Metagenres and medicinal product information*

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Abstract: "Metagenres" such as directives, regulations and institutional guidelines regulate and reinforce typicality in terms of the macro- and microstructure of other genres. The notion of metagenre helps to elaborate the legal, ideological and power operations of genre systems within institutional contexts and between institutions and companies or individuals (Schryer & Spoel, 2005). I will present the genre system which systematizes "medicinal product information genres" and the restrictions and conventions imposed by metagenres which implement healthcare rules and are issued by regulatory authorities.
Key words: metagenre, genre systems, medicinal product information, pharmaceutical translation.

Metagéneros e información sobre medicamentos
Resumen: Ciertos «metagéneros», como las directivas, los reglamentos y las directrices institucionales, regulan la macroestructura y la microestructura de otros géneros reforzando su tipicidad. El concepto de metagénero nos ayuda a entender las relaciones legales, ideológicas y de poder que se establecen en el seno de los sistemas de géneros, tanto en contextos institucionales, como en las relaciones entre instituciones y personas físicas o jurídicas (Schryer y Spoel, 2005). En esta aportación presentaré el sistema de géneros que engloba los géneros relativos a la «información sobre medicamentos», así como las restricciones y convenciones impuestas por los metagéneros en los que se materializan las normativas sanitarias emitidas por las autoridades competentes.
Palabras clave: metagénero, sistemas de géneros, información sobre medicamentos, traducción farmacéutica.

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1. Introduction

Genre systems focus on interaction among genres, and thus many collaborative uses of communication in professional domains may be analysed through such a lens, which specifically addresses the contextual and temporal interconnections between individual genres.

I suggest that practising and prospective medical writers and translators, in the pharmaceutical sector, and even healthcare communication teachers, may find the description of the *medicinal product information* genre system and the metagenres that interact with the genre system especially useful, as it may facilitate and optimise the process whereby individuals learn the culture of the professional group they are working with, through experience, observation and instruction.

Medicinal products are highly regulated in the European Union (EU) and are subject to a complicated system of approvals that governs how, when, where, and in what form such products will be allowed to be sold within the EU. The process of providing product information on a medicinal product for its marketing, sale and use involves a sequence of interrelated communicative actions structured in a system of genres that I have called the *medicinal product information genre system* (Ezpeleta Piorno, 2012). I will present the application procedures, the genres of the genre system, the metagenres interacting with them and the participants involved.

2. Genre systems and metagenres

Studies in genre provide an especially useful framework to explore texts in their social contexts. They are particularly productive for understanding the connections between specific communication practices and the activity of professional groups (Borja, 2005).

The notion of *genre system* refers to the existence of interdependent genres which appear as certain typical sequences and which form relations with one another and have interacting purposes and forms (Bazerman, 1994; Ezpeleta Piorno & Gamero Pérez, 2004; Spinuzzi, 2003; Yoshioka, Herman, Yates, & Orlikowski, 2003). Moreover, understanding the rhetorical motives, structures and functions of specific genres requires recognition of their interconnections with other genres in a specific communicative context within and across the professional communities that use them or bring them into play.

In the pharmaceutical sector, for example, the *summary of product characteristics* is part of a genre system, together with the *company core data sheet,* the *product profile,* the *package leaflet*, and *medicinal product advertisements*, amongst others. In order to market and sell any medicine in the European Union, all these genres will be interacting in a complex communicative network.

According to Giltrow (2001: 190), a "*metagenre* is situated language about situated language". In her research on mental health discourse, Berkenkotter (2001: 339) has

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demonstrated that certain genres, such as professional manuals, can have metageneric functions for standardising and mediating the localised epistemological communicative practices of psychiatrists. She has explained that metagenres can be seen as "a mediational means or tool for stabilizing practices". Thus metagenres such as directives, regulations or institutional guidelines regulate and reinforce typicality in terms of the macro- and microstructure of other genres, they can be constraining and enabling, "ruling out certain kinds of expression, endorsing others" (Giltrow, 2001: 191).

3. The medicinal product information genre system and application procedures

The primary purpose of the rules governing medicinal products is to safeguard public health. However, European authorities consider that this objective must be achieved by means which do not hinder the development of the pharmaceutical industry or trade in medicinal products within the Community. Thus the pharmaceutical legislation of the EU consistently pursues two objectives: the protection of public health and the free movement of medicinal products.

Before they can be placed on the EU market, all medicinal products for human use have to be authorised either at Community or member state level. The procedures for application for a marketing authorisation in the EU are the *centralised procedure* and the *national procedure*.

Via the *centralised procedure*, European approvals of medicines are overseen by the European Medicines Agency (EMA). The application is scientifically evaluated by the Committee for Medicinal Products for Human Use (CHMP). This procedure results in a single marketing authorisation that is valid in all EU countries, as well as in Iceland, Liechtenstein and Norway, allowing the marketing authorisation holder to make the medicine available to healthcare professionals and patients. The centralised procedure is mandatory for human medicines for the treatment of acquired immune deficiency syndrome (HIV/AIDS), cancer, diabetes, neurodegenerative diseases, auto-immune and other immune dysfunctions, and viral diseases; biotechnological medicinal products, such as genetic engineering; advanced-therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines; and officially designated "orphan medicines" (medicines used for rare human diseases). For medicines that do not fall within these categories, companies have the option of submitting an application to the EMA for a centralised marketing authorisation, as long as the medicine concerned is a significant therapeutic, scientific or technical innovation, or if its authorisation would be in the interest of public health.

The documents required for the grant of a centralised marketing authorisation (summary of product characteristics, labelling, and package leaflet) have to be translated into all EU official languages as well as Norwegian and Icelandic.

If an applicant wishes to obtain a licence in one member state, through the *national procedure*, an application must be made to the national Competent Authority, which then issues a national licence. With the exception of products granted a marketing authorisation under the centralised procedure, as set out above, all products are granted marketing authorisations on a country-by-country basis by the competent authorities in each member state.

There are also two other possible routes available to companies for the authorisation of these medicines in several countries simultaneously: the *decentralised procedure* and the *mutual recognition procedure*. These procedures are based on the idea that a licence approved in one member state should be mutually recognised in other member states, assuming that the evaluation criteria in the EU member states are sufficiently harmonised and are of the same standard. Via the decentralised procedure companies can apply for simultaneous authorisation in more than one EU country of a medicine that has not yet been authorised in any EU country and that does not fall within the mandatory scope of the centralised procedure. Through the mutual recognition procedure companies that have a medicine authorised in one EU member state can apply for this authorisation to be recognised in other EU countries (Directorate General for Health and Consumers (DGHC) of the European Commission, 2007).

3.1. The genres of the system and the metagenres

A genre system provides expectations about the content of the whole genre system as well as the sequence and content of its constituent genres. For the medicinal product information genre system, the constituent genres provide, with different degrees of specialisation and levels of detail, all the relevant information which is necessary and indispensable for the appropriate prescription and safe use of a particular medicinal product (Montalt Ressurrecció & González Davis, 2007).

The main genres involved are: the summary of product characteristics (SPC), the package leaflet (PL), the labelling, and medicinal product advertising texts. 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), etc. This set of interdependent genres is implemented in a well-defined sequence, and their purpose and form typically interconnect.

Between the CCSD, the SPC, the PL, press releases and advertisements there is a wide spectrum of communicative situations of decreasing degrees of required expertise and formality. Thus, the series of interrelated communicative actions structured in the medicinal product information genre system is enacted within and across pharmaceutical and medical communities.

The central document, the *summary of product characteristics* (SPC), is prepared by the manufacturer and may appear in the national compendia in the countries where it is sold. The SPC may also form the legal basis for advertising and promotional materials, as well as for reimbursement of the cost of the drug to the patient by insurance companies or the authorities, since use of the medicine for unapproved (unlabelled) indications may not be covered. It is written in accordance with the CCDS and the CCSI. These are prepared by the marketing authorisation holders and are not always made public (DGHC, 2009). The SPC provides all the information on the product that is essential

for the safe and efficacious use of the medicine, so that the benefits are maximised and the risks are minimised. It explains how to use and prescribe it, and includes a description of the characteristics of the product, its uses, dosing, contraindications, warning, pregnancy information, drug interactions and adverse events. The SPC does not give general advice on the treatment of particular medical conditions. On the other hand, specific aspects of the treatment related to use of the medicinal product or its effects must be mentioned. Similarly, general advice on administration procedures is not included but any advice specific to the medicinal product concerned has to be included.

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,* consists of a summarised and simplified patient-friendly version of the SPC. The information provided and the way it is written and structured are intended to ensure that it is accessible to and can be understood by lay people so they can safely use the medicine concerned.

The SPC, the labelling and the PL must be included in the application for marketing authorisation. Once the authorisation has been obtained, pharmaceutical company representatives are legally obliged to provide the SPC to prescribers and dispensers. They must ensure that medicines will reach patients and users accompanied by the PL and with the approved labelling.

Advertising and other *promotional material* on medical products contributes to the information available but could affect public health. Thus, by regulation, an advertisement must comply with the particulars listed in the SPC. Also, medicinal products which do not have a marketing authorisation may not be advertised. A distinction is made between the advertising of medical products to the general public and to persons qualified to prescribe. The European regulations prohibit the advertising of prescription-only medicines (POM) to the general public. They also prohibit advertising to the general public of medicinal products for the treatment, prevention or diagnosis of certain diseases or conditions. Advertising to the general public of medicinal products legally classified as over-the-counter (OTC) products is allowed (Directive, 2001: 70-95).

In addition, there are a series of documents prepared by the marketing authorisation holder (MAH) which are not always made available to the public and which are used as reference for periodic safe reporting and in the preparation of the SPC. These include not only product information but also safety information, pharmacovigilance data, and other issues concerning the product. The *company core data sheet* (CCDS) or *core data sheet* (CDS) is a summary of the key characteristics of the product. In addition to safety information and pharmacovigilance data, it contains information on indications, dosing, pharmacology and other information concerning the product that is not necessarily applicable in all countries where the product is sold. MAHs often create a new document which is referred to as *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 created for a new product, to be available at the time of the initial submission of a national procedure application in its first market, or at any later point in a product's life cycle. It is updated as necessary and accompanies the periodic safety update reports. *Periodic safety update reports* (PSURs) present the worldwide safety experience of a medicinal product at defined times post-authorisation, in order to: report all relevant new safety information from appropriate sources; relate these data to patient exposure; summarise the market authorisation status in different countries and any significant variations related to safety; periodically create the opportunity for an overall safety reevaluation; and indicate whether changes should be made to product information in order to optimise the use of the product (DGHC, 1986-2012[a], 1986-2012[b]).

The dynamics of institutional interrelations among the mentioned genres are set out in a series of *metagenres* such as directives, regulations and institutional guidelines, so as to guarantee the highest possible level of public health and to secure the availability of medicinal products to citizens across the European Union. *Regulations* are directly effective as supranational law and are addressed to the citizens of the EU member states. *Directives* are addressed to the member states and have to be implemented in national law by the legislation of the member states. *Guidelines* are not legally binding, but where an applicant chooses not to comply with a guideline, that decision must be explained and justified. Guidelines are addressed to professional writers and scientific staff of authorities and companies. For the purposes of this article, these metagenres will be considered as tools for stabilising practices which rule the flow of information and the way it has to be provided.

The rules and regulations governing medicinal products for human use in the European Union are collected in Volume 1 (Pharmaceutical Legislation for Medicinal Products for Human Use) of *The Rules Governing Medicinal Products in the European Union* (DGHC, 1986-2012[a]). The legislation is supported by a series of guidelines compiled in Volume 2 (Pharmaceutical Legislation Notice to applicants and regulatory guidelines medicinal products for human use) of the same publication (DGHC, 1986-2012[b]). These institutional guidelines are related to procedural and regulatory requirements such as renewal procedures, dossier requirements, variation notifications, summary of product characteristics and package leaflet requirements, and classification for the supply and readability of the labelling and package leaflet requirements.

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. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use establishes a Community code which brings together, in a single instrument,

all the provisions in force governing the placing on the market, production, labelling, classification, distribution and advertising of medicinal products for human use (Directive, 2001: 70-95). Specifically, the advertising of medicines is controlled by medicines regulatory authorities in member states and other national regulatory bodies, together with self-regulation by the pharmaceutical industry. However, The Directorate General for Health and Consumers (DGHC) of the European Commission exercises supervision to ensure that the distribution of information to prescribers, dispensers and the general public, and its content and placing, are in accordance with European laws on product safety, consumer rights and public health in all EU countries.

All EU directives, regulations, guidelines, points to consider, recommendations and procedures for the regulation of human medicines can also be consulted at the European Medicines Agency website (European Medicines Agency, 1995-2012).

3.2. The participants

The range of *participants* involved in the process of providing information for the marketing, sale and use of products is very wide. They are: researchers and scientific staff and medical writers and linguistic mediators working for pharmaceutical companies or marketing authorisation holders, who generate the genre system and compose the various documents involved in the process; the authorities, which regulate and supervise the process; the receivers, who are the competent intermediaries; healthcare professionals, prescribers and dispensers; and, finally, patients and the general public who use the product.

According to the European Medical Writers Association, the tasks performed by *medical writers* and *linguistic mediators* mainly concern the communication of clinical and scientific data and information to a range of audiences in a wide variety of formats. They have to combine good knowledge of science and research skills with an understanding of how to present information. They also have to be able to pitch it at the right level for the intended audience. Usually, their background is a medical or life science qualification (e.g. biology, biochemistry, physiology or chemistry). However, there are many medical writers and translators who enter the profession with backgrounds in language rather than science. The competence required is a high-level understanding of basic human anatomy and physiology, a good knowledge of diseases and their treatment, and, of course, very good writing and word-processing skills. Medical writers and translators also need to have good interpersonal skills, for, as we have seen through this paper, they collaborate in interdisciplinary teams (European Medical Writers Association, n.d.). They usually work for pharmaceutical companies, contract research organisations (CROs) or communications agencies.

In a pharmaceutical company, medical writers prepare documents for submission to the regulatory authorities and manuscripts for publication. However, depending on the company, they may also be involved in other writing projects, such as training manuals, promotional material for marketing purposes, and websites.

Contract research organizations (CROs) are services companies that support pharmaceutical, medical device or biotechnology companies. They provide such services as biopharmaceutical development, preclinical research, clinical research and clinical trials management. Usually, they also offer services in medical product information and marketing. They help pharmaceutical companies to get their products registered with international regulatory authorities, and offer their clients the expertise necessary to take a new medicinal product from conception to European Medicines Agency marketing approval, without the marketing authorisation holder having to maintain a staff for these purposes. In general, medical writers in CROs are involved with preparing a range of documents for these regulatory submissions, including summaries of product characteristics and product information leaflets.

Medical writers in communications agencies generally prepare manuscripts for publication, items for conferences (e.g. posters, abstracts and slide presentations), promotional items for pharmaceutical marketing, training material, and multimedia (e.g. websites).

The *Marketing Authorisation Holder* (MAH) is the company or firm in whose name the marketing authorisation has been granted. This party is responsible for all aspects of the product, including quality and compliance with the conditions of marketing authorisation. The authorisation holder must be subject to legislation in the country that issued the marketing authorisation, which normally means being physically located in the country, or the European Union. Companies or firms have to be established in accordance with the law of a member state and have their registered office, central administration or principal place of business within the Community. They have to be constituted under civil or commercial law, including co-operative societies, non-profit-making organisations and other legal persons governed by public or private law.

In order to help ensure the highest possible level of public health protection within the European Union, the EU established the *European Medicines Agency* (EMA) in 1994. The EMA is a decentralised agency of the EU, located in London, with the main task of coordinating the scientific evaluation of the quality, safety and efficacy of medicinal products that undergo an authorisation procedure and providing scientific advice of the highest possible quality. The Agency is also responsible for the linguistic review process of product information in the centralised procedure. The document *Operational procedure on the linguistic review process of product information in the centralised procedure – human* presents the review process within the Commission's Decision-Making Process (DMP) timeframes and provides details on its practical implementation (European Medicines Agency, 2011).

In addition, once a medicinal product has been authorised in the Community and placed on the market, its safety is monitored throughout its entire lifespan to ensure that in the event of adverse reactions that present an unacceptable level of risk under normal conditions of use, it is rapidly withdrawn from the market. This is done through the EU system of pharmacovigilance (which is beyond the scope of this article). Six scientific committees, composed of members of all

European Union (EU) and European Economic Area (EEA)-European Free Trade Association (EFTA) states, conduct the main scientific work of the Agency:

- Committee for Medicinal Products for Human Use (CHMP);
- Committee for Medicinal Products for Veterinary Use (CVMP);
- Committee for Orphan Medicinal Products (COMP);
- Committee on Herbal Medicinal Products (HMPC);
- Paediatric Committee (PDCO);
- Committee for Advanced Therapies (CAT).

The *Working Group on the Quality Review of Documents* (QRD) provides assistance to the Agency's scientific committees and to companies on linguistic aspects of the product information (summary of product characteristics, labelling and package leaflet) for medicines (Quality Review of Documents Group, 2012). It was established in June 1996 and is composed of representatives from member states' national authorities, the European Commission and the Agency. The QRD's tasks include:

- ensuring linguistic clarity, consistency and accuracy of the product information;
- verifying the terminology used in translations and their consistency with the original versions;
- promoting legibility of product information;
- reviewing and updating templates for opinions of the scientific committees and for product information, to ensure compliance with European Union rules on medicinal products and taking practical experience into account; and
- contributing to the development of a common understanding on the implementation of legislation and guidelines in relation to product information and labelling.

The *Directorate General for Health and Consumers* (DGHC) of the European Comission, among other, has monitoring responsibilities. It exercises supervision to ensure that the that the distribution of information to prescribers, dispensers and the general public, and its content and placing, are in accordance with European laws on product safety, consumer rights and public health.

4. Conclusion

In this work, I propose that the notion of genre systems can help us to understand how communicative actions are carried out by professional communities. In particular, we have seen the complex communicative processes of medicinal product information in the pharmaceutical sector, and the activities and roles played by the different agents involved.

I have presented the *medicinal product information genre system*, the interconnections among the main genres involved, the institutional metagenres interacting with them, and their settings and users. I have explained how metagenres interact with the genre system, how they regulate the interaction and sequence of the salient constituent genres of the system.

It is suggested that knowledge of these dimensions and of the institutional operations of metagenres can play an important role in the socialisation of medical writers and linguistic mediators as communicative agents of the pharmaceutical sector.

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

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