

## **An example of genre shift in the medicinal product information genre system**

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*Medical writers and translators need information of three kinds: conceptual, contextual and textual. When in possession of this information, they can progressively improve their efficiency. Textual genre has proved to be useful to linguistic mediators of professional texts, providing them with the communicative and textual competence required. I suggest that the scope of textual genre can usefully be widened to include the notion of genre systems. This notion can be particularly useful for obtaining contextual information and understanding complex communicative activities in professional groups and can help enhance the professional competence of medical writers and translators. This paper has a two-fold objective: to describe the dynamic continuum of medical communication that operates in the genre system constituted by product information genres in the pharmaceutical sector also considering the restraints, genre conventions and sequence imposed by metagenres; and to illustrate the intralinguistic genre shift translation process that takes place between the summary of product characteristics and the package leaflet.*

### **1. Introduction**

This paper builds on the tradition of genre studies and the work of the GENTT (Textual Genres for Translation) research group<sup>1</sup> by arguing that some genres form sets of interdependent genres or genre systems as a means of performing complex social actions, and that the scope of textual genre analysis can usefully be widened to include the notion of genre systems.

Acquiring competence in genre and genre systems can be considered an effective means of acquiring the abilities needed by medical writers and other linguistic mediators of professional texts, like translators, as it facilitates their socialization as communicative agents in the medical and pharmaceutical sectors.

I shall concentrate on the communicative process carried out by pharmaceutical companies, which is intended to facilitate the prescription of the medicine by the competent intermediaries (prescribers, dispensers, etc.) and its safe use by patients and the general public. This process is

structured in a system of genres that I have called the *medicinal product information genre system*. I shall describe the genre system, the interconnections between the genres involved, and the metagenres interacting with them, paying particular attention to genre shift (Montalt Resurrecció & González Davis, 2007, pp. 162–164) between the summary of product characteristics and the package leaflet as an intralingual translation process which operates from a more to a less specialized genre.

## 2. Genre theory and genre systems in discourse communities

To be a good specialized writer or linguistic mediator, one of the skills that is most evidently required is the ability to understand and produce texts that conform to the conventions of the areas of expertise one is working with, where the very deep conceptual and contextual knowledge required determines the way in which textual and communicative competence should be acquired and applied.

The connection between genres, situated discursive practices and the activity of professional groups seems clear, especially if genres are considered as devices which combine the formal, socio-communicative and cognitive aspects of communication (García Izquierdo, 2005; García Izquierdo & Montalt Resurrecció, 2002) and as symbolic structures (Schryer & Spoel, 2005) which bring social and textual resources shaped by past practitioners forward for current practitioners to use. Studies in genre thus, are well positioned a) to produce results that relate texts to their professional contexts; b) to help to understand how actions are carried out by professional communities; and c) to improve professional linguistic practices in professional communities.

Carolyn Miller's article "Genre as social action" reconceptualized genres as "typified rhetorical actions based in recurrent situations" (1984, p. 159). This perspective provided a framework for understanding genres in terms of exigency, purpose and social action (Devitt, 2000). Reflecting Miller's work (1984) and following Bakhtin's (1986) insights, researchers exploring textual genres in professional settings (Bhatia, 1997; Freedman & Medway, 1994) expanded the concept of audience to include their shifting and changing social contexts. Studies were published exploring the "fluid and dynamic" (Freedman & Medway, 1994, p. 11) nature of genres, how genres are related to complex forms of agency (Schryer, 2001), issues of power and hierarchy (Giltrow, 2001), and social intentions (Bazerman, 1994). Concepts such as genre systems (Russell, 2001; Yates & Orlikowski, 2001, 2002), genre ecologies (Spinuzzi, 2003), family of genres (Ezpeleta Piorno & Gamero Pérez, 2004), or genre networks (Schryer & Spoel, 2005) emerged to explain the complex interaction of genres in the workplace. The theory of genre applied to translation and its correlation with the acquisition

of specialized writing and translation competences started also to be explored (García Izquierdo, 2005; Montalt Resurrecció, Ezpeleta Piorno, & García Izquierdo, 2008; Trosborg, 1997).

### 3. Methods and framework

Our theoretical and descriptive framework of *genre systems* is informed by Bazerman's (1994) notion of "systems of genres [as] interrelated genres that interact with each other in specific settings" (p. 79), and the ongoing theoretical development of this view by researchers such as Berkenkotter (2001); by the mentioned Russell (2001), Spinuzzi (2003), Yates and Olikowski (2001, 2002); and by the GENTT research group (Ezpeleta Piorno & Gamero Pérez, 2004; Montalt Resurrecció et al., 2008). Genre systems are collections of genres that, despite having different characteristics, are related to each other either because they rely on each other or because they complement each other in a specific communicative context within a specific discourse community.

The advantage of studying communicative actions using a genre system approach is that while genres and genre systems both have attributes, a genre system additionally has relational properties that indicate links among constituent genres. Whether the multiple operations of a single genre or the interactions of various genres are being examined, a genre-systems approach highlights larger complex and dynamic networks of power relations with legal implications and practical consequences.

Yates and Orlikowski's (2001, 2002) empirical work on the use of genres in organizational practice illustrated the fact that genres are linked to each other so as to constitute a structure that coordinates communicative actions, and thus they create expectations about the *purpose*, the *content* and *form* (including expectations about structuring devices and linguistic elements) of the whole system as well as those of its constituent genres. A genre system designates the *participants* involved, who typically initiates which genres, and to whom such genres are typically addressed. The different genres are also related by their relative *timing* and *location*, which may be physical or virtual, within the system. Altering the sequence of the constituent genres may create a different variant or invalidate the overall purpose of the genre system.

As Schryer and Spoel have pointed out, *metagenres* help to elaborate the legal, ideological and power operations of genre systems, especially within institutional contexts, but also between institutions and companies or individuals (2005, pp. 256–257). They regulate and reinforce typicality in terms of the macro- and microstructure of other genres and provide a valuable way to understand the dynamics of institutional interrelations among genres. Berkenkotter (2001) has explained that metagenres can be

seen as “a mediational means or tool for stabilizing practices” (p. 339). Thus metagenres such as *institutional guidelines* can be constraining and enabling, “ruling out certain kinds of expression, endorsing others” (Giltrow, 2001, p. 191).

As previously stated, one of the advantages of studying communicative actions using a genre system approach is that they provide the linguistic mediators with the contextual and textual knowledge required. Genre systems description is particularly useful, then, not only for recognizing the aspects of communicative interaction of the whole structure but also for understanding the specific function that each of them fulfils and the specific textual requirements imposed by the whole communicative structure, metagenres included.

In the following sections I first of all present an overall contextual description of the dynamic continuum of medical communication that operates in the genre system constituted by product information genres in the pharmaceutical sector. To do so, I consider the restraints, genre conventions, and sequence imposed by their different settings and users, and especially by those metagenres specific to the genre system.

Then I present the different genres and explore the textual properties and relations between genres, paying particular attention to two of the salient genres of the system, which are closely related: the *summary of product characteristics* (SPC) and the *package leaflet* (PL) in terms of their content and form. Finally, the intertextual operations that take place between the specialized genre and the lay-friendly genre are explored. For this last purpose, I illustrate the intralinguistic translation process from the SPC into the PL, taking the example of a particular medicinal product (*VIAGRA 25 mg film-coated tablets*), and using as a framework Montalt Resurreció and González Davis' (2007) proposals on genre shift strategies and determinologization procedures.

#### **4. Description of the medicinal product information genre system**

The process of medicinal product information and promotion of a medicinal product for its marketing, sale and use implies a sequence of interrelated communicative actions structured in a genre system that I have called *medicinal product information*.

Medicinal products are highly regulated in the European Union (EU). The dynamics of institutional interrelations among the genres involved are set out in a complicated system of *metagenres* issued by regulatory authorities such as regulations, directives and institutional guidelines. These govern how, when, where, and in what form such products will be allowed to be marketed and sold within the EU so as to safeguard and guarantee the highest possible level of public health and to

secure the availability of medicinal products to citizens (Directorate General for Health and Consumers (DGHC), 1986–2012b, chap. 2). Thus, the connections between the genres involved, the information given, the structuring devices, stylistic and linguistic aspects, and even translation matters, are standardized and normalized.

The rules and regulations governing medicinal products for human use in the EU are collected in Volume 1 of *The Rules Governing Medicinal Products in the European Union* (DGHC, 1986–2012a). The legislation is supported by a series of guidelines addressed to professional writers and scientific staff which are compiled in Volume 2 of the same publication. Specifically, Volume 2C contains, among other things, a list of regulatory guidelines related to the full information to be included in the SPC and PL, stylistic matters and requirements for the readability of the labelling and PL (DGHC, 1986–2012b). These also have to be read in conjunction with other relevant guidelines, recommendations and templates developed by the Quality Review of Documents (QRD) group (European Medicines Agency (EMA), 1995–2012). Advertising and promotional material of medical products is also subject to strict and specific control measures and effective monitoring by the European and local authorities.

The series of interrelated communicative actions structured in the genre system is enacted within and across pharmaceutical and medical communities, and its ultimate *purpose* is to facilitate the prescription of the medicine by the competent healthcare intermediaries and to secure its availability and safe use by patients.

The range of *participants* involved in the process is very wide. They are: researchers, scientific staff, medical writers and linguistic mediators working directly or indirectly for pharmaceutical companies or the Marketing Authorization Holder (MAH), who generate the genre system and compose the various documents involved in the process; the authorities—mainly the European Medicines Agency (EMA), The Working Group on the Quality Review of Documents (QRD), and The Directorate General for Health and Consumers (DGHC) of the European Commission— which regulate and supervise the process; healthcare professionals (prescribers, dispensers, etc.) who are the competent intermediaries; and, finally, patients and the general public who use the product. The knowledge generated in laboratories and hospitals is distributed top-down (Montalt Resurrecció & González Davis, 2007, p. 46) and the scope of the involvement and responsibility of the various participants in the genre system is dissimilar.

#### **4.1. The genres of the medicinal product information genre system**

The main genres of the system are: the summary of product characteristics (SPC), the package leaflet (PL) and the labelling. Pharmaceutical

companies or MAHs are legally obliged to provide the SPC to prescribers and dispensers. MAHs must also ensure that medicines will reach patients and users accompanied by the PL and with the approved labelling (DGHC, 1986–2012b). There are also other genres involved, such as the company core data sheet (CCDS), the company core safety information (CCSI), periodic safety update reports (PSURs), promotional texts, etc. This set of interdependent genres whose purpose, content, timing and form typically interconnect is implemented in a well-defined sequence that offers a wide spectrum of communicative situations of decreasing degrees of required expertise and formality.

The central document, the *summary of product characteristics* (SPC), contains the essential information for healthcare professionals on how to use the medicinal product safely and effectively. It is written in accordance with the CCDS and the CCSI, which are prior documents containing all the relevant information concerning the product (DGHC, 2009a).

The SPC, in turn, is the document on which the patient information leaflet and the labelling are based. The *package leaflet* (PL), also known as *patient information leaflet* (PIL) or *package insert*, is the leaflet included in the pack with the medicine. It is a summarized and simplified patient-friendly version of the SPC, and it has to be composed in such a way as to ensure that it is accessible to and readable by non-professionals, so that they can use their medicine safely and appropriately.

Besides, any *promotion of a medicine, advertising, press releases*, etc. (when allowed) has to be drawn up in accordance with the SPC and must be within the terms of the most up-to-date SPC (DGHC, 1986–2012b, 2008).

In addition, there are a series of documents prepared by the MAH which are not always made available to the public and which have to be used as reference for periodic safe reporting and in the preparation of the SPC (DGHC, 2009a). The *company core data sheet* (CCDS) or *core data sheet* (CDS) is a summary of the key characteristics of the product. In addition to product information, it contains safety information and pharmacovigilance data. It also includes information on indications, dosing, pharmacology and other issues concerning the product. Many companies compile a *product monograph* or *product profile* that is quite similar to the CCDS and includes much if not all of the same information. A practical option for the purpose of periodic reporting is for each MAH to use the safety information contained within its major document (the CCDS) as a reference, and then create a new document: the *company core safety information* (CCSI). This document contains the pharmacovigilance section of the CCDS in its entirety or a summary of it. It is intended as the minimum safety information for the product in all the countries of the world where that product is marketed. A CCDS may be updated as necessary and

accompanies the *periodic safety update reports* (PSURs). PSURs present the worldwide safety experience of a medicinal product at defined times post-authorization (DGHC, 1986–2012a, 1986–2012b).

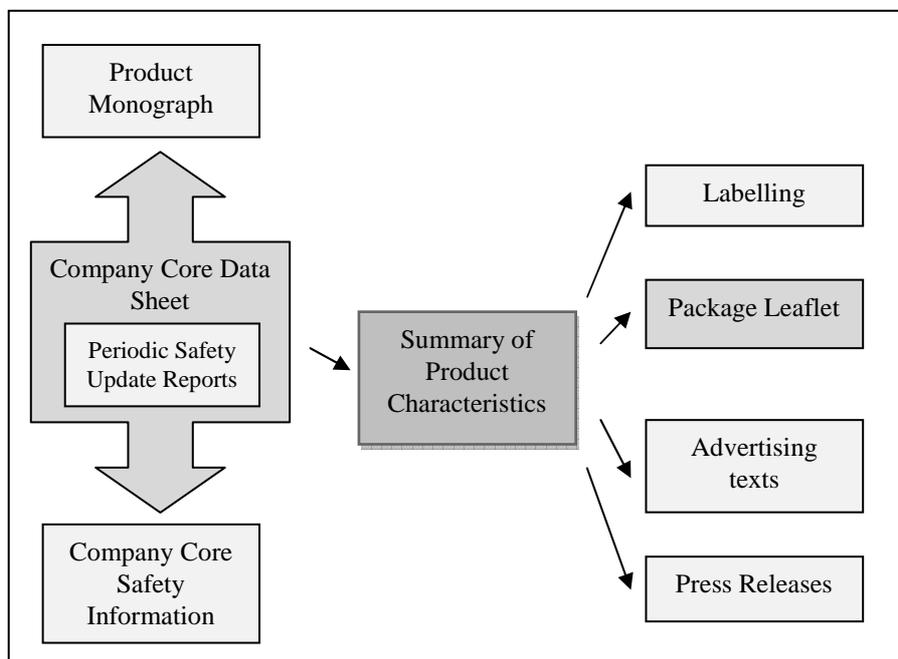


Figure 1: Medicinal product information genre system template (adapted from Montalt Resurrecció & González Davis, 2007, p. 69)

#### 4.2. Summary of product characteristics and package leaflet: content and form

The Summary of product characteristics has an agreed standard template which ensures consistent presentation of data across all SPC documents and enables the specialized reader to retrieve the information easily. The documents “A guideline on summary of product characteristics” (DGHC, 2009a) and “Quality Review of Documents (QRD) human product information annotated template: revision of the product information” (Quality Review of Documents Group (QRD), 2012, pp. 4–8) provide the standardized headings, the phrase sets and phraseology that should be used and/or included when necessary, and give advice on the principles of presenting information.

Sections 1 to 3 of the template contain pharmaceutical data; Sections 4 and 5 contain clinical information (Section 4 relates to the clinical usage

of the medicine and Section 5 includes the relevant scientific information and pharmacological details); Section 6 contains pharmaceutical particulars, and Sections 7 to 10 include administrative information.

Phraseological units are provided for all sections. For example: “<This medicinal product is for diagnostic use only.>”, “<Precautions to be taken before handling or administering the medicinal product>” (QRD, 2012, pp. 4–8).

Consistent medical terminology has to be used and the documents must be worded in clear, concise and unambiguous language. The use of the *Medical Dictionary for Regulatory Activities* (MedDRA) (2012) should be applied throughout the SPC, particularly for Sections 4.3, 4.4 and 4.8. The lists of the *Standard Terms Database* published by the European Directorate for the Quality of Medicines and Healthcare (EDQM) of the Council of Europe (2008) cover dosage forms, routes and/or methods of administration, and containers, closures and delivery devices used for medicines. The EDQM also provides standardized nomenclatures and quality standards for medicinal substances and products, which are published in the *European Pharmacopoeia* (EDQM, 2010).

Package leaflets, too, have a standardized template where headings and sets of phraseological units are set down, such as: “Talk to your doctor <or> <, > <pharmacist> <or nurse> before <taking> <using> X”, “<The recommended dose is...>”, etc. (QRD, 2012, pp. 10–15).

Other institutional guidelines on the readability of PLs contain indications on text type, size and font, the design and layout of the information, the print colour, syntax, style, paper weight, and use of images, etc. There are also specific recommendations for blind and partially-sighted patients (DGHC, 2008, 2009b).

## 5. Summary of product characteristics and package leaflet genre shift

The medicinal product information genre system description shows that the different genres in the system deal with the same topic, but they fulfil different functions and each of them covers specific reader needs. These textual relationships, called *referential* and *functional intertextuality*, are of relevance to the medical writer and translator (Montalt Resurrecció & González Davis, 2007, pp. 55–56) because they underline the fact that genres are dependent on each other as far as communication is concerned but have to be written according to different processes of rhetorical composition with decreasing degrees of specialization and formality. To illustrate these intertextual operations we have chosen two of the genres that are more closely related: the SPC and the PL.

PLs are composed from SPCs in a translation process known as *genre shift* —also known as heterofunctional or transgeneric translation—

(Montalt Resurrecció & González Davis, 2007, p. 163) in which changes in rhetorical purpose and audience inevitably affect the texture and manner of re-presentation in predictable ways (Fahnestock, 1998). In this particular instance of *intra-linguistic* genre shifting, the source genre, the SPC, is an expository genre addressed to experts and professionals, and the target genre, the PL, is an instructional genre addressed to lay readers. Genre shifting is used to bridge the gap between the patient's right to know and the patient's ability to understand, and guarantees the continuity of communication between different expertise communities.

If we put the templates of both genres (QRD, 2012, pp. 4–8, 10–15, presented as Tables 2 and 3 in the Appendix) side by side, we can observe that major structural changes are introduced, PLs are simpler and shorter. The information on pharmaceutical data in Sections 1 to 3 of the SPC is presented in different places, mainly at the end of the PL (Section 6), and sometimes more than once. In PLs the information on clinical particulars (Section 4 of the SPC) goes at the beginning of the PL (Sections 1 to 3). Relevant scientific information, pharmacological properties and pharmaceutical details in SPCs (Sections 5 and 6) are reduced to the minimum in PLs.

Table 1: Comparison of SPC and PL templates

SPC	PL
1. Name of the medicinal product	{(Invented) name strength pharmaceutical form}
2. Qualitative and quantitative composition	{Active substance(s)} 6. Contents of the pack and other information What X contains
3. Pharmaceutical form	[6.] What X looks like and contents of the pack
4. Clinical particulars	1. What X is and what it is used for
4.1 Therapeutic indications	
4.2 Posology and method of administration	3. How to <take> <use> X
4.3 Contraindications	2. What you need to know before you <take> <use> X Do not <take> <use> X<:>
4.4 Special warnings and precautions for use	[2.] Warnings and precautions
4.5 Interaction with other medicinal products and other forms of interaction	[2.] Other medicines and X
4.6 Fertility, pregnancy and lactation	[2.] Pregnancy <and> <,> breast-feeding <and fertility>

4.7 Effects on ability to drive and use machines	[2.] Driving and using machines
4.8 Undesirable effects <Paediatric population>	4. Possible side effects <Additional side effects in children <and adolescents>>
4.9 Overdose	[3.] <If you <take> <use> more X than you should>
5. Pharmacological properties 5.1. Pharmacodynamic properties 5.2. Pharmacokinetic properties 5.3. Preclinical safety data	
6. Pharmaceutical particulars 6.1. List of excipients 6.2. Incompatibilities 6.3. Shelf life 6.4. Special precautions for storage 6.5. Nature and contents of container <and special equipment for use, administration or implantation> 6.6. Special precautions for disposal <and other handling>	6. Contents of the pack and other information What X contains  5. How to store X
7. Marketing authorization holder	[6.] Marketing Authorization Holder and Manufacturer
8. Marketing authorization number(s)	
9. Date of first authorization/renewal of the authorization	
10. Date of the revision of the text	[6.] This leaflet was last revised in <{MM/YYYY}> <{month YYYY}.>

As Montalt Resurrecció and González Davis point out (2007, pp. 162–164), besides structural simplification, there are other procedures used by linguistic mediators when genre shifting specialized genres into genres for patients:

- Synthesizing information.
- Expanding relevant information for the target reader.
- Shifting from author and content to reader comprehension.
- Adjusting tenor to achieve more personalized communication.
- Simplifying syntax.
- Using verbs instead of complicated nouns or noun phrases.
- Determinologizing complex terms.

In order to illustrate the shifts introduced and the procedures employed when genre shifting SPCs into PLs, we will compare the original SPC and the target PL of a particular medicinal product, *VIAGRA 25 mg film-coated tablets* (Pfizer Limited, 2009–2010), putting different examples of original fragments of the SPC and the mediated corresponding fragments of the PL side by side.

In Example 1 below, information concerning clinical usage of the medicine, pharmaceutical particulars and pharmacological details of the SPC is synthesized to the minimum in the PL, and content focus third person declarative mode of the SPC is translated into second person factual conditional in the PL: “if you are... your doctor may”. Thus, the missing information in PL and any possible action will be handled by the reader of the SPC, the doctor. The reader of the PL is considered a non-powerful participant and any interpretation and form of action by patients is excluded.

Also, the passive sentence “co-administration of sildenafil with ritonavir is not advised” and the negative wording “in any event the maximum dose of sildenafil should under no circumstances exceed 25 mg within 48 hours” are translated into an active positive sentence: “your doctor may start you on the lowest dose (25 mg) of VIAGRA”.

#### Example 1

<p>[SPC] [4.5 Interaction with other medicinal products and other forms of interaction] Co-administration of the HIV protease inhibitor ritonavir, which is a highly potent P450 inhibitor, at steady state (500 mg twice daily) with sildenafil (100 mg single dose) resulted in a 300% (4-fold) increase in sildenafil C<sub>max</sub> and a 1,000% (11-fold) increase in sildenafil plasma AUC. At 24 hours, the plasma levels of sildenafil were still approximately 200 ng/ml, compared to approximately 5 ng/ml when sildenafil was administered alone. ...</p>	<p>[PL] [2.] [Taking other medicines:] If you are taking medicines known as protease inhibitors, such as for the treatment of HIV, your doctor may start you on the lowest dose (25 mg) of VIAGRA.</p>
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<p>[SPC] This is consistent with ritonavir's marked effects on a broad range of P450 substrates. Sildenafil had no effect on ritonavir pharmacokinetics. Based on these pharmacokinetic results co-administration of sildenafil with ritonavir is not advised [...] and in any event the maximum dose of sildenafil should under no circumstances exceed 25 mg within 48 hours.</p>	
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When shifting from author and content to reader comprehension, to facilitate the PL's readability, other changes are also introduced, as in Examples 2, 3, 4 and 5. In the next example, the information listed in the SPC is translated into descriptive full sentences. In addition, the heading "Pharmaceutical form" of the SPC is expanded into the PL's heading "What VIAGRA looks like and contents of the pack":

#### Example 2

<p>[SPC] [3. PHARMACEUTICAL FORM] Film-coated tablet. Blue rounded diamond-shaped tablets, marked "PFIZER" on one side and "VGR 25" on the other.</p>	<p>[PL] [[6.] What VIAGRA looks like and contents of the pack] VIAGRA film-coated tablets are blue, with a rounded-diamond shape. They are marked "PFIZER" on one side and "VGR 25" on the other side.</p>
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In Example 3 below, relevant information for the target reader is clarified. As in "for oral use" translated as "Swallow the tablet whole with a glass of water". Also, technical terms like "posology", "toleration" or "indicated" are omitted. Complete sentences are used instead of noun phrases; for example: "sexual activity" is translated as "you plan to have sex". Moreover, imperatives, bold type and modality are used to increase the degree of obligation and to express emphasis and caution, as in: "you should...", "you may find...", or in the sentence "Viagra is not indicated for" rewritten as "Viagra should not be given to":

## Example 3

<p>[SPC]</p> <p>4.2 Posology and method of administration</p> <p>For oral use.</p> <p>Use in adults:</p> <p>The recommended dose is 50 mg taken as needed approximately one hour before sexual activity. Based on efficacy and toleration, the dose may be increased to 100 mg or decreased to 25 mg. The maximum recommended dose is 100 mg. The maximum recommended dosing frequency is once per day. If VIAGRA is taken with food, the onset of activity may be delayed compared to the fasted state.</p> <p>[...]</p> <p>Use in children and adolescents</p> <p>VIAGRA is not indicated for individuals below 18 years of age.</p>	<p>[PL]</p> <p>3. HOW TO TAKE VIAGRA</p> <p>Always take VIAGRA exactly as your doctor has told you. [...] The usual starting dose is 50 mg.</p> <p>You should not take VIAGRA more than once a day.</p> <p>You should take VIAGRA about one hour before you plan to have sex.</p> <p>Swallow the tablet whole with a glass of water.</p> <p>[...]</p> <p>You may find that VIAGRA takes longer to work if you take it with a heavy meal.</p> <p>[...]</p> <p>Special considerations for children and adolescents</p> <p>VIAGRA should not be given to individuals under the age of 18.</p>
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In the following example we can observe how specialized terms are dealt with so that a non-specialist reader can understand them. The characteristic nominalization of scientific language, for example, “contraindications”, “hypersensitivity”, is translated into full imperative sentences: “Do not take Viagra”, “If you are allergic (hypersensitive)”. Also, the medical term “hypersensitive” is retained but in parenthesis after the popular term “allergic”:

## Example 4

<p>[SPC]</p> <p>4.3 Contraindications</p> <p>Hypersensitivity to the active substance or to any of the excipients.</p>	<p>[PL]</p> <p>Do not take VIAGRA</p> <p>– If you are allergic (hypersensitive) to sildenafil or any of the other ingredients of VIAGRA.</p>
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To achieve a more personalized communication, the tenor is adjusted in PLs, the language is more personal and the passive is less frequent. In Example 5, we can notice that the degree of formality decreases (e.g., “penile erection” translated as “to get or keep a hard, erect penis”, “satisfactory sexual performance” translated as “sexual activity”). Also, the personal pronoun “you” is introduced in the passive form: “sexual stimulation” is translated as “you are sexually stimulated”.

#### Example 5

<p>[SPC]  4. CLINICAL PARTICULARS  4.1 Therapeutic indications  Treatment of men with erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance.  In order for VIAGRA to be effective, sexual stimulation is required.</p>	<p>[PL]  1. WHAT VIAGRA IS AND WHAT IT IS USED FOR  VIAGRA is a treatment for men with erectile dysfunction, sometimes known as impotence. This is when a man cannot get, or keep a hard, erect penis suitable for sexual activity.  VIAGRA will only help you to get an erection if you are sexually stimulated.</p>
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As we have mentioned, when the context of communication of medical knowledge moves from specialists to the general public, terminology, which is a quick, clear and precise way of transmitting information for the specialist, may hinder comprehension for the lay reader. Determinologization is therefore a requirement. Montalt Resurrecció and González Davis (2007, pp. 252–253) state that the determinologization procedures that can be used by translators and medical writers when, for example, producing press releases from medical research articles, include the following:

- Scientific terms are retained and followed by explanations.
- Scientific terms are retained in parentheses after the explanations.
- Scientific terms are followed by popular terms.
- Scientific terms are completely avoided and replaced by explanations.

In the process of genre shifting from SPCs into PLs a comprehensive operation of determinologizing the original text is also required of the linguistic mediators. In our example of *VIAGRA 25 mg film-coated tablets*

(Pfizer Limited, 2009–2010) we can find instances of the following determinologization procedures:

- Scientific terms retained and followed by explanations and/or popular terms: the phrase “patients who have conditions which may predispose them to priapism (such as sickle cell anaemia, multiple myeloma or leukaemia)” in the SPC is translated as “If you have sickle cell anaemia (an abnormality of red blood cells), leukaemia (cancer of blood cells), multiple myeloma (cancer of bone marrow)” in the PL.
- Scientific terms retained after the explanations in the PL, as in “If you are allergic (hypersensitive)” or “If you have a deformity of your penis or Peyronie’s Disease”.
- Scientific terms followed and/or accompanied by popular terms in the PL, as in “angina pectoris (or ‘chest pain’), “the drugs known as nitric oxide donors such as amyl nitrite (‘poppers’), or “If you have a deformity of your penis or Peyronie’s Disease”.
- Scientific terms completely avoided and replaced by popular terms: for example, “Impaired renal function” in the SPC becomes “kidney problems” in the PL; and “Impaired hepatic function” in the SPC is determinologized as “liver problems” in the PL.

As a summary, we can state that the different shifts observed when genre shifting from SPCs into PLs are:

- Shifts that are intended to facilitate the PL’s readability for patients.
- Shifts that are intended to exercise control over patients’ actions and that have power implications.
- Shifts that personalize communication and try to get closer to readers.

## 6. Conclusions

In this study, I propose that the notion of genre systems can be a valuable analytic device for studying the roles played by the context and the different agents involved in complex communicative actions such as the medicinal product information, and a means to provide medical writers and translators with the contextual and textual information that their task requires. Our purpose here is to help to illustrate how genre systems description can be used to address the multifaceted issue of medicinal product information.

I have described the *medicinal product information genre system*, focusing on how metagenres interact with the genre system, how they regulate the interrelations and sequence of the constituent genres, and how

they contribute to stabilizing the content and form of communicative product information practices, paying special attention to two of the salient and more closely related genres, the SPC and the PL.

The system as a whole, as well as the individual genres, can be said to have a socially recognized purpose and common formal characteristics. It is suggested that the contextual knowledge of these dimensions and of the institutional operations of metagenres can benefit and play an important role in the socialization of medical writers and linguistic mediators as communicative agents of the pharmaceutical sector.

To approach the way in which textual competence should be acquired and applied by linguistic mediators, the intertextual operations that take place between the specialized genre and the lay-friendly genre have been explored. Our method here is not corpus-based; we have rather illustrated the genre shift or intralinguistic transgeneric translation process from the SPC into the PL, both genres belonging to the medicinal product information genre system, taking the example of a particular medicinal product (VIAGRA 25 mg film-coated tablets). Although the mediator's decisions in the process of genre shifting from SPCs into PLs are restricted by norms and rules, there are certain areas that offer scope for rhetorical composition, which are governed in turn by the communicative needs and purposes of PLs. I have identified different types of shift; and genre-shifting strategies and determinologization procedures have been illustrated. It is suggested that they may be used by (prospective) professional medical writers and translators to work more efficiently and to achieve the intended communicative function of the texts produced. However, further corpus-based analysis will be needed to consolidate (or extend) the list of strategies and procedures identified. Also, the power implications that we have just pointed out and that may underlie the shift from the specialized into the lay-friendly genre will require a more careful consideration.

This study may also contribute to the development of conceptual and cognitive resources for researchers interested in medical communication processes, and to the improvement of tools for the teaching and acquisition of medical writing and translation competence, in its formal, social and cognitive aspects.

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**Appendix**

Table 2: Summary of product characteristics template (QRD, 2012, pp. 4-8)

SUMMARY OF PRODUCT CHARACTERISTICS	
1.	Name of the medicinal product
2.	Qualitative and quantitative composition
3.	Pharmaceutical form
4.	Clinical particulars
4.1.	Therapeutic indications
4.2.	Posology and method of administration
4.3.	Contraindications
4.4.	Special warnings and precautions for use
4.5.	Interaction with other medicinal products and other forms of interaction
4.6.	Fertility, pregnancy and lactation
4.7.	Effects on ability to drive and use machines
4.8.	Undesirable effects
4.9.	Overdose
5.	Pharmacological properties
5.1.	Pharmacodynamic properties
5.2.	Pharmacokinetic properties
5.3.	Preclinical safety data
6.	Pharmaceutical particulars
6.1.	List of excipients
6.2.	Incompatibilities
6.3.	Shelf life
6.4.	Special precautions for storage
6.5.	Nature and contents of container <and special equipment for use, administration or implantation>
6.6.	Special precautions for disposal <and other handling>
7.	Marketing authorization holder
8.	Marketing authorization number(s)
9.	Date of first authorization/renewal of the authorization
10.	Date of the revision of the text

Table 3: Package leaflet template (QRD, 2012, pp. 10-15)

<p>Package leaflet: Information for the &lt;patient&gt; &lt;user&gt; {(Invented) name strength pharmaceutical form}</p>
<p>What is in this leaflet</p> <ol style="list-style-type: none"> <li>1. What X [the medicine] is and what it is used for</li> <li>2. What you need to know before you &lt;take&gt; &lt;use&gt; X <ul style="list-style-type: none"> <li>Do not &lt;take&gt; &lt;use&gt; X&lt;:&gt;</li> <li>Warnings and precautions</li> <li>Children &lt;and adolescents&gt;</li> <li>Other medicines and X</li> <li>X with &lt;food&gt; &lt;and&gt; &lt;,&gt; &lt;drink&gt; &lt;and&gt; &lt;alcohol&gt;</li> <li>Pregnancy &lt;and&gt; &lt;,&gt; breast-feeding &lt;and fertility&gt;</li> <li>Driving and using machines</li> <li>&lt;X contains {name the excipient(s)}&gt;</li> </ul> </li> <li>3. How to &lt;take&gt; &lt;use&gt; X <ul style="list-style-type: none"> <li>&lt;Use in children &lt;and adolescents&gt;&gt;</li> <li>&lt;If you &lt;take&gt; &lt;use&gt; more X than you should&gt;</li> <li>&lt;If you forget to &lt;take&gt; &lt;use&gt; X&gt;</li> <li>&lt;If you stop &lt;taking&gt; &lt;using&gt; X&gt;</li> </ul> </li> <li>4. Possible side effects <ul style="list-style-type: none"> <li>&lt;Additional side effects in children &lt;and adolescents&gt;&gt;</li> </ul> </li> <li>5. How to store X</li> <li>6. Contents of the pack and other information <ul style="list-style-type: none"> <li>What X contains</li> <li>What X looks like and contents of the pack</li> <li>Marketing Authorization Holder and Manufacturer</li> <li>This leaflet was last revised in &lt;{MM/YYYY}&gt; &lt;{month YYYY}&gt;.&gt;</li> <li>&lt;Other sources of information&gt;</li> </ul> </li> </ol>

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