



Package leaflet (PL) improvement initiative

Feedback from stakeholder representatives

PCWP-HCPWP joint meeting, EMA

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Goals of QRD template review

- To shorten the length of the package leaflet
 - Improve the understandability of the information
 - Make the package leaflet more relevant to patients & users*
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- Recognition that healthcare professionals need to explain and go beyond the patient leaflet, however
 - HCP-patient/user interactions increasingly time-constrained, and patients value written information to supplement and support conversations with HCPs

Importance of the initiative

➤ *Ensuring users can find and understand key information*

1. **Current PL difficult to understand**

“Patients understanding of the leaflet could be improved – many do not read the leaflet in its entirety or understand the information it contains”. (Patient/carer response to survey 1)

2. **Current PL does not contain the information patients want and need**

“Benefits and risks must always be communicated together since the perception of risk is always proportional to the expected benefit of the medicine”. (EMA, Workshop with patient and consumers, 2009)

3. **Positive impact on downstream information producers/providers**

Involvement of stakeholders

- Thanks to Kaisa, Monica and Alexios
- Patient/user perspectives and stakeholder feedback has been taken on board
- E.g. the need for improvements in communication, format and ordering of side-effects, warnings and precautions (sections 2 & 4)
- Please respond to second survey!
- Additional opportunities for groups to feedback during public consultation period

Opportunities and constraints

1. Inclusion of key information section may be only chance to present clear and accessible information on demonstrated benefits and harms together in a way patients can more easily evaluate
2. Legislation governing content and structure of PL has not changed
3. Need for additional user testing – further evidence needed on understanding and accessibility/ease of use re: wording, alternative formats, overall structure etc

Additional reflections and concerns

1. Concerns about length of the leaflet and having to update content of paper leaflets
2. Concerns about having to police promotional claims
3. Inclusion of benefit information will be voluntary
4. *Patients receive these too late in the process to facilitate shared decision-making