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Stakeholders and Communication Division

EMA action plan related to the European Commission's recommendations on product information[1]

The European Medicines Agency (EMA) recognises the importance of the European Commission report[2] and its recommendations to improve the EU product information. This represents a unique opportunity to improve the information EU patients receive on their medicines, within the boundaries of the current legislation.

In order to meet high public expectations that the report has generated, it is important that any action is properly planned and executed, relevant stakeholders are involved and due consideration is given to the required expertise, timing and resources.

The following is an analysis of the timelines, technicalities which will be needed to implement the necessary actions to meet the objectives set in the report.

This analysis has not taken into account the impact of Brexit. However it needs to be noted that prioritisation, timelines and resource allocation will depend on how activities will be affected during the Agency's relocation and business continuity plan (BCP).

The different actions are broken down by each of the Commission's recommendations:

1. Room for improvement of package leaflet (PL) rather than summary of product characteristics (SmPC)

As far as the PL is concerned, patients' comprehension of the PL and its readability can be improved. The language used is often too complex and the design and lay-out are not always user-friendly. The elderly and those with low literacy skills are particularly disadvantaged, but generally these problems hold for all patient groups.

On the other hand, fewer problems were identified with regard to the SmPC, although improvements can still be made, especially with regard to its readability. Representatives of healthcare professionals generally judge the quality of the SmPC as reasonable and value most of the current topics addressed in the SmPC as being important.

[1] In accordance with Article 59(4) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use
[2] https://ec.europa.eu/health/sites/health/files/files/documents/2017_03_report_smpc-pl_en.pdf

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Recommendation: Generally, there should be more focus on improving the PL rather than the SmPC. However, for any potential improvement of the PL it should be also considered whether a corresponding or related change of the SmPC would be appropriate.

Proposed actions
Ensure that any change which is introduced to the PL is applied to the SmPC as needed.
Timelines
In parallel to the whole project implementation.

2. Amendments of guidelines and Quality Review of Documents (QRD) templates to enhance readability of PL

Content and layout-related issues have been identified in the PIL-S Study. It is considered that future work on guidelines relating to the PL, and possibly also the SmPC to some extent, has the potential to solve a number of these issues.

Guidelines should include more details on the principles of good information design in which content and layout are jointly considered. This would help to ensure compliance with the legal requirement that the PL shall be "clearly legible".

Moreover, improvements related to the language used would help to ensure that the information is "clear and understandable" as also required by the legislation.

These issues could be best addressed by improving the existing guidelines, in particular the Readability Guideline, the Packaging Information Guideline and, where appropriate, the SmPC Guideline. The relevance and importance of the QRD template is also acknowledged in this respect as it is the main tool to provide guidance to the industry in a harmonised way. The QRD template should rely on principles of good information design and pay attention also to the needs of some specific groups of patients, such as elderly, young people or people with mental illnesses.

Small font size, narrow line spacing and the length of the PL were identified as the main issues.

Guidelines and QRD templates are also considered too restrictive in some respects. They should allow for more flexibility to adapt the PL to the specificities of each product whilst respecting the limits provided by the legislation. Deletion of some information that is currently required by the QRD template, but that is of limited relevance for patients may allow more space to improve the content and layout of package leaflets and should, therefore, be considered.

More attention should also be paid to the translation of the user-tested PL into other languages. It is considered important to keep the 'lay-ness' of the user-tested version when the leaflet is translated.

Recommendation: It should be considered to revise the existing guidelines, in particular the Readability Guideline, the Packaging Information Guideline and, where appropriate, the SmPC Guideline to include principles of good information design and consider allowing more flexibility in the information recommended in the QRD template, as long as the relevant legislation allows it. These revisions should also include introduction of guidance on translations that go beyond the principle of faithful translation.

The aim should be to ensure that the lay language introduced through user testing in the original language version is not lost during translation.

Proposed actions
In order to achieve valid results, there is first a need to establish areas for improvement and revision, which must be endorsed by stakeholders. In order to identify such areas, EMA will need to work with experts and stakeholders to understand well the problems and concerns and explore the possible options. • Review Readability Guideline; • Review SmPC Guideline (to ensure adequate alignment with the PL – see recommendation 1); • Review QRD template; • Produce guidance on translations.
Technical requirements
• Involvement of external experts, including academic experts (on benefit/risk communication, on linguistic matters, especially in the field of translation, etc.); • Incorporation of principles of good information design in guidelines (by use of academic expertise); • Involvement of all stakeholders (patients, consumers, healthcare professionals, industry); • Adequate public consultation; • Possible stakeholder workshop; • Need to work with Member States (and incorporate their input as well as existing initiatives at national level).
Timelines
• Two years – starting as soon as resources are available[3].

3. Improving patient input in developing and testing of PLs

The assessment recognised the usefulness of patient involvement and the importance of user testing of the PL. It is equally important that methodology for such testing is well defined. The assessment further identified the need for strengthening the input from the patient perspective which could also help in getting more understanding on how to present benefit-risk information for a particular medicine.

Recommendation: The input from patients during the process and the related methodology should be further improved, for example by considering the requirement to make the user testing process more iterative and to ensure that a sufficiently mature version of the PL is user-tested. This iterative user testing would be coordinated by regulatory authorities in parallel to the assessment in a way that does not disrupt the whole marketing authorisation process. The iterative testing should focus on the content of the PL, rather than the format and layout, to ensure that information is clear and written in a way which is

[3] Resource allocation will depend on business continuity plans linked to Brexit and the impact of EMA's relocation

easily understood by patients. Potential amendments of the Readability Guideline could be considered in this respect, taking also into account the use of structured benefit-risk approaches and visual representations to communicate benefits and risks to different stakeholders in different situations, including those approaches developed by the European Medicines Agency in the context of the Benefit-Risk Methodology project[4] and by the Innovative Medicines Initiative (IMI) Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium (PROTECT) project[5].

Proposed actions
It is important that the iterative user-testing is integrated into the current assessment process so that it is able to deliver maximum results while avoiding any delay in the evaluation and authorisation processes. • Design user-testing which can be adapted and integrated into the current assessment process; • Define scope of testing, aligning it with assessment requirements and making it complementary to the applicant's testing, ensuring it adds value and avoids duplication; • Establish process for iterative user-testing, minimising impact on assessment; • Establish process to allow payment of services to patients enrolled in the user-testing.
Technical requirements
• Involvement of external experts (including experts in user-testing); • There currently exists an internal EMA process by which patients review the PL for readability purposes. This process will be used as a basis to develop a proper user-testing. The existing database of EMA patient experts can be used as a source of patient experts. Currently EMA relies on volunteers when seeking patients' contribution. This can no longer be maintained in the case of iterative user testing and it will be needed to establish a process to allow payment of services to patients enrolled in the user-testing; • Need to involve stakeholders (mainly through EMA Working Parties with Patients, Consumers and Healthcare Professionals, (PCWP and HCPWP)).
Timelines
• 18 months – starting as soon as resources are available[6].

4. Promotion and exchanges of best practice

The assessment concluded that good, user-tested examples of the PL and to some extent also the SmPC as well as their development process could be promoted more by regulators to facilitate and improve the development of these documents.

Recommendation: Best practice examples of aspects of the PL (and the SmPC) design could be made available for pharmaceutical companies on a platform that would be suitable for that purpose and that

[4] http://www.ema.europa.eu/docs/en_GB/document_library/Report/2012/03/WC500123819.pdf
[5] http://www.imi-protect.eu

[6] Resource allocation will depend on business continuity plans linked to Brexit and the impact of EMA's relocation

could be regularly updated. These examples should include not only the end products, but also information on the process of development, where possible. The selection of these examples should be evidence-based.

Proposed actions
• Develop criteria for selection of examples to be published (involving the relevant external expertise); • Develop a dedicated webpage which enables feedback for communication and exchange; • Establish a process for maintenance of the on-line platform.
Technical requirements
• Involvement of external experts and potential users of the on-line platform; • Need to involve stakeholders (patients, consumers, healthcare professionals, industry, academics); • Need to work with Member States (to ensure the on-line platform meets also their needs); • Consideration should be paid to all EU languages; • IT support required to build the online platform.
Timelines
• One year for full implementation – starting as soon as resources are available[7].

5. Electronic SmPC/PL formats

Electronic formats bring new opportunities for SmPCs and PLs. As more Europeans gain access to information technologies, the assessment identified potential benefits in developing key principles as to how electronic formats can be used to provide the information to individual EU citizens in accordance with the existing legislation (e.g. in terms of presentation, format or use of multiple languages). In any event, electronic PL formats should be complementary to paper PLs that are required by the legislation and should not replace them at this stage in order to ensure availability of the information for all patients.

Recommendation: It is recommended to explore the use of electronic media to provide the information included in the SmPC and PL in the future. It should be further explored what opportunities new technologies offer to optimize the presentation and design of SmPC and PL. In this context the opportunities for the information included in the SmPC and the PL to be more easily used as an integrated part of the care process should be explored. For example, developing mechanisms through electronic tools to inform patients and healthcare professionals on changes in the SmPC and PL should be considered. The exploratory work in this area should be based on and further develop the existing work done by EMA in this area and should follow a multi-stakeholder approach involving also the pharmaceutical industry, patients, consumers, healthcare professionals, the Member States and the European Commission. The aim will be to develop the key principles for the use of electronic SmPC and PL formats. The results of this exploratory work should be submitted to the Commission for any follow-up action as appropriate.

[7] Resource allocation will depend on business continuity plans linked to Brexit and the impact of EMA's relocation

Proposed actions
• As a first step, organise a European Commission (EC) / EMA multi-stakeholder workshop on product information and electronic media; • Perform a mapping of current initiatives in the field to ensure adequate representation in the EC/EMA workshop, so that all voices can be heard; • Develop key principles for the use of electronic SmPC/PL formats; • Collaborate with the European Commission on any follow-up actions.
Technical requirements
• It is essential that the mapping exercise is able to provide a comprehensive overview of all existing initiatives, so that it can be a way to align them and to avoid overlapping and potential tool duplication; • Need to involve all stakeholders (patients, consumers, healthcare professionals, industry, academics, IT technical expertise, etc.); • Need to work with Member States and incorporate existing initiatives at national level.
Timelines
• Workshop to be held in Q3 2018, with preparatory work (mapping and discussion with stakeholders) starting in Q4 2017.

6. Potential key information section in the SmPC and PL

The potential introduction of the 'key information' section in the SmPC and PL with the objective to allow patients and healthcare professionals to rapidly identify key safety messages, balanced with information on the benefits of medicines, has been also subject to the assessment. The key information section is not specifically envisaged in the existing EU legislation on medicinal products for human use. The outcome of the assessment is that more experience and evidence needs to be gathered and that currently testing can be considered as a means to further determine the potential usefulness of the inclusion of a key information section in the SmPC or PL.

Recommendation: More evidence would need to be gathered before considering introduction of a key information section in the Product Information. It is suggested to continue further exploratory work on the use of such key information in the PL as well as the possibility to use Quick Response (QR) codes[8] as another way to make available information to patients. Appropriate testing (e.g. user testing) could be a way to demonstrate the clear evidence of the usefulness and added value to patients to introduce a key information section in the PL. In this respect, the work currently being undertaken by EMA as part of its strategy to improve information on benefit-risk to patients and healthcare professionals could be taken into account. In particular, the planned testing of adding a 'key information section' to the 'EPAR[9] summary' for each centrally authorised medicinal product could be used for this purpose. This may help to

[8] QR code is a machine-readable optical label (bar code) that contains information about the item to which it is attached. A QR code may link to a website, web page (e.g. standalone PDF document) and/or smartphone applications specifically created for that purpose.
[9] European Public Assessment Report.

decide on the type of information that should be provided in the PL and the category or type of medicines where such a key information section could be useful and appropriate.

Proposed actions
• Implement pilot testing of 'key information section' in the EPAR summaries; • Use academic expertise and develop pilot research; • Analyse experience and explore feasibility to apply it in the context of PL, involving academics; • Discuss results with stakeholders.
Technical requirements
• External academic expertise in the field of benefit-risk communication is key to make progress on this recommendation; • Need to involve all stakeholders (patients, consumers, healthcare professionals, industry, academics); • Results to be shared and discussed also with Member States.
Timelines
• Two years – starting as soon as resources are available[10].

[10] Resource allocation will depend on business continuity plans linked to Brexit and the impact of EMA's relocation