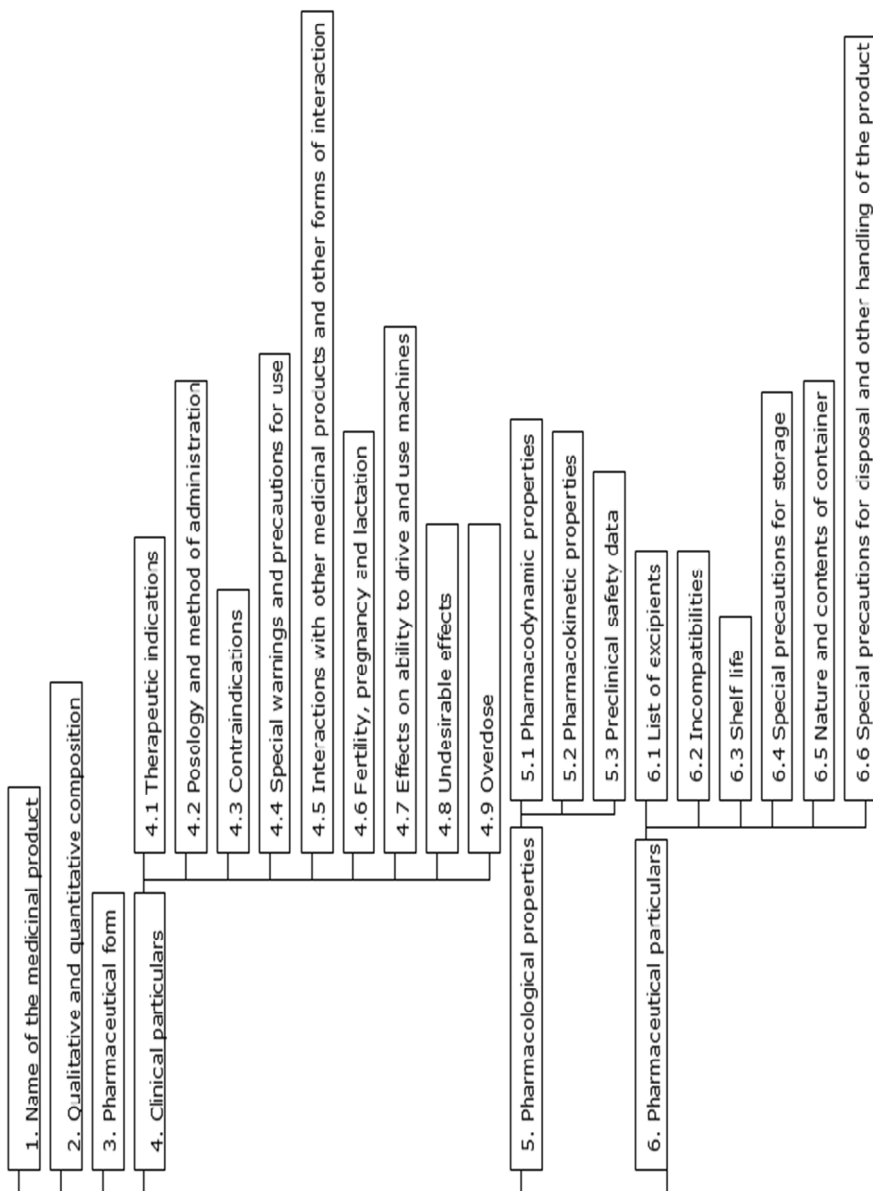
Figure 2. Sequential headings in the Summary of Product Characteristics.

What is in this leaflet
- 1. What Telmisartan Teva Pharma is and what it is used for
- 2. What you need to know before you take Telmisartan Teva Pharma
- 3. How to take Telmisartan Teva Pharma
- 4. Possible side effects
- 5. How to store Telmisartan Teva Pharma
- 6. Contents of the pack and other information

Table 1. Pre-defined headings in Patient Information Leaflets.

In what follows we look at some relevant similarities and differences between both documents in terms of functional, structural, and content-related aspects.

Text function, structure and content

As already indicated, both documents are functional-pragmatic texts, which primary objective is to convey information on a drug's therapeutic use for experts and patients respectively (Wright 1999: 85; Dickinson 2003). Regarding the macrostructure SmPCs and PILs represent so-called controlled documents that are strictly formalized according to a predefined format following the QRD templates.[4]

Both documents are also subject to strict regulations in terms of content and linguistic realization: in either case the information should be accurate, up-to-date, and relevant to the respective target group (healthcare professionals, patients). Furthermore, the information should be presented in clear and concise language in order to be easily legible and understandable for the respective target audiences. To this end, SmPCs adhere to the standardized MeDRA terminology,[5] whereas PILs use wordings, which comply with defined linguistic standards (see Directive 2001/83/EC, art. 63.2).

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[4] The so-called QRD templates (Quality Review Documents) contain the mandatory wording for the Product Information document in the Centralized Procedure. The template texts in all EU languages have been developed in close collaboration with the respective national authorities. The templates are available at http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing /document_listing_000134.jsp.

[5] The Medical Dictionary for Regulatory Activities (MedDRA) is a standardized medical terminology to facilitate sharing of regulatory information internationally for medical products used by humans.