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Evaluation of the Patient Information Leaflets (PIL) of drugs marketed in Cameroon

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Abstract: In the last five decades, cases of serious adverse effects, toxicity, controversial management or regulation of medicines have raised and increased the public's need of appropriate risk communication. As it became widely known that there is no medicine without risk, people increasingly wish to know more about medicines they receive [1,2]. Patient Information Leaflet (PIL) is related to a written and comprehensible information providedby Marketing Authorization Holder (MAH) in order to guarantee an appropriate and safe use of the product by patients [6, 7]. The primary endpoint of this study was to assess the quality of information contained on PILs of drugs registered in Cameroon. Materials and Method: Data have been collected from PILs in a community pharmacy located in Yaoundé-Cameroon through a surveyof 35 items. In the sampling process, we supposed that all the PILs of each laboratory have the same design. Consequently, only one sample of drug has been included per Marketing Authorization Holder (MAH). Results: A total of 143 PILs related to 116 international nonproprietary names have been evaluated.12% of the MAHs were from Africa, 63.63% from EU and 23,77% from Asia. Apart from indication and contraindication, none of the other important informations required were present in all the leaflets. There was a great heterogeneity between the designs and the content of PILs. While some were empty, the others were very lengthy with usefulness information for the patient. Discussion: While informations were not missing, their understanding was not guaranteed for all the readers. Nevertheless, Package leaflet coming from EU had more information and better presentation than those from Africa and Asia. The Regulatory Authorities should design guidelines related to the readability and comprehensibility of the PIL which is one of the three (3) key documents of post-marketing risk communication.

Key words: *Patient information leaflet, post-marketing risk communication, Pharmacovigilance*

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I. INTRODUCTION

In the last five decades, cases of serious adverse effects, toxicity, controversial management or regulation of medicines have raised and increased the public's need of appropriate risk communication. As it became widely known that there is no medicine without risk, people increasingly wish to know more about medicines they receive [1,2]. Moreover, as self-medication and direct-to-consumer advertising of prescription drug are becoming popular, reliable source of risk communication for each drug marketed must be made available and accessible for patient [3]. Indeed, in order to promote rational use of medicine and to mitigate risk related to its use, post-marketing risk communication is very important nowadays. Generally, three (3) key risk communication documents are required to prevent, minimize or manage risk of medicines when they are released on the market: the Prescribing information (PI), the Risk Management Plan (RMP) and the Patient Information Leaflet (PIL) [4]. While the PI is deserved to inform health care professionals about the benefits and risk related to a specific product, the RMP aims to plan how to mitigate relevant risk by setting up adapted methods allowing appropriate minimization of risk for the patient. Concerning the patient information leaflet which is considered by patients as the second source of information behind Health care professionals, it's an important technical document included in every medicine package [5]. PIL is a written information related to a specific medication and its main purpose is to inform patients about the way to use, condition of administration, benefits and harms [6]. All those informations must be comprehensible in order to guarantee an appropriate and

safe use of the product by patients [7]. In order to reach these goals, every PIL must communicate high quality information [5, 8]. Several studies which aims to assess the quality of Patient Information Leaflet have been carried out in Europe [6, 9]. Nevertheless, we could not find in the literature studies related to the use of PIL or patient information in Africa. There is a lack of such studies in Cameroon particularly. That is why, in order to fill the gap, the primary endpoint of this study was to assess the quality of patient information leaflets of drugs authorized in Cameroon.

II. MATERIAL AND METHODS

This is a descriptive cross-sectional study which aimed to assess the quality of information contained in the Patient Information Leaflets of drugs registered in Cameroon was carried out between April and June 2016 in a community pharmacy located in Yaoundé.

Study Design: Descriptive cross- sectional study
Study Location: This was a study done in a community pharmacy located in the city of Yaounde-Cameroon
Study Duration: April to June 2016.
Sample size: 143 patient information leaflets
Sample size calculation: The sample size was not estimated but randomly determined on the basis of drugs marketed during that period in the community pharmacy. Indeed, we assumed that all the PILs of each laboratory have the same design. Consequently, only one drug was included per Marketing Authorization Holder (MAH). The sample size actually obtained for this study was 143 package leaflets.
Subjects & selection method: The drugs were randomly included in the study without any consideration of their pharmaceutical form, neither for active ingredients nor for their pharmacological classes.

Inclusion criteria:
1. Drugs included should be marketed and on store in the community pharmacy where the study was carried out

Exclusion criteria:
1. one drug was included by MAH, all the others medicines manufactured by the same MAH were automatically excluded
2. Drugs reserved for hospital administration were systematically excluded

Procedure methodology:

After the authorization of the pharmacy's Director was obtained, a well-designed questionnaire was used to collect the data on the Patient Information Leaflets. Designed on the basis of recommendations of the FDA guidance on PIL [10],the questionnaire includedinformation such as, Characteristics of the drugs, the MAH, the country of the MAH, international nonproprietary name, and pharmacological classes, presentation and readability of PIL, information on risk, and special information.Questions were closed with the possibility of answer previously listed in order to easily choose the correspondent answer during the checking process. We didn't aim to check accuracy of the information in this study but only the presence of identified categories of informations on the PIL no matter if they were true, complete or not. Nevertheless, notes were taken down when a relevant point was observed. All the PILs have been checked by the same investigator who was a pharmacist with arelevant background in pharmacovigilance in order to mitigate investigator bias. A pilot test has been done with 15 PILs before initiating the study. That test allowed us to improve the quality of our questionnaire by reformulating, adding and cancelling questions. At the end of the test, several questions have been cancelled from the initial survey. The latter were related to the accuracy of information, vocabulary, absence of promotional information in the text and finally, presence of visuals illustrations. Indeed, those questions have been excluded because of the potential subjectivity which could be related to their answer. Generally, the two types of possible answer for the most of the questions were "yes" or "no". Nevertheless, when the questions could not be applied to a given drug, a third option "not applicable" was available.All the drugs available in the study site have been checked one by one. Whatever, as above mentioned, one drug was included by MAH, all the others medicines manufactured by the same MAH were automatically excluded. The PILs were checked instantly in the community pharmacy. As it was necessary to read all the PIL in order to correctly answer the questions, not more than 10 PILs were read by day in order to avoid bias related to concentration decrease.

Statistical analysis

Data was analyzed using SPSS version 17. Only descriptive statistics were used for the analysis. The results were presented for each step under the form % (n) where the percentage (%) is related to the rate of PILs

where a given instruction or section was present or not and n the exact corresponding number of PILs where that information has been observed.

III. RESULTS

Identification, characteristics and origins of the drugs' PILs

At the end of our study, we have checked 143 PILs related to 116 international nonproprietary names (INN) and 50 different pharmacological classes. Marketing Authorization Holders (MAHs) of the concerned medicines came from 26 countries. 12% of the MAHs were from Africa, 63.63% from EU and 23,77% from Asia (Table n°1).

Information presented in Patient information Leaflets

- **Information presented on the top position and the way information are presented on the PILs**

Among 143 drugs evaluated in this study, a summary of the document allowing reader to easily find desired information or a part was not present in about 62% (89) of the PILs.

We also found that about 27% (38) of the PILs didn't have a sufficient size, and 17% (24) didn't have adequate space between letters, lines, sentences and paragraphs in order to allow an easier reading by the consumer. Most of the PILs (91.6%) were not judged lengthy or cumbersome while 21.7% (31) where not found bilingual as required by the legislation. To make the document more personal, only 52% (75) wrote directly to the reader using the **"you voice"**. For the half of package leaflets, it was not asked to the patient to carefully read the instructions contained in the document neither to keep it for an eventual future use. Moreover, in about the half of the cases (48%), statements encouraging discussion with the healthcare professional about the medicines and claiming that it is important to follow the dosing instructions provided bythe doctor were not mentioned. The percent of PILs where specifics information where presented in a particular way or on the top position by country and continent are showed on the table n°2.

- **Information on risk**

Generally, there was a great heterogeneity on the presentation of information related to risk among the MAHs located in different countries or continent (table n°4). Concerning the required information on risk, we noticed that indications and contra-indications where always presented on all the PILs. Concerning advices related to the rational use of drugs, we noticed that 45, 5% (65) of the PILs didn't mention if the drug should be taken with food or water, neither before, during nor at distance of meals. In 62.7% (89**)** of the cases, the patient was not informed how he should manage if he missed a scheduled dose. In 63% (90) of the PILs it was stated what to do in case of overdose but in 66% (95) of the cases, symptoms of overdose were not listed. The frequency of adverse effects was not described in 72% (103) of the cases, but described as rare in 2% (3), common, rare and extremely rare in 18% (26). In 45,5% (65) of the cases the patient was not informed that he will not obligatory get the listed adverse drugs reaction (ADR). The latter were clearly listed for 92% of the PILs. The frequency of adverse reactions occurrence was presented verbally in 9% (13) and both verbally and statistically in 19% (26). While 42% of the PILs didn't encourage patients to consult their doctors if they experiment new adverse effects, the half didn't encourage patient to consult if side effects became serious even if they were mentioned in the PILs. Regarding precautions and warnings, 80% (114) have mentioned precautions in pregnancy and lactation, but 57% (81) of the PIL didn't mention the effects on ability to drive and use of machines, and 20% (29) didn't present the drugs to avoid because of drug-drug interactions. Among the 115 MAHs which presented the statement of drug-drug interactions, 21% (24) didn't list the drugs but just asked the patient to tell to his doctor if he used another medicines (table n°5). Furthermore, in 14% (20) of the PILs, storage conditions were not presented. Warning against using the product after the expiry date were not presented in 41% (48). Warning concerning eventual visible signs of deterioration were not presented in 96,5% (5).

Special statements

During this study notes were taken down when we noticed relevant information that we didn't include in our check-list. Indeed, we noted that 4,1% (6) PILs presented pharmacological properties of the drugs such as pharmacokinetic and pharmacodynamics. All the MAHs in that case were from India. In 11% (16) of the documents there were special statement concerning notification of ADRs where it was clearly explained to the patients the importance of the notification and the different ways he could do it. Among the latter 15 came from France and 1 from Italy. Special instructions encouraging the patients to protect their environment by bringing back useless or expiry medicines to their doctor were also gave in 45 (31%) PIL. Most of the MAHs which reported that statement were from Europe (tableau n°3).

Table n°1: percentage of drugs patient information leaflets by country and continent.

Continent	Country	Number of Drugs	Percentage (%)	Percentage
Europe	Austria	1	0.7	**91(63.63%)**
	Cyprus	1	0.7	
	England	5	3.7	
	France	53	37.1	
	Germany	3	2.1	
	Island	3	2.1	
	Italy	5	3.5	
	Luxembourg	2	1.4	
	Portugal	4	2.8	
	Spain	6	4.2	
	Switzerland	7	4.9	
	Turkey	1	0.7	
Africa	Cameroon	3	2.1	**17(11.88 %)**
	Egypt	2	1.4	
	Mauritius	1	0.7	
	Ivory coast	1	0.7	
	Morocco	7	4.9	
	Senegal	1	0.7	
	Tunisia	2	1.4	
ASIA	China	4	2.8	**34 (23.77%)**
	Emirates	1	0.7	
	India	26	18.2	
	Jordan	1	0.7	
	Pakistan	1	0.7	
	Saudi Arabia	1	0.7	
America	Canada	1	0.7	1 (0.7%)
TOTAL		143	100	100%

Table n°2: Shows percent of PILs where specifics information where presented in a particular way orposition by country and continent.

Information presented on the PILS	AFRICA (17 PILS)%	ASIA (34 PILS)%	EU (91 PILS)%	France (53 PILS) %	INDE (26 PILS) %	ALL (143 PILS) %
Read the PIL before using your medicines	5.9	17.6	71.4	86.8	11.5	**72(50.3)**
Keep the PIL you might need it	5.9	17.6	70.3	88.7	11.5	**71(49.7)**
Discuss with your doctor	5.9	17.6	73.6	88.7	11.5	**74(51.7)**
Addressing the reader as "**You**"	5.9	23.5	72.5	81.1	19.2	**75(52.4)**
Plan or summary of the PIL	0	8.8	56	73.6	3.8	**54(37.8)**
PIL has sufficient and large Size	64.7	47.1	84.6	90.6	53.8	**105(73.4)**
PIL is Cumbersome and lengthy	0	14.7	7.7	9.4	15.4	**12(8.4)**
Information are presented in French and English	82.4	97.1	70.32	64.2	100	**112(78.3)**
Respect the dosing instructions	17.6	14.7	60.4	71.7	11.5	**64(44.8)**

Table n°3: Shows percent of PILs where special statements were presentedby country and continent.

Information presented on the PILS	AFRICA (17 PILS) %	ASIA (34 PILS) %	EU (91 PILS) %	France (53 PILS) %	INDE (26 PILS) %	**ALL (143 PILS) %**
Sign of deterioration presented	0	2.9	4.4	7.5	0	**5(3.5)**
Warning against expiry date	35.3	23.5	78	86.8	19.2	**85(59.4)**
The PIL is specifically designed for the drug	70.6	82.4	89	88.7	80.8	**122(85.3)**
Take expired and unwanted medicines to your doctor	0	2.4	30.7	25	3.8	**45(31.4)**
Storage conditions are presented	64.7	88.2	90.1	92.5	88.5	**123(86)**

Table n°4: Shows percent of PILs where specifics information related on risk were presented by country and continent.

Information presented on the PILS		AFRICA (17 PILS) %	ASIA (34 PILS) %	EU (91 PILS) %	France (53 PILS) %	INDE (26 PILS) %	**ALL (143 PILS) %**
What to do in case of overdose		29.4	58.8	71.4	69.8	61.5	**90(62.9)**
Overdose symptoms are listed		23.5	26.5	38.5	34	30.8	**48(33.6)**
What to do in case of missed dose		5.9	14.7	51.6	58.5	7.7	**53(37)**
ADR are clearly listed		82.4	91.2	95.6	94.3	96.2	**132(92.3)**
Frequency of ADR presented	*Not described*	94.1	73.5	67.0	71.7	76.9	**103(72)**
	Rare	0	2.9	2.2	1.9	0	**3(2.1)**
	Common, rare, extremely rare	0	17.6	22	20.8	19.2	**26(18.2)**
	Rare and extremely rare	0	0	3.3	3.8	0	**3(2.1)**
	Extremely rare	0	0	2.2	0	0	**2(1.4)**
	Only common	5.9	2.9	1.1	0	3.8	**3(2.1)**
	Common and rare	0	2.9	2.2	1.9	0	**2(1.4)**
Communication of ADR frequency	*Verbal*	0	11.8	9.9	7.5	3.8	**13(9.1)**
	Verbal and statistical	5.9	11.8	20.9	18.4	15.4	**24(16.8)**
	Not presented	94.1	73.5	68.1	71.7	76.9	**104(72.7)**
Patients are informed that You may not get ADR		29.4	20.6	72.5	84.9	15.4	**78(54.5)**
Consult your doctor if ADR become Serious		17.6	20.6	68.1	86.8	15.4	**72(50.3)**
Consult your doctor if you experience an ADR not mentioned on the PIL		29.4	20.6	78	88.7	15.4	**83(58)**
Drugs to avoid in order to prevent Drug-Drug interaction are presented		9(52.9)	26(76.5)	80(87.9)	45(84.9)	22(84.6)	**115(80.4)**
Using of the product during Pregnancy /lactation		41.2	73.5	90.1	88.7	73.1	**114(79.7)**

Table n°5:shows the number of PILs per country where MAHs didn't list medicines to avoid drug-drug interactions but just used the statement "talk to your doctor if you are taking others medicines*"*

		Number	**Total**
Country	**France**	14	14
	ISLAND	1	1
	JORDAN	1	1
	Luxembourg	1	1
	MOROCCO	2	2
	INDIA	1	1
	Portugal	1	1
	SPAIN	2	2
	TUNISIA	1	1
Total		24	24

IV. DISCUSSION

Through this study we were able to outline the way informations are communicated on patient information leaflets of Drugs registered and marketed in Cameroon. To obtain a valid evaluation and a good overview of PILs, we have collected our data in PILs designed by 143 different Marketing authorization holders from Africa, EU, Asia and America.

Information presented on the top position and the way information are presented on the PILs

Generally, results of this study have showed that there was a great heterogeneity between the designs and the content of PILs. While some were too short and empty, the others were very lengthy, cumbersome with inappropriate and usefulness information for the patient. Mechanism of action, pharmacokinetics, pharmacodynamics, clinical trials' results, gram coloration, bacteria spectrum…we found numerous of such information which are not really important for patient. Moreover, those informations require a technical or pharmacology knowledge to be understood. That was the case of 4.1% (6) medicines included in this study and all the MAHs concerned were from India. Results showed that 22%of the MAHs didn't present the information on the two languages required by the Cameroonian regulation. This is a very relevant problem of compliance of the MAHs because Cameroon is a bilingual country were French and English are both the official languages. It is widely known that when a country has more than one official language, a multilingual PIL should be mandatory [7]. Nevertheless, despite the fact that the European directive 011/83/EC in his article 63 state that "package leaflets have to be available in the official language or languages of a Member State and the language used should be clear and understandable", we noticed that among the 31 medicines which didn't have bilingual PILs, 87.09% (27) came from Europe [7]. Indeed, each risk communication process must focus in the three main element of communication: the message, medium and audience. When a patient can't read the message contained on the PIL because of the language barrier, it means that the risks are not communicated. Consequently, the two main objectives of the PILs which are to inform and persuade patients to follow instructions mentioned cannot be fulfilled. Without using the same language, communication is impossible with patient. As information in a multilingual package leaflet must be the same in all the official languages, the PIL can become lengthy [7]. That was the case of 8.4% (12) of medicines in Cameroon. This survey also raised that in 72% of medicines, there is no, at the top of the PIL**,** summary or plan presenting the different sections and information communicated. Our experiment during the checking process of information contained on the PILs has showed that it's very difficult to find information without a plan. Indeed, patients are not specialists and surely, is not easy for them to deal with scientific terminology. In general, it has been showed that in order to allow patient to easily find researched information, it is important to present the plan at the beginning of the PIL. That will be very useful and enable easy navigation through the leaflet particularly when the write text doesn't have a sufficient size and there is no adequate space between letters, lines, sentences and paragraphs as respectively 27%(38) and 17% (24) of package leaflets evaluated in this study. In order to improve the understanding of the message, it's important that the different categories of information should be presented following the order of importance [8,11]. Numerous papers recommend that the message communicated on the PILs should use an imperative and conversional tone of voice by using the "you"[7, 12,13]. Indeed, to make more personal the safety advices, a PIL should directly address to the reader. Only 52% did it on our study. Use the "You Voice" is very important because when a patient read the PIL, he should feel in front of his doctor who is talking to him. This will probably increase not only his understanding, but also his compliance to the instructions. In order to allow him to follow those instruction, it should always be asked to the patient since the top of the PIL to read all the instructions before using the medicines and to keep the notice for an eventual future use. Unfortunately, we noticed that only the half of the pharmaceutical companies did it.

Information on risk

In Europe, the section 4 of the PIL is of particular relevance to risk communication. For statements of that section, the survey results showed that they were not always mentioned by all the Marketing Authorization Holders (MAHs). When Adverse Drugs Reactions (ADR) are presented, it is important to mention their frequency in the right way. In our study, 9% were presented verbally, 18% both verbal and statistic while 73% of the MAHs didn't present them. The latter rate (73%) don't favor the good understanding of the consumer. In 2008, Carrigan and al found that 40% of the PILs in UK gave no indication at all of the likelihood of adverse effects occurring [2]. Those informations are essential and must always be presented because generally, one of the most important categories of information that patients want to know about the drug they are taking is the likelihood or probability of adverse effects [2,14]. That's why, Narhu U raised in his review of the research related to drug information for consumers and patients, done in 2006 that manufacturers should improve the understanding of side effects information, including their frequency [15]. When the likelihood is not presented under a comprehensive way, patients could stop taking their medicine because of the fear of experiencing adverse effects [8,16]. MAHs should be aware that, the presentation of statistic is a common cause of interpretation bias in risk communication. Indeed, it is very important to present adverse effects both verbally and statistically. Concerning statistics, itis better to present absolute risks rather than relative risks. Indeed, use of natural frequencies is better than conditional probabilities, and mortality rates are better understood than survival rates [17]. As several studies have shown that readers feel insecure after reading the insert, instruction informing patients thatall the listed ADRs will not necessarily occur ishighly important on PILs. We noticed that there was heterogeneity on the presentation of that statement among the leaflets. Some examples of the different presentation are: "you may not get any of them'', "*like all medicines this drug can cause side effects*", "*some of the following side effects may appear*". While the first sentence is more conversional, the two last sentences seem not clear and could be interpreted differently by readers. Whichever is the sentence chosen, the message should be clear without ambiguity, asking the reader not to fear and finally, use the "imperative and you voice". It is the only way to guarantee that most of the patients will understand that is not because side effects are presented that they will occur. Nevertheless Readers should be aware that they must go back to their doctor in case of a serious or new ADR. Another negative point raised by this study is that only 44.8% of PILs have presented the statements *'' respect the dosing instructions provided by the doctor''.* That point is very importantbecause of the increasing rates of self-medication and the fact that disrespect could lead to overdose or lack of efficacy. Described in only 34% of PIL here, the symptoms of overdose should always be described because they are important for a self-diagnose of overdose by the patient. Lacking of information in what to do in case of missed dose is a very important consideration in pharmacovigilance. Indeed, the normal thinking of a patient would be to double the dose in order to catch up the missed dose. Such behavior could be dangerous if the drug has a narrow safety window and because it increases the occurrence probability of "type A" of Adverse Drug Reaction [18]. Indication and contra-indication were the categories of information always mentioned on the PILs while cautions related to pregnancy and lactation, and drug to avoid drug-drug interaction were listed in 80%. Concerning drug-drug interactions, it is important to precise that among the 80%, a consequent part didn't list the drug but ask the patient to tell to his doctor if he was under any other therapy even if he bought drugs without prescription. Such instructions are not very useful because the patient always read the PIL at the moment he want to take his medication. What should he normally do in front of such statement? He shouldn't take his treatment and go back to his doctor? We think that it will be better if drug-drug interactions are clearly listed or if it is clearly mentioned that they are not yet known at the moment rather than send back the patient to his doctor.

Presentation of special statements

The very good mark that we sorted in that study were the presence of special statement which favor the protection of the environment, spontaneousreporting, information for rational use of antibiotic and the cautions on sign of deterioration of the drugs. Explain the reasons and the importance of ADR reporting is very important because it could increase the number of adverse events reporting by patients. If it becomes mandatory to present such information on PILs, that could be a great catalyzer for the development of pharmacovigilance in countries without stringent regulations and worldwide it could help to face underreporting of ADR. The description of the sign of deterioration, is very helpful in sub-Saharan countries where the weather and the respect of the storage condition can't always be fulfilled. Promote the protection of the environment by asking patient "*Take any unwanted medicines back to your medical doctor or pharmacist for safe disposal"*on the PIL is related to Ecopharmacovigilance (EPV). Indeed, EPV is a new concept and an emerging science that is not yet well regulated. At the International Society of Pharmacovigilance annual meeting in Ghana in November 2010, the approach of EPV has been described as *the science and activities associated with the detection, evaluation, understanding and prevention of adverse effects of pharmaceuticals in the environment* [19, 20]. Such information isimportant and should be required on PIL since several studies have shown the adverse

environmental impact associated with the widespread detection of pharmaceuticals such as diclofenac and ethinylestradiol in the environment and the potential for effects in wildlife species [20,21,22,23]. One of the reason of the spread of antimicrobial resistance (AMR) is the non-adherence and the fact that patients usually don't finish their treatment and throw drugs and expired medicines in the environment. That's why presenting information on the rational use of antimicrobials are very important for patient education, prevention and control of AMR. As shown on the table II, 98% of those special statements were provided by MAHs of European Union where there is a stringent regulation.

This study has the merit to be the first study aiming to evaluate the quality of Patients Information Leaflet in Cameroon and maybe in Africa but, it has as any other his limits. Even if only one drug where assessed for each MAHs, if we accept that it is widely probable that all the PILs have the same design in the same industry, we can say that by focusing on the MAHs rather than in drugs, this survey gave a better overview of the quality of the information contained in the drugs marketed in Cameroon. Because this study was conducted in only one community pharmacy, it is possible that all the MAHs of drugs registered in Cameroon were not included. Furthermore, several recommended and important information required on the PIL were not evaluated in this study. Indeed, this study didn't assess accuracy or the completeness of information such as indication, contraindications, the presence of overall ADRs, the vocabulary, the neutrality or absence of promotional information in the text, and neither, the presence of visuals illustrations. Subjectivity could remain in some questions such as the size and length of the text for which the answer could change. Another negative mark is that we only include in our check-list sections that should normally be presented without taking in consideration those which shouldn't be included. Whatever, even if it was not systematically, we rated the presentation of some usefulness information for PIL such as, pharmacokinetic and pharmacodynamic properties, mechanism of action, chemical formula, metabolism related to CYP450.

V. CONCLUSION

Excepted indication and contraindication, none of the others important information required were presented in all of the leaflets evaluated. In fact this study revealed a great heterogeneity about the content and the presentation of PIL in Cameroon. While informations were not missing, their understanding was not guaranteed for all the readers. The latter should be improved because it is unhelpful to write a statement on a routine risk communication document without being sure that the reader will understand what it means [24]. Nevertheless, Package leaflet coming from EU had more information and better presentation than those of Africa and Asia. In light of all we have noticed in this survey, it is important to stress that the Regulatory Authoritiesof Africa should improve the legislations related to pharmacovigilance and particularly, guidelines related to the readability and comprehensibility of the PIL which is one of the 3 key documents of post-marketing risk communication. Indeed, effective communication between regulators and medicines users is vital if people want to take informed decisions about their treatment and the regulators' ultimate goal of improving public health is to be met [17]. In order to improve the quality of the PIL, Countries should impose as in EU that PILs should be tested on people before authorization. Furthermore, the presence of special statement related to ecopharmacovigilance, rational use of antibiotics and "sign of deterioration" should also be mandatory on all the PILs. Finally, post-marketing surveys should be conducted on a regular basis in order to allow Patients to express their concerns and opinions about the quality of information communicated on patient information leaflets. In this study we focused on the information for the patient, but information for healthcare professionals should also be considered.

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