

IMPORTANCE OF THE ENFORCEMENT OF THE LAW AND EU DIRECTIVES CONCERNING TRANSLATION OF PHARMACEUTICALS LEAFLETS

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Abstract

Purpose : Confirmation of health effects caused by the not translation of the leaflet in the national official language. Problems in patients caused by the absence of leaflets translation were verified for the antibiotics but also for the dietary supplements.

Method : Population of various ages, sick or not, were asked to answer a questionnaire about some basic problems that were found in our daily work. The survey was conducted in several ways by asking random people on the street, health center or by phone calls. The questionnaire had a geographical expansion in several major cities of our country. Medicaments and dietary supplement products that were provided in study were all imported and their leaflets were examined if they were translated into Albanian or not. The only data association we did was related to the same active substance that had different dosage forms of the same pharmaceutical manufacturer. This association has been done for ease of study and to have more precise conclusions.

Result : After statistical processing of results we found out that by 1500 respondents, 60% of them did not understand the explanations for their medicines because they were in a foreign language, 25% were obliged to seek the assistance of relatives or friends, 10% of people translate paper, 5 % were not interested in trusting the doctor or the pharmacist, 44% have had at least once a concern from incorrect use of the drug. 35% of them had no Albanian translation of leaflet.

Conclusions : Translation of leaflet in the official language is a necessity and an obligation of all importers. The absence of leaflets translation is in disagreement with the legislation of our country but also with the EU Directives on drugs commercialization and consumer's health protection. The strengthening of regulatory agencies control in order to prevent the violation of the law is closely connected with the extensive interests of the citizens.

Keywords: Leaflet, laws, patients, side effect

Introduction

Leaflet of drugs are essential and very important in terms of a better use of the drug. Based on the very important information, which they contain, they are valid for doctors, pharmacists, as well as, for patients. Instructions given in these leaflets should be written in terms, which are understandable by all and, which include a summary of the characteristics of the drug. A leaflet should contain sufficiently detailed information about how to administer a drug, adverse effects, and drug interaction with other drugs or, when this drug is forbidden to be used. Under the PE and CE directives, translation in the official language of the country, in which those drugs circulate, is obligatory. According to the legislation of our country, importers of those drugs are obliged to translate in the Albanian language all the leaflets, which are found in any container of any pharmaceutical form of each medicament. There is a negligence of some importers to provide imported drugs with the leaflet translated into Albanian language. In this case, we have an open violation of law and, therefore leading to combating the problems that arise from their failure to comply.

Background Information

The purpose of the study is exactly the authentication of the incidence of health consequences as a result of failing to translate the leaflet. That is evidence that failure to translate the leaflet has led to health consequences not only in medicine, but also to dietetic supplements. The study was based on the implementation of a combined approach, which includes two stages.

- First, the study of the leaflet receipt.
- Second, drafting of a questionnaire which was addressed to different people.

The study addresses the importance of the translation of leaflet, which was found inside the drugs package. First, let's explain what is needed to understand through the leaflet.

Leaflet is a very important element, which provides explanations about active substances, about the drug, its dosage and, what is most important, about the side effects or

interactions with the other drugs, or its disuse in the case of certain diseases or in the certain age groups. The obligation to provide drugs with leaflets is laid down in Directive 2001/83 / EC, in the Law No. 9323 of 25 November 2004 “On medicines and health service in Albania” and, in Law No. 9902 of 17 April 2008 “ On the protection of consumers”. Doctors and pharmacists receive information on how a drug should be used in the summary of product, while information for the patient can be included on the label. Under the aforementioned Directive and national legislation, the importing entities, before importing the drugs, should not only be subject to the obligation providing the drugs with the leaflets, but they should also translate them into the official language, which, in our case, is Albanian.

We should address such challenges, which we encounter in our daily practices, and we as professionals should play the role of translator in the cases when the drugs do not have the leaflet translated into Albanian.

The pharmaceutical market in Albania is sufficiently heterogeneous, therefore having a wide range of pharmaceutical companies from various countries of five continents and, as a result of this, the leaflets may be written in several languages. The open pharmacies and hospitals network includes a circulation of more than 600 active substances in various forms of pharmaceuticals.

Why is translation of leaflets important?

- 2.1.a To eliminate misuse of the drug.
- 2.1.b To eliminate drug use by persons who are of the age, for which it is clearly stated that they should not use it.
- 2.1.c To prevent incompatibility between drugs.
- 2.1.d To continue treatment for the period necessary to achieve the desired effect.
- 2.1.e To use a recommended dose for different ages and bodyweights.
- 2.1.f To stop using it in the case of other diseases present in the body.
- 2.1.g To maintain the drug in optimal condition.
- 2.1.h To understand what are the adverse effects which may occur during the use of the drug.

Who uses the information provided in the leaflet?

- 2.2.a Doctors, when new drugs enter circulation after registration in the NCDC, or after receiving the permission of the Ministry of Health.
- 2.2.b Nurses in order to prevent errors in their use.
- 2.2.c Pharmacists in order to provide to the patients precise guidelines on the use of the drug.

2.2.d Patients and their families to be as clear as possible about the use and preservation of the drug especially in the case of drugs that are in the list of OTC drugs.

The relationship between the translation and the good use of the drug.

2.3.a Translation of chemical composition of active substances and auxiliary substances informs the patients about the possibility of the presence of allergies in one or more ingredients. Incompatibility with other drugs, which the patient uses as active substances or as excipients.

2.3.b Translation of the side effects as listed by level of frequency will provide the patients and/or medical staff with the opportunity to share a frequent effect with an unexpected side effect.

International Standards of leaflets translation.

Patients should be fully aware of their therapeutic treatment, therefore the information available to them must fully comply with the summary of product characteristics. The marketing authorization holder bears the responsibility for the best translation of the leaflets. Under the legislation in force, the translated text should not be short and simple, therefore it should be clear, readable, easy to understand for any age and gender.

Methods

The following drugs constitute the scope of this study. For the convenience of the study and to reach more precise conclusions, these substances were grouped according to the active pharmaceutical form and manufacturing firm. National products were excluded from this study for the sole reason that their Leaflet have been in Albanian. The exact number of leaflets, which represented an active substance of a certain manufacturing company, was 400, including also the dietary and nutritional supplements. According to a simple counting we carried out regarding these leaflets, it resulted that 35% (140) had not been translated into Albanian, 35% (25) of which belonged to nutritional supplements.

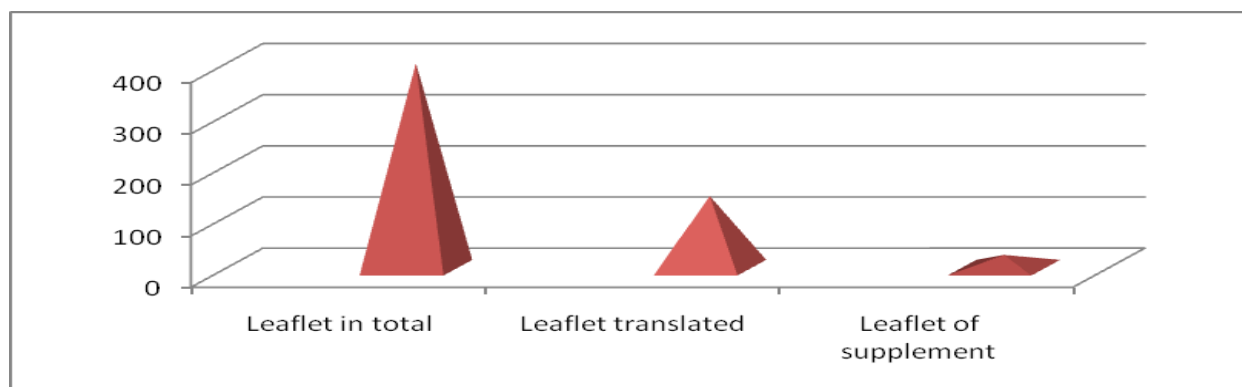


Figure1. Number of leaflets included in the survey.

Leaflets included in the study were obtained in different languages as follows: 35% (140) in English, 35% (140) in Italian, 10% (40) in German, 10% (40) in Slavic languages, 3% (12) in Turkish, 7% (28) in French

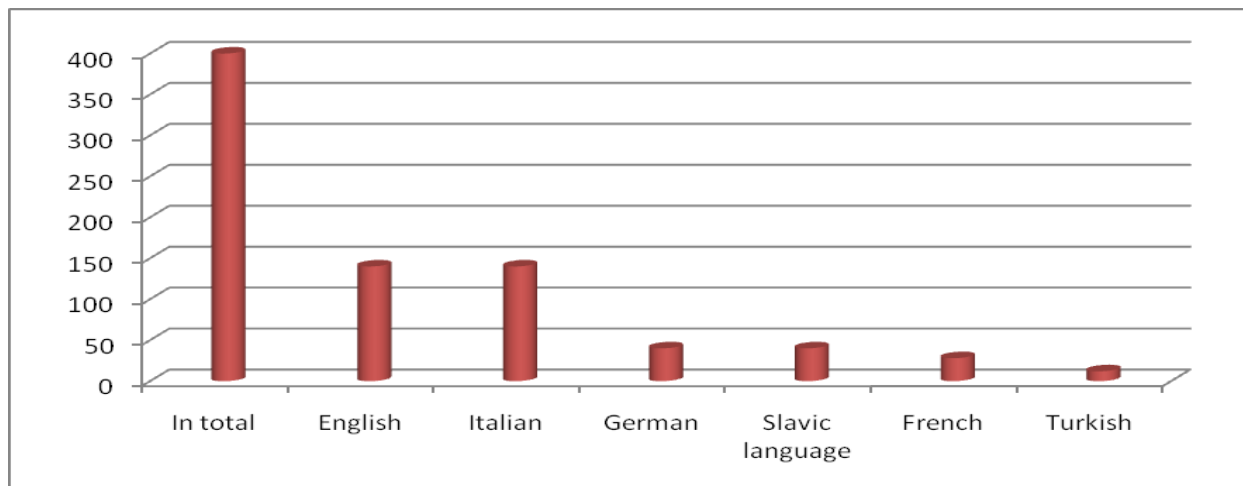


Figure 2. Foreign languages, in which the surveyed leaflets were written.

In Albania, continuous efforts have been made to increase the readability of leaflets based on BE Directives. The task of the study was to test the readability of the leaflets. Testing addressed all respondents without any prior selection and included the readability of five leaflets in English, Italian, German, Turkish, French. The selected leaflets belonged to drugs, which are widely used by all age groups.

Respondents had to explain some of the key information transmitted to the patients through the leaflets. The following graphic presentation provides a schematic description of the processing of results, which came out of the questionnaire.

People, sick or not, and people of different ages were asked. They were surveyed in ambulatory centers, in hospitals, pharmacies, on streets or via phone.

The respondents were of different ages ranging from the age 18. There was not any preliminary careful selection to see if they were regularly users of drugs, instead it was all random.

Those patients and many other citizens were subjects of our survey. The drafted questionnaire consisted of certain questions, which were related exactly to the problem that was addressed.

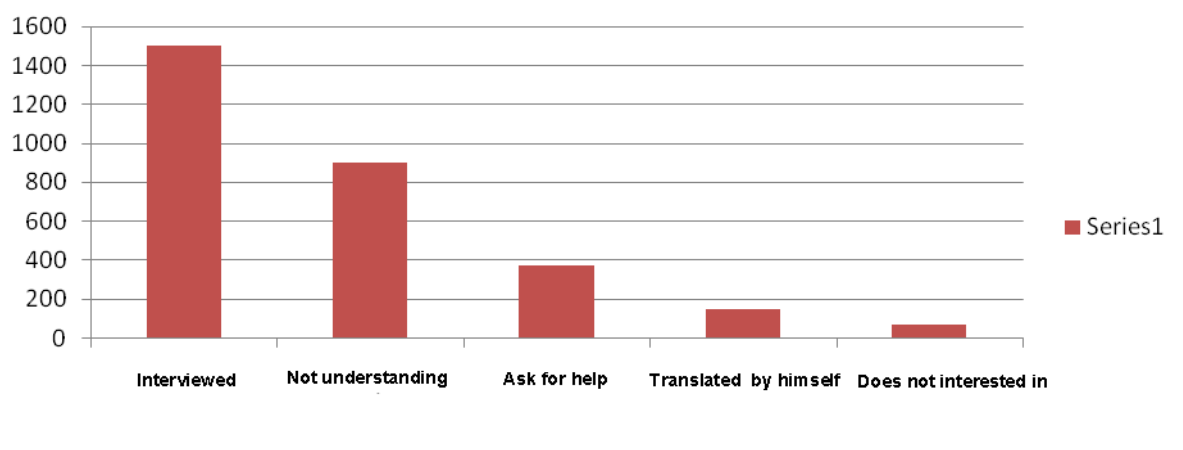


Figure 3. Survey results on readability of leaflets.

Test results of the test are satisfactory when 90% of the respondents manage to understand the information, which is provided in the leaflet and do not have difficulties to act accurately under the guidelines that are provided there. The questionnaire included several key safety messages:

- 3.1.a why patients need to take the product;
- 3.1.b maximum dose or duration of treatment;
- 3.1.c significant drug interactions
- 3.1.d circumstances, in which the drug should be stopped
- 3.1.f when the drug is strictly forbidden to use.

Many prestigious companies, such as Novartis, Glaxo, Bayer and others had not Leaflet of their own active substances in the Albanian language. Substances of these companies had an active diverse form and doses are referred to antibiotics, antihypertensive, antidiabetic, dermatological, gynecological etc.

The difficulty of understanding the leaflet in many cases has led to health concerns in the case of patients who have used these drugs.

Summary and Conclusion:

Following the statistical processing of the results, we found that out of 1500 respondents 60% (900) of them did not understand explanations of drugs, because the explanations were in foreign languages, 25% (375) were obliged to seek assistance from family members or friends, 10%(150) had to translate the leaflet by themselves , 5% (75) were not interested because they trusted a doctor or a pharmacist, 44% (660) had been, at least, once concerned about the incorrect use of drug.

The survey results showed that patients want more information than they currently receive and use through leaflets, serving as an information source for physicians and pharmacists.

Accurate information helps the participation of patients and the medical staff when the latter recommend the drugs. In the case of OTC medications, complete information should be taken to avoid in advance treatment errors, which may be the result of insufficient information that may be received when a non-professional translation attempt is made by the specialist of the language in question.

The label accompanying the drug should also include guidance for the patient in the form of a leaflet (PIL), which provides information complying with the Summary of Product Characteristics (SPC). This information would be very useful mainly for chronic patients who use medications for extended periods of time. In order to understand the leaflet more easily, the medical staff and patients are required first to take into account a number of criteria, which are listed as follows:

- 4.a Do not use medical jargon, which is difficult to be understood by the large public.
- 4.b Translation should be in the official literary language.
- 4.c Use short and clear sentences.
- 4.d Do not use stereotyped phrases to explain the side effects of the drug.
- 4.e Side effects should be grouped and ranked according to the degree of threat and the frequency of incidence to enable the patient to take measures if they would occur.

There have been improvements but there is still much to do. A large number leaflets, which are inside the packaging of drugs and, which are in the market, are not translated correctly or, the information that they convey to patients is inadequate. In order to achieve perfection in translating these leaflets, a larger investment is required to be made by the importing companies. Improvement of translation should be done without altering the content and based on the relevant guidelines, therefore working more with how these leaflets should be formatted, the type of writing and the size of the font to be used, the placement of information in order to facilitate in this way reading and understanding.

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