EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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

Patients and consumers organisation training session
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Product information Quality

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Legal basis

- There are certain aspects of the implementation of the new pharmacovigilance (PhV) legislation, which have an impact on the product information:

1) 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. *(Art. 11 and 59 of Directive 2001/83/EC and Art. 23(5) of Regulation (EC) No 726/2004).*

- The package leaflet will tell you if the medicine you are taking is under additional monitoring

Legal basis

2) 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. *(Article 107a(1) (Art. 11 of Directive 2001/83/EC and Art. 59 of Directive 2001/83/EC).*

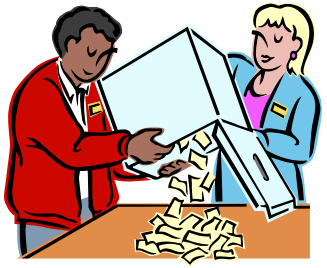
- *You will now have the possibility to directly report side effects to the national authorities (via the internet and alternatives ways defined at national level (e.g. phone, mails..) and the leaflet will tell you how!!*

Implementation of the new legislation
Development of the draft proposals

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.

- 1st step: analysis and discussion on the data provided by the Member States (use national experience, if any, already in place)

- 2nd step: several rounds of consultation (internal and public consultations)



Implementation of the new legislation

Who did we consult?

ALL the different stakeholders!!

- 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.
- CROs specialised in user testing/communication experts
- academia

Why a black inverted triangle to identify products under additional monitoring?

- Abstract symbol not linked to a meaning/connotation, which is less likely to cause confusion/wrong interpretation or alarm to patients
- Does not clash with other symbols already established for pharmaceuticals.
- Solid representation and easy to reproduce in a consistent manner.
- Symbol already in use in two MSs for similar pharmacovigilance activities, therefore (BE and UK).
- The black inverted triangle (▼) was the preferred option of patients, consumers and healthcare professionals.

Black Triangle Scheme : MHRA - Windows Internet Explorer

http://www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/Reportingsuspectedadversedrugreactions/Healthcareprofessionalreporting/BlackTriangleScheme/index.htm

Favorites | Web Slice Gallery | 03 PIQ-QRD Tasks

Black Triangle Scheme : MHRA

In Healthcare professional reporting

- What to report
- How to report
- Points to consider when assessing causality
- Adverse drug reactions
- Serious and severe reactions
- Frequently asked questions

Home › Safety information › Reporting safety problems › Adverse drug reactions › Healthcare professional reporting ›

Black Triangle Scheme

This section provides information about reporting suspected adverse drug reactions for healthcare professionals. Information for patients is available in the 'Patient reporting of suspected adverse drug reactions' section (please see 'Related information on the right of this page').

Printer friendly version (new window)

Related information:

MHRA pages:

- Commission on Human Medicines
- Patient reporting of adverse drug reactions
- Reporting safety problems

Other sites:
(open in a new window)

- British National Formulary (BNF)

Help viewing PDFs:

- Help viewing PDF files
- Download Acrobat Reader for free
- Adobe text conversion tools

What are Black Triangle drugs (▼)?

When medicines come onto the market, we have relatively limited information about their safety from clinical trials in the UK. These trials generally involve only small numbers of eligible patients who take the medicine for a relatively short period of time. Therefore, patients in clinical trials may not be fully representative of those who will use the medicine when it is marketed.

Only when large numbers of patients have taken a medicine are rare or long-term adverse effects identified. Therefore, effective surveillance after marketing is essential for the identification of rare adverse effects, and to ensure that appropriate action is taken.

New medicines are intensively monitored to ensure that any new safety hazards are identified promptly. The Commission on Human Medicines (CHM) and the MHRA encourages the reporting of all suspected reactions to newer drugs and vaccines, which are denoted by an inverted Black Triangle symbol (▼). This symbol appears next to the name of a relevant product:

- the British National Formulary (BNF)

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Agence Fédérale des Médicaments et des Produits de Santé

Centre Belge de Pharmacovigilance pour les médicaments à usage humain (CBPH)

▼ Liste des médicaments qui font l'objet d'une attention particulière

JUIN 2012 : MEDICAMENTS A BASE D'UN NOUVEAU PRINCIPE ACTIF OU NOUVEAUX MEDICAMENTS BIOLOGIQUES

(classés par principes actifs)

▼

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

- Final endorsement of the statements by CHMP(Dec 12).
- Statements will then be translated in all EEA languages
- Publication of the new template in March/April 2013 (TBC)
  - Once the black symbol is selected by the EC.
- Communication is key in the success of the implementation and recognition of the black triangle by patients and healthcare professionals across Europe.
- **You can help us launch an awareness campaign and convey the information to your members.**

THANKS