Chapter 10
Navigating the Complexities of the OTC Medicine Ecosystem

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Abstract The previous chapters have analysed the difficulties a patient may face in purchasing a medicine, even though supported by the prescription and the information he or she may receive, in written or verbal form, from the doctor during the examination and from the pharmacist during dispensing of the medicine. However, some medicines do not need to be prescribed by the doctor but can be purchased independently by the patient. In these cases, even more so than in the case of medicines dispensed on prescription, it is necessary for the information accompanying the medicine to be comprehensive, understandable and to make certain information available to the patient before the medicine is purchased. This is the case here with over-the-counter analgesics.

10.1 The Over-the-Counter Analgesics

When we have quite common symptoms as headache, toothache, a few fever lines, we use medicines (as Aspirin) that can reduce inflammation (antiphlogistics), or lowering body temperature in case of fever (antipyretics). Several painkiller medicines are defined as over-the-counter (OTC) or non-prescription (SOP) medicines. OTC drugs, also defined as self-medication drugs, are those medicines that are displayed above the pharmacy counter or in areas to which patients have free access.

They can alleviate many symptoms without the intermediation of a doctor. However, as Lynch suggests,[1] the safe use of these drugs requires knowledge,

[1] Shalini S. Lynch, *Panoramica sui farmaci da banco* [*Overview of over-the-counter medicines*], https://www.msdmanuals.com/it-it/casa/farmaci/farmaci-da-banco/panoramica-sui-farmaci-da-banco, (consulted on 21.11.2022).

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common sense, and responsibility, because there may be some contraindications, so it is essential to read the package leaflet.

Patients can access them without the requirement of a prescription, they can buy them autonomously, under the advice of a pharmacist, or on the suggestion of advertising which is permitted for this category of medicines. This differentiates OTC from SOP drugs[2] which, although they do not require a prescription, cannot be advertised.

OTC can be acquired at pharmacies, parapharmacies, at supermarkets in specific dedicated corners with a pharmacist, or online. They belong to band C-bis (a subclass of band C); therefore, their cost is fully charged to the citizen (they can't be reimbursable by the National Health System).

Analgesics, from Greek *ἀναλγησία* «insensibility to pain», derivation from *ἀναλγής* «without pain», made by *ἀν-* privative and *ἄλγος* «pain»,[3] are medicines that are used in therapy to counteract painful stimuli of varying origin and severity (mild, moderate, or severe).

As stated in the MSD (manual version for patients and professionals)[4] analgesics fall into three categories:

- Non-opioids;
- Opioids (narcotics);
- Adjuvants (drugs usually used to treat other problems, such as convulsions or depression, but which can also relieve pain).

Non-opioid painkillers can be utilized for mild to moderate or sometimes severe pain. They are the medicines of first choice for contrasting pain. They don't create the risk of developing physical dependence and are well tolerated.

Among non-opioid analgesics, ibuprofen, ketoprofen and naproxen, are available over the counter, but higher dosages may require a prescription; on the contrary Aspirina C and Paracetamol (for example, the well-known *Tachipirina*), are non-opioid analgesics, and both are over-the-counter drugs.

Many of the most used non-opioid painkillers are also classified as non-steroidal anti-inflammatory drugs (in Italy FANS,[5] NSAID abroad).

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[2] Non-prescription medicines—more simply referred to as SOPs—are those medicines that can be dispensed in pharmacies without a prescription, they can be taken for ailments that are considered mild and transient. Unlike OTPs, the law prevents SOPs from being advertised in any way and it's necessary the intermediation with a pharmacist.

[3] See https://www.treccani.it/enciclopedia/analgesici_%28Enciclopedia-Italiana%29/, (consulted on 21.11.2022).

[4] James C. Watson, *Pain Treatment*, on https://www.msdmanuals.com/it-it/casa/disturbi-di-cervello,-midollo-spinale-e-nervi/dolore/trattamento-del-dolore?query = analgesico, (consulted on 22.11.2022).

[5] The most diffused FANS are ibuprofen, naproxen, diclofenac, celecoxib, mefenamic, acid etoricoxib, indomethacin, nimesulide, high-dose aspirin, https://www.issalute.it/index.php/la-salute-dalla-a-alla-z-menu/f/fans-farmaci-antinfiammatori-non-steroidei?highlight=WyJhc3BpcmluYSJd#tipologie-di-fans, (accessed 2022 Nov. 22).

They can be taken for short periods of time, without consequences, but it's fundamental to follow the instructions on the package leaflet and to go to a doctor if the symptoms persist or worsen.

As reported in Italy by *Istituto Superiore di Sanità,*[6] it's important to ask the doctor or pharmacist if there is one of these conditions:

- age over 65;
- supposed or real pregnancy status;
- during breast-feeding;
- the patient suffers from asthma;
- there were allergic reactions to FANS in the past;
- there are stomach ulcer problems;
- the patient suffers from heart, liver, kidney, circulatory, intestinal, or high blood pressure problems;
- the patient is taking other drugs (see interactions with other drugs;
- any medication containing aspirin should be avoided to children under 16 years of age.

Despite the ease of purchasing and assuming these medicines, there are many risks of side effects: stomach pain, nausea and diarrhoea, stomach ulcers, which can cause internal bleeding and anemia; it is often necessary to take gastroprotection drugs, such as proton pump inhibitors, along with FANS perforation of the stomach or intestine, headaches, drowsiness, dizziness, allergic reactions, in rare cases liver, kidney, heart and circulatory problems, including heart failure, stroke and heart attack.[7]

For these reasons it is essential that information on the secondary packaging and package leaflet is accessible and comprehensible to all patients.

Another element of complexity is the large number and variety of these drugs in terms of denomination, dosage, and reference pharmaceutical companies.

If we consider the most common medicines based on paracetamol and acetylsalicylic acid, we can find approximately: 46 different denominations and 57 pharmaceutical companies for paracetamol, and 22 different denominations and 19 pharmaceutical companies for drugs with the active ingredient acetylsalicylic acid. The dosages and types of approved packaging are even more varied and numerous.[8]

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[6] Istituto Superiore di Sanità, ISS, https://www.issalute.it/index.php/la-salute-dalla-a-alla-z-menu/f/fans-farmaci-antinfiammatori-non-steroidei?highlight=WyJhc3BpcmluYSJd#farmaci-alternativi-ai-fans, (accessed 2022 Nov. 22).

[7] See FANS side effects on https://www.issalute.it/index.php/la-salute-dalla-a-alla-z-menu/f/fans-farmaci-antinfiammatori-non-steroidei?highlight=WyJhc3BpcmluYSJd#farmaci-alternativi-ai-fans, (accessed 2022 Nov. 22).

[8] See the medicines database, prepared by the Italian Medicines Agency (AIFA), is the only official database allowing consultation of the updated Summary of Product Characteristics (RCP) and package leaflets (PIL) of medicines authorized in Italy, https://farmaci.agenziafarmaco.gov.it/bancadatifarmaci/.

From this first overview, a very complex context emerges, an ordinary patient may find it difficult to purchase an OTG drug on his or her own, there is a question of whether the information available to him or her is readily readable, comprehensible, and communicatively consistent.

In this regard, it is important to remember, as reported by Di Pace (2019, p. 28), that before drugs can enter the market, they must obtain Marketing Authorisation (AIC) granted by the EMA (European Medicines Agency) and in Italy by the Italian Medicines Agency in collaboration with the Ministry of Health.

Furthermore, the legal basis for the requirements relating to labels and package leaflets are in Directive 2001/83/EC on the Community code relating to medicinal products for human use as amended by Directive 2004/27 EC. The legal basis for the requirements relating to the safety feature appearing on the packaging of medicinal products is in regulation (EU) 2016/161.

These guidelines bind the member states to achieve the envisaged objectives, they are translated into legislative decrees that may vary between the different states of the European Union.

As reported by Di Pace (2019, p. 28), in Italy, the law that implemented the European directive is Legislative Decree No. 219 of 24 April 2006,[9] among the articles, the decree imposes the obligation to use the package leaflet (Art. 76) and the following are regulated: the contents of the package leaflet (Art. 77), changes to the labelling and package leaflet compatible with the summary of product characteristics (Art. 78), signs or pictograms (Art. 79), the language used (Art. 80), the general characteristics of the information in the package leaflet and labelling (Art. 81), the consequences in the event of non-compliance with the labelling and package leaflet provisions (Art. 82).

10.2 A Matter of Texts, Paratexts and Multiple Translations

In the context of over-the-counter analgesics, in this research work, we have analysed more in detail one of the most sold and well-known OTC medicines, that we will call in this chapter Medicine X.

The goal is to frame it within an ecosystem that includes different communication artefacts surrounding the medicine, to analyse it according to semiotic and translation theories.

More specifically, we focused on the relationship between Medicine X and three types of textuality: primary packaging, secondary packaging and the package insert.

[9] Legislative decree No 219 of 24 April 2006. Implementation of Directive 2001/83/EC (and subsequent amending directives) on a Community code relating to medicinal products for human use. Entry into force of the decree: 6-7-2006 (Last update to the act published on 12/08/2022).

For more information see the link https://www.normattiva.it/uri-res/N2Ls?urn:nir:stato:decreto.legislativo:2006-04-24;219!vig= (accessed 2022 Nov. 23).

A medical product can be considered, from a semiotic perspective, as a "text", defined by Marrone as an overall configuration of meaning that, by using an expressive support, ensures the creation, transmission, and interpretation of social and cultural meanings (Marrone 2010, p. 18).

Medicines-texts, influence social behaviours, both are located in a unitary framework in which experiences, texts, models, gestures, codes, communicate with each other and only thus function (Lorusso 2010, p. 76).

This perspective places the medicinal product within a social and communicative dimension, in which the community of experts (doctors, pharma companies, legislative authorities), the patients, the cultural and social context, the languages with their codes and rhetoric, constitute a unitary tissue (the semiosphere).[10]

The medicine doesn't live alone, just as a text, it is supported and accompanied by other texts, several productions, multiple communicative artefacts,[11] «which surround and prolong it, to present it, indeed, in the current sense of the term, but also in its strongest sense: to make it present, to ensure its presence in the world, its reception and its consumption», (Genette 1989, p. 3).

These accompanying texts can be defined in term of *paratexts*,[12] although they are themselves texts.

In our specific sector, paratexts can be represented by the summary of product characteristics (SPC),[13] the primary and secondary packaging,[14] the packaging leaflet, the dedicated website, the formats that vehicle advertising.

According to Genette, they are the privileged place of a pragmatics and strategy, of an action on the audience, (Genette 1989, p. 4).

[10] The whole semiotic space can in fact be considered as a single mechanism (if not as an organism). It is then not this or that brick that plays a primary role, but the <<big system>> called the semiosphere. The semiosphere is that semiotic space outside of which the existence of semiosis is not possible (Lotman 1985, p. 58).

[11] «Our initiative, in keeping with the design, fabricative, operational, poietic inclination of our discipline, consists rather in considering the visual communicative phenomenon by seeing it as constituted by the material objects produced that make it up. Indeed, we criticise the very notion of visual communication as a generic abstraction and tend to replace it, as a definition or indication of the object of investigation, with the concept of communicative artefact», (Anceschi 1981, p. 14).

[12] The paratext is nothing more than an auxiliary, an accessory to the text. […] A threshold cannot but be crossed (Genette 1989: 404).

[13] This is the expert-to-expert text which in expert terminology describes contents, side effects etc. It is meant for health professionals such as doctors. Furthermore, the SPC provides the authorization body, EMEA, with information about the medicine for them to assess whether the medicine should be authorized, (Brøgger 2013)

[14] With primary packaging we intend the packaging in direct contact with the medicine aimed at its protection and preservation, with secondary packaging we refer to the external packaging that protect the primary packaging and also convey information about the medicine. Secondary packaging is important because it constitutes a communicative artefact aimed at the 'staging' of the pharmaceutical product within analogue or digital sales spaces. See at this regard, Bucchetti (1999).

From this perspective paratexts of medicines are strictly connected to their context and are subjected to a series of *translation*[15] processes that relate them to their users with specific purposes.

These translation processes can be summarised in terms of *endolinguistic translations* (defined also in term of reformulation or intralinguistic translations), *typographical translations* finalized to the transcription of verbal content, *intersemiotic translations* (for example from the verbal content to the visual or vice versa), *interlinguistic translations* (when we translate one language to another), *inter-format translations* (when we have to search new format solutions), and *inter-media translations* (when we transpose contents in the digital involving multimodal directing practices), (Caratti et al. ii 2021, pp. 1105–1112).

Through translation practices, the medicine-text and its paratexts not only determines its own internal heterogeneity, but also it relates to external contexts, multiple media, several users, produces different behaviours, and it opens itself up to a continuous semiotic exchange with other texts or paratexts.

From this point of view, as Lorusso asserts referring to Lotman, the semiotic space (the semiosphere), appears to us as a multi-layered intersection of various texts, which together form a certain layer, with complex internal correlations, varying degrees of translatability and spaces of untranslatability, (Lorusso 2010, p. 83).

The intersection between texts and paratexts and their continuous interexchange can be explained by the concept of *intertextuality*, which Barthes describes as the opening of the text onto other texts, other codes, other signs (Barthes 1991, p. 184), and Genette defines in term of the effective presence of one text in another (Genette 1989, p. 4), the observation of this phenomenon allows us to consider a very common OTC medicine that we will call in this chapter Medicine X, starting from its connections with other texts and more in detail its paratexts.

This theoretical premise allows us to frame the point of view from which we will analyse and deconstruct the traits of Medicine X, conceived semiotically as a text which relates intertextually with its paratexts and other texts. More in detail, we will focus on the relationship among our case study and three typologies of paratexts: the primary and secondary packaging and the package leaflet.

The first step of the research work was to place Medicine X within the context of over-the-counter analgesics based on acetylsalicyclic acid.

10.3 Multiple Formulations Based on Acetylsalicylic Acid

Our case study, Medicine X, has acetylsalicylic acid as its active ingredient and it is a drug that is used as an analgesic (to relieve mild pain), antipyretic (to reduce fever), anti-inflammatory.

[15] According to Peeter Torop (2010) translation consists of a deep and total semiotic process involving a transfer from a source text to a target text.

Medicines with acetylsalicylic acid as an active ingredient are numerous, the AIFA (*Agenzia Italiana Farmaco*) drug database site[16] contains 61 entries of which: 22 correspond literally to the term acetylsalicylic acid, (they differ in the pharmaceutical company of reference), 7 to the term Medicine X (with multiple pharmaceutical companies), 7 retain the name of Medicine X but with the addition of terms specifying its purpose (e.g. Medicine X *dolore e infiammazione),* or with the diminutive of the medicine, or with a prefix specifying its use (e.g. CardioMedicine X), 4 maintain the same suffix but with a different denomination (e.g. Xdol), and the others 21 have a completely different name with a different pharmaceutical company.

On the same database, if we look for information on the Medicine X, we find a list of sixteen entries: ten of them correspond to the item Medicine X but differ by pharmaceutical company. Medicine X is present together with other five related products: with the suffix *Actim* (it has been revoked), in association with the terms flu and stuffy nose, with the suffix Act, with the terms pain and inflammation, and with the further specification ACT Pain and inflammation.

On the Italian web site of the pharmaceutical company, Medicine X is communicated with ten different product declinations: from the core product to other differentiations related to their packaging (e.g., in sachets), or intended use (e.g., flu and stuffy nose).

Given these premises, it is evident that for an ordinary Italian patient who needs a remedy against cold diseases, toothache, or headache, it's quite difficult for him to find his way alone around the many declinations of medicines based on acetylsalicylic acid as its active ingredient.

These medicines are present in the market with different use destinations, dosages, multiple packaging systems, different pharmaceutical companies of reference and sales systems, it's extremely important for the patient that all paratextual elements (as packaging and packaging leaflet) support the patient from an informative point of view.

10.4 Focus on Medicine X Effervescent Tablets 400 mg

As reported on the website dedicated to Medicine X, the formulation in effervescent tablets is a product with antifebrile, anti-inflammatory and analgesic action. It acts from the first symptoms of colds and flu, providing rapid relief. It contains vitamin C which has a positive effect on the immune system.

Medicine X with C vitamin is the product that belongs to the pharmaceutical company historical tradition (since the '50–'60 s) with a very high reputation around the world. It's distributed in the world with the same active ingredient and the main graphical codes, but with small differences in the secondary packaging.

[16] See https://farmaci.agenziafarmaco.gov.it/bancadatifarmaci/cerca-farmaco, (accessed 2022 Dec.3).

Before analysing the characteristics of Medicine X with vitamin C, it's important to reaffirm that, in the pharmaceutical sector, primary and secondary packaging responds to regulatory aspects defined by the Directive 2001/83/EC, with its subsequent amendments and supplements and a new transposition in Italy by Legislative Decree 219/2006. This Decree was subsequently amended by Legislative Decree 274/2007.[17] It follows that the design of all elements of the medicine and its paratexts are subjected a numerous constraint and structured content.

The Italian version of Medicine X is represented by white and circular effervescent tablets with a diameter of 250 mm and a thickness of approximately 2 mm. The pharmaceutical logo is engraved on one side of the tablet.

Each tablet is placed in a paper pack in strip (primary packaging) sealed at the sides; the tablets are placed two by two in a cardboard box that constitutes the secondary packaging for a total of 10 tablets, in the commerce there is also the 20 or 40 tablet pack.

The primary packaging is the first paratextual element of the medicine, it is the outcome of an endolinguistic translation, in other words it's a reformulation and simplification of the secondary packaging. Its role is to protect and store the medicinal product by maintaining a close semantic correlation with the secondary packaging. Medicine X primary packaging shows the pharmaceutical company logo in the top left-hand corner, the name of the medicine (Medicine X), the dosage, the format (effervescent tablets with Vitamin C) and the active ingredient (acetylsalicylic acid). The typographic and chromatic codes, and the icon represented by the bubble-encircled shield are the same of the secondary packaging, they vary only in size. Additional signs in white are represented by the pictogram of a small scissor with the lowercase words 'open here' flanked by a numerical code. The reverse side of the primary packaging is totally white and bears the batch number (BT175E1 /2) and the expiry date printed on it.

The secondary packaging of Medicine X is the paratext that more than others performs an appellative function,[18] it is characterized by a seductive potential that lends itself to various expressions of ostensive character[19] (Bucchetti 1999, p. 33).

In the last year the pharmaceutical company updated the secondary packaging with the aim of standardizing its identity at European level, the new elements, compared to the past, are: a more contemporary typography; the presence of a yellow symbol with gradient bordered in silver with 3D transparent little bubbles and the central letter C; one effervescent white tablet with little white 3D bubbles on the left (in an older version there were two tablets). This icon was designed to highlight the role and support of vitamin C as an active ingredient (the bubbles) with a defensive action (the symbolic value of the shield). This is a constant element that we can find on the touch points, in the point of sale and in television advertising.

[17] For more details see https://www.aifa.gov.it/sites/default/files/2016-05-18_Ranalli.pdf, (accessed 2022 Dec.12).

[18] The appellative or conative function is aimed at generating a reaction in the patient and influencing his behaviour.

[19] By ostensive character we mean a property that tends to show or demonstrate.

The main color codes of the secondary packaging are green as background (this shade of green has been a constant for many years), white for the tablet on the left and white for the closing flap (where the batch number and expiry date are printed), other colors are yellow and metallic grey.

The company logo, the name of the medicine and the informative text are white, while the dosage, drug formulation and active principle are green on a yellow background, also the letter C in the symbol is green with a little orange shadow on a gradient yellow background.

The front of secondary packaging presents elements that fulfil both communicative-informative and communicative-seductive functions (Bucchetti 1999, p. 112), the upper side of the box bears the logo with the name of the drug and the yellow symbol with a C, while the lower side contains text on the therapeutic indications, the composition with the active ingredients (acetyl salicylic acid and ascorbic acid), and the excipients, the mode of use (oral) and the specification that it is a self-medication medicine. On the right-hand side at the bottom, we find the name of the pharmaceutical company.

The backside of the secondary packaging reports the barcode label in the middle, with two short written texts. Above there is a prescriptive and standardized text suggesting reading the package leaflet before use, keep the medicine out of the sight and reach of children and store the medicine at a temperature below 25 °C, there is also an informative short text that states that the expiry date refers to the intact product, correctly stored. The lower text is informative and reports the AIC number, the AIC holder represented by the pharmaceutical company, on the left side rotated by 90° we find the indication with an arrow that suggests reading the expiry date on the left flap.

The right flap reports again the name of the medicine, the number of effervescent tablet and the central mark specifying that it is a non-prescription medicine.

The name of the Medicine X (also embossed in Braille) with company logo and all details reported on the secondary packaging should orient the patient in the process of selection of the medicine: the front of the package informs the patient about the dosage of the effervescent tablet (400 mg), the active principle of the drug (acetyl salicylic acid), the addition of vitamin C (the letter C is enlarged and surrounded by a symbol), and the number of effervescent tablets (10).

For more details about therapeutical indication and composition the patient needs to rotate downwards the box, the body of typographical text is very small and the contrast of the white lettering on the green background makes the reading difficult, especially for an elderly or visually impaired person.

The therapeutical indications report different kind of manifestations: symptomatic treatment of febrile states and influenza and cold syndromes; symptomatic treatment of headache and toothache, neuralgia, menstrual pain, rheumatic and muscular pain.

It then specifies that Vitamin C participates in the body's defense system. This block of information is followed by the composition of the effervescent tablet with the precise dosage of active principles (acetylsalicylic acid 0.4 g. and ascorbic acid 240 mg. = 0.24 g.), but without the dosage of excipients (there is the short indication

that it contains sodium).[20] It's specified that the usage is oral, and this is a self-medication drug.

The back of the box suggests reading the package leaflet before the use, but it's impossible to do it at the time of purchase. This is a quite critical issue, because the patient is not always aware of any contraindications or adverse drug interactions. Another important aspect that is overlooked is the age of the patient, which must be over 16 years, but this information is only given in the package insert.

In this case the presence of a QR code[21] on the box could help the patient in accessing web pages containing detailed information on the drug in multiple languages and different modalities (for example through a vocal or video description of the required information).

10.5 Package Leaflet of Effervescent Tablets 400 mg

The package leaflet, also named in Italian as "*bugiardino*",[22] is the paratext which supports the medicine from an informative and prescriptive point of view.

It's characterized by different registers, in the specific case of Medicine X its content is verbal, but also tactile and to some extent sonorous properties, (for the consistency of the foiled paper), are significant. For this reason, it can be considered a hybrid text.

Package leaflet of Medicine X consists of a sheet of 350 × 315 mm with a 3-mm gluing in the middle part to make it more functional when opened, its dimensions when closed are 175 × 315 mm, and the paper weight is approximately 40/50 g/m2. It is folded to form a strip measuring around 300 × 315 mm, which in turn is folded in half to wrap the tablets inside the box.

From a content perspective, it is an example of "highly binding" textuality (Di Pace 2019, p. 25), modelled on technical texts (such as instruction for use) and standardized at European level according to the directive 2001/83/EC, supplemented by directives of 2003/94/EC, 2004/27 EC, 2008/29.[23]

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[20] The excipient list is very important it should enable the patient to quickly detect the presence of substances to which he or she is allergic. The Medicine X package leaflet specifies that this medicinal product contains 467 mg of sodium (main component of table salt) per tablet. This is equivalent to 23% of the maximum daily recommended dietary sodium intake for an adult.

[21] For more information on the use of QR code see Use of the QR Code on printed matter (CPR, package leaflet, labelling) medicines: state of the art https://www.aifa.gov.it/sites/default/files/2017-02-23_QR.code_BRAGHIROLI_AFI_febbraio_2017.pdf, (accessed 2022 Dec.15).

[22] The term "bugiardino" means deceitful, as De Pace asserts the most credible interpretation of the origin of this term concerns the medical field and more specifically the recognition of the omission of a series of information concerning the negative aspects of taking a medicinal product (Di Pace 2019: 15).

[23] The latest update in 2022 provides a reference standard for electronic medicinal product information (Epi), the digital version of the package leaflet and pharmaceutical product characteristics (Rcp). The agreement represents a crucial step in the project that aims to complement the paper

A coloured header, recalling the main front of the packaging, and a four-sided written text, (black left-aligned on a white background), constitutes the content. The typeface is linear with a size of 8 points and a line spacing of 1.5.

The content of the package leaflet derives from an endolinguistic translation (interpretation of verbal signs by means of other signs in the same language, Jakobson 1987, p. 429), the source text is represented by RCP (Riassunto delle Caratteristiche del Prodotto), named abroad SPC (Summary of Product Characteristics) and the arrival text is the package leaflet (named also as PIL—Patient Information Leaflets). The RCP/SPC is initially developed by the pharmaceutical company, then it is controlled and approved by the local medicine agency (in Italy AIFA, Italian Medicines Agency) and the European Medicines Agency (EMA), (Jensen 2013, p. 5). RCP/ SPC is an expert-to -expert text that is translated in PIL through a terminological simplification for less experienced readers. The package leaflet in English is then subjected to an interlinguistic translation into the other Member State languages.

In brief the Italian version of Medicine X package leaflet is the result of both endolinguistic and interlinguistic translation, with an evident asymmetry between the highly specialized medical language of the RCP/SPC and the language of the patients.

As De Pace asserts, the leaflets share many linguistic traits of the medical report, starting with the use of impersonal verb forms (confirms, seems to appreciate), continuing with the use of entire nominal sentences (not clear evidence […]), and the use of proper and collateral technicalities as in the case of the expression appreciate (2019, p. 27).

The text of the package leaflet of Medicine X begins with a paragraph inviting the patient to read the leaflet carefully or follow the advice of the doctor or pharmacist, then illustrates in a bulleted list[24] the contents of the leaflet structured in six main points based on a question/answer method (these six paragraphs are articulated in sub-paragraphs highlighted with the use of bold):

- What Medicine X effervescent tablets with Vitamin C is and what it is used for;
- What you should know before taking Medicine X 400 mg effervescent tablets with Vitamin C;
- How to take Medicine X 400 mg effervescent tablets with Vitamin C;
- Possible side effects;

information accompanying each medicine with a dematerialized version that is more manageable for patients and healthcare professionals. The adoption of a common standard will enable faster updating of drug information, its harmonization within the EU, and thus faster and more informed choices by consumers and healthcare professionals. An Epi, in fact, can be updated in real time as soon as a change is approved, or new information becomes available. For more details https://www.fpress.it/estero/ue-approvato-lo-standard-per-i-bugiardini-elettronici-dei-farmaci/(accessed 2022 Dec.18).

[24] This textual structure follows a scheme inspired by the *Guideline on the Readability of the Labelling and Package Leaflet of Medical Products for Human Use,* as reported here https://health.ec.europa.eu/system/files/2016-11/2009_01_12_readability_guideline_final_en_0.pdf

- How to store Medicine X 400 mg effervescent tablets with Vitamin C;
- Package contents and other information.

Overall, the text is very dense over four pages, bold highlighting of paragraphs and sub-paragraphs helps the patient in the reading process and in identifying the most important issues such as warnings, allergic reactions, interactions with other drugs, undesirable effects etc.

It is quite common that when faced with such a dense and lengthy text, the patient limits himself to reading the information on the first page and omits the details on the following pages, for example the list of the interaction with other medicines or undesirable effects.

Some important information, that should be mentioned also on the secondary packaging, risk being overlooked with significant consequences: children and adolescents should not take the medicine if they are under 16 years of age, and people over 70 years of age should consult their doctor before taking this medicine.

The poor comprehensibility of the package leaflet is due both to the presence of technical or over-specialised language (for example the list of medicines that could have harmful interactions with Aspirin C), but also to the use of vague expressions which may determine some ambiguities (for example "the use of the product is reserved for adult patients only" is reported on the first page of the informative leaflet, only in the second page it's specified that the medicine should not be taken by children and young people under 16 years of age and there are risks for people over 70 years of age).

The incipit of the section of undesirable effects itself (point 4) has an impersonal and nebulous tone: "like all medicines, this medicine may cause undesirable effects although not all people experience them. […] most side effects are dependent on both dose and duration of treatment".

In synthesis, the content of the package leaflet has a structure and a lexicon that privileges the referential function to the detriment of the communicative function, centred on the reader.

We must highlight the fact that the package leaflet is not only a prescriptive or informative text, but also a legal document aimed at protecting pharmaceutical companies.

10.6 Conclusion

Medicine X has been defined as "wonder drug" for its long story because it is something that has few equivalents in the annals of medical science and one of the most enduring and successful commercial products of all time (Jeffreys 2005, p. 5). Medicine X with C vitamin is equally prodigious, on the market since the 1950s, is one of the best-selling anti-influenza, anti-inflammatory and analgesic drugs internationally. Around this medicine, different paratextual elements have been designed and updated over time, consolidating the brand and its communicative and informative dimension at systemic level.

These paratexts, the primary and secondary packaging and package leaflet, are the result of a series of translation steps that attempt to find a mediation between a plurality of languages of a prescriptive, technical, informative, expositive, or evocative nature.

This is not an easy task; the issues of readability and comprehension of information is still an open question with multiple risks for the patients.

With reference to our case study we can highlight some fundamental issues:

- in the face of a common headache, the patient must orient himself between multiple medicines with the same active ingredient. He/she generally buys the medicine that has the greatest communicative resonance or that belongs to his/her personal history;
- Medicine X is an OTC medicine and as such can be purchased without a prescription. The patient must be informed in advance about the conditions of use and the risks associated with his/her age or with certain pathologies or interactions with other medicines;
- the information on the packaging is not complete and at the time of purchase the patient does not have access to the information on the package leaflet. There are limitations associated to the instant content access, but also to its translation in multiple languages;
- the content of the paratexts is an asymmetric "highly binding textuality" modelled not on the patient and his/her peculiarities, but according to technical and standardised texts. It should be translated in a language more comprehensible, accessible and inclusive, closer to the informal language of a common patient;
- the graphical components of paratexts are regulated by the European Commission, and as many medicines on the market, the visual design of Medicine X is standardized and unsupportive. There should be a further effort by the pharmaceutical company in maximising the number of people who are able to read and understand the information immediately and unambiguously. It's not only a problem associated to the visual codes or visual hierarchies but it's an issue of content accessibility and comprehension.

In conclusion, we would like to affirm that design and communication design can play an active role in the context of health and pharmaceutical products, also in the case of Medicine X, design can facilitate a series of mediation processes with the perspective of creating a stricter relationship with the patients and his / her differences. This entails different aptitudes and competencies: to have the capability of understanding the nature of a problem in all its components, to have the capacity of involving all stakeholders in the design process, to have the sensitivity of observing and measuring the current state of things, to have the expertise of developing and text prototype solutions and iteratively developing and testing prototypes until an optimum solution is found, to have the ability of implementing and monitoring the solution in use (Sless 1992, p. 9). As observes Swann, design for health is now emerging from the shadows to be recognized as a distinct design discipline in its own right. A new discipline with patient safety at its hearth, an evidence-based practice that necessitates system thinking and collaboration to tackle complex challenges and practice governed by a stringent ethical framework (Swann 2017).

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