EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Communication of additional monitoring

PCWP/HCP WG joint Meeting, 27 February 2013

Context

Problem statement:

- Black symbol new in most MS; complex concept; potential alarm.
- Phase-in
- Concept must be explained clearly, information must be readily available.

Desired outcome:

- EU citizens receive a clear, consistent and coordinated message about what the black symbol means.

Communication campaign

- Co-ordinated by EMA, with national regulators
- Target audiences: patients and healthcare professionals
- Limited resources
- Involvement of patient and healthcare-professional organisations, other information multipliers
- EMA will:
  - Publish clear information at time of main milestones.
  - Provide material for use at national level and dissemination to members.

Main actions

April (publication of initial list):

- Publish public friendly information (Q&A) on EMA website
- Disseminate translated Q&A

Summer:

- Publish video on EMA website and YouTube
- Label medicines with black symbol on EMA website (EPAR pages)

September (inclusion of black symbol in new authorisations affected):

- Provide information packs to information multipliers:
  - Q&A
  - EMA video
  - Digital campaign material
  - Internal briefing/messages as required

Main actions (contd.)

Ongoing:

- Promote via existing channels: social media, news and media activities, internal communication, etc.

Early 2014 (black symbol included in all authorisations affected):

- Take stock of impact and usefulness of initiatives (surveys, web statistics, etc.)

Key messages

- Medicines are authorised based on data from clinical trials. Only medicines whose benefits are greater than their risks can reach the market. Information continues to be collected after marketing, to monitor real-life experience with all medicines.
- The black symbol identifies medicines where monitoring is particularly intensive. This may be because there is less experience with the medicine in normal clinical settings, for example because it is new and works in a different way to available medicines, so regulatory authorities want to gather as much information as possible while making the medicine available to patients.
- The authorities encourage patients to report any suspected side effects directly to the health authorities in their country and to discuss any questions or concerns with their doctor. Regulators will look at these reports alongside all the information they already have on these medicines to ensure the benefits remain greater than the risks and take any regulatory action if needed.

Next steps

- Share strategy document and key messages
- Consider differentiation of messages for patients and healthcare professionals
- Feedback/suggestions welcome

Thank you!