



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Brainstorming on targeting EMA information to patients & healthcare professionals





Background

- Objective - brainstorm and obtain feedback on the information that the Agency publishes on its website (e.g. Q&A documents, Press releases).
- The implementation of the new Pharmacovigilance legislation will mean new information is published - good opportunity to review existing practices and identify any areas for improvement.
- Preparatory work: collected views from healthcare professional organisations and patient/consumer organisations.
- Points raised are expected to be used as a basis for initiating discussion and to formulate some questions for further analyses.



Participants considered:

- Whether EMA documents respond to patients/healthcare professionals information needs,
- If they are easily located on the website / published in a timely manner,
- If there is a need to improve or change the current practices and documents, and if so, in what way.

This brainstorming referred only to information on medicines in the context of the EMA's role and responsibilities and did not include EPARs, SmPCs or package leaflets.



Issues raised referred to:

1. Type of information on medicines which is required
2. format and timing of the information
3. Gaps in information
4. Others:
 - information written in an appropriate language?
 - Sufficiently detailed?
 - Easy to find?



Information – content/format

- How understandable is the information we provide?
 - Is the information written in an appropriate language?
 - Is the information sufficiently detailed?
 - Are there any gaps in the information we provide?
 - Are there clear instructions / is it clear what you have to do?
 - Are you clear about the risks and the benefits of the medicine concerned?
 - If you could change one thing in the information we provide, what would it be?



Issues raised: content/format

- The language used is patient-friendly (sufficient level of detail), and also adequately written for healthcare professionals although they would welcome additional background/scientific data supporting EMA recommendations.
- The press release and Q&A documents are equally important and useful.
- The key 'advice' could be in bold text so that it is located quickly.
- The PCOs appreciate receiving draft documents for review prior to publication.
- No divergences found in the information received from the pharmaceutical industry compared to the information published by the EMA.



Information – timing and distribution

- What do you do with the information we send?
 - Do you disseminate information we send to your members/member organisations?
 - Do your member organisations disseminate EMA information to their members?
 - Do you publish EMA information on your website?
 - Do you link to EMA information on your website?
 - Do you distribute EMA information through social media (twitter, facebook, etc.)?



Information – timing and distribution continued

- What do you do with the information we send?
 - Is any of the information provided by EMA translated by you or any of your member organisations?
 - Do you ever receive any feedback from your members/member organisations on EMA information?



Issues raised: timing and distribution

- The EMA should further promote its website.
- Organisations also have a role in disseminating EMA information.
- Organisations would like information on whom EMA disseminates messages.
- HCPOs appreciate receiving emerging information (safety communications; shortages; recalls) as soon as published and would also like to have DHPCs published in the EMA website.
- HCPs appreciate newsletters but suggest adding a targeted alert system on (e.g. new approvals, extensions and new indications).



Information – other aspects

- Do you get information from the EMA when you need it?
- What is your preferred format for receiving information? i.e. html; pdf document
- Where do you get information on medicines from?



Issues raised: other aspects

- Searching by disease/therapeutic area/class of medicinal products could be optimised.
- The patients/carers and healthcare professionals dedicated webpages could be enhanced (e.g. further clarification on what can and cannot be found).
- A mouse-over glossary could be useful.
- There is no guidance on how to use the EMA website; training would be useful.



Summary

- Feedback received indicated that current information provided by the EMA is sufficient and of good quality.
- Targeting better this information and increasing accessibility would be welcomed.
- Both the press release and the Q&A documents are needed; key information should be prominent at the upper level, with more detail following thereafter.
- HCPs would like additional background/scientific data with EMA recommendations.
- The search functionalities on the website could be improved, especially disease-specific information.