

## Use of Patient Information Leaflets in the Algerian Context. Current Situation and Regulatory Framework



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**ABSTRACT:** This paper aims to present the marketing and translation process of patient information leaflets (PILs) into Arabic and their accessibility to the public, taking the Algerian market as a case study. PILs are the main source of information related to medication and are required to be lay-friendly as part of the process of marketing authorization. Lay-friendliness in the Algerian context means that the information contained in the PILs, (1) is conveyed through the receiver language, i.e., Arabic, and (2) is written in a language that is understandable by the receiver. To test these hypotheses, an assessment of the regulatory framework of PILs in the Algerian context was carried out. Furthermore, a study was conducted based on 1) a questionnaire targeting 56 participants to assess the readability of PILs, and 2) a field survey in pharmaceutical laboratories to document the translation stage in the marketing process. The assessment showed that the use of Arabic is mandatory in addition to a foreign language. The questionnaire showed that participants tend to read the Arabic content of the PIL. The survey's results reported that the translation task is delegated to a sworn translator's office though the examination of 16 randomly-selected (out of 72 PILs) revealed some linguistic discrepancies.

**KEYWORDS:** patient leaflet information; drug packaging; package leaflet; medicine labelling; EU guidelines

### INTRODUCTION

Patients are interested in reading patient information leaflets (PILs) in addition to the information they receive from their healthcare providers (Hamrosi 2014). According to Koo et al. (2006), the extent to which a PIL is readable as well as its presentation, are factors that could affect its use, along with social, cultural, or educational factors. However, studies that examined the general tendency for medication information use showed that PILs are often considered hard for patients to comprehend (Borgsteede et al. 2011) due to their linguistic complexity, including long sentences and expert register (Askehave, & Zethsen 2005, Pander Maat & Lentz, 2010). Furthermore, studies have shown that translation is also an additional factor contributing to the complexity of PILs (Askehave & Zethsen, 2003). Other studies showed that poor readability and comprehensibility in patient leaflets negatively impact adherence to drug therapy (Munsur et al. 2017). Additionally, confusion about drug treatment could lead to reduced compliance among patients, which goes against the main purpose of PILs (Bjerrum & Foged, 2003)

In the Arabic-speaking regions, few studies have evaluated the extent to which PILs are used. Some reported inadequacies and shortcomings in the quality of information provided by PILs in Saudi Arabia (Sukkari et al. 2012) and Egypt (Abdel Raazeq 2011) or low readability scores in Qatar (Munsur et al. (2017). The daily *Al-Bayan* newspaper in the United Arab Emirates reported that a high proportion of patients do not read medical leaflets, according to doctors at the Dubai Health Authority (Abdalhamid and Abdelhamid, 2016). Some researchers (Luk 2010) have called on regulatory authorities and manufacturers to improve the language quality and presentation of PILs' content to increase their readability and comprehensibility.

Against this background, it was worthwhile to gather information about the extent of PILs use and comprehensibility by end-users in order to document field research data and have a better understanding of them. A field questionnaire was conducted to verify the use and readability of patient leaflets among users. This method was coupled with an interview with stakeholders to understand how leaflets are processed as part of the pharmaceutical marketing management.

To shed a new light on the use of leaflets and their comprehensibility, a small-scale study was conducted with a group of people in an eastern town in Algeria. Algeria has been chosen for four reasons. Firstly, its prosperous pharmaceutical industry and mandatory use of Arabic in PILs. In fact, the country's local production of medicine covers over 50% of its national needs, making

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it the first in the MENA region to achieve this (Biopharm 2020, Fournieris 2022). Additionally, Algeria is one of the fewest Arabic-speaking countries to early introduce the use of Arabic and readability requirements through regulatory 'force' (Decree 2008). Secondly, the authors of this paper had easy access to natural data through field research. Thirdly, no documented information related to the actual use of leaflets in the country was found except from a short video of street interviews for the TV news posted in 2017 by *AL-Shuruq al Jazairya*. Finally, field discussions with pharmacists and medical representatives also revealed that an increasing number of patients are asserting that they read drug leaflets and even return to pharmacists to request more explanations and inquiries when in doubt about side effects, for instance. These factors prompted the present study.

The following research questions consequently guided our work:

What is the regulatory framework for PILs' production in the Algerian market in comparison with the EU's long-standing regulatory experience?

Does the end user/patient read PILs?

Are they comprehended by the end-user/patient?

How are PILs processed and translated?

This paper provides an overview of the regulatory frameworks for PILs in Algeria and the EU (section 2), followed by a description of the study methodology (section 3), including the use of questionnaires and field surveys to gather data on PIL use and comprehensibility. The results of the study are discussed, and concluding remarks are presented in section 4.

### Patient Information Leaflet Regulatory Framework in Algeria and the EU Guideline

Understanding the regulatory framework for PILs production and their preparation process by regulatory authorities and manufacturers is crucial to explaining patients' attitudes towards PILs. Therefore, it is essential to comprehend the legal context of a PIL since it strongly influences its production process and, ultimately, its content.

Over the past two decades, the pharmaceutical market in Algeria has experienced substantial growth due to population increase and high demand for medicine. In 2012, the per capita consumption of medicine reached \$91, an increase of 550% from \$14 in 1992 (Mahfoud, Brahamia and Coppieters, 2017). According to a report from the Oxford Business Group, the proportion of drugs manufactured locally in Algeria has increased significantly, from 25% in 2008 to 65% in 2018, with the expansion of the local production capacity and foreign investment in the local market (Derouiche 2019). Currently, there are about 70 Arab and foreign laboratories established in Algeria from 42 countries, mostly from the EU, the United States, India, and Arab countries. The market, which already responds to 50% of its drug needs, is hoping to achieve the objectives of covering 70% of drug demand through national production and penetrating foreign markets (AAPI 2023). The dynamism of this sector led to the creation of a new Ministry of Pharmaceutical industry in 2020, demonstrating the importance given to this strategic sector in the national economy (IOPA, 2020).

Given the thriving production of medicine, drug information management is strictly controlled. Thus, labelling and package leaflets are considered as tools of risk reduction (CNPM 2019). An application for a license for each new drug is then filed by the manufacturer in order to enter the local market (*Autorisation de Mise sur le Marché-AMM*) (ANSM 2023). This application includes a lengthy leaflet, which is a summary of product characteristics (*Résumé des caractéristiques du produit-RCP*), with comprehensive information about the drug, including its components, acceptable doses, and all side or unwanted effects recorded in the clinical experiments (Decrees setting out the technical conditions for importing pharmaceutical products and medical devices for human medical use, 2008, 2018 and 2021). Based on the product characteristics, a Patient Information Leaflet (PIL) is drafted as the most condensed form of the summary of product characteristics (RCP) intended for patients.

Drug registration requires the provision of a PIL that is easy-to-read in Arabic and French, or another language used in Algeria. Thusly, pharmaceutical regulations stipulate that a medicine's packaging must be accompanied by an easy-to-read PIL, written in visible, easily legible and indelible characters, in Arabic and any other foreign language used in Algeria<sup>1</sup> (Ministry of Health, 2008 and 2018, a requirement reiterated by the Ministry of Pharmaceutical Industry, 2021). Although Arabic is the official language in Algeria, French is commonly used in medical and pharmaceutical contexts, as university programmes in medicine and pharmacy are provided in French. Therefore, the medicine's labelling is initially prepared in French then translated into Arabic. Hence the importance of weighing up the use of PILs. Ultimately, the regulation on leaflet readability can open up real possibilities to standardize and appraise labelling, drafting, and translation in Arabic, in order to ensure readability and comprehensibility.

By referring to best practices and models in other pharmaceutical contexts, and the EU's regulations on the readability of PILs particularly, lay-friendliness becomes a fundamental requirement to reach patients' full leaflet accessibility.

The European Union has applied a robust regulatory framework in relation to PILs since 1992, when they became compulsory. This framework regulates all processes in the application for drug marketing authorization, including requirements for PIL preparation (European Parliament and of the Council, 2001). Lay-friendliness is an essential condition in the PIL drafting process in all official languages of the EU Member States. (European Parliament and of the Council, 2004). In 2009, the *Guideline on the readability of the labelling and package leaflet of medicinal products for human use* was published in order to ensure that the information on the labelling and is accessible by those who receive it, "so that they can use their medicine safely and appropriately"

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(6, European Commission, 2009). Besides instructions on the design and layout of information, linguistic aspects, such as style and syntax are addressed. Finally, Directive 2001/83/EC as amended by Directive 2004/27/EC, Article 56(a) aims to achieve full accessibility by including the requirement of including the Braille format, intended for blind and partially sighted persons.

Sets of regulations in Algeria and the EU overlap in terms of language lay-friendliness and the use of official state language requirements. However, there are significant differences between the two contexts. While the EU provides guidelines and rules outlining conditions for achieving PILs' lay-friendliness, no such guidelines exist in Algeria. Such guidelines would cover the terminology, style and syntax necessary to enhance the quality of information and ensure readability from a language perspective. Consequently, instructions on how content should be clearly and simply worded would also establish common standards for the translation of PILs into Arabic. In Algeria, unlike in the EU, no template or model is provided to complete the package leaflet, and to guide marketing authorization applicants in producing consistent and uniform information leaflets.

Any endeavour to introduce a template for labelling would improve the use and efficiency of PILs, if it explicitly involves blind and partially sighted end-users, and sets requirements to make package leaflet available in formats suitable for them.

Before achieving such an objective, it was important to conduct a field study on how PILs are used by the public. The study utilized both questionnaire and interview tools in order to gain insight into the use of leaflets, as well as the process of drafting and translation by marketing authorization applicants.

### METHOD

Based on the preliminary assessment of the PILs' regulatory framework in Algeria, benchmarked with the EU Guideline on the readability of the labelling and package leaflets, a small-scale study was conducted using two methods of data collection. Firstly, a questionnaire was administered to 56 participants to assess the usefulness and comprehensibility of PILs among end-users. Secondly, a field survey was conducted through interviews with representatives from drug companies to document the translation stage in the marketing process.

#### *Questionnaire method – Use of PILs and comprehensibility*

As previously mentioned, literature on the usefulness and comprehensibility of PILs in Arabic-speaking regions is scarce. To address this issue, we gathered preliminary data by seeking answers from two groups of real-world users: students and pharmacy clients. The method of data collection by closed questionnaire responses was selected. The questionnaire was designed to be short and structured to reach a large number of people who can read Arabic, French or both, as PILs are usually available in both languages in the Algerian market. The choice of closed questions was made in order to collect quantitative data which results can be quantified and objectively analyzed. The questionnaire consisted too of multiple-choice options to assess specific outcomes deemed to answer certain research questions, such as the language(s) used in reading leaflets.

Participants were asked to respond to a series of 6 questions related to the use and comprehensibility of PILs. The questions aimed to assess three primary aspects: firstly, the extent of PIL use; secondly, the language in which PILs are read; and thirdly, comprehensibility of PILs. In this study, the comprehensibility encompasses the degree to which terms, sentences, and the text as a whole are easily understood.

#### *Participants*

A random sample of 56 participants was reached in two different locations. The subject group was divided into two sub-groups considering the place where the questionnaire was administered, that is a university campus and number of drugstores/pharmacies. The difference between the two types of profiles was consequently considered in the analysis of results. All participants voluntarily agreed to participate and signed a consent form.

The first group consisted of students at Mentouri Constantine University (located in the eastern part of the country). As university-level students, they are expected to have proficiency in reading and understanding Arabic, French and presumably another foreign language, most likely English. The second group consisted of non-expert individuals who visited a pharmacy to buy medicines for themselves or someone close. This sample represented, as was observed, middle-aged and older individuals, although age was not explicitly recorded in the questionnaire and therefore will not be a significant factor in discussing the findings.

#### *Quantitative Results*

A total of 34 university students accepted to answer the questionnaire, while 22 respondents were gathered from pharmacies. The questionnaire was randomly distributed to university students and pharmacy clients, and the following findings were obtained.

Table 1 shows the results of question 1: Do you read the Patient information leaflet (PIL), especially when you use a drug for the first time?

**Table 1. Use of PILs.**

	Yes	Sometimes	No
Students	49%	16%	35%
Pharmacy clients	56%	34%	10%

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We observe that there is a higher percentage of students who reported not reading PILs at all compared to pharmacy clients. This difference between the two groups is surprising given the expected higher level of medicine awareness and education among students compared to the general public. However, it is not surprising that medicine buyers, who are presumably adults and may themselves be patients taking medicines, are more aware of the importance of reading leaflet content. This higher rate can be attributed to their accumulated experience with taking prescribed drugs or their proximity to medicine for chronic diseases. This segment of cases is less represented in a limited sample of students.

Based on their experience and daily interactions with patients, pharmacists have reported a prevalent indifference towards the content of PILs. However, they have also observed a noticeable new trend towards precaution among an increasing number of people who read leaflets to confirm doses, for instance. Furthermore, pharmacists have noted that some patients compare new drugs on the market with other similar medicines they are familiar with, based on the information provided in PILs. This trend is particularly prevalent among patients with chronic diseases who take certain types of drugs for example, and who are, according to pharmacists, keener to understand the chemical compositions, compare the effective doses, and identify potential side effects.

Table 2 shows the results of question 2: If you read the content of the PIL, do you read it in a) Arabic language, b) French or c) both languages

**Table 2. Reading language.**

	Arabic	French	Arabic and French
Students	59%	12%	29%
Pharmacy clients	43%	20%	37%

In regard to the second question, we observe that although pharmacy clients preferred to read exclusively in Arabic, a significant number of them also used both Arabic and French. This confirms our previous observation that this group primarily consists of adult visitors of the pharmacy. The tendency to use French may be attributed to factors such as academic background, as many middle-aged and elderly individuals likely received a bilingual education with French. On the opposite hand, students, most likely young adults, showed a different trend with the majority of them reading the Arabic version only. This could be attributed to their familiarity with reading content in Arabic (and not French) due to the widespread use of the language in different social life contexts.

Table 3 shows the results of question 3: When you read the leaflet in Arabic, is the content comprehensible?

**Table 3. Readability in Arabic.**

	Yes	No
Students	69%	31%
Pharmacy clients	69%	31%

The same majority score is observed in both groups, with the highest score among all the provided answers. It is noteworthy that there is prevailing opinion about comprehensibility of PILs drafted in Arabic, despite the expectation of lower levels of understanding of medical terminology in Arabic among the general public. Surprisingly, when respondents were asked about difficulties encountered in reading leaflets, sentence structure and word complexity were selected as the primary sources of incomprehensibility of leaflets (see Table 4).

Table 4 shows the results of question 4: If the content is not comprehensible, what makes the leaflet difficult to understand? a) the words used, b) sentence structure, or c) ambiguity in meaning

**Table 4. Source of incomprehensibility.**

	Word level	Sentence structure	Semantic ambiguity
Students	56%	12%	22%
Pharmacy clients	15%	56%	29%

When examining the reasons for the lack of comprehensibility of PILs, it is apparent that students primarily cited difficulty at the word level, while the exact proportion of pharmacy clients evoked sentence structures as the most significant obstacle. Additionally, pharmacy clients are more critical than students of the syntactic quality of leaflets, suggesting they are more aware of editing issues. Thus, it appears that, combined, word and sentence level difficulties constitute a significant challenge for PIL comprehensibility. Although semantic ambiguity was relatively minimal (22% to 29%), it should not be underestimated given the importance of information related to medicines. Question 2's results indicate Arabic and French are both used to read leaflets, implying that both groups may attempt to compensate for comprehension challenges by reading the content in both languages

Table 5 shows the results of question 5: Does the small size of the font make the leaflet difficult to read?

**Table 5. Size and font**

	Yes	Relatively	No
Students	49%	35%	16%
Pharmacy clients	50%	30%	20%

It is evident that the presentation of PILs' contents continues to raise a problem of readability as the majority of students and of pharmacy clients, albeit relative, found the small font size to be a hindrance to reading PILs. On the grounds of the questionnaire's results, it appears that the Arabic content of the leaflet is actually read and comprehensible by the majority of respondents (69%). However, due to the small sample size of only 56 respondents, it may not be possible to generalize this conclusion. Given this identified trend, it was necessary to enquire about the process of translating PIL content into Arabic.

### **Field Interview - PILs Marketing Process and Translation**

In light of the findings on the use and comprehensibility of PILs, we conducted further fieldwork through a small-scale survey to gain a deeper understanding of how the Arabic version of PILs is prepared. Consequently, we contacted several interlocutors working in the administrations and communication units of pharmaceutical companies and laboratories, to obtain reliable information from the field. However, only three out of seven of these interlocutors responded to the interview and provided us with comprehensive information.

A number of key questions guided the interview. One important inquiry was identifying who is responsible for translating the drug leaflets into Arabic for pharmaceutical products manufactured by the company, whether they are imported or produced locally. This helped to determine whether the translation is carried out by translators, linguists or specialists in the medical or pharmaceutical fields. Additionally, it was crucial to enquire about any oversight bodies in charge of assessing and controlling the quality of the Arabic translation, as well as determining whether the translation is conducted according to specific instructions or recommendations from the competent authority or marketing authorization holder.

These questions helped to crystallize the subject and understand its potential implications. After an interview with three pharmaceutical companies who agreed to participate, it was possible to gather information about the process of translating and reviewing leaflets in Arabic prior the marketing phase.

### **PILs Translation**

The three institutional respondents, namely the *LDM Groupe Complexe for pharmaceutical products, HUPP PHARMA Constantine Branch* and *Union Pharmaceutique Constantinoise Company*, in Constantine, a major city in North-Eastern Algeria, agreed to participate and provided direct and comprehensive information during the first visit.

On the grounds of the gathered information, the three interlocutors confirmed that PILs undergo an Arabic translation stage, regardless of whether the medicines are locally manufactured or imported. In fact, all packaging documents are issued locally in French, and when medicines are imported, the PIL is mainly written in French, English or German. However, they are always translated into Arabic for public use. The translation process begins after the drug has received market authorization, which includes a report confirming that the product meets conditions related to user safety and security, therapeutic efficacy, and approval of the original leaflet.

Based on the detailed drug leaflet (RCP), the PIL is initially drafted in French then sent for translation. According to the three respondents, in the absence of a language service body within the companies, the French version of the PIL is sent to a sworn translator or a translation office accredited by the company for translation. Biologists or pharmacists from the company check the accuracy and correctness of the translation and validate it in terms of information relevancy. A final approval of the Arabic version is then delivered by the relevant national control body. It is the green light for the drug laboratory to print and include the leaflet inside the marketed drug package for the first time.

In light of this, a sample of 16 Arabic PILs were randomly selected from different drug packages to assess the quality of Arabic PILs' content. They were then analysed and compared against their French or English original versions. During the analysis, many discrepancies were noted. The figures 1, 2 and 3 are a few examples highlighting shortages at the language level.

There were disparities in the use of abbreviations related to measurement units. For instance, in a number of PILs, the word milligrams (mg) is written in different forms, [milijim], [milighim], [migh].



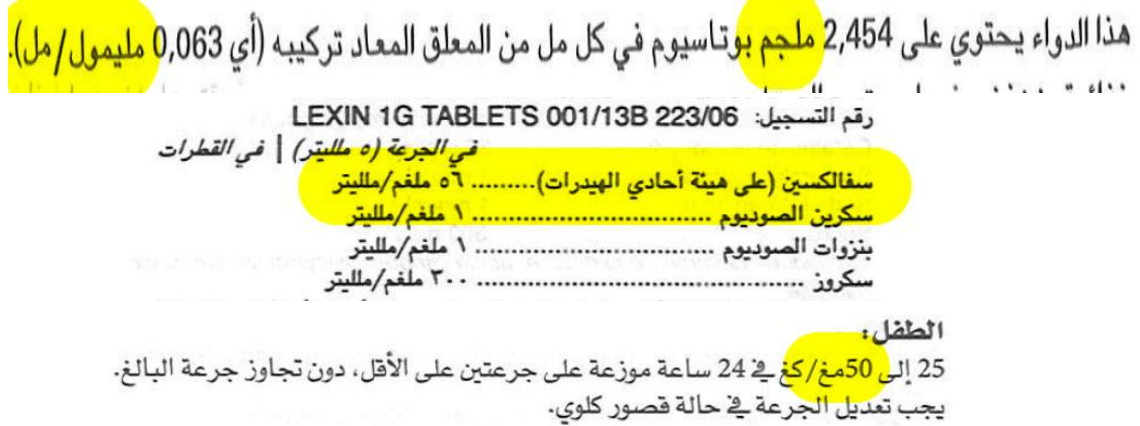
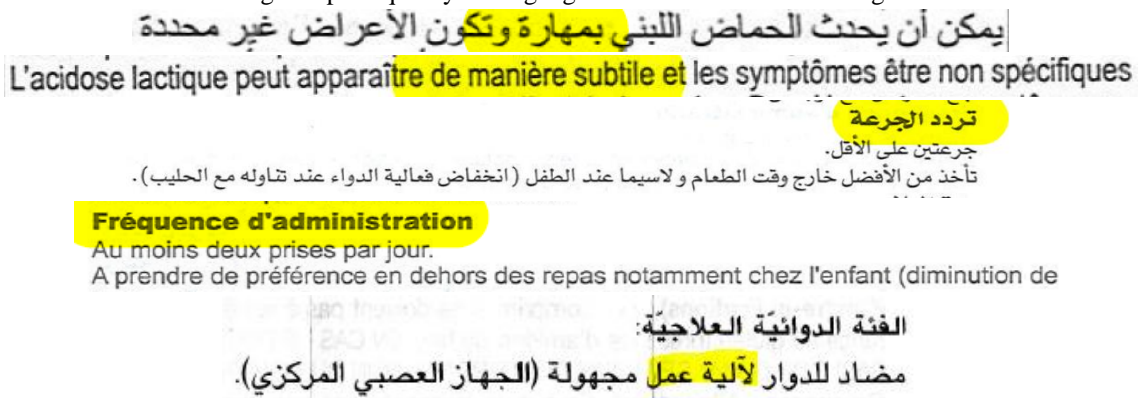


Figure 1. Disparities in the use of abbreviations related to measurement units.

Instances of literal translation leading to a poor quality of language or nonsense were recurring.



**Pharmaco-therapeutic class: ANTIVERTIGO AGENT WITH UNKNOWN ACTION MECHANISM** (Central nervous system).

Figure 2. Literal translation

Grammatical errors were also identified, thus making the quality of the language very poor.

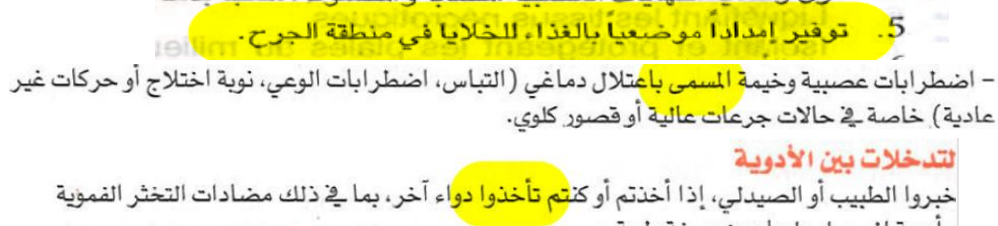


Figure 3. Grammatical errors

## CONCLUSION

In this study, our objective was to address two key questions related to the use and comprehensibility of patient information leaflets and the manner in which their translated versions are prepared. To collect field data, we used both questionnaire and interviews. The questionnaire results revealed that over half of the participants read PILs, with more than half of them reading them in Arabic. Furthermore, the majority of users (69%) found the PILs to be comprehensible, although it is important to note that this conclusion is based on a sample of only 56 questionnaire replies and thus, cannot be generalized. While the readability and comprehensibility scores are encouraging, the results still reveal challenges at word, sentence and meaning levels that can hinder understanding of PILs.

As for the interview results, it seems that the three companies asserted relying on the services of certified translations in the translation stage, which may indicate that the same approach is adopted by other pharmaceutical laboratories or companies. However, upon analyzing and reviewing a small sample of randomly selected PILs, numerous translation errors and language inconsistencies were identified. This conclusion provides a broader context for understanding the importance of having a designated body or a reference person in pharmaceutical companies to ensure the accuracy and clarity of PILs, and optimize their use by the public.

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The current regulatory framework for preparing PILs' packages is clearly insufficient in meeting linguistic requirements and needs to be upgraded. One way to achieve this is by creating a PIL template that can assist leaflet designers and translators in providing more coherent information, including consistent terminology and information that is easier to locate, for example, and that all national and international marketing authorization holders must follow. Specific recommendations should also be provided to guide the writing and translation of a readable PIL that ensures safe and appropriate use of the medicine it accompanies. Such guidelines could include recommendations on style (e.g., active instructions), syntax (e.g., short sentences), terminology (e.g., uniform terms), type size (e.g., large letters), layout (e.g., space between lines), etc. to ensure that the information provided to patients is clear and easily understandable and would ultimately promote safe and appropriate use of medicinal products that come with PILs.

### Disclosure Statement

The authors report there are no competing interests to declare.  
...The authors ensure that the work is original and all data are authentic.

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### Endnotes

<sup>i</sup> Extract from Ministerial Orders in the *Algerian Journal Officiel (Official Gazette)*:

Art. 13. “*Chaque produit pharmaceutique et dispositif médical doit être accompagné d’une notice aisément lisible, rédigée en langue arabe et toute langue étrangère usitée en Algérie et comportant outre les informations exigées ci-dessus.*”(Titre 1, Section 1, Ministerial Order setting out the technical conditions for importing pharmaceutical products and medical devices for human medical use, Algerian [Official Journal N°70](#), dated 14/12/2008.

Art. 14. — “*Chaque conditionnement de médicament doit être accompagné d’une notice aisément lisible, rédigée en langue arabe et en toute autre langue étrangère usitée en Algérie, comportant obligatoirement les mentions suivantes, conformément à la réglementation en vigueur.*”(Chap 1<sup>er</sup>, Section 1, 2021, Ministerial Order setting out the technical conditions for importing pharmaceutical products and medical devices for human medical use, Algerian [Official Journal N°15](#), dated 2/03/2021)



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