

INFORMA(C)TION

How to do things with medicine information leaflets

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Abstract – This paper analyses how Patient Information Leaflets (PILs) of over-the-counter medical products convey information. More precisely, the article focuses on “instructions” on how to use medicines and related “instructional information” (Trimble 1985). The latter is used in PILs to explain why consumers should follow the instructions. The aim is to show, then, how and whether the PILs sampled help consumers to translate effectively the information contained into actions. The first part of the article examines the deontic devices employed in 8 English and Italian PILs of the most common over-the-counter medicines for human consumption used to relieve the same symptoms. The second part, instead, analyses whether and how the eight leaflets sampled followed the ‘instructions’ contained in one of the authoritative works by Sless and Shrensky in this field (2006). Both Australian authors, indeed, provide useful advice on how to write directives and related explanations in PILs.

Keywords: patient information leaflet for medicine; instructions; deontic modality; unmodalized directives; D. Sless.

1. Introduction

Patient Information Leaflets (PILs) for medicines are documents “based on summaries of product characteristics, a description of a medicine’s properties and the conditions attached to its use”.¹ They are folded and inserted in the packaging of medicines, at least they are in the United Kingdom and in Italy. By contrast, in Australia, New Zealand, and the United States the leaflet is not mandatory. Instead, in these countries, the information is most commonly computer generated in the pharmacy.²

PILs may be considered a sort of mini instruction manual. They contain “directives” (Searle 1976), that include orders, requests, warnings, explanations about the directives (Sless, Shrensky 2006; Trimble 1985) and information about the product. In other words, they tell patients what the medicines are for and how to use them safely and efficiently.

As a result, PILs can be classified as “hybrid texts”, according to Taylor’s definition based on Snell-Hornby’s conclusions (Taylor 1996, p. 285), insofar as they fulfil the referential and the conative functions (Jakobson 1960) at one and the same time. They do indeed “provide facts and factual information”, but concurrently they also aim “at making the receiver act, think or behave in a certain way” (Dodds 2012, p. 58).

As far as the “conative function” and, in particular, the directive function of language is concerned, Palmer (1986) reminds us that directives

¹ <http://www.mhra.gov.uk/spc-pil/index.htm> (7.12.2015).

² The information is available at the following link:

http://www.academia.edu/422017/Consumer_Medication_Information_In_the_United_States_Europe_and_Australia_A_Comparative_Evaluation (8.05.2015).

are not only subjective, but also performative[:] they actually initiate action by others [...]. For that reason they will always be related to the future, since only the future can be changed or affected as a result of them being expressed. (1986, p. 97)

Besides containing directives, PILs belong to the “testi a distanza” (Ciliberti *et al.* 1992, p. 42) in that “neither the instructions [and the explanations for the instructions] are given when the instructor is present.” (1992, p. 42)³. As a consequence, as Letts⁴ underlines,

[t]he act of prescribing or recommending a medicine does not guarantee that it will be taken as advised for as long as advised, or even at all. These are decisions people make for themselves everyday.

However, “what is essential”, continues Letts, “is that the decisions people make about medicines should be informed ones”. As Reynor highlights, indeed, “to make good decisions [...] patients must have access to good information. And good information needs to be accessible and understandable.”⁵

This does not imply that PILs should only be “focused on the content of the information” (Sless, Shrensky 2006, p. 1). On the contrary, a “consumer-focused approach” (Sless, Shrensky 2006, p. 1) that asks “What do we want people to do with the information?” (Sless, Shrensky 2006, p. 6) is far more preferable.

Indeed, “successful communication takes place when the purpose of the message is encoded effectively and decoded appropriately” (Ulrych 1992, p. 32) and, more precisely, when and if “orders and commands acquire a cooperative value” (Ciliberti *et al.* 1988, p. 274)⁶.

2. Aims and methodology

This article analyses how PILs of over-the-counter medical products convey information. More precisely, the article focuses on “instructions” and “instructional information” (Trimble 1985). The latter is used in PILs to explain why consumers should follow the instructions. The aim is to show, then, how and whether the PILs sampled help consumers to translate effectively the information contained into actions.

The first part of this paper focuses on the deontic devices employed in 8 PILs of the most common over-the-counter medicines for human consumption used to relieve the same symptoms (four sold in the U.K. and four in Italy).⁷ The second part, instead,

³ My translation. Ciliberti *et al.* 1992, p. 42: “...l’istruzione non avviene sul momento, alla presenza dell’istruttore [...]”

⁴ The information is available at the following link:
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/391090/Always_Read_the_Leaflet_getting_the_best_information_with_every_medicine.pdf (8.05.2015).

⁵ http://www.europarl.europa.eu/RegData/etudes/workshop/join/2010/433440/IPOL-ENVI_AT%282010%29433440_EN.pdf (8.05.2015).

⁶ My translation. Ciliberti *et al.* 1988, p. 274: “...gli ordini e i comandi assumeranno una valenza cooperativa.”

⁷ The PILs analysed in this work include: (English leaflets) Boots Soluble Aspirin® tablets 300 mg (from now on Aspirin®), last revised in August 2008; Imodium® Instant (from now on Imodium®), last revised September 2008; Lemsip® Cold & Flu Lemon (from now on Lemsip®), last revised in April 2006; Vicks® Sinex Soother 0,5 mg/ml (from now on Vicks® Sinex), last approved in May 2010. The Italian

analyses whether and how the eight leaflets sampled followed the ‘instructions’ contained in one of the authoritative works by Sless and Shrensky (2006).⁸ Both Australian authors, indeed, provide useful advice on how to write directives and related explanations in PILs.

Sless and Shrensky’s work has been specifically chosen among others, which are certainly equally valid,⁹ for several reasons. To start with, it was produced by the Communication Research Institute of Australia. Secondly, it was published by the Australian Government Publishing Service, first, and then by the Australian Self-Medication Industry. Thirdly, the European Commission “reflected the work of Professor David Sless”¹⁰ when drafting its own *Guideline*¹¹ and, in particular, the user testing method.¹² Last but not least, much research in the UK takes it into account. For example, the *Report of the Committee on Safety of Medicines Working Group on Patient Information*, published by the British Medicines and Healthcare products Regulatory Agency.¹³

For the sake of clarity, it needs to be said that this article will not be analysing the directives conveyed through nominalization (Bathia 1993; Gotti 2003) or by means of pictures or pictographs.¹⁴ Nor will it focus on epistemic modality (Palmer 1985) or whether there are similarities or not in terms of the information conveyed in the leaflets. The latter consideration originates from an article published in 2007 arguing that there are several significant differences in terms of side effects, usage, or dosage between PILs of medicines sold in different countries by the same pharmaceutical companies.¹⁵

leaflets instead are: Aspirina 400mg compresse effervescenti con vitamina C (from now on Aspirina®), last revised in July 2009; Imodium®, last revised in October 2009; Tachifludex®, last revised in May 2010, and Vicks® Sinex Spray Nasale Soluzione (from now on Vicks® Sinex), last revised in April 2012.

⁸ It is to be noted that all the references contained in this article are taken from the e-book version, *Writing about Medicines for People. Usability Guidelines for Consumer Medicine Information*, by D. Sless and R. Shrensky (3rd edition). The first and second edition were written by D. Sless and R. Wiseman and published in 1994 and in 1997 respectively.

⁹ For a complete list of the institutions, centres, and researchers who work for a plain language in the health care field, see the following links:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/391090/Always_Read_the_Leaflet_getting_the_best_information_with_every_medicine.pdf (8.05.2015) and

<http://www.entilocali.provincia.le.it/nuovo/files/Progetto%20di%20semplificazione%20del%20linguaggio.pdf> (8.05.2015).

¹⁰ The information is available at the following link:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/391090/Always_Read_the_Leaflet_getting_the_best_information_with_every_medicine.pdf (8.05.2015).

¹¹ The full title is *Guideline on the Readability of the Label and Package Leaflet of Medicinal Products for Human Use*, September 1998.

¹² To know more about the user testing method, see the conclusions of the present article.

¹³ http://www.medilingua.com/pdf/Readability_Testing_EPC.pdf (13.05.2015) and

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/391090/Always_Read_the_Leaflet_getting_the_best_information_with_every_medicine.pdf (8.05.2015).

¹⁴ Among others, see Katz *et al.* at the following link

http://healthliteracy.worlded.org/pictorial_med_instructions.pdf (29.05.2015) and Zeng-Treitler *et al.* at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2656019/> (29.05.2015).

¹⁵ <http://www.altroconsumo.it/organizzazione/media-e-press/comunicati/2007/stesso-farmaco-bugiardino-diverso-in-spagna-italia-portogallo-belgio-inchiesta-altroconsumo-sui-foglietti-illustrativi-dei-farmaci> (8.05.2015).

3. Direct instructions in the English and Italian leaflets¹⁶

According to Trimble (1985: 20), “instructions can be roughly defined as the rhetoric of telling someone what to do and how to do it [as well as what not to do] to achieve a certain goal.” More precisely, he suggests that:

instructions are of two types: direct instructions, which are characterized by the use of the imperative form of the verbs, and indirect instructions, which are characterized by the use of modal verbs, the passive mood, and – most frequently – a combination of the two; that is the passive modals. (Trimble 1985, p. 96)

As far as direct instructions are concerned, they have indeed been conveyed in the English leaflets, mainly through the use of imperatives, both in the case of prescriptions and of proscriptions:

If you get any of these serious side effects, stop taking the tablets (Aspirin®)
 Do not give to children under 16 years (Aspirin®)
 Consult your doctor if you develop new symptoms [...] (Imodium®)
 Do not chew (Imodium®)
 Keep all medicines out of the reach and sight of children (Lemsip®)
 Do not take more than four sachets in a total of 24 hours (Lemsip®)
 Always use Vicks Sinex Soother exactly as your pharmacist or doctor has told you (Vicks® Sinex)
 Do not exceed the recommended dose (Vicks® Sinex).

There is only one occurrence of a proscription written in the informal style of the contracted form:

Don't take more than 12 tablets in 24 hours. (Aspirin®)

The preferred choice in the Italian PILs sampled, instead, is the infinitive form (71 occurrences)¹⁷

Usare solo per brevi periodi di trattamento (Aspirina®)
 Non superare le dosi indicate senza il consiglio medico (Aspirina®)
 (vedere *Cosa fare durante la gravidanza e l'allattamento* [sic]) (Imodium®, cross-reference)
 [...] non assumere più di 8 compresse orosolubili al giorno (Imodium®)
 Chiedere consiglio al medico o al farmacista prima di prendere qualsiasi medicinale (Tachifludec®)
 Non somministrare per oltre 3 giorni consecutivi [...] (Tachifludec®)
 Impiegare con cautela nei primi mesi di gravidanza e, per il pericolo, di ritenzione urinaria [...] (Vicks® Sinex)
 Attenzione: non utilizzare il medicinale dopo la data di scadenza indicata sulla confezione (Vicks® Sinex),¹⁸

¹⁶ For the analysis, it may be useful to know that the PIL of Aspirin® is composed of 844 words; Imodium®, 1449; Lemsip®, 718; Vicks® Sinex, 1208. As for the Italian PILs, Aspirina® contains 2619 words; Imodium®, 1370; Tachifludec®, 1374; Vicks® Sinex, 1331.

¹⁷ Figures refer to the whole of the written parts in the leaflets, inclusive of texts, headings and cross-references enclosed in round brackets. More precisely Aspirina® contains 19 occurrences; Imodium®, 21; Tachifludec®, 14; Vicks® Sinex, 17.

¹⁸ The Italian leaflet of Vicks® Sinex does not contain cross-references (the English counterpart of the same product does so only once).

with only one instance of a pronominal infinitive (Dardano, Trifone 1995, p. 310):

Attenersi con scrupolo alle dosi consigliate. (Vicks® Sinex)

As for the imperative, the second person plural (24 occurrences) is preferred for prescriptions

Per maggiori informazioni e consigli rivolgetevi al farmacista (Aspirina®)
 Se state usando altri medicinali chiedete consiglio al vostro medico o farmacista (Imodium®)
 Consultate il medico nel caso sospettiate uno stato di gravidanza o desideriate pianificare una
 maternità (Tachifludec®)
 [...] conservate sia la scatola che il foglio illustrativo (Vicks® Sinex)

rather than for proscriptions, for which indeed it occurs only once:

Non usate IMODIUM [sic] se state seguendo una terapia a base di farmaci che possono
 rallentare l'attività dello stomaco o dell'intestino [...] (Imodium®)

There is also only one instance, then, in the Italian leaflets and, precisely, in Tachifludec®, where both forms (infinitive plus imperative in the second person plural) co-occur within the same sentence:

In caso di ingestione/assunzione accidentale di una dose eccessiva di Tachifludec avvertire
 immediatamente il medico o rivolgetevi al più vicino ospedale. (Tachifludec®)

In Imodium®, instead, they have been found in consecutive sentences:

Iniettare naloxone. Se necessario, ripetere l'iniezione di naloxone dopo 1-3 ore e monitorare il
 paziente per almeno 48 ore. In caso di ingestione/assunzione accidentale di una dose eccessiva
 di IMODIUM, avvertite immediatamente il medico o rivolgetevi al più vicino ospedale.
 (Imodium®)

Unlike Serianni's findings (2005, p. 256), then, in the Italian leaflets there are no cases of direct instructions for prescriptions in the second person singular. Surprisingly, instead, three out of the four Italian leaflets only once use the third person singular "lei" at a certain point in the text:

Se ha qualsiasi dubbio sull'uso di Aspirina 400 mg compresse effervescenti [...] si rivolga al
 medico o al farmacista (Aspirina)
 Chieda al farmacista come eliminare i medicinali che non utilizza più (Vicks® Sinex)
 Chieda al farmacista come eliminare i medicinali che non sono più utilizzati. (Tachifludec®)¹⁹

Generally speaking, in both the English and Italian leaflets sampled, almost all the direct instructions consist of a verb followed by a direct object. However, in the English leaflet of Aspirin®, two examples of the verb + adjective construction have also been found:

¹⁹ Actually, also in the Italian leaflet of Imodium® the third person "lei" is used twice but not in directives: "Questo medicinale contiene una fonte di fenilalanina. Può esserle dannoso se è affetto da fenilchetonuria" and "Chiedere al farmacista come eliminare i medicinali che non utilizza più."

- (1) Before you take these tablets, make sure that you tell your pharmacist about ANY [sic] other medicines you might be using at the same time, particularly the following:
 - Methotrexate (for cancer, skin and rheumatic problems),
 - Warfarin [...]”²⁰
- (2) Please be ready to give the following information.

On closer inspection, in the latter instance (2), “ready” refers to users and/or relatives/carer of the users. By contrast, in the first example (1), the adjective “sure” refers to an external situation explained after the conjunction “that”. This strategy allows the addresser caringly to convey two distinct actions to be carried out on the part of the addressees. The first one consists of “telling the pharmacist about the medicines they might be using at the same time”; the second, of being “sure” of telling everything. This means that the adjective “sure” implicitly also refers to the addressees in that the action to be checked²¹ is going to be performed by the addressees themselves and not by others.

Furthermore, the whole of the first sentence also implies that consumers often do not say everything to pharmacists/doctors. This explains why, a few words later, not only do we find the capitalization of the indefinite adjective “any”, but also the repetition of the same directive at the end of the bullet points. This time, though, the PIL chooses the adjective in the negative form (“unsure”), explicitly referring to the addressees:

If you are unsure about interactions with any other medicines, talk to your pharmacist.

4. Indirect instructions

Directives are also expressed in more indirect ways both in English and Italian. The third person (Downing, Locke 2002, p. 391; Gotti 2003, p. 135) with animate subjects and modals (Trimble 1985, p. 96) in the active form are some of them. These devices “are useful [...] to mitigate the directness, although not the inescapability of the obligation” (Downing, Locke 2002, p. 391). They indeed “[...] often sound more like suggestions than commands but [...] actually function as imperative statements” (Trimble, 1985, p. 21).

4.1 Modalized forms and semi-modals in English and Italian leaflets

As was to be expected, in the four English leaflets there are no instances of the modal “must”. This is due to the fact that marketing authorisation holders tend to avoid imposing a strong command and obligation (Downing, Locke 2006, p. 386) on consumers. On the other hand, they “ha[ve] [no] confidence that the recommendation will be carried out.” (Quirk *et alii* 1985, p. 227)

As far as “should” and “should not” are concerned, instead, more than half the clauses (12 out of 17 occurrences) are written in the active affirmative form:

If your symptoms change or you are concerned about anything [sic] you should talk to your doctor (Imodium®)
You should ask the pharmacist before taking Lemsip Cold & Flu Lemon if: [...] (Lemsip®)

²⁰ In the example above, only two of the five bullet points have been quoted.

²¹ According to the definition of “make sure” in the *Oxford Advanced Learner’s Dictionary* 2010, p. 1556: “To check that sth is true or has been done.”

You should check with your doctor or pharmacist if you are not sure. (Vicks® Sinex)

The Aspirin® leaflet also contains one occurrence of a negative plus affirmative command within the same sentence:

This medicine can be taken by adults and children aged 16 years and over. However, some people should not take this medicine or should seek the advice of their pharmacist or doctor first.

Another important strategy consists in using the third person with inanimate subjects and deontic modals in the passive form (Trimble 1985). This helps, on the one hand, to “avoid offence or imposition” (Giannoni 2001, p. 319); on the other, often deliberately to leave the sentences ambiguous in order “to impede understanding on the part of the receiver” (Dodds 2012, p. 58). This way the marketing authorisation holders are less likely to be liable for what the consumers actually do.

As far as the passive voice is concerned, it is not merely an alternative form of the active (Lewis p. 132; Ulrych 1992, p. 159). Rather, it is used to “depersonalise discourse” by omitting the agent in order to “emphasize the effect or outcome of an action rather than its cause or originator” (Gotti 2003, p. 96).

In the English leaflets sampled, there are only 5 passives, of which 2 are in the negative form (with no contracted forms):

Reye’s syndrome is a very rare disease, which can be fatal. For this reason aspirin should not be given to children aged under 16 years, unless on the advice of a doctor (Aspirin®)
Medicines should not be disposed of via wastewater or household waste. (Vicks® Sinex)

In the first example, actually, not only does the form “should not be given” lead to the omission of the agent (consumers or a relative or a carer of the consumer) but also to underline their potential responsibility in following the instructions accordingly.

Unlike the English leaflets, the passive form is much more used in the Italian ones. There are 18 occurrences out of 27 (16 affirmatives and 11 negatives). Then, in most cases, there is also a tendency to put the subject before the verb (23) rather than after it:

L’uso di acido acetilsalicilico come di qualsiasi farmaco inibitore della sintesi delle prostaglandine e della cicloossigenasi potrebbe interferire con la fertilità; [...] di ciò *devono essere edotte* le donne che hanno problemi di fertilità o che sono sottoposte ad indagini sulla fertilità (Aspirina®)
IMIDIUM [sic] non deve essere usato durante la gravidanza e/o l’allattamento. (Imodium®)

On closer inspection, the expression “di ciò devono essere edotte le donne” in the first example looks like a passive but actually is not. The word “edotte” (“informed”) is used in Italian as an adjective²² and not as a past participle. In order to use “edotto” in the passive form, another construction is required: “Rendere edotto qualcuno”. This means that, to be syntactically correct, the sentence in the leaflet should have been reformulated as “di ciò devono essere rese edotte le donne”. Nevertheless, the resulting expression would still be difficult to understand due to the word “edotte”, which is rather formal and unknown by the layman.

That said, the original expression also does not help to identify the agents involved either. Indeed, it is not clear whether women should be either informed by the PIL itself,

²² <http://www.treccani.it/vocabolario/edotto/> (31.05.2015).

by one of their relatives/carers or by pharmacists/doctors. In the first case, the meaning is ambiguous, and redundant at the same time, insofar as consumers are already being informed while reading the leaflet. Actually, the unsuccessful expression belonging to the subheading “Fertilità” should have served in the Italian leaflet to warn women that the piece of information placed underneath only referred to women’s fertility and not to men’s. A reformulation of the subheading in “Donne sottoposte ad indagini di fertilità” or “Donne e fertilità” would have been more effective.

Among other modals used to convey directives, in the English and Italian PILs sampled there have been found a few occurrences of the modal “can” (“potere” in Italian) + the passive:

It can be used to relieve headache, migraine, rheumatic pains, neuralgia, period pain, toothache and the symptoms of colds and flu (Aspirin®)

This medicine *can be taken* by adults and children aged 16 years and over. However, some people should not take this medicine or should seek the advice of their pharmacist or doctor first. (Aspirin®)

Questo è un medicinale di AUTOMEDICAZIONE [sic] che *potete usare* per curare disturbi lievi e transitori, facilmente riconoscibili e risolvibili senza ricorrere all’aiuto del medico. *Può essere quindi acquistato* senza ricetta, ma va usato correttamente (Aspirina®)²³.

The first and the third example, in particular, are ambiguous utterances. They can mean either that it is possible to use Aspirin® “to relieve” the pains listed (epistemic modality) or that the addresser is warning the addressees “to use” Aspirin® only to relieve the specific pains mentioned and not others (deontic modality).

The modal “potere” used with a deontic meaning sparingly occurs in few other cases throughout the leaflets:

In caso di emergenza e in assenza di controindicazioni (quali ad esempio: condizioni di riduzione/assenza dei riflessi protettivi delle vie aeree o di coscienza ridotta o di soggetti a rischio di emorragia o perforazione gastrointestinale o in caso di contemporanea assunzione di corrosivi) *può essere tentato* di favorire l’eliminazione dell’acido acetilsalicilico assunto per via orale attraverso, [sic] la somministrazione di carbone attivo o l’esecuzione di una lavanda gastrica. (Aspirina®)

IMODIUM [sic] può essere usato negli adulti e nei bambini di età superiore ai 12 anni (Imodium®)

[...] il farmaco non può essere assunto dai bambini di età inferiore ai 12 anni (Tachifludec®)

Il prodotto può essere assunto senza rischio dai soggetti affetti da celiachia. (Vicks® Sinex)

The impersonal passive “può essere tentato di” in the first example is quite rare and syntactically distorted in Italian. It should rather be replaced, if anything, by “si può tentare di”. Moreover, the whole sentence can convey both the epistemic and deontic meaning, again. In the latter case, the utterance conveys the idea of the marketing authorisation holder’s permission for the consumers to perform two directives in a serious context (“in caso di emergenza”). However, the passive here does not help to distinguish all the agents involved in both actions. To start with, it is not clear who should give the active carbon to the users: they could be either the consumers themselves or a relative or carer of the consumers. The second action, that is “eseguire una lavanda gastrica”, implies, instead, the presence of two agents: both the patients/their family/carer who should decide and go to the hospital, and the doctor who should perform the gastric lavage.

²³ The extract is taken from the box at the top of the first page of each Italian leaflets. The said box and its contents are required by law.

As for the semi-modal “need” (Downing, Locke 2006, p. 380), there are not many occurrences. Except for Lemsip®, which has none, the other three leaflets contain one single case each in affirmative sentences:

This medicine is available without prescription to treat minor conditions. However, you still need to take it carefully²⁴ to get the best results from it (Aspirin®)

This medicine is available without prescription to treat minor conditions. However, you still need to take it carefully to get the best results from it (Vicks® Sinex)

You will need to replace the fluid by drinking more liquid than usual. (Imodium®)

As we can see, while the first examples are in the present tense, the last one is the only example in all the English leaflets containing the auxiliary modal “will”. This way, co-occurring with the semi-modal, instead of merely “predicting [a] probable event” (Webber *et al.* 2001, p. 404), it talks about future obligation and makes the instruction sound less direct (Swan 1995, p. 351).

There have not been detected, instead, any examples of the semi-modal “have to”. Even though it refers to external obligation (Downing, Locke 2006, p. 388), it is in fact “often felt to be more impersonal than must, in that it tends to lack the implication that the speaker is in authority” (Quirk *et alii* 1985, p. 226). Furthermore, it is rather commonly used in conversation (Biber *et alii* 2002, p. 180).

As for the Italian equivalent of “need”, it has been replaced by other forms as we will see in the following paragraph.

4.2. Unmodalized forms to convey indirect instructions

Other forms of indirect instructions have been mostly found in the Italian leaflets rather than in the English ones. However, in the English PILs, it is interesting to underline four occurrences of the use of gerund to convey implicitly a separated instruction than that conveyed through the main verb:

Dissolve by *stirring* into a mug of hot water and sweeten to taste (Lemsip®)

You will need to replace the fluid by *drinking* more liquid than usual (Imodium®)

If anyone takes too many Imodium Instants tablets, contact your doctor or nearest Accident and Emergency department (Casualty) *taking* this leaflet with you (Imodium®)

You should only take this medicine as required *following* the dosage instructions above carefully. (Imodium®)

In the first and the last example, it is to be noted that, although the imperatives precede the gerunds, the actions to be carried out through the gerunds come before those conveyed through the imperative (“dissolve”) and the modal (“you should only take”). Hence, both examples can be paraphrased with two imperatives, “Stir and dissolve into a mug of hot water”, and “Follow the dosage instruction and only then take this medicine”. Instead, in the second example, “by drinking [...]” is actually the main instruction within the sentence, while “You will need to replace the fluid” may be considered as a piece of

²⁴ Although they are not included in the analysis of the present article, it is also important to say that the seriousness of a directive can also be conveyed through other signals. Among them, we should mention adverbs of time (“immediately”, “immediatamente”), of frequency (“always”), of manner (“with caution”, “carefully”, “con cautela”, “con scrupolo”) or restrictive adverbs (“only”, “soltanto”) as we have already seen and will see in many examples taken from the PILs sampled quoted in this work.

“instructional information”.²⁵ Indeed, it explains why consumers should “drink more liquid than usual”.

Another feature in the PILs sampled is the impersonal construction “it is” + “adjective” + “infinitive”. However, unlike the English leaflets, where only one occurrence has been found

It is important to drink plenty of fluids when suffering from colds and flu (Lemsip®),

in the Italian ones the above-mentioned construction is quite common (17 occurrences) with a preference for the adjective “importante” (11),²⁶ followed by “opportuno” (8) and then “necessario” (2):

E' importante comunicare al medico o al farmacista la comparsa di effetti indesiderati non descritti nel foglio illustrativo (Aspirina®)

E' importante avere sempre a disposizione le informazioni sul medicinale, pertanto conservare sia la scatola che il foglio illustrativo (Tachifludec®)

E' opportuno consultare il medico anche nei casi in cui tali disturbi si fossero manifestati in passato (Imodium®)

L'uso, specie se prolungato, dei prodotti topici può dare luogo a fenomeni di sensibilizzazione; in tal caso è necessario interrompere il trattamento e istituire una terapia idonea. (Vicks® Sinex)

Other forms of conveying indirect instructions and avoiding mentioning the addressees in Italian include the structure “va”+ “past participle”. In the PILs sampled it is used both without a syntactic subject in all four leaflets within the same example (4 occurrences)

Può essere quindi acquistato senza ricetta medica ma va usato correttamente per assicurare l'efficacia e ridurre gli effetti indesiderati

and with an inanimate syntactic subject (only 2 occurrences):

L'uso va anche evitato nei caso sospettiate uno stato di gravidanza o desideriate pianificare una maternità (Imodium®)

Il prodotto va tenuto lontano dalla portata, e dalla vista dei bambini, poiché l'ingestione accidentale può provocare sedazione spiccata. (Vicks® Sinex)

It is interesting to note that there is only one occurrence of the passive with the future form of the verb “venire” followed by an inanimate agent:

Porre la compressa orosolubile sulla lingua

La compressa verrà dissolta rapidamente dalla saliva. Imodium 2mg compresse orosolubili non richiede l'uso dell'acqua. (Imodium®)

In this example, taken from the heading “Come”, that is to say the English equivalent for “How to take the medicine”, Imodium®’s pharmaceutical company conveys a directive ambiguously. First of all, it goes without saying that the real agents in the sentence above are the consumers who, through their saliva, will dissolve the tablet. What is implied, instead, is that, since the whole expression follows a sequence of five directives, it is an

²⁵ See paragraph 5.3 of the present article.

²⁶ The 11 occurrences are inclusive of the four headings “E' importante sapere che” present in each of the four leaflets.

instruction itself. Or, rather, it can be either paraphrased as a directive (“Do not chew the tablets”) or as a directive + a piece of “instructional information”, namely “Do not chew as the tablets dissolve rapidly”.

In both cases, however, both communication functions of the original sentence fail. Indeed, if the pharmaceutical company knows that, instinctively, people tend to chew tablets or swallow them with water, a sequence of far more direct instructions such as “Do not chew the tablets. Dissolve them in your mouth” would have been more immediate and effective.²⁷

Other forms “to depersonalise discourse” (Gotti 2003, p. 96) are conveyed in the PILs sampled through “the impersonal operator *si*” (Gotti 2003, p. 96):

Si consiglia dunque di bere molto per reintegrare le perdite (Imodium®)
 Si sconsiglia l’uso concomitante di inibitori dei citocromo CYP450 (Imodium®)
 Si raccomanda di tenere il prodotto fuori dalla portata e dalla vista dei bambini (Imodium®)
 Impiegare con cautela nei primi mesi di gravidanza, per cui si consiglia di consultare il medico nel caso sospettate uno stato di gravidanza o desiderate pianificare una maternità (Vicks® Sinex).²⁸

In these examples, however, the action performed by the addresser (“Si consiglia”, “si sconsiglia”) is separated from that to be performed by the addressees (“di bere”, “di tenere”, “l’uso”). This does not occur with other strategies, such as the “subject” + “is” + “past participle” construction (“è” + “past participle” in Italian):

This medicine is not recommended for children under 12 years old. (Imodium)
 Children under 12 years - not recommended (Vicks® Sinex)
 E’ vietata un’assunzione diversa, per schema posologico e per via di somministrazione, da quelle riportate (Vicks® Sinex)
 E’ sconsigliato l’uso del prodotto se il paziente è in trattamento con antinfiammatori. (Tachifludec®)

Other indirect ways that have been found in the Italian leaflets are “da” + “infinitive” (2 occurrences) and “è da” + “infinitive” (1 occurrence) both for prescriptions and for proscriptions:

Da non usare nei bambini al di sotto dei 12 anni (Imodium®)
 [...] Tachifludec gusto limone e miele contiene 5,9 mmoli (135,8 mg) di sodio per bustina: *da tenere* in considerazione in persone con ridotta funzionalità renale o che seguano una dieta a basso contenuto di sodio. (Tachifludec®)
 È *da tener presente* la variabilità del quadro clinico: anche il vomito può [...] (Aspirina®)

It should be noted that, for an Italian native speaker, both forms “è vietata” and “da non usare” are equivalent to imperatives. Yet, the meaning carried by the verb “vietare” is more immediate, implying more negative effects than the other construction if the action is not performed accordingly.

Among other devices, only Aspirina® and Imodium® use the impersonal structure with “bisogna” and “occorre”, both followed by an infinitive:

Dato che l’acido acetilsalicilico può essere causa di sanguinamento gastrointestinale occorre tenerne conto nel caso fosse necessario eseguire una ricerca di sangue occulto (Aspirina®).

²⁷ It is interesting to underline that in the English counterpart of the same product the directive “Do not chew” has been included instead, as we will see in the next paragraph of the present work.

²⁸ There are no such occurrences in Aspirina® and Tachifludec®.

Imodium non deve essere impiegato, inoltre, nei seguenti casi: [...] - in tutti i casi in cui bisogna evitare una inibizione della motilità intestinale. (Imodium®)

On the other hand, the English leaflets, more than the Italian ones, avoid the passive construction “by turning the verb into a past participle and using the latter as a premodifier” (Gotti 2003, p. 70):

Do not take more than the amount *recommended* above (Aspirin®)
 Alle dosi *consigliate*, o anche nell'ipotesi in cui si dovesse assumere l'intera confezione, non dovrebbero comparire sintomi da sovradosaggio di paracetamolo (Tachifludec®)
 The *recommended* dose in adults and children over 12 years (Vicks® Sinex)
 Do not exceed the *recommended* dose (Vicks® Sinex)
 Attenersi con scrupolo alle dosi *consigliate*. (Vicks® Sinex)

This strategy allows the pharmaceutical company to repeat and thus underline the importance of the instructions already provided, scattered throughout all the leaflets under other headings (“How to use [name of the medicine]”/“How to take this medicine”).

4.3. Other indirect ways to convey directives

Many other ways to convey indirect instructions have been found in the leaflets sampled.

Let us start with the following examples which have been detected only in the English and Italian leaflet of Vicks® Sinex (one occurrence each):

No effect on ability to drive or use machines has been observed (Vicks® Sinex)
 Non sono stati osservati effetti sulla capacità di guidare veicoli e di utilizzare macchinari.
 (Vicks® Sinex)

Both statements are written under the headings “Driving and using machines” and “Guida dei veicoli e utilizzo dei macchinari” respectively. The passive, here, allows one to convey two distinct consecutive actions on the part of the same agent to be conveyed. The first one refers to the fact that there “have not been observed” any effects “on the ability to drive” by the pharmaceutical company. More than in the Italian leaflet, the “quantity-based scalar implicature” (Horn 1996, p. 312) in the English one with the indefinite adjective in the highest value in the scale (“No effect...”) leads to a second action: permission from the same company is being granted for the consumers to drive and use machines. This means that the verb “to observe”, which normally does not carry a deontic meaning in the passive form, when contextualised in PILs, can be paraphrased as follows: “You can [drive or use machines while taking this medicine]” or “You are allowed to [drive or use machines]”.

There are other examples with verbs that may be employed deontically through the passive form even though they seem to fulfill the referential function:

Imodium Instants is a medicine which *is used* to treat sudden short-lived (acute) attacks of diarrhoea in adults and children aged 12 years and over. (Imodium®)

The previous example is placed under the heading “What the medicine is for”. The consumers expect to find, then, immediately afterwards, which symptoms that medicine heals and, as such, why and when they should take it. The verb “to use”, thus, carries the meaning of an action that should only be performed by the consumers, who have been omitted owing to the passive.

The same holds true with the past participle of the verb “to use” only when it is

placed, again, under the heading “What is the medicine for” and the like. In other words, only when it refers to the medicine the leaflet describes and not to other medicines (in the latter case it only fulfills the referential function). Compare:

- (1) Vicks Sinex Soother is a nasal spray *used* for localised relief of the symptoms of a blocked nose in association with a cold or sinusitis (inflammation of the passages leading to the nose) (Vicks® Sinex)
- (2) If you are taking any other medicines, including: ritonavir (used to treat HIV) or quinidine (used to treat abnormal heart rhythms or malaria). (Imodium®)

The first example (1) is taken from the heading “What Vicks Sinex Soother is and what it is used for”. The past participle carries a deontic meaning in that it warns the addressees when and why to use the medicine. It may indeed be reformulated as follows: “Vicks Sinex is a nasal spray. Use it to relieve the symptoms of a blocked nose [...]”. In the second example (2), instead, placed under the heading “Before taking this medicine”, both past participles (“used”) only describe what these “other medicines” are used for. They do not convey any directive or warning saying that Imodium® consumers should use “ritovanir” and “quinidine” to “treat HIV” and “abnormal heart rhythms or malaria” respectively. It goes without saying, indeed, that a marketing authorisation holder can only convey directives on when to use their own product and not the others.

There have not been found many examples with the verbs “to use” employed deontically in the past participle form:²⁹ in Aspirin® and Lemsip® and in all four Italian PILs there are none. Two more cases (in the English leaflet of Vicks Sinex® and the Italian one of Tachifludec® respectively) only fulfill the referential function (they occur in if-clauses).

Similar examples, instead, with the same illocutionary force (Austin 1962) have been found in the Italian leaflets when they employ the so-called *si passivante* to give a transitive verb in the active form a passive value (Dardano, Trifone 1995, p. 330):

Perché *si usa* (heading in all four leaflets)

Aspirina *si usa* per la terapia sintomatica degli stati febbrili e delle sindromi influenzali e da raffreddamento [...] (Aspirina®)

IMODIUM [sic] *si usa* per il trattamento sintomatico delle diarree acute (Imodium®)

Tachifludec *si usa* per il trattamento sintomatico dell'influenza, del raffreddore e degli stati febbrili e dolorosi ad essi correlati [...] (Tachifludec®)

VICKS SINEX SPRAY NASALE SOLUZIONE [sic] *si usa* per alleviare gli sgradevoli sintomi legati alla congestione della mucosa nasale (naso chiuso) tipici del raffreddore e dell'influenza. (Vicks® Sinex)

Another interesting example of an indirect way to convey directives is the following one from the English PIL of Imodium®:

Place the correct number of tablets on the tongue

The tablets dissolve quickly in your mouth, so you don't need water to swallow them. Do not chew.

As we have already seen in the Italian PIL of the same product, the above examples are taken from the heading “How to take the medicine”, so consumers expect to find a sequence of procedural instructions.

²⁹ There have not been found examples with the past participle “impiegato” either.

Indeed, after the first one, in the imperative form (“place”), the PIL goes on to ask the consumer to melt the tablets in a far more indirect way. The property of tablets to dissolve, indeed, is neither an intrinsic characteristic of the Imodium® tablets nor of tablets in general. They “dissolve” because consumers are asked “to place them on [their] tongue” and to melt them thanks to their saliva. The present indicative “dissolve” thus is more than just a description of the Imodium® tablets (referential function).

A second instruction, then, follows immediately after, containing the ordinary lexical verb “need” + “noun”. This strategy as well as the use of the contracted form of the primary verb (“don’t”) helps to soften a more explicit proscription: “Do not swallow them with water”.

Finally, the second proscription (“Do not chew”) implies that the first clause containing the present indicative (“dissolve”) does not prevent consumers from chewing the tablets. Consumers are likely to chew them instinctively because they do not find a more explicit directive immediately after the first one (“Place the correct number [...]”). The PIL, then, would have been more effective if, besides writing all the directives through imperatives, it had inverted the order of the two proscriptions and of the prescription “The tablets dissolve quickly” as follows:

Place the correct number of tablets on the tongue.
Do not chew them.
Dissolve the tablets with your saliva.
Do not swallow them with water.

In the Italian PIL of Imodium®, the equivalent proscription for “you don’t need water to swallow them” has been conveyed in a far more indirect way than the English PIL:

La compressa verrà dissolta rapidamente dalla saliva. Imodium 2mg compresse orosolubili non richiede l'uso dell'acqua. (Imodium®)

It goes without saying that it is not the inanimate subject of the sentence (“Imodium tablets”) but rather the consumers who are asked to swallow tablets without water. It is also to be noted that the verb is in the third person singular, that is, it refers to “Imodium” and not to “compresse orosolubili”. This sounds strange not only from a syntactic point of view, but also in terms of the PIL’s consistency. Throughout the whole leaflet, in fact, the name of the product is always written as “IMODIUM” [sic] and never as “Imodium 2mg compresse orosolubili”.

Besides the referential function, this article also argues that the directive function can also be fulfilled in sentences containing the verb “to be” when they occur under the heading “What the medicine is and what it is used for”. See the following examples:

Aspirina è un analgesico (antidolorifico: riduce il dolore), antinfiammatorio ed antipiretico (antifebbre: riduce la febbre) (Aspirina®)
Imodium Instants *is* a medicine which is used to treat sudden short-lived (acute) attacks of diarrhoea in adults and children aged 12 years and over. (Imodium®)
Vicks Sinex Soother *is* a nasal spray used for localised relief of the symptoms of a blocked nose in association with a cold or sinusitis (inflammation of the passages leading to the nose) (Vicks® Sinex)
VICKS SINEX SPRAY NASALE SOLUZIONE [sic] è un decongestionante nasale per uso locale, cioè libera il naso chiuso (Vicks® Sinex)

Rather than simply conveying an objective description of the medicines, the communicative force of the utterances mentioned above turns the declarative sentences

into warnings. On the one hand, they advise consumers to use those medicines for the specific pains listed and not for others; on the other, as in the case of Vicks® Sinex, for example, to put the medicine into one's nose and not in other parts of the body. This warning should not be underestimated if we consider that in 2010, to cite an example, several women swallowed a product which was supposed to be for colon cleansing.³⁰

Another interesting example is taken from the English leaflet of Imodium®. By repeating under the heading “What the medicine is for” that Imodium “*is a medicine*”, not only does it state a fact, but also that Imodium® should be used with caution. In other words, it warns consumers to take only the recommended dosage and not to overlook the effects of Imodium®, even though, for instance, the pills are actually quite small.

Under specific headings in PILs also the verb “to contain” conveys a deontic meaning. In the following examples, besides providing an objective description of the medicines

If you have phenylketonuria (an inherited genetic disorder), please note that this product *contains* aspartame, a source of phenylalanine (Lemsip®)

Each sachet of powder *contains* the active ingredients paracetamol 650 mg, phenylephrine hydrochloride 10 mg. (Lemsip®)

What Vicks Sinex Soother *contains* (heading)

Questo prodotto medicinale *contiene* sodio: può non essere adatto per i soggetti che devono seguire una dieta a basso contenuto di sodio (Aspirina®)

Una compressa *contiene*: principi attivi: acido acetilsalicilico 0,4 g, acido ascorbico (Vitamina C) 0,240 g (Aspirina®),

the verb “contains” (or “contiene” in Italian) aims at warning consumers not to use the products with other medicines also *containing* specific ingredients. The illocutionary force in the first example above mentioned is furthermore underlined by the presence of an imperative at the beginning of the sentence: “Please *note* that this product contains aspartame [...]”. In other words, this strategy is a far more indirect way than just saying “Please inform your doctor or pharmacist if you are taking, or have recently taken, any other medicines, even those obtained without a prescription.” (Vicks® Sinex)

As already stated, however, the verbs in the present indicative form do not always convey a directive. Indeed, under the heading in Vicks® Sinex, “What Vicks Sinex Soother looks like and contents of the pack”, the verb “to contain” simply describes a state and does not imply any illocutionary force:

The pack contains an amber glass bottle with a white pump on top.

In conclusion, only in certain contexts (PILs) and, more precisely, under certain conditions (specific headings/subheadings in PILs), the directive function predominates over the referential one; other times they “merge” and are “mutually compatible” (Coates 1983, p.17). At other times, instead, only the referential function is conveyed.

³⁰ http://www.corriere.it/salute/10_luglio_28/lavanda-vaginale-intossicati_54c7d846-9a5d-11df-8969-00144f02aabe.shtml (2.06.2015).

5. How to write instructions and “instructional information”

In their work, *Writing about Medicines for People* (2006),³¹ Sless and Shrensky provide a whole series of guidelines on how to present all the items in a PIL, from the name of the product and its phonetic transcription to the layout of the whole leaflet.

To start with, the first important requirement for leaflets is that (2006, p. 18):

[i]nformation users must be able to separate what they have to do from why they have to do it; they must be able to tell at a glance what is important from what is not important; they must be able to tell which item is a piece of advice and which is an urgent warning; and so on.

To this end, both authors suggest that “instructions must be easily found [...] and written in such a way that consumers know what to do, even if they read nothing else in the leaflet.”³² As a result, they recommend that (2006, p. 20):

- Instructions are always written in bold font
- Nothing else in the body of the [leaflet] is in bold font.

5.1. “Instructions are always written in bold font”

If we analyse the eight leaflets sampled, not one totally adheres to the first and the second ‘instruction’ by Sless and Shrensky because very few directives are written in bold (sometimes they are even partially written in bold). Compare the English leaflets where within the same PIL we can find instructions written both in bold and in normal font:

Do not drink alcohol (wine, beer, spirits) whilst taking this medicine (Aspirin®)
Do not give to children under 16 years (Aspirin®)
Now read this whole leaflet carefully before you use this medicine (Imodium®)
If you forget to take a dose, take a dose after the next loose stool (bowel movement). **Do not** take a double dose (Imodium®)
Do not give to children under 12 years (Lemsip®)
Keep all medicines out of the reach and the sight of children (Lemsip®)
Keep all medicines out of the reach and the sight of children (Vicks® Sinex)
Contact your doctor if symptoms worsen or do not improve after 3 days. (Vicks® Sinex)

As for the Italian leaflets, Aspirina® and Vicks® Sinex contain 2 and 1 occurrence of instructions respectively, each written in bold. By contrast, in Imodium® and Tachifludec® none are in bold:

Tenere il medicinale fuori dalla portata e dalla vista dei bambini (Aspirina®)
Utilizzare sempre il dosaggio minimo efficace ed aumentarlo solo se non è sufficiente ad alleviare i sintomi (dolore e febbre) (Aspirina®)
Attenzione: non utilizzare il medicinale dopo la data di scadenza indicata sulla confezione. (Vicks® Sinex)

On the other hand, some PILs, especially the English leaflets of Imodium® and Vicks® Sinex, contain other parts of speech (nouns, adjectives, etc.) in bold too, thus leaving most of the time instructions in normal type:

³¹ For the full title, see footnote n° 8 or the references within the present article.

³² This assumption originates from “research that has shown that readers of information generally search for, and read, only what is important to them.” (Sless, Shrensky 2006, p. 34)

If you have **AIDS** and your **stomach becomes swollen**, stop taking the tablets immediately and contact your doctor (Imodium®)

Take **two tablets** initially, followed by **one tablet** after each loose bowel movement (Imodium®)

Please inform your doctor or pharmacist if you are taking, or have recently taken, any other medicines, even those obtained without a prescription:

- **monoamine oxidase inhibitors** (MAOIs) are used in the treatment of Parkinson's disease and depression) - **Do not use** Vicks Sinex Soother if you have taken MAOIs during the past two weeks.
- **tricyclic antidepressants** - inform your doctor if you are taking drugs used in the treatment of depression such as amitriptyline and imipramine. (Vicks® Sinex)

The last example is taken from the paragraph under the heading "Taking other medicines". To start with, we can see that the first instruction "Please inform your doctor..." is written in normal font and it is then repeated next to the second bullet point. Secondly, both nouns in the bullet list and the instruction ("Do not use") are written in bold. To make the readability worse, both are placed not only within the same paragraph but also very close to each other.

That being said, in the last example, we cannot help noticing also a mix of punctuation marks within the same line, namely the bullet point before the first element in bold, and the hyphen before "Do not use". Not to mention the inappropriate round bracket after the word "depression", and a full stop instead of a colon after the word "prescription" (in the introduction before the bullet points). All of this is really disturbing and makes the readability of that section of the leaflet really difficult.

It is also interesting to note, then, how other leaflets, such as Aspirin® and Imodium®, for example, respectively invert the parts in bold within the bullet points list under the heading "Do not take this medicine":

If you have severe liver or kidney problems (Aspirin®)

If you have a blood clotting disorder or gout (Aspirin®)

If you have **severe diarrhea** after taking antibiotics (Imodium®)

If you are **constipated** and your **stomach appears swollen** [sic]. (Imodium®)

In the Italian leaflet of Vicks® Sinex, there are no words written in bold; while in Tachifludec® and Imodium® the only lines in bold are those in the mandatory box at the top of the first page of each leaflet. Conversely, Aspirina® contains two adjectives in bold:

L'avvelenamento **cronico** da salicilati può essere insidioso dal momento che [...]

La caratteristica principale dell'intossicazione **acuta** è una grave alterazione dell'equilibrio acido-base [...]

However, they are so crammed with other words under the same heading that both of them go unnoticed.

According to Sless and Shrensky, "[t]he only case when instructions must be in 'plain text' and not in bold is in the numbered list of instructions" (2006, p. 42). This leads to another consideration by both authors (2006, p. 38):

If you want consumers to carry out two or more separate actions, give them two or more separate instructions [and] try [not] to compress more than one action into a single sentence.

Among the eight leaflets, the Italian Imodium® is the one which best follows the above said guideline, insofar as each line contains a single instruction and not one is written in bold:

Per liberare la compressa dal blister:

-sollevare il bordo della pellicola di alluminio

-tirare la pellicola

-premere leggermente per far fuoriuscire la compressa.

Poichè [sic] le compresse orosolubili sono fragili, non devono essere spinte attraverso la pellicola del blister.

Porre la compressa orosolubile sulla lingua.

La compressa verrà dissolta rapidamente dalla saliva. Imodium 2 mg compresse orosolubili non richiede l'uso di acqua.

In contrast, the English counterpart of the same product inserts several prescriptions and also proscriptions within the same line, even though not in bold:

- Peel back the lid and tip the tablet out. Do not push the tablets through the lid.
- Place the correct number of tablets on the tongue. The tablets dissolve quickly in your mouth, so you don't need water to swallow them. Do not chew.
- For oral use only.
- Do not use more than the stated dose shown in the tables.

The English Vicks® Sinex and Aspirin® PILs, unfortunately, closely follow the English Imodium® leaflet:

(Vicks® Sinex)

1. Remove the cap. Keep the bottle upright with the nasal applicator just into the nostril. Hold the other nostril closed.
2. Spray and breathe in deeply through your nose at the same time. Repeat for the other nostril.
3. Adults and children over 12 years may repeat steps 1 and 2 once if necessary.
4. Wipe the nasal applicator with a clean, wet tissue and replace the cap immediately after application

(Aspirin®)

Check the foil is not broken before use. If it is, do not take that tablet.

Follow the instructions in the table on the back of the leaflet.

Stir the tablets in a small glass of water until dispersed and drink immediately.

It is to be noted, however, that Aspirin® contains a list of instructions separated by double spacing rather than bullet points or a numbered list. However, by referring to the “back of the leaflet” for the instructions about the number of tablets to take per day, the leaflet clashes with the second important point highlighted by Sless and Shrensky (2006, p. 39): “Do not refer consumers to instructions in another section. You can refer consumers to previous steps in a clearly numbered list of instructions.”

All the English and Italian leaflets so far mentioned convey their procedural instructions on how to take the medicines separated by bullet points and spacing. On the contrary, the other leaflets insert them within a single long line, without signalling them accordingly. Compare:

For oral use. Dissolve in a mug of hot but not boiling water. Stir until dissolved. If preferred sweeten to taste with sugar, honey or your usual sweetener (Lemsip®)

Sciogliere una bustina in un bicchiere d'acqua molto calda e, a piacere, diluire con acqua fredda per raffreddare e dolcificare come si desidera (Tachifludec®)
 Tenere il flacone in posizione verticale, introdurre nella narice l'estremità del nebulizzatore e premere il nebulizzatore stesso con moto rapido e deciso. Dopo la nebulizzazione, inspirare profondamente a bocca chiusa. (Vicks® Sinex)³³

Also when there is not a sequence of procedural instructions, most of the leaflets “compress” several directives together. Let us consider the following example:

If you use too much Vicks Sinex Soother you should contact your doctor or go to a hospital immediately and take the bottle or pack with you.

First of all, the missing comma after the name of the product does not immediately help the readers find the beginning of the directive. Secondly, the sequence of verbs, of the additive and alternative conjunctions “and” and “or” respectively (Halliday, Hassan 1976, pp. 233-237) and of nouns makes the sentence longer. It also creates a false parallelism in that, unlike the previous chunk (“contact your doctor or go”), the word “pack” after the second alternative conjunction is a noun and not a verb.

5.2. Instructions as commands

As for instructions, Sless and Shrensky also suggest writing them “as commands, with the action word (keep, tell, do not take it, etc.) first” (2006, p. 38). This is due to the fact that research shows that “readers assume that the most important matter will come first in a sentence or paragraph and often only read the first part” (2006, p. 34).

This advice means we should try to “avoid the passive voice” (Sless and Shrensky 2006, p. 43) in that when we use it

- It is often not clear who is to take a particular action
 - The action gets lost in the sentence
 - The sentences are generally longer.
- (Sless and Shrenky 2006, p. 43)

As we have seen in paragraph 4.1. of the present work, the English leaflets performed better than the Italian ones in terms of their spare use of the passive voice (5 versus 27). However, Sless’ and Shrensky’s considerations are valid whether there be five instances or seventeen in a leaflet. For instance, let us mention the following example taken from the English leaflet of Lemsip®

Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.

The “action” conveyed through the passive “should be sought” is somewhat “lost in the sentence”, while, paradoxically, the word “Immediate” at the beginning of the clause is assumed to catch the readers’ attention: its meaning, urging one to do something soon, actually comes later on, syntactically speaking, in the sentence. A more practical, efficient

³³ The Italian leaflet of Aspirina® has not been inserted because, under the heading “How to take the medicine”, it only contains one instruction within a single line: “La compressa di Aspirina 400 mg compresse effervescenti con vitamina C deve essere sempre sciolta in mezzo bicchiere d’acqua prima dell’uso.”

and at the same time concise form might have been: “Seek medical advice immediately in the event of an overdose”.

The two Australian authors also recommend using “positive instructions [...] whenever possible” and negative instructions “only when you want consumers to avoid specific actions” (2006, p. 40). In this regard, all the eight leaflets perform quite well, even though the English leaflets do so better than the Italian ones. In this respect, however, it is interesting to cite the following example taken from the Italian leaflet of Vicks® Sinex:

Non deve essere usato oralmente. Evitare il contatto del liquido con gli occhi.

At a first glance, it may seem that the first sentence contains a negative instruction (“Non deve [...]”); the second, a positive one. On closer inspection, they both contain proscriptions, with the second being conveyed through a positive statement (“Evitare”) but carrying a negative meaning. It would have been interesting to see how the English counterpart rendered it, but, unfortunately, it is not available.

The previous example is not the only one in the eight leaflets that mixes prescriptions and proscriptions within the same line and sometimes even in the same sentence and same paragraph:

This medicine can be taken by adults and children aged 16 years and over. However, some people should not take this medicine or should seek the advice of their pharmacist or doctor first (Aspirin®)

Do not take a double dose if you forget to take the previous dose; instead, continue using according to the administration instructions (Vicks® Sinex)

Comunque, in assenza di risposta terapeutica completa entro pochi giorni, consultare il medico; in ogni caso, il trattamento non deve essere protratto per oltre 4 giorni consecutivi per evitare un effetto rebound e fenomeni di rinite indotti dal farmaco [...] (Vicks® Sinex)

Non usare per più di 4 giorni, in assenza di risposta terapeutica completa entro tale termine, consultare il medico. (Vicks® Sinex)

In fact, Sless and Shrensky do indeed talk about the possibility to “change the action-first rule” in the case of if-clauses (2006, p. 38). In this regard, they also remind us to “separate the condition (the ‘if’ part of the statement) from the instruction using a comma” when the if-clause precedes the independent clause (2006, p. 38), as common grammar books also state.

The analysis of the eight leaflets strikingly shows that, apart from few cases, several if-clauses at the beginning of a sentence have been detected without being followed by a comma. To cite some examples:

If symptoms do not go away talk to your doctor (Aspirin®)

If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this medicinal product (Lemsip®)

If symptoms persist for more than 24 hours talk to your doctor (Imodium®)

Qualora si manifestassero i suddetti sintomi chiamare immediatamente il medico (Imodium®)

Se si ha qualsiasi dubbio sull'uso di Tachifludec rivolgersi al medico o al farmacista (Tachifludec®)

Se state usando altri medicinali chiedete consiglio al vostro medico o farmacista. (Vicks® Sinex)

5.3. How to write “instructional information”

In his 1985 work, Trimble distinguishes “instructions” from “instructional information”, stating that the latter is:

discourse that ‘assists’ instructions by providing corollary information: cautions, warnings, specifying statements, descriptions, and theoretical considerations.” (1985, p. 96)

In other words, instructional information “can help users to understand the reasons for particular instructions” (Sless, Shrensky 2006, p. 35).

As a consequence, “instructional information”, Trimble continues, “cannot stand alone but is always associated with either direct or indirect instructions” (1985, p. 98). At the same time, Sless and Shrensky underline that an “explanation for instructions”, as they call “instructional information”, is “not always necessary, but when you give one, make sure it follows the instruction.” (2006, p. 38). It is important to underline here that by “follows” they mean writing the explanation under the instruction and not in the same sentence or in the same line.

There is a possible association between aspirin and Reye's syndrome when given to children. Reye's syndrome is a very rare disease, which can be fatal. For this reason aspirin should not be given to children aged under 16 years, unless on the advice of a doctor (Aspirin®)
 La diarrea può indurre una cospicua perdita di liquidi e di sali. Si consiglia dunque di bere molto per reintegrare le perdite (Imodium®)
 E' importante avere sempre a disposizione le informazioni sul medicinale, pertanto conservare sia la scatola che il foglio illustrativo. (Tachifludec®)

In many cases, as in the examples above, instead, in both the English and Italian leaflets the “instructional information” precedes the instructions and both are placed within the same line without any spacing between them. The first consequence is that an “important” instruction, as the one contained in the first Aspirin® example, under the heading “Other important information” risks being missed because, as we have already said, consumers “often read the first part” only.

Sless and Shrensky also advise against the use of “an instruction to justify or explain an action” (2006, p. 38), and “conjunctions [...] to join subordinate clauses to add information to the instruction” (2006, p. 44). In the eight leaflets this rule is often broken to the detriment of the shortness of the sentences and, as a consequence, of the readability of the leaflets. Here are some examples:

Do not take this medicine if you are breast-feeding *as* small amounts may get into your milk (Imodium®)
 Immediate medical advice should be sought in the event of an overdose, even if you feel well, *because of* the risk of delayed, serious liver damage (Lemsip®)
 [...] inform your doctor before use if you are taking bethanidine, debrisoquine and guanethidine *as* their effect may be reduced (Vicks® Sinex)
 Bisogna informare il medico se: Dovete essere sottoposti ad un intervento chirurgico (anche di piccola entità come ad esempio l'estrazione di un dente) *poiché* l'impiego pre-operatorio può ostacolare l'emostasi intraoperatoria (Aspirina®)
 Dato *che* l'acido acetilsalicilico può essere causa di sanguinamento gastrointestinale [sic] occorre tenerne conto nel caso fosse necessario eseguire una ricerca di sangue occulto (Aspirina®)
Poichè [sic] le compresse orosolubili sono fragili, non devono essere spinte attraverso la pellicola del blister. (Imodium®)

As we can see in the sentences above, when the “instructional information” is signalled by conjunctions (“as”, “because of”, “dato che” “poiché”, “perché”), it is clear that it occurs within the sentence containing the directive. Sometimes, instead, the explanations follow the directives (as in the first four examples); other times, they precede the instructions (as in the last two examples). To add insult to injury it should be noted that both instructions and explanations for instructions are written in the same font, with no distinction between bold and normal print, within the same sentence and often within the same line and paragraph.

To conclude, the following paragraph taken from the Italian leaflet of Vicks® Sinex, besides conveying the instructional information sometimes placing it before and at other times after the directives, it is above all an example on how not to write the pieces of information (directives and instructional information) in PILs:

Impiegare con cautela nei primi mesi di gravidanza e, *per* il pericolo di ritenzione urinaria (difficoltà ad urinare), negli anziani. Impiegare con cautela anche nei pazienti con angina e diabete. Comunque, in assenza di risposta terapeutica completa entro pochi giorni, consultare il medico; in ogni caso, il trattamento non deve essere protratto per oltre 4 giorni consecutivi *per* evitare un effetto rebound e fenomeni di rinite indotti dal farmaco. In tal caso è necessario interrompere il trattamento ed istituire una terapia idonea. Attenersi con scrupolo alle dosi consigliate. Il prodotto va tenuto lontano dalla portata, e dalla vista dei bambini, *poiché* [sic] l'ingestione accidentale può provocare sedazione spiccata. Non deve essere usato oralmente. Evitare il contatto del liquido con gli occhi.

A paragraph, like the one above, made up of 120 words compressed in 13 lines, one next to the other, is really hard to read and understand till the end.³⁴ Not to mention the expression such as “effetto rebound”.³⁵ Its English counterpart’s situation of the same product is not better: its paragraph contains 116 words inserted in bullet points and, as we have seen, with items indiscriminately written in bold whether they were verbs or nouns.

6. Conclusions

Since 1999, when EU legislation required a comprehensive medication information leaflet to be supplied to patients with every medication³⁶, many improvements have been made with regard to these patient information leaflets (PILs).

One of the most significant changes in 2004 includes the new requirement that “PILs are tested with target users” and that the “manufacturer has to deliver readability test reports (with a positive conclusion) to the authorities”.³⁷ Article 59(3) of the Directive 2004/27/EC states indeed: “The package leaflet shall reflect the results of consultations with target patient groups to ensure that it is legible, clear and easy to use.”³⁸

³⁴ As for the length of sentences in a PIL, Sless and Shrensky recommend that “If a sentence is over 20 words long, try to reduce it.” The third sentence contains 39 words, but, even if the other have less than 20 words, all the sentences are crammed together within the same paragraph.

³⁵ “The rebound effect is the production of increased negative symptoms when the effect of drug has passed or the patient no longer responds to the drug”. The information is available at the following link: <http://www.medicinenet.com/script/main/art.asp?articlekey=5234> (21.06.2015)

³⁶ The information is available at the following link:

http://www.academia.edu/422017/Consumer_Medication_Information_In_the_United_States_Europe_and_Australia_A_Comparative_Evaluation (8.05.2015).

³⁷ <http://www.samedanltd.com/magazine/11/issue/77/article/1736> (7.12.2015)..

³⁸ http://ec.europa.eu/health/files/eudralex/vol-1/dir_2004_27/dir_2004_27_en.pdf (16.05.2015).

Yet, as Adriesen underlines, “the Directive requires only one language version to be readability-tested.”³⁹ As a consequence, the linguistic review of all EU languages (including Icelandic and Norwegian), performed “to ensure high quality and consistent product information of Centrally Authorised Products in all Member States”,⁴⁰ is only content-focused. As a result, it is assumed that “the approved leaflet will be properly translated”⁴¹ in other EU languages.

Moreover, the new legislations apply only “for new or significantly revised products”.⁴² Instead, much improvement is needed as well for the PILs of medicines already on the market, irrespective of whether they have followed either the centralised or the decentralised procedure.⁴³

As we have seen in the present article, the eight over-the-counter PILs sampled show several differences as well as problems in terms of readability and comprehension. Not only among the leaflets circulating in different countries (the UK and Italy) and of medicines produced by the same marketing authorization holder (Imodium®, Vicks® Sinex), but also among those existing in the same country.

Adapting the expression from the title of this article to the findings in this analysis, we can say that both English and Italian leaflets sampled rather provide *disinforma(c)tion*. In other words, the pieces of information contained, both directives and the related explanations, that should have helped consumers to translate them into actions, have not often been properly conveyed.

Indeed, what emerges in this analysis is that, in both the English and the Italian PILs sampled, most directives are not actually that *direct*. This is due to several reasons: to start with, because of the syntax (use of passive, impersonal structures, modals, etc.). Secondly, due to the wording, giving rise in some cases to expressions that are even syntactically incorrect, such as “devono essere edotte le donne” and “può essere tentato di” (Aspirina®), or that seem to fulfill the referential function (“The tablets dissolve quickly in your mouth”, Imodium®). A third reason is the place where they are located (very often next to other prescriptions and proscriptions in the same paragraph; other times, also within the same sentence and not in separated lines one under the other).

We have seen, for instance, that the Italian leaflets tend to prefer the passive voice so that the “action gets lost in the sentence” (Sless, Shrensky 2006). However, even when both English and Italian leaflets use imperatives, the action often “gets lost” as well because it is “compressed” with other directives and/or informational instructions. “Do not chew” in the English leaflet of Imodium®, for example, follows Sless and Shrensky’s advice in that it uses “negative instructions in order that consumers avoid specific actions” (Sless and Shrensky 2006, p. 40). However, it is placed far away from the first directive conveyed through the imperative “Place the tablets...” Conversely, the Italian counterpart of the same medicine chooses a more implicit statement such as “La compressa verrà

³⁹ <http://www.samedanltd.com/magazine/11/issue/77/article/1736> (7.12.2015).

⁴⁰ The information is available at the following link:
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004182.pdf (15.05.2015).

⁴¹ <http://www.samedanltd.com/magazine/11/issue/77/article/1736> (7.12.2015).

⁴² <http://www.samedanltd.com/magazine/11/issue/77/article/1736> (7.12.2015). See also <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:334:0007:0024:en:PDF> (16.05.2015).

⁴³ For the several EU marketing authorizations procedures see the following link:
http://www.ema.europa.eu/docs/en_GB/document_library/Brochure/2014/08/WC500171674.pdf (16.05.2015).

dissolta dalla saliva”. However, both directives also risk being missed by readers because they are hidden in several sentences.

Furthermore, there are also differences between PILs of medicines produced by the same company, too. For example, while the English Vicks® Sinex performs better than the Italian one in terms of shorter sentences and increased visibility of the headings and subheadings, conversely, the Italian Vicks® Sinex performs better than the English one in that it avoids using the bold font both for directives and nouns. The English counterpart, as well as the English leaflet of Imodium®, uses the bold type indistinctively for directives and nouns within the same paragraphs, thus disturbing and compromising the readability and the understandability of the whole leaflet.

Moreover, both countries’ leaflets still contain excessively long paragraphs which certainly do not help consumers to find what they are looking for rapidly. To make the situation worse, in 2012 a new Aspirina® leaflet was published with more pieces of information than the one analysed in this work and in which the limited spacing that existed has now been totally eliminated.

Another important yet sad feature that has been found in the PILs sampled is the inaccuracy in terms of punctuation, both in the English and Italian leaflets. The if-clauses at the beginning of a sentence, indeed, are very often not followed by a comma. Furthermore, a mix of punctuation marks co-occur within the same sentence (hyphens immediately after bullet points standing for round brackets, as we have seen in the English leaflet of Imodium®).

In conclusion, if we consider Sless and Shrensky’s advice, from among the eight leaflets analysed there is not one that performed best. However, what the present article also aims to underline is that “it is the [PIL] that has to perform well, not the user” (Sless, Shrensky 2006, p. 6). It is a pity that NOT many pharmaceutical companies of existing over-the-counter and prescription medicines seem to know this incontrovertible truth.⁴⁴

⁴⁴ It is interesting to learn, however, that in 2002 in the US the Target Corporation bought, patented and adopted the bottle design of ClearRx prescription medicine created by Deborah Adler as part of her thesis project when she was a design student at the School of Visual Art in New York City. Adler came up with her idea when “her grandmother became ill by mistakenly taking her husband’s prescription instead of her own”. See <http://www.corporate-ethics.org/transparency-by-design/> (18.05.2015).

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