QUALITATIVE HEALTH COMMUNICATION
VOLUME 1, ISSUE 1, 2022
ISSN: 2597-1417

PILs that give you a headache? The lay-friendliness of non-pharmacy restricted, over-the-counter information leaflets

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ABSTRACT

Background: Over-the-counter (OTC) medication, and in particular non-pharmacy restricted OTC medicines, sold in supermarkets or online, is subject to the same EU legislation as prescription medication. However, it seems that due care is often not taken to ensure maximum patient comprehension even though the Patient Information Leaflet (PIL) is potentially more important due to lack of access to the advice of pharmacy staff. **Aim**: The aim of this article is to explore the legislative background and practice of the PILs of non-pharmacy restricted OTC medicines in a European context. **Methods**: It provides a qualitative textual analysis of Danish PILs for the potentially most dangerous products with a view to finding out to which extent the PILs comply with current legislation and guidelines. **Findings**: The textual analysis shows that the PILs are far too complex to stand alone as a source of information. **Discussion**: The article discusses the nature of non-pharmacy restricted OTC medicines, the potential consequences of a lack of understandable patient information, and whether it is in the interest of consumers that these products are available outside the pharmacy. **Conclusion**: It is recommended that the potentially most harmful non-pharmacy restricted OTC medicines, such as analgesics, are restricted to pharmacies.

KEYWORDS

Lay-friendliness, non-pharmacy restricted, over-the-counter medication, patient information leaflet, readability

BIOGRAPHY

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Introduction

Since they were made mandatory in the European Union in 1995, the lay-friendliness, or readability as some scholars prefer to term it, of Patient Information Leaflets has been much discussed as it soon became clear that many patients find it difficult fully, or sometimes even partially, to comprehend the information provided, if they read it at all (Askehave & Zethsen, 2010, 2014; Calamusa et al., 2012; Horwitz, Reuther & Andersen, 2009; Nisbeth Jensen, 2013; Pander Maat & Lentz, 2010; Pires, Vigário & Cavaco, 2015; Tong, Raynor & Aslani, 2014; Webster, Weinmann & Rubin, 2017). In spite of EU legislation which dictates that PILs must be "written and designed to be clear, understandable and enable the users to act appropriately" (Article 63(2) of EU Directive 2001/83/EC; European Parliament and Council, 2001), and in spite of EU templates and guidelines, ostensibly to ensure lay-friendliness, many studies have documented problems for instance in the form of expert language transferred from the product summary to the PIL, complex and impersonal syntax, very long documents, too long lists of side effects the likelihood of which is difficult to gauge, too small font size, etc. etc. (Askehave & Zethsen, 2000, 2010, 2014; Horwitz et al., 2009; Nisbeth Jensen, 2013; Pander Maat & Lentz, 2010; Raynor, 2007). It does seem that increased focus on the problems and cooperation between the research community and the pharmaceutical industry generally have had some positive effects on the complexity of the language of PILs, for instance as witnessed by the UK PIL of the Month initiative (Askehave & Zethsen, 2010). However, there are still numerous problems, among other things with the sheer length of PILs as well as mandatory and very detailed information on e.g. extremely unlikely side effects, which may cause information overload for the patient, thus drowning the most important information. It is not uncommon now to see headlines such as "Do not take xx if […]" instead of "Contraindications", or to see personal pronouns and active voice, but on the other hand, there still seems to be many remnants of expert language in most PILs making them difficult for laymen to understand, and certainly more complex than the goal of e.g. the Danish authorities that they should be understandable for a 12-year-old (Madsen et al., 2009, p. 18). In spite of legal requirements and some progress in lay-friendliness, at least in some respects, Calamusa et al. (2012, p. 400) found that for instance Italian PILs were still not easy to understand and Foley, Kelly, Deluca and Kimergård (2018, p. 5) calls for improvements in PILs, which could educate the public further in safe use and potential risks.

Much of the research carried out on the lay-friendliness of PILs has been concerned with prescription medication. This is often a natural choice since the potential consequences of not understanding the PIL are more serious *per se* when prescription medication is involved. However, this does not mean that over-the-counter (OTC) medication cannot be harmful and OTC medication is in fact subject to the same EU legislation and guidelines as prescription medication. There is a general lack of research on OTC PILs (Hedenrud & Håkonsen, 2016; Pires et al., 2015), and especially the PILs of non-pharmacy restricted OTC medicines are in need of investigation, since they are purchased without the possibility of consultation with a pharmacist (in addition, supermarket staff in Denmark are in fact not allowed to provide advice on OTC medication). Many countries now allow the purchase of medication containing ibuprofen, codeine and paracetamol (acetaminophen) in supermarkets and other non-pharmacy outlets as well as online, though in the EU, 16 out of 28 countries do not even allow

OTC sale of codeine (Foley et al., 2018, p. 2). Morthorst et al. (2018) investigated the sale of paracetamol tablets in non-pharmacy outlets in European countries (not limited to EU members). Answers were obtained from 21 countries, and out of these, 14 countries do not allow the sale of paracetamol tablets in non-pharmacy outlets. It is interesting to note that Sweden, which had allowed non-pharmacy restricted OTC sale of paracetamol since 2009 rescinded the permission in 2015 for safety reasons, among other factors due to an increase in the number of paracetamol poisonings (according to Foley et al., 2018, p. 7, OTC sale of codeine-containing medication is not allowed in Sweden either). A study by Morthorst, Soegaard, Nordentoft and Erlangsen (2016) found that the lowest rates of paracetamol-related calls to poison information centres were found in those European countries where sales outside pharmacies were not allowed compared to those European countries where non-pharmacy sales were allowed. Furthermore, in a Swedish study, Gedeborg et al. (2017) showed a link between the availability of OTC analgesics and poisonings.

This article analyses a selection of Danish PILs for the potentially most dangerous OTC products with a view to finding out to which extent the PILs comply with current legislation and guidelines as far as lay-friendliness is concerned. The article furthermore discusses the nature of non-pharmacy restricted OTC medicines, the potential consequences of a lack of understandable patient information, and whether other countries, such as Denmark, should follow in the footsteps of Sweden.

Literature Review

When OTC medication is the subject of health communication research, focus is often on analgesics as these are among the potentially most harmful OTC products. Medications containing ibuprofen, codeine and paracetamol, on their own or in a combination, are some of the most widespread painkillers in the world, but it is well-documented that they can lead to addiction and that when taken in too large doses they can be very dangerous (Foley et al., 2018, p. 3). However, studies indicate that knowledge about these everyday products leaves much to be desired, which is a cause for concern since there has been a "worldwide increase over the last 15 years in the use and overuse of OTC medication" (Bennin & Rother, 2015, p. 331). An Italian study published in 2012 (Calamusa et al., 2012, p. 395) found that around 42% of respondents were unable to calculate simple dosages in connection with OTC medication and that 30% could not tell the difference between 'contraindications' and 'side effects' (398). Female gender and high educational level had a positive effect on scores. A study by Zhao, Chen, Han and Westland from 2020 found that the majority of UK university students do not know the risks of taking codeine, and Zhao et al. furthermore cite Van Hout and Norman (2016), Kinnaird et al. (2019), and Bennett and Holloway (2013) in support of the fact that the majority of UK citizens were not fully aware of the potential risks when they started using codeine. In the US, only 46% of patients knew that acetaminophen was the active ingredient in Tylenol (the most common OTC painkiller in the US) according to a study by Hornsby, Whitley, Hester, Thompson and Donaldson (2010), and only 33% knew the recommended maximum daily dose. This means that even if many people are aware of the potential dangers of acetaminophen, this knowledge would be of no use to those who do not know that this is in fact the active ingredient of Tylenol. A later US study by Ip, Tang, Cheng, Yu and Cheongsiatmoy (2015, p. 502) confirmed "the lack of basic acetaminophen knowledge among the general public regardless of educational levels or health literacy". Especially when Tylenol

PM (a pain reliever and sleep aid combined) is concerned, less than half the respondents were aware that acetaminophen was the active ingredient (p. 501). Likewise, Hedenrud and Håkonsen (2016) have studied the use of paracetamol in Sweden and only 50.8% of respondents remember having heard about the potential risks of paracetamol (2016, p. 38). In their systematic review on PIL readability, Pires et al. (2015) looked at two exploratory studies (Cavaco & Pires, 2012; March et al., 2010), which found that patients prefer to get information about their medication orally from health professionals (the review is not focused on OTC). Hedenrud and Håkonsen (2016, p. 38) found that 12% of those buying paracetamol at the pharmacy in Sweden ask the staff for advice and those with the lowest level of education asked significantly more for advice (2016, p. 39). Yet oral advice is not possible when OTC medication is bought at the supermarket and the most common source of information about OTC medication is the PIL (Hedenrud & Håkonsen, 2016, pp. 38-39). This means that the consumer of non-pharmacy restricted medicines becomes very dependent on the PIL for information, which makes the question of lay-friendliness of PILs crucial.

In the above-mentioned systematic review concerned with PIL readability in general (Pires et al., 2015), the authors concluded that PILs are generally complex and difficult to understand and printed in a too small font size. Several of the studies included found that too little was done to make PILs readable for those with low literacy or numeracy skills. In 2014, Tong et al. published a review article on design and comprehensibility of OTC product labels and leaflets. The review is based on 35 articles published between 1987 and 2013, and the overall conclusion of the review article was that consumer understanding of key information varies from “relatively adequate” to “significant consumer misunderstanding” (Tong et al., 2014, p. 869). Examples of significant misunderstandings are for instance when only 40% of caregivers having access to all package labelling are able to determine an appropriate dose of paracetamol for a child under their care (Simon & Weinkle, 1997). Of these 40%, a third did in fact not measure the correct intended dose, i.e. the correct dose was by accident, and only approx. 30% calculated the correct intended dose (82% of respondents with high school education or more). Or when more than 50% of caregivers indicated that they would give an OTC paediatric cough/cold medicine to a child of less than 2 years, in spite of the fact that the label called for medical advice from a doctor prior to use in this age group (Lokker et al., 2009). Furthermore, the review concluded that well-designed (both from a layout and a linguistic point of view) labels and PILs contribute to improved understanding. In an intervention study by Fuchs and Hippius (2007), only 9.4% of paracetamol consumers could correctly nominate the maximum daily dose when using the existing PIL, whereas 84.9% were able to do this on the basis of the redeveloped PIL. Finally, Calamusa et al. (2012, p. 399) found that only about 38% of their respondents professed to completely understanding the PIL of OTC medication.

The Danish context

In Denmark, approx. 3800 non-pharmacy outlets have been approved for the sale of OTC medicine for humans (Lægemiddelstyrelsen, 2019a), and Denmark is among the EU countries that permit the non-pharmacy restricted sale of analgesics such as paracetamol, and is in fact the only EU country permitting the non-pharmacy restricted sale of codeine (Foley et al., 2018, p. 3). According to Danish legislative guidelines on the advertising etc. of medicines (Lægemiddelstyrelsen, 2014 especially 3.1 under General Terms and 4.4. on Mandatory Information), direct advertising to the general public is not permitted in connection with

prescription medicine (as is the case in the entire EU), but OTC medication, including non-pharmacy restricted products, can be advertised. The advertisements cannot be misleading or exaggerate the abilities of the medicine (or try to create higher consumption than necessary), and the most important information concerning the medication must be included in the advertisement. However, this is typically done by printing a long text in extremely small font at the bottom of the page of the ad, typically in supermarket printed ads or online catalogues. It is interesting to note that the legislative requirement of printing the most important information relates to the Summary of Product Characteristics (for experts) and not the PIL, thus potentially increasing the risk of expert language in the information for patients. The most important information required is very similar to the headings of the PIL and includes information about indications, side effects, dosage etc., but with permission to exclude information that is deemed less relevant to the general public. Only one comment relates to the language of the printed information and this is in connection with indications: "If the wording of the summary of product characteristics is deemed to be difficult to understand for ordinary consumers of medicine it can and should be reworded into a more easily comprehensible language" ((Lægemiddelstyrelsen, 2014 4.4 (4)). Translated from Danish by the author). However, what seems to happen is that the advertisement text is a linguistically and graphically compressed version of the PIL, which makes it more difficult for the lay-reader. Below is a typical illustrative example from the warning section of the ad (for the dietary fibre supplement HUSK® from an ad by the Danish supermarket chain Føtex 11 December, 2020. Translated from Danish by the author): "Speak to the doctor if you have bowel inflammation, swallowing difficulties, disturbance in liquid or salt balance, have used laxatives for a long time". The corresponding warning from the PIL (Lægemiddelstyrelsen, 2020a) is as follows:

> Speak to your doctor if you
>
> - have a flare-up of inflammation of your bowel.
> - have problems swallowing.
> - have disturbances in the body's liquid or salt balance.
> - need to use laxatives every day for a long time so that the doctor can check the reason for your indigestion.

The PIL is not perfect, but the example illustrates how the text of the ad is condensed by leaving out explanations, personal pronouns and the hyphen structure. All features which may potentially harm lay-friendliness.

The present article does not offer a comprehensive analysis of the information printed in connection with advertising, but the author is yet to see examples of such information being in a lay-friendly format, linguistically or graphically. If the ad information was in fact a lay-friendly summary of the most important information, it could potentially be of great help to consumers of supermarket-bought medication, providing an easy-to-read and quick overview. But as it is now, it seems that the PIL is the only material purporting to offer lay-friendly information, which is why this article will analyse the entire PIL.

Methods

Data

The Danish Medicines Agency divides non-pharmacy restricted OTC medicines into three groups. HF, HX and HX18. HF is medicine that can be sold without age or amount restrictions. HX means that only one (small) packet can be bought a day, and HX18 means that in addition, the buyer has to be at least 18 of age. The categories HX and HX18 are for the non-pharmacy restricted OTC medicines, which are potentially most dangerous if taken in the wrong way or abused. For this reason, I have assembled a text corpus which consists solely of the PILs of HX/HX18 medication. The Danish Medicines Agency publishes a list of non-pharmacy restricted OTC medicines, and on the basis of this list, I have identified all HX/HX18 products sold in Denmark (Lægemiddelstyrelsen, 2019b). On the face of it, there are more than 40 products (the list is updated daily), but this list can be narrowed down to groups of products based on the same active ingredient(s), but sold under different names. A total of seven HX/HX18 product groups were identified, and I have chosen the PIL of the first product on the list for each group, thus creating the text corpus seen in Table 1 (the actual texts have been found on Lægemiddelstyrelsen, 2020b).

Table 1: HX/HX18 product groups

Active ingredient(s)	**Against**	**Name**	**Category**	**Form**
Aciclovir (1)	Herpes	Acivir	HX	Cream
Cyclizin (2)	Transport sickness	Gotur	HX18	Tablets
Flurbiprofen (3)	Sore throat	Strefen	HX18	Lozenges
Paracetamol (4)	Pain and fever	Arax junior	HX18	Tablets
Ibuprofen (5)	Pain	Ibumax	HX18	Tablets
Codeine and acetylsalicylic acid (6)	Pain	Kodimagnyl	HX18	Tablets
Acetylsalicylic acid (7)	Pain	Treo	HX18	Effervescent tablets

In this way, all HX/HX18 product groups are represented in the corpus, and the pharmaceutical company behind the product representing the group chosen at random. The seven PILs come from six different pharmaceutical companies.

Analytical method

Based on Askehave & Zethsen (2000), a textual analysis of the seven PILs has been carried out. The aim of the analysis is to assess whether the PILs are likely to be "clear and understandable" to laymen as required by law. All PILs were read carefully in order to identify words, passages or features which are deemed potentially to hamper lay-friendliness. This does not mean that all instances identified will necessarily be problematic to all people at all times, but simply that lay-friendly alternatives exist, and if they were used, more people would be likely to understand the text as intended. Askehave & Zethsen (2000) aims at identifying and systematising the main problems in PILs from a readability point of view. These problem areas are, for instance, expert terminology, abbreviations, officialese, synonymy, premodification (when typically adjectives or other nouns are used before the head noun in a phrase and thus

resulting in very long noun phrases which may be difficult to deconstruct), compound nouns, nominalisation (turning a verb into a noun and thus hiding the agent), passive constructions, ellipsis, presupposition etc. In the present study, a systematic analysis was carried out by means of several readings of the texts focusing on different parameters for each reading such as lexis, syntax and layout/structure in order to ensure that no features were overlooked. As can be seen in the Results section, all problem areas which were found in several PILs have been given their own category, such as "Premodification" or "Officialese". I have translated the Danish text as literally as possible and provided the number of the source PIL in brackets (see Table 1).

Results

The seven PILs analysed in depth generally display the same negative features as far as lay-friendliness is concerned. Some PILs are more complicated than others, but they all contain several, and sometimes a large number of, examples of most of the categories. Due to limitations of space, only illustrative examples will be provided of some of the most problematic categories, namely lack of agent, medical terms, officialese, presupposition, and layout/structure and linguistic correctness (when not self-explicatory, the focal point is in italics. All translations from Danish are done by the author and placed in square brackets after the example).

Main negative features

Lack of agent

Several linguistic features force the agent out of the sentence, and it may therefore be difficult for the lay reader to determine with certainty who the intended agent is. The most obvious example is the use of passive voice as in:

> Brugen af Acivir crème *bør* kun *overvejes* [...] (1) [the use of Acivir cream should only *be considered* […]]

The patient may be in doubt who the agent is supposed to be. Also, nominalisations often deagentivise the text. Common nominalisations, which are used every day are unproblematic, but more artificial nominalisations may complicate the sentence unnecessarily:

> Øget *svedtendens* (6) [increased *sweat tendency*]
>
> *Vandladningsstop* (2) [*urination stop*]

It may be easier to understand and feel more relevant to the patient if it said "you may sweat more" or "if you stop peeing". In many cases, nominalisation is combined with the passive voice resulting in fairly complex sentences:

> *Forsigtighed tilrådes* ved samtidig *indtagelse* af alkohol (2) [*carefulness is advised* at simultaneous *intake* of alcohol]
>
> Hvis du har taget for mange Arax Junior tabletter, bør hurtig *behandling* med N-acetylcystein *igangsættes* (modgift) (4) [If you have taken too many Arax Junior tablets, fast *treatment* with N-acetylcysteine should *be initiated* (antidote)]

Again, it may be difficult to gauge who the agent is and in the latter example, the agent is in fact NOT the patient. Finally, the gerund is often used:

Livs*truende* (6) [life *threatening*]

Feber*nedsættende* (4) [fever r*educing*]

This has the effect that again the agent is avoided. In all these examples, the message is likely to be easier to understand and feel more relevant if relative clauses and personal pronouns were used. This is also the case in connection with premodification, including compound nouns, which combine hidden agents with the compression of large amounts of information into a single noun phrase.

Premodification

Øjeblikkelige alvorlige allergiske reaktioner (1) [immediate serious allergic reactions]

Akut generaliseret eksantematøs pustulose (5) [acute generalised exanthem matous pustulosis]

Kodimagnyl ikke-stoppende DAK filmovertrukne tabletter (6) [Kodimagnyl non-congestion DAK film-coated tablets]

Dosisrelateret mild, forbigående leverbetændelse (gulsot) (6) [dosis-related mild, transient inflammation of the liver (jaundice)]

Compound nouns are a special challenge to lay-friendliness in Danish since words can be combined orthographically to a larger extent than is possible in for instance English.

Compound nouns

Vandladningsbesvær (2) [water passing difficulty]

Blødningsforstyrrelser (3) [bleeding disturbances]

Overfølsomhedsreaktioner (4) [allergy reactions]

Medicinoverforbrugshovedpine (4) [medicine overuse headache]

These compound nouns sometimes result in very long and complex words which are not part of common language.

Medical terms

Perhaps the most well-known category in relation to lay-friendliness is the use of expert medical terms in texts for laymen. In Danish and other Nordic languages, there are normally two sets of medical terms; an expert term of Latin/Greek origin, unknown to most laypeople, and a lay term of Nordic origin. The Nordic languages are not as Latinate as e.g. English, and it is therefore more difficult for non-experts to figure out what an expression means (Zethsen, 2004). In English, an ulcer is an ulcer to experts and laymen alike, but in Denmark, all non-experts would call it “mavesår” [stomach wound], and very few Danes would know what an “ulcer” is. All seven PILs include a large number of expert terms. To illustrate the extent of the problem the occurrences have been divided further, with the first category being instances where the expert term stands alone:

Unexplained expert terms

Kontaktdermatitis (1) [contact dermatitis]

Hjerteinsufficiens (3) [heart insufficiency]

Symptomatisk behandling (4) [symptomatic treatment]

Åndedrætsdepression (6) [breathing depression]

The last example is further complicated by the fact that most Danes know the word "depression" in connection with mental health, and it may thus be a false friend.

Sometimes a lay term or an explanation is added in brackets after the expert term, no doubt to help the layman reader. However, this strategy may be problematic since it results in long phrases, and sometimes it may even be difficult to figure out whether the brackets contain an explanation or additional information.

Lay term/explanation in brackets after expert term

Angioødem (hævelse af tunge og/eller ansigt) (1) [angio oedema (swelling of tongue and/or face]

Toksisk epidermal nekrolyse (kraftig afskalning og afstødning af hud) (3) [toxic epidermal necrolysis (strong flaking and shedding of skin]

Aggregation af blodplader (dvs. at blodcellerne klæber sammen og danner en blodprop) (7) [aggregation of blood plates (i.e. the blood cells stick together and form a blod clot]

In these cases, it does not seem that the patient has any use for the expert terms. An argument for doing the opposite, i.e. providing a lay-friendly term first and then an expert term in brackets, is often that patients with chronic illnesses may find it useful to know the expert term for future reference, especially in connection with diagnostic terms. It may also be helpful to non-native readers. However, in many cases, the expert terms provided in brackets do not seem very useful to patients.

Unnecessary expert term in brackets

Acivir crème er et lægemiddel mod virusinfektioner (antiviralt lægemiddel) (1) [Acivir cream is medication against virus infections (antiviral medication)]

Medicin mod angst (Anxiolytika) (2) [medication against anxiety (Anxiolytics)]

Luft i maven (flatulens) (3) [air in stomach (flatulence]

Risiko for hjerteanfald (myokardieinfarkt) (3) [risk of heart attack (myocardial infarction)]

In other cases, the explanation is simply too detailed as seen below.

Too detailed medical explanation in brackets

Lægemidler, som nedsætter et forhøjet blodtryk (…angiotensin-II-receptorantagonister som f.eks. losartan) (5) [Medication, which reduces a too high blood pressure (…angiotensin-II-receptor antagonists such as e.g. losartan]

Medicin mod type 2-diabetes (…tolbutamid (afledt af sufonylurinstof [sic])) (5) [Medication against type 2-diabetes […tolbutamide (derived from sulfonylurea)]

Gulsot pga. nedbrydning af røde blodlegemer hos patienter med medfødt glucose-6-phosphat dehydrogenase (6) [jaundice due to degeneration of red blood cells in patients with congenital glucose 6-phosphate dehydrogenase]

To patients who are not strong readers and who do not have a very high level of health literacy, these often very long Latinate medical terms and expressions may have the effect that the PIL seems too daunting and is abandoned.

Officialese, including false friends

The PILs often make use of officialese, i.e. the traditionally rather pompous language known from communication from the authorities. It is not medical expert language, but the expert language of officials and often much more complex than everyday language:

> Efter *fremkomst* af infektionen (1) [after *appearance* of the infection]
>
> Desorienteret (2) [disoriented]
>
> Ikke kendt [bivirkninger] (kan ikke estimeres ud fra forhåndenværende data) (3) [not known [side effects] (cannot be estimated on the basis of the present data)]
>
> *Indtagelse* af alkohol (2) [the *imbibing* of alcohol]

Also, in connection with small function words, the long versions have often been chosen even when shorter and/or more common alternatives exist in Danish:

> Ligeledes (1) [similarly]
>
> Lejlighedsvis (3) [occasionally]

In between expert medical language and officialese, there is a category of words and expressions which are common in Danish, but not as used in the PILs. These false friends do indeed belong to formal or expert language, but are disguised as common language and may therefore cause misunderstandings:

> *Lokal* anvendelse (1) [*local* use] – i.e. on parts of the body
>
> Administration (1) [administration] – e.g. how to apply a cream
>
> Orale (3) [oral] – in Danish only used in connection with academic examinations or sex

Presupposition

The category of presupposition covers instances where it seems that too much background knowledge is expected from the reader. This is the case in the following examples.

Vague expressions

> Brugen af Acivir crème bør kun overvejes, når de potentielle fordele vejer tungere end muligheden for ukendte risici (1) [The use of Acivir cream should only be considered when potential advantages outweigh the possibility of unknown risks]

Also relative adjectives or adverbs are very often used:

> *Høje* doser acetylsalicylsyre (3) [*high* doses of acetylic acid]
>
> [Kontakt lægen] hvis du er *ældre* (5) [[contact your doctor] if you are *elderly*].

The expression “elderly” is often used and only one of the PILs writes specifically “if you are over 65 years old” which is much easier for the patients.

Hvis du *snart* skal tage den næste dosis (5) [if you are *soon* to take the next dose]

Længerevarende brug (6) [*long-term* use]

Euphemisms

[slimhinder] i munden, i øjnene eller i *vagina* (1) [[mucosa] in the mouth, the eyes or in the *vagina*] - "vagina" is not the common Danish term which is more graphic

Afbrydelse af graviditet (3) [interruption of pregnancy]

Luft i maven (flatulens) (3) [air in the stomach (flatulence)]

Euphemisms may make the reader unsure as to what is meant precisely. However, this is one of the few categories, which are not represented in every PIL.

Abbreviations (unexplained)

SSRI-præparater (3) [SSRI medication]

DRESS-syndrom (5) [DRESS syndrome] - described as a serious skin reaction, but the abbreviation is not revealed

Kodimagnyl ikke-stoppende DAK filmovertrukne tabletter (6) [Kodigmagnyl non-congesting DAK film-coated tablets] - used both in PIL headline and throughout PIL. "DAK" is never explained

Af typen NSAID (6) [of the NSAID type]

Superfluous information

A kind of reverse presupposition is very frequently found in the PILs. This is a situation where the leaflets contain much more information than the patient could possibly need. For instance, all PILs provide very detailed information of the appearance of the medication:

Hvide, runde, bikonvekse tabletter uden filmovertræk med delekærv på den ene side (2) [White, round, biconvex tablets without film-coating and scored on one side]

Sugetabletterne er runde med et præget varemærkelogo og en ugennemsigtig lysegul farve (3) [The lozenges are round with an embossed trademark logo and an untransparent light yellow colour]

Also the above-mentioned examples under "Unnecessary expert terms" and "Too detailed medical explanation" belong to this category.

PIL not updated

Several of the PILs have not been updated since the medication was released for supermarket sale, which may confuse the patient:

Fortæl altid til lægen eller på apoteket, hvis du tager anden medicin (2) [Always tell the doctor or pharmacist if you take other medication]

Lægen har ordineret Ibumax til dig personligt. Lad derfor være med at give medicinen til andre (5) [The doctor has prescribed Ibumax for you personally. Therefore, do not give the medication to others]

Also, some of the PILs include the following sentence:

Se den nyeste indlægsseddel på www… [see the most recent patient information leaflet at www…]

Such a formulation may leave the reader unsure of whether it is sufficient to read the printed PIL in hand.

Layout and linguistic correctness

Layout and structure

As far as layout is concerned, the analysed PILs confirm what we already know from many other studies (see e.g. Askehave & Zethsen, 2000), namely that font size 8 which is normally used is too small. It is in fact so small that it may be difficult even for young people to read, but of course, it generally becomes even more problematic with age (even though this age group consumes more medicine than the younger segment). Also, the length of the PIL may be problematic (PIL no 6 consists of six compact pages which is not unusual), and e.g. the long lists of side effects, even those highly unlikely, may be a challenge to many readers. With such long PILs, patients may find it difficult to locate the most relevant information. Using questions for headings is a well-known means of making a leaflet seem personal and relevant to the reader and helping the reader locate information, but none of the PILs apply this means. Finally, the chronology of the PILs may be problematic as the most important information is not always provided in the beginning. In several of the PILs (e.g. 5 and 6), warnings about possible infertility are not given until page 5 and warnings that xx must not be given to pregnant women in the last trimester or children under the age of 15 with fever (6) are given on the bottom of page 1 and on page 2, respectively. In the case of the warning regarding children under the age of 15 with fever, the information is somewhat confusing since about an entire page later the reader is furthermore warned *never* to give the product to children under the age of 15 without consulting a doctor.

Linguistic correctness

The majority of the PILs analysed contain one or more linguistic errors ranging from lack of comma (5), misspellings (“cr*è*me” (1), “d*o*gsdosis” (4), “mor*ph*in” (6), “ånde*b*rætsdepression” (6)), and some of the misspellings are even repeated throughout the document. None of the linguistic errors are deemed to hinder the lay-friendliness of the PILs, but they may affect the credibility of the documents. Who can be sure that there are no typos in dosage information for instance?

Positive features

Although all the PILs analysed abound with linguistic features which could be improved, there are some positive features too. Especially PILs 1, 2 and 4 contain many sentences which are relatively short, and in some parts of the same PILs, they make use of active voice and personal pronouns. In addition, all of the PILs often make use of the imperative, especially in connection with warnings, instead of a passive construction, thus making it easy for the patient to understand when to act. To this should be added that even if the PILs, as shown above, contain far too many expert terms, quite a few layman terms are used where expert terms could have been used.

General comments

The PILs analysed generally fluctuate as regards lay-friendliness with some passages being considerably more difficult to understand than other passages of the same PIL. The voice often alternates between active and passive voice, and the PILs are marked by what are presumably many small revisions where the tone of the language changes or slightly inconsistent information is provided. This gives the impression that no one is responsible for the PIL as a whole each time it is updated. The layout of the PILs is problematic, which in part is due to the fact that they follow the mandatory EU template. The detailed analysis carried out above shows a legion of features which may hinder lay-friendliness, and what is more, these features frequently occur together in the same sentence thus making it even more inaccessible to the lay reader. Based on the analysis, it can be concluded that none of the PILs analysed are deemed to be "clear and understandable" to the consumer as required by law.

Discussion

The increasing trend in some EU countries of releasing more and more medicinal products for non-pharmacy restricted OTC sale is presumably fueled by a wish to make these products easily accessible and cheaper. In addition, a positive aspect of increased self-medication can be enhanced patient empowerment where patients experience greater independence in making decisions about their own health (Calamusa et al., 2012, p. 395). However, to be safe and effective, increased self-medication must be based on informed decisions, which among other things, requires knowledge about potential risks, contraindications and when to seek professional help. In other words, these decisions rely heavily on patient comprehension of the PIL for safe use of the medicine since the patient cannot receive oral advice from professionals in connection with the purchase. As the above textual analysis shows, PILs are still long and linguistically complex, with many remnants of expert language contrary to the EU requirement of clear and understandable PILs. Consequently, it must be assumed that many patients will not be able to fully understand important information about the medication purchased. Especially information about dosage and contraindications may be crucial for safety reasons even in non-pharmacy restricted OTC medication and important information about for example fertility impact certainly risks being overlooked due to its placement towards the end of very long PILs.

The signal value of releasing a product for non-pharmacy restricted sale may well be that the product is very safe to consume, and this may lead the consumer to underestimate the potentially harmful effects of the products. Especially analgesics such as paracetamol, ibuprofen and codeine have potentially very dangerous side effects if taken for too long or in too large doses. Especially codeine abuse is recognised around the world as a serious problem (Nielsen, MacDonald & Johnson, 2018), and in addition, many consumers combine several types of OTC painkillers, which may enhance the potential problems. Finally, the fact that many of the products analysed above exist in versions with some kind of fruit flavour etc. may make them resemble products ingested for pleasure and seem more harmless to consumers.

The Swedish study by Hedenrud and Håkonson (2016, p. 38) concluded that young people and those with a low level of education were significantly more likely to purchase paracetamol in supermarkets and other non-pharmacy outlets. This seems worrying since these groups may

well be in need of more information than average, and the study also shows that consumers with a low level of education who bought paracetamol in pharmacies were more likely to ask for advice than others. On this background, the Danish 18-year rule seems very sensible and is furthermore supported by the findings of Morthorst et al. (2020), namely that the Danish age restriction which was introduced in 2011 (as well as the pack size restriction introduced in 2013) was associated significantly with a reduction in the number of poisonings. Also Gedeborg et al. (2017) showed a link between the availability of OTC analgesics and poisonings, and Foley et al. (2018, p. 5) calls for further studies into a potential correlation between sales restrictions and codeine misuse/abuse.

The right to advertise is an added complication of non-pharmacy-restricted OTC medication as the text which by law must be printed with the ad is an extremely condensed version of the product summary both linguistically and graphically and seems to be very lay-*un*friendly. One may speculate if this taste of information may deter some consumers from reading the actual PIL enclosed with the medication, giving up in advance so to speak. Under all circumstances, the consumer is still completely left to the mercy of the PIL as it is not possible, or even allowed, to get advice at the supermarket.

On the basis of the literature review and the textual analysis, it seems that the time has come to review current Danish legislation (and that of other European countries) as far as the sale of non-pharmacy-restricted OTC medication, especially analgesics, is concerned. The main source of information for consumers is the PIL which is not very lay-friendly in its current state and may lead to very harmful and potentially fatal misunderstandings. Also Foley et al. (2018, p. 5) conclude, on the basis of their findings, that it is important to review and challenge current European legislation. As mentioned above, Denmark is the only European country permitting the non-pharmacy-restricted OTC sale of codeine, and 16 European countries do not even allow OTC sale of codeine. Sweden rescinded the permission to sell paracetamol in supermarkets in 2015, and in 2017, France restricted codeine to prescription only. In August 2020, UK's medical agency, the MHRA, announced that they consider banning all OTC sale of codeine and other opioid-based painkillers (which are currently pharmacy-restricted in the UK) (Pearce, 2020).

Conclusions

Non-pharmacy-restricted OTC medication is far from harmless, but nevertheless, Danish consumers, and consumers in other EU countries allowing supermarket sales of OTC medication, are left to the mercy of the PIL for information. A document, which in connection with prescription medication has long been known for its lay-*un*friendly design and language. This is also the conclusion reached by the present analysis of the PILs of Danish non-pharmacy-restricted OTC medication subject to pack size and age restrictions. In general, the PILs analysed are not clear and understandable to laymen and do not live up to the EU legislation and guidelines as far as lay-friendliness is concerned. Combined with new knowledge about misunderstandings leading to wrong dosages, poisonings, abuse, etc., as established above, it seems that the time has come to review current Danish legislation with a view to rescinding permissions to sell analgesics outside pharmacies or even, in the case of opioid-based painkillers, on prescription only. And finally, it is recommended that legislation is changed to demand the inclusion of a small, framed summary of the most important information in the

very beginning of the PIL. In this way, information such as the fact that a product may cause temporary infertility would not be relegated to page 5 of a compact PIL. This basic summary could also be included when the products are advertised, instead of the condensed and inaccessible small-print information which is the norm at present.

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QUALITATIVE HEALTH COMMUNICATION

VOLUME 1, ISSUE 1, 2022