HEALTH LITERACY INNOVATION: A SURVEY TO UNDERSTAND THE PATIENT'S NEED. THE TIME IS COMING TO ADAPT THE PACKAGE INSERT USING DIGITAL TECHNOLOGY.

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Abstract - This study was carried out in collaboration with a patient association, "*Patient Focused Medicines Development*"(PFMD),that has developed a survey of 18 questions to understand patient perspectives and expectations regarding the drug package insert. It was shared with a large group of responders (1029) from different countries (71% Northern America;25% Europe; 4% others), different age groups and pathologies (chronic / non-chronic).The most represented age group is 60 to 69 years old (26.7%) then 50 to 59 years old (19.2%) and those over 70 years old (18.6%). Of the respondents, 81.9% had a chronic illness. The patient insert is the main and only required documentation for communicating information about the drug use to the patient. The literature mentions the importance of the information provided to the patient to stick to their treatment but also underlined the limitation of this source of information. The result of this study showed among the responders, only 24%of our subjects read the paper version of the package insert exclusively.The objective of this paper is to understand why drug insert paper support is not sufficient to address patient needs, 76% responders read the package leaflet or information available for the medication provided by the company, through websites or other sources (North America 73.1%, Europe 82.1%). In addition, almost half of the subjects do not keep the package insert for future reference or verification because they have access to the information on the internet.
Throughout our study, we also highlighted the difficulties that our subjects faced, such as the lack of lay language, the size of the font, the layout and the amount of information. Some individuals find themselves drowning in information written in medical jargon that they do not always understand. The challenge today lies in designing a leaflet that is adaptable to all and that responds to patients' complaints and needs. In the future, the patient insert will be interactive and digitalized.

Keywords - Digital Labeling, Perception Public, Medicine Information, Medicine Labeling, Health Literacy.

I. INTRODUCTION

Now more than ever, patients are looking for transparent health information, especially about their drug treatments. Several studies have shown that understanding the package leaflet of the drug improves treatment adherence and patient satisfaction[1]. Furthermore, many patients demonstrate sub-optimal management of their condition, often because they do not have all the necessary information [2].To ensure an effective and safe treatment, the patient's knowledge of their drugs is paramount [3]. This knowledge should focus not only on the reason for the choice of drug, but also on how the drug is taken, as well as the expected benefits of the treatment and the potential adverse effects. A good understanding of their drug treatment would allow the patient to make better use of the drug and have better adherence to the treatment[4].The result is increased therapeutic efficacy and therefore greater patient safety. However, patients generally do not have adequate knowledge [5]. Thus, patient adherence is crucial to achieving the therapeutic goal. However, it does not apply to the entire population, for various reasons, including the onset of adverse effects, lack of motivation or information [6]. The patient often misunderstands or forgets much of the information they receive from the healthcare professionals (HCP) they meet. The pharmacist therefore has a strategic place in the patient care process. The pharmaceutical care provided, encompassing dispensing drugs, providing information and advice to the patient as well as follow-up, is the "last defense" between the doctor's instructions and when the patient finds themselves face-to-face with their drug and the accompanying leaflet [7]. In addition to oral information, written information is critical to increase the amount of information that the patient retains and puts into practice. It will remain available for future reference, not only for the patient, but also for their relatives and for caregivers [8]. Each registered drug has a package leaflet inside its packaging. This package leaflet provides product information, including but not limited to clinical pharmacology, recommended dose, method of administration, warnings and contraindications, adverse effects and precautions to avoid or minimize risks[9]. The World Health Organization (WHO) estimates that more than 70% of patients receiving medications do not read the package leaflet (particularly in developing countries) (World Health Organization 2002). This study should help to define a new concept for the patient leaflet to better address the patient's need.
Main points will be studied in this paper.

II. MATERIALS AND METHODS

The patient association, *Patient focused Medicines Development* (PFMD) is an independent, non-profit association. This association brings together many stakeholders and actors in the health system, whether

they are patients or they act within the pharmaceutical industry, academic or regulatory system. They work together on different projects to improve patient engagement and inclusion in the development of drugs and health products. The association developed the questionnaire (Table 1) which we have analyzed. In this article we will have an overall analysis of the answers to the questions.

A. Patient questionnaire (Table 1)

The questionnaire consists of eighteen questions, including open-ended questions and multiple-choice questions. For six of the eighteen questions, the respondent had the option to write their answer in their own words. There are two scenarios, depending on whether or not, there is a chronic disease and whether long-term medications are taken.

Table 1 - List of survey questions.

Q1: Who are you?
Q2: Choose your gender
Q3: Choose your age group
Q4: Choose your location
Q5: Do you or the person you care for have a chronic condition (i.e. a condition that lasts for a long time such as diabetes, cancer, asthma, etc)?
Q6: What is your current condition?
Q7: Did you / Do you read the package leaflet or information available for the mediation provided by the company, through websites or other sources?
Q8: Did you find the provided information (within the package leaflet for the medication) easy to understand?
Q9: What would you like to know before taking the medicine?
Q10: Is there any other information you would like to see on an information leaflet (e.g. signposting to other resources)?
Q11: When would you want to see this type of information?
Q12: How would you like to receive this information?
Q13: When would you like to receive this type of information?
Q14: What would be your preferred format for this information?
Q15: Please tell us how you normally take the prescribed treatment /medication by choosing the most relevant statement.
Q16: Do you find the current language used in patient information leaflet understandable?
Q17: Would receiving an additional information leaflet with the necessary information in understandable language support you in taking medication as prescribed?
Q18: Would you like to tell anything else related to this topic that we didn't ask you about?

B. Questionnaire design methodology

A literature review was conducted by PFMD Working Group 4. For the design of these questionnaires, it was important to first determine the different aspects of the development of package leaflets including patients and to understand the relationship between the package leaflet and treatment adherence. The literature review on this topic enabled an objective analysis to be conducted of the current knowledge of package leaflets for patients.

C. Database

The database primarily used is PubMed. Other databases have been consulted, including MEDLINE, Embase, CINHAL, PsychINFO and DARE. The list of references of each article resulting from the research were also examined to identify other articles relevant to our topic. The websites of the Food and Drug Administration (FDA), European Medicines Agency (EMA) and other regulatory agencies have also been consulted.

III. RESULTS AND DISCUSSION

D. Respondent profile.

87.9% of respondents were patients, 7.6% were parents and 4.6% were others, i.e. healthcare professionals, former patients (Figure 1).

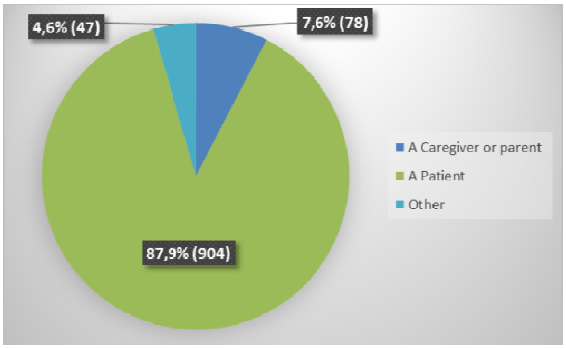
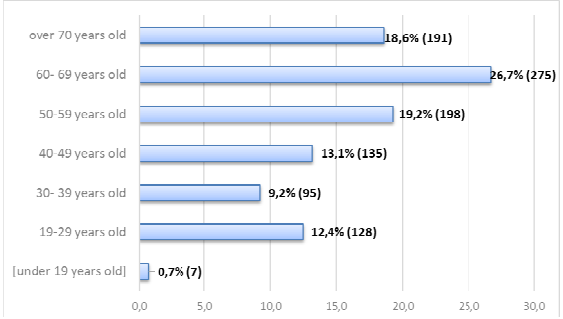


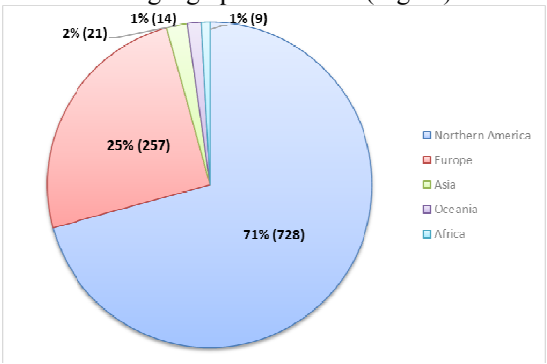
Fig.1.The different types of individuals who completed the questionnaire.

Of these, 63.7% were female (655), 36.2% were male (372) and 0.2% were other (2).

Distribution of age (Fig.2a)



Distribution of geographic location (Fig.2b)



The most represented age group is 60 to 69 years old (26.7%) then 50 to 59 years old and those over 70 years old. Of the respondents, 81.9% had a chronic illness. Of the respondents, 93.7% were on drug treatment; the responders (1029) are established in different countries (71% Northern America;25% Europe; 4% others).

E. Patient labeling, use and understanding

In question Q7: *Did you / Do you read the package leaflet or information available for the mediation provided by the company, through websites or other sources?*

Of the 1029 respondents, 76% of patients answered yes to this question and read the package leaflet or information available for the medication provided by the company, through websites or other sources.

In the group of respondents who do not read the package leaflet, or the drug information provided by the manufacturer, the majority explain that this because they have already received the information from a HCP.Some mention other reasons: the leaflet contains too much information, I read the leaflet for the first use, the content is too technical, the text is too small, I am familiar with my drug, I read other sources, I only read the side effects, I have medical training, I don't want to know.

F. Patient information support and format

Question 12: *How would you like to receive the information?*.

The majority of patients choose via HCP then via the internet, and a few via patient organizations. (Fig.3.)

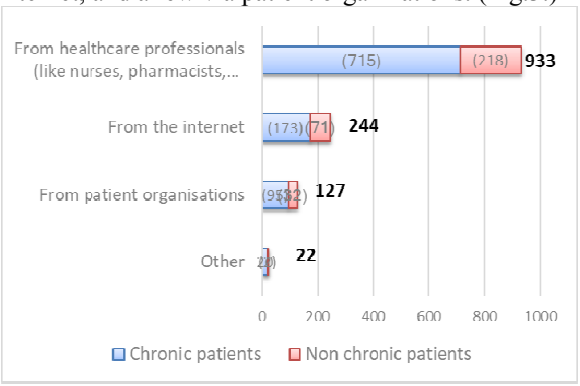


Fig.3.Preferred sources of information on the drug

Question13:*When would you like to receive this type of information?*

It appears from our survey that the majority of subjects wish to receive information about their treatment when they discuss the different treatment options with healthcare professionals (57% or 579 subjects); 36% (376 subjects) wish to receive information before taking the drug, 7% (74 subjects) wish to receive information after taking the drug. Our results shows that the majority of subjects would like to receive additional information from HCPs.

Question14: *What would be your preferred format for this additional information?*

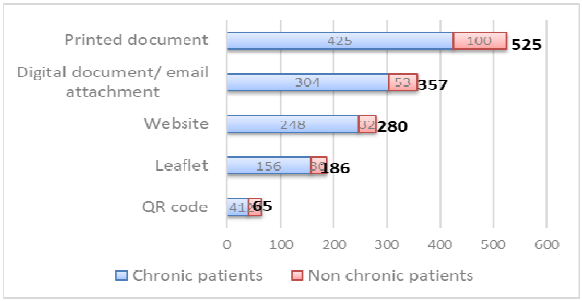


Fig.4. Subjects' preferred format

Approximately 50% of subjects would choose a paper format (525+186) and 50% a digital format (357+280+65) to receive additional information.

Question 17: *Would an additional package leaflet with information written in clear, understandable language help you take your treatment as prescribed?*

63.1% yes, 30.4% no, the majority of respondents want additional explanations to better understand their leaflet.

G. Variables studied

As this is a global survey, it is important to understand the key parameters that could influence the choices of survey respondents. Therefore, we will review the answers of the questions 7,8,9 of the survey (table 1).

This is a descriptive statistical study intended to identify trends among respondents of varying geographical origin (#1) (Fig.2.) of different ages (#2) (Fig.2.), with or without a chronic disease (#3).

#1 The influence of geographical location: 70% of respondents are based in the USA and 25% in Europe.

#2 The influence of age: The age range most represented in this study (~2/3) is 60 to 69 years old (26.7%), followed by 50 to 59 years old (19.2%) and over 70 years old (18.6%).

#3 The influence of chronic or non-chronic condition. The majority of respondents (80%) suffer from a chronic illness, primarily renal failure.

What is the influence of the answers according to these 3 variables on the 3 questions (No. 7; No. 8; No. 9)?Main results will be discussed.

Question 7: *Do you read the package leaflet or information available for the medication provided by the manufacturer through websites or other sources?*
#1 North America yes 73.1%, Europe 82.1%. The geographic parameter does not have a significant influence for respondents in the majority group in this question. #2 Is age an influencing factor?

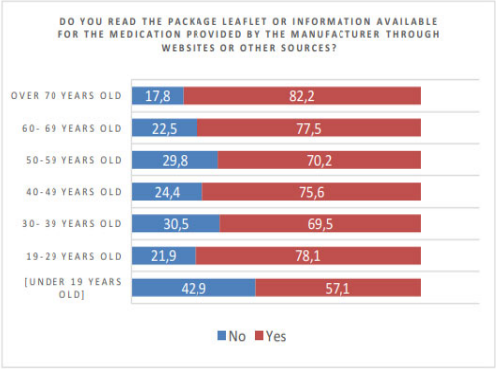


Fig.5.The proportion of individuals reading the package leaflet according to age.

We observe little disparity between the different age groups of respondents when it comes to the question regarding reading the package leaflet or searching for other sources of information on the drug; except in the group under 19 years old, who are the patients of the future and who must be taken into consideration to develop the future package leaflet. #3 The majority of responders (76%) read the package leaflet or information available for the medication provided by the company, through websites or other sources. In this group the majority (59.4%) are chronic patients.

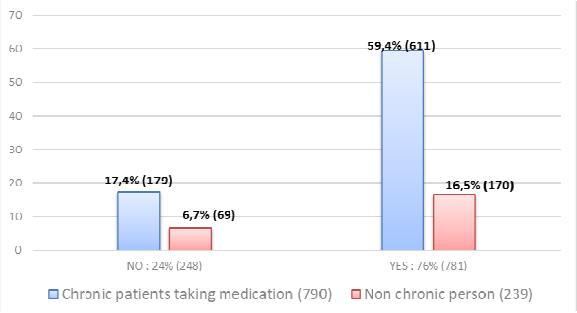


Fig.6. The proportion of responders (1029) reading (76%) or not reading medication (24%) provided by the manufacturer through website of other sources, with a chronic or non-chronic treatment.

Question 8.*Did you find the provided information (within the package leaflet for the medication) easy to understand?*
#3- A large majority of respondents (753 individuals, 96.4%) who read the package leaflet say that they understand the information it contains (Fig.7.). 75,7% in this group of responders are chronic patient.

Question 9: *What would you like to know before taking the medicine*? (1029 responders)?
#3- In the 2 groups of responders (Chronic / Non-Chronic-No medication) group, the most important information is the list of side effects. The section 'how to use the drug') is listed as important (2nd ranking for Chronic patients and 3rd ranking for non-chronic patients). Description of the medicines is ranked 3rd (ranked 5th non-chronic) for Chronic patients and how long to take the medicine is ranked 5th (ranked 3 non-chronic).

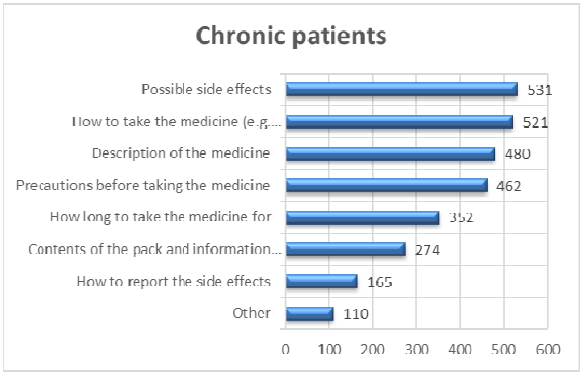


Fig.7a

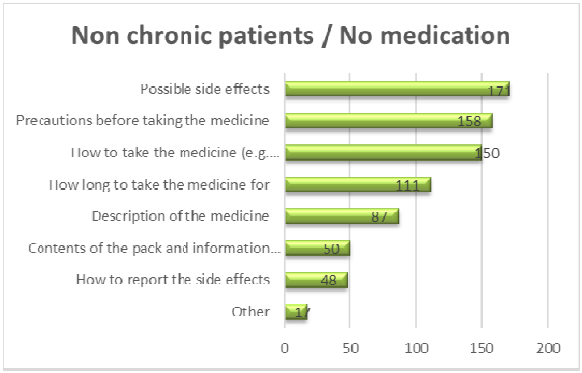


Fig.7b

What respondents would like to know before taking the medication? This means that the 5 important chapters of the patient labeling is common in the 2 groups of patients. Side effects are the most important information, while the way to report side effects listed as less important. This highlights the need for the Health Authorities to clearly communicate to the customers (patient), the importance to report side effects.

Question 15 *Please tell us how you normally take the prescribed treatment /medication by choosing the most relevant statement*?

We observe that41.4% of respondents reported stopping the drug after reading the warnings and precautions mentioned in the leaflet. The information in the section "warnings and precautions" have the role of alerting and protecting the patient in the event that they have a medical condition, lifestyle or if they are already on a drug treatment incompatible with the drug in question. This observation leads us to question the impact that these warnings have on the proper use of drugs by patients: did the responders (58,6%) who reported continuing the drug after

reading the warnings and precautions consciously ignore them despite being concerned, or were they simply never concerned by them? A digitalized, up to date patient leaflet with interactive links could help the patient to take the best decision for his treatment.

IV. CONCLUSION

Our study is based on a survey of 1029 patients globally, reflecting their critical opinion on the information they currently have about their medication and what they expect. According to the results of the study, patients are now looking for information outside of the paper format of the package leaflet provided by the manufacturer, regardless of the age or geographic origin of the 1,029 respondents (20–30%). However, in the group of young respondents (under the age of 19, who are the reflection of future patients), 50% report reading information about their drugs from digital sources. In addition to educating and training healthcare professionals, who remain the main point of contact for patients regarding their health, we hypothesize that access to digital sources controlled by the Health Authorities (EMA, FDA, National Health Agencies), via an electronic patient leaflet, will help solve the problems revealed in our study. Today, some Health Authorities around the world are actively working on developing guidance to provide the patient with a reliable and accessible digital source of information on the package leaflet [10]. Creating an online version of the drug package leaflet would make it possible to optimize its use by the patient and thus improve the proper use of the drugs. The digital package leaflet will enable interactive consultation. The patient will be able to access the information concerning them in a readable and easily accessible format, enabling them to consult it multiple times and allowing updates, especially regarding side effects. According to our study, this is the section most often consulted when searching for information. Our study demonstrated that the package leaflet in its current format does not fully meet the patient's need. The structure of the questionnaire developed by the patient association demonstrates the key role it can play in helping the regulator to develop a package leaflet that addresses patients' real needs. The patients of the future will no longer read the leaflet in its current format but on a digital medium addressing their specific needs.

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CONFLICTS OF INTEREST

All authors declare that they have no conflicts of interest.

(1) *"The opinions and viewpoints expressed by Isabelle Rooseleer are her own and do not necessarily reflect the opinions and viewpoints of her current employer, Organon Belgium BV."*

(2) *"The opinions and viewpoints expressed by Michèle Noumbissie are her own and do not necessarily reflect the opinions and viewpoints of her current employer, AIXIAL Belgium".*

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