BEUC The European Consumer Organisation

The Consumer Voice in Europe

BEUC response to the EMA consultation on changes to product information

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Summary

The changes to the product information introduced by the new EU legislation on pharmacovigilance represent an important and positive step to improve the quality of the information provided to consumers about medicines. It is of outmost importance that consumers receive complete information on the possible risks associated with the medicines - including the lack of data with regard to certain safety aspects - and that they are encouraged to report adverse reactions. The information should be clear, exhaustive and reader friendly.

BEUC comments on the Quality Review of Documents (QRD) human product information annotated template (EMA/468498/2012)

1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	The changes to the product information introduced by the new EU legislation on pharmacovigilance (Directive 2010/84/UE and Regulation 1235/2010) represent an important and positive step to improve the quality of the information provided to consumers on medicines and in particular they are in line with the right of all medicines users and carers to have more information on the safety profile of a medicinal product. It is of outmost importance that consumers receive complete information on the possible risks associated with the medicines, including the lack of data with regard to certain safety aspects. The information should be clear and exhaustive and at the same time it should not generate an unnecessary increased perception of risk that could prevent the patient to actually take the medicine. It is also vital that consumers are informed about the importance of reporting adverse reactions and are encouraged to report. When changing the layout or the content of product information it is necessary to take into account	

	the reader literacy skills and the actual consumer behaviour when assessing the information. To this end user testing remains an important tool to ensure that the information provided meets consumers' needs and reach the intended purposes. BEUC is very pleased that the comments provided in the context of the preliminary consultation conducted among the patients and consumers working party (PCWP) at the end of 2011 as well as the results of the studies on package leaflet presented to the PCWP by our members (e.g. DECO focus group on the readability of package leaflets for non-prescription medicines) are reflected in the proposed template. We provide below some additional comments. In particular we would like to reiterate the importance of better explaining why certain medicines are submitted to additional monitoring. Some of our comments refer to parts not subject to changes (not in blue) but we hope they will be taken into account during future reflections and in view of the continued efforts to improve the readability and the usefulness of package leaflets and other product information.	

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
<u>Summary of product characteristics</u> *Page 4* *[Black symbol] This medicinal product is subject to additional monitoring*		**Comment**: It should be explained why the product is subject to additional monitoring. We understand the intention to introduce the same sentence to be used for all products but it can be easily standardised offering a closed number of options in line with the wording of the legislation (i.e recital 10 of the Directive). This includes all medicinal products with a new active substance and biological medicinal products, including biosimilars, which are priorities for pharmacovigilance. Competent authorities may also require additional monitoring for specific medicinal products that are subject to the obligation to conduct a post-authorisation safety study or to conditions or restrictions with regard to the safe and effective use of the medicinal product. **Proposed change**: Add explanation as the following*: This medicinal product is subject to additional monitoring because:* *a) it has a new active substance* *b) it is biological medicinal*	

		product / biosimilar *c) it is subject to the obligation to conduct a post-authorisation safety study* *d) it is subject to conditions or restrictions with regard to its the safe and effective use*	
<u>Summary of product characteristics</u> Page 5 *4.8 Undesirable effects*		**Comment:** Health care professionals, patients and all those involved in pharmacovigilance should be informed about this important change. The SPC is the best tool to spread this information. For consistency with the legislation we also suggest to add in this section, especially at the benefit of health care professionals, that the suspicion of an adverse drug reaction is a sufficient reason for reporting. **Proposed change**: - Add the following "*adverse reaction covers noxious and unintended effects resulting not only from the authorised use of a medicinal product at normal doses, but also from medication errors and uses outside the terms of the marketing authorisation, including the misuse and abuse of the medicinal product" or a shorter version such as "adverse reactions resulting from medication errors, misuse or abuse of the medicinal product should also be reported*". - Add "*The suspicion of an adverse drug reaction is*	

		a sufficient reason for reporting".	
<u>Package leaflet</u> Page 10 *{Black symbol} This medicine is subject to additional monitoring*.		**Comment:** The consumer has the right to know the reason why the product is under additional monitoring. Further explanations can help the consumer understand why reporting is important and also avoid generating doubts on the safety of the product (see also above comments on the same part for the SPC). In order to reassure consumers on the fact that safety information have already been collected we suggest to specify that the product is under additional monitoring because further information, in addition to the one already assessed, is necessary. **Proposed change**: - Add " *additional*" "in the sentence "*This is to allow any <u>ADDITIONAL</u> safety information on the medicine to be identified rapidly*". - Add explanation as the following*:* *This medicinal product is subject to additional monitoring because:* *a) it has a new active substance* *b) it is biological medicinal product / biosimilar* *c) it is subject to the obligation to conduct a post-authorisation safety study* *d) it is subject to conditions or restrictions with*	

		regard to its the safe and effective use	
Package leaflet Page 11 *Warnings and precautions*		**Comment:** is the point on "warning and precautions" only intended for non-prescription medicines? If not, we suggest reconsidering the added value of this sentence and also its position in the leaflet.	
Package leaflet Page 11 *Children and adolescent* *And Use in children and adolescent*		**Comment:** we suggest reconsidering the position of this heading in the leaflet as it may induce some readers to think that the points below only apply to children and adolescents. We also encourage the QRD group to consider the introduction of a specific sub-heading for 'elderly people" as there might be specific precautions and indications or lack of safety data for the elderly population.	
Package leaflet Page 11 *Other medicines and X and X With food, drink, alcohol.*		**Comment:** Interactions with herbal products, vitamins and food supplements should also be mentioned. **Proposed change:** Add after *"other medicines" " herbal products, vitamins and food supplements".*	
Package leaflet Page 11 *How to*		**Comment :** we understand companies can choose between two options, possibly depending on the classification of the medicine as prescription	

<take> *<use> X*		only or as non-prescription but in both cases we suggest to use the second option "*Always take/ use this medicine exactly <u>as described in this leaflet</u> or as your doctor, or pharmacist, or nurse has/have told you. Check with your doctor or, pharmacist or nurse, if you are not sure.*	
<u>Package leaflet</u> Page 12 *3.Reporting of side effects*		**Comment**: Consumers should be encouraged to talk to their doctor or pharmacists also when they get side effects listed in the package leaflet. Consumers should be informed that adverse events are not only those resulting from the correct use of the medicines but also those resulting from abuse, misuse and medication errors (see also above). Direct reporting is particularly useful to detect adverse events generating from medication errors as one might argue that health care professionals might be reluctant to report them. **Proposed change**: - Rephrase as follows "*This includes any possible side effects, ALSO THOSE not listed in this leaflet"* to explain that both known and unknown side effects should be discussed with the health care professional. - *Add "Side effects include noxious effects resulting from the correct use but*	

		also from medication errors, abuse and misuse of the medicine". It could be added after "*This includes any possible side effects not listed in this leaflet".*	
Package leaflet Page 12-13-14 *For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder*		**Comment**: The whole list of addresses for each country usually take one page or more of the entire package leaflet and it is not proportionate with its utility. According to survey conducted by our members on what consumers do with the package leaflet after they read it some said they throw it away simply because it is too big and some face problems in putting it back in the box. It is true that some patients cross the national borders and can use a medicine outside their country of origin but we believe that if they require any information from the marketing authorisation holder they will tend to write in their mother tongue to the local representative of the marketing authorisation holder in their country. **Proposed change** (if any): Include only the address of the marketing authorisation holder where the product is distributed or at least assess other options to reduce the space taken up by this information in the package leaflet.	
Package leaflet		**Comment**: We believe it is outside the remit of EMA to	

Page 15 *There are also links to other websites about rare diseases and treatments*		indicate other sources of information. The information provided in the leaflet is approved high quality statutory information while other websites about rare diseases and treatments are not. Moreover a lot of information provided on websites about treatments is of poor quality, unreliable and misleading. EMA should refrain from directing the reader of the package leaflet to information that can be of poor quality and that can put patient's health at risk. **Proposed change** (if any):Delete this sentence	

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