EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Session of "first experiences": black symbol and product information

6th Stakeholders Forum
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Legal basis

Black symbol and additional monitoring

- For medicinal products for human use subject to additional monitoring:
  - The summary of product characteristics and the package leaflet shall include the statement "This medicinal product is subject to additional monitoring". That statement shall be preceded by a black symbol which shall be selected by the Commission following a recommendation of the Pharmacovigilance Risk Assessment Committee by 2 July 2013*, and shall be followed by an appropriate standardised explanatory sentence (Art. 11 and 59 of Directive 2001/83/EC and Art. 23(5) of Regulation (EC) No 726/2004).

* (Final draft) REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EC) No 726/2004, as regards pharmacovigilance.

Legal basis

Reporting suspected adverse reactions (ADRs)

- For all medicinal products for human use:
  - A standard text shall be included in the summary of product characteristics expressly asking **healthcare professionals** to report any suspected adverse reaction in accordance with the national spontaneous reporting system referred to in Article 107a(1) (Art. 11 of Directive 2001/83/EC).
  - A standardised text shall be included in the package leaflet, expressly asking **patients** to communicate any suspected adverse reaction to his/her doctor, pharmacist, healthcare professional or directly to the national spontaneous reporting system referred to in Article 107a (1), and specifying the different ways of reporting available (electronic reporting, postal address and/or others) (Art. 59 of Directive 2001/83/EC).

Implementation of the new legislation

Development of the draft proposals (1/2)

- The European Medicines Agency (EMA), through the Quality Review of Documents (QRD) group, worked on the draft proposals to be implemented in the product information.
- Aspects to be covered by the draft proposal:
  - **To identify a black symbol.**
    - To assist PRAC when drafting the recommendation on the black symbol for the Commission.
  - **To specify the location** of the symbol and the new standardised statements within the QRD human product information template.
  - **To define the wording** for the new standardised statements.
    - Additional monitoring.
    - Encouragement of the reporting of adverse reactions.

Implementation of the new legislation

Development of the draft proposals (2/2)

- After analysis and discussion on the data provided by the Member States, the first draft proposals were agreed by the QRD group in November 2011:
  - Standardised statements.
  - Black symbol:
    - The QRD group proposed the symbol currently being used to identify products under intensive surveillance in the United Kingdom and Belgium, i.e. an 'inverted black triangle' (▼), as the preferred choice of the group.
    - Alternatively, the development of a symbol resembling a 'magnifying glass' was considered to be the second best option.

Implementation of the new legislation

Consultation on the draft proposals

- The proposal was circulated for further consultation by various parties:
  - Members of the Patients' and Consumers' Working Party (PCWP).
  - Members of the Healthcare Professionals' Working Group (HCP WG).
  - National Competent Authorities (NCAs).
  - Pharmaceutical industry associations.
- External (public) consultation (only on standardised statements!).
  - 29 set of comments (pharmaceutical industry, CROs specialised in user testing/communication experts, patients', consumers' and healthcare professionals' organisation and academia).
  - Meeting with QRD members and interested parties after the external consultation to discuss the comments received.

PRAC plenary meetings

Points discussed

- **3-5 Sep 12:** Presentation of the compiled information and initial discussion on the black symbol.
- **1-3 Oct 12:** Finalisation of the recommendation on the black symbol.
  - Participation of a representative from the PCWP to present the views of the patients, consumers and healthcare professionals organisations:
    - The black inverted triangle (▼) was presented as the preferred option of patients, consumers and healthcare professionals.
    - Communication about additional monitoring and the black symbol was identified to play a key role in the success of the implementation and recognition of the black triangle by patients and healthcare professionals across Europe.
    - The consulted organisations were keen to collaborate with EMA and NCAs to launch an awareness campaign and convey the information to their members.
- **29-31 Oct 12:** Endorsement of the standardised statements.

Identification of the black symbol

PRAC recommendation (1/3)

- Based on the information compiled throughout the different rounds of consultation and on the views expressed by the patients, consumers and health care professionals, the PRAC reached a consensus regarding the following recommendation:
  - **Identification of the symbol:** The black symbol should be an inverted equilateral triangle (▼).
  - **Specifications of the symbol:** The symbol should be black and be proportional to the font size of the subsequent standardised text. In all cases its size should be not less than 5 mm per side.

Identification of the black symbol
PRAC recommendation (2/3)

- Points considered by the PRAC for the recommendation:
  - Abstract symbol not linked to any meaning/connotation, which is less likely to cause confusion/wrong interpretation or alarm to patients.
  - The black symbol does not necessarily have to have a meaning or to directly allude to an action as long as the accompanying text is clear enough and conveys the right message.
  - The inverted triangle does not clash with other symbols already established for pharmaceuticals.
  - Solid representation and easy to reproduce in a consistent manner.
  - Symbol is already in use in two MSs for similar pharmacovigilance activities, therefore, the meaning is already well known to physicians in BE and UK.
  - Easily available (world-wide character that works with most languages).

Identification of the black symbol
PRAC recommendation (3/3)

- The PRAC supported the views of the patients, consumers and healthcare professionals about the need to coordinate a communication strategy on the black symbol across Europe.
- The following was considered to play a key role in the communication:
  - The EMA/NCAs websites should provide further information on '*additional monitoring*' in lay language.
  - MSs are expected to play an active role in raising awareness on the symbol.
  - Patients', consumers' and HCPs' organisations could use the 'core' explanatory information prepared by the EMA in their 'awareness campaign'.
  - EMA's web should provide specific information material as a point of reference.
  - Patients', consumers' and HCPs' organisations play a crucial role in conveying the information to their members.

Location and wording of the statements

Additional monitoring

- Summary of product characteristics (SmPC): above section 1.

< ▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions.>

1. NAME OF THE MEDICINAL PRODUCT

{(Invented) name strength pharmaceutical form}

- Package leaflet: below main heading.

Package leaflet: Information for the <patient> <user>

{(Invented) name strength pharmaceutical form}
{Active substance(s)}

< ▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects. >

Location and wording of the statements

Encouragement ADR reporting

- Summary of product characteristics - SmPC): end of section 4.8.

> **4.8 Undesirable effects**
>
> Reporting of suspected adverse reactions
> Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions <via> <through> {insert information on the relevant 'national reporting system' – *see Appendix V*}.

- Package leaflet: end of section 4.

> **4. Possible side effects**
>
> **<Additional side effects in children <and adolescents>>**
>
> **Reporting of side effects**
> If you get any side effects, talk to your <doctor> <or> <,> <pharmacist> <or nurse>. This includes possible side effects not listed in this leaflet. You can also report side effects <directly> <(see details below)>. By reporting side effects you can help provide more information on the safety of this medicine.

Next steps

- CHMP endorsement of the QRD template (Dec 12).
- Implementation plan.
  - Ongoing discussion.
- To initiate the translation exercise of the revised QRD template with Centre de Traduction (CdT) in Luxembourg.
- Validation phase of the translations by the Member States.
- Publication of the new template in March/April 2013 (TBC)
  - Once the black symbol is selected by the EC.

Thank you!