



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Towards electronic product information in the EU - EMA action plan related to the European Commission's recommendations on product information

PCWP & HCPWP joint meeting
17 April 2018, London





- EMA recognises the importance of the European Commission report
- Unique opportunity to improve the information EU patients receive on their medicines, within the boundaries of the current legislation
- EMA committed to its implementation
- Action Plan implementation will involve all stakeholders (patients, consumers, healthcare professionals, industry, academics) and in collaboration with EU Member States and EC



1- Room for improvement of Package Leaflet rather than of SmPC

2- Amendments of Guidelines and QRD templates to enhance readability of Package Leaflet

- Review of Readability guideline
- Review of QRD product information template
- Review of SmPC guideline (to ensure adequate alignment with the Package Leaflet)
- Produce guidance on translations

In order to achieve valid results, there is first a need to establish areas for improvement and revision, through involvement of relevant stakeholders.



3- Improving patient input in developing and testing of PLs

- Design and implement EMA user-testing which can be adapted and integrated into the current assessment process
 - complementary to the applicant's own testing and aligned with assessment timelines
 - to be built upon existing EMA process by which patients review PL and give feedback
 - existing database of EMA patients' experts to be used



4- Promotion and exchanges of best practice

- Develop a dedicated webpage on EMA website which enables feedback for communication and exchange
 - Develop criteria for selection of examples to be published
 - To be used as an interactive online platform
 - Representative of EU languages

5- Electronic SmPC/PL formats

- As a first step, organise an EC/EMA/HMA 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.
 - Outcome from the workshop: develop key principles for the use of electronic SmPC/PL formats

The mapping exercise is an essential tool to obtain a comprehensive overview of all existing initiatives, so that it can be a way to align and coordinate them to avoid overlaps and duplication



6- Potential key information section in the SmPC and PL

- Implement pilot testing of 'key information section' in the EPAR summaries
 - Use academic expertise on benefit-risk and develop pilot research
 - Analyse experience and explore feasibility to apply it in the context of PL



- **Activity 5** (electronic formats) given the highest priority and implementation will start in 2017
- Other actions will be initiated based on available resources.
- In the context of the Agency's relocation, implementation can only be initiated once the Agency's workforce is stable enough and above a certain limit of staff retention, which can guarantee our ability to go beyond essential core activities



Thank you for your attention

Further information

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