EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Additional monitoring of medicines and side effects reporting – impact on the product information

EMA Human Scientific Committees' Working Party with Patients' and Consumers' organisations (PCWP) meeting
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Implementation of the PhV legislation
Impact on the product information

- There are certain aspects of the implementation of the new pharmacovigilance (PhV) legislation, which have an impact on the product information:
  - **Additional monitoring of medicines:** a black symbol and a standardised explanatory sentence to be included in the summary of the product characteristics (SmPC) and in the package leaflet (PL) for medicinal products subject to additional monitoring.
  - **Encouragement of side effects reporting:** standardised text to encourage adverse reactions reporting to be included in the summary of the product characteristics (SmPC) and in the package leaflet (PL) for all medicines.

Development of the draft proposals Steps taken

- The Quality Review of Documents (QRD) group, together with the Medical Information Sector at the EMA, has worked on the **draft proposals** to be implemented in the product information.
  - First draft agreed in November 2011.
- December 11 - Consultation on the draft proposal with patients, consumers and healthcare professionals organisations.
- January/February 2012 – Consultation on the amended draft proposal with the EMA/Member States (PhV project teams).
- 28 February 2012 – Status update PCWP/HCP WG Joint meeting.
- 1 March 2012 - Status update to the QRD group.

Development of the draft proposals Current status

- The draft proposal was further amended based on the comments received from the EMA and Member States (PhV project teams) during the consultation held in Jan/Feb 12.
- Further consultation on the amended draft proposal has/is taken place:
  - 10-17 April 2012 – Consultation with the EMA/Member States [Project Coordination Group (PCG)].
  - 23 April–10 May 2012 – Consultation with pharmaceutical industry associations and the Pharmacovigilance Working Party (PhWP).

Amended draft proposal (latest version) Additional monitoring

- Summary of product characteristics (SmPC)

<{Black symbol*} This medicinal product is subject to additional monitoring to allow any safety information to be identified rapidly. Healthcare professionals are encouraged to report any suspected adverse reactions. See section 4.8.>

1. NAME OF THE MEDICINAL PRODUCT

<{Black symbol}>{(Invented) name strength pharmaceutical form}

- Package leaflet

<{Black symbol}> {(Invented) name strength pharmaceutical form}
{Active substance(s)}

<{Black symbol} This medicine is subject to additional monitoring to allow any safety information on the medicine to be identified rapidly. You can help by reporting any side effects you may get*. See section 4.>

Amended draft proposal (latest version) Encouragement side effect reporting

- Summary of product characteristics (SmPC)

4.8 Undesirable effects

Reporting of suspected adverse reactions

Reporting suspected adverse reactions is an important way to continuously monitor the benefit/risk balance of the medicinal product in the real conditions of use. Any suspected adverse reactions should be reported according to {insert information on the relevant 'national reporting system' – *details will be defined at national level*}.

- Package leaflet

4. Possible side effects

Reporting of side effects

If you get any side effects, talk to your <doctor> <or> <,> <pharmacist> <or nurse>. This includes any possible side effects not listed in this leaflet. You can also report any side effects directly to the national reporting system via the internet at {insert link to the relevant 'national reporting system website' - *details will be defined at national level*}; alternatively you can report via {insert alternative ways of reporting – *details will be defined at national level*}. By reporting side effects you can help provide more information on the safety of this medicine.

Development of the draft proposals
Next steps

- 24 May 2012 – Possible finalisation of the proposals with the QRD group (otherwise the proposals will be finalised by written procedure during June/July 2012).
- Public consultation of the human QRD template including the proposals (1 month).
- Final proposal and collated information to be provided to the Pharmacovigilance and Risk Assessment Committee (PRAC).

Thank you!