EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Additional monitoring of medicinal products – update of the implementation

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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

- Implementation plan.
  - Ongoing discussion with EC.

- Translation exercise of the revised QRD template with Centre de Traduction (CdT) in Luxembourg => **completed**
- Validation phase of the translations by the Member States => **completed**
- Publication of the new template in March/April 2013 (TBC)
  - Once the black symbol is selected by the EC.

Thank you!