Black Triangle Scheme - new medicines and vaccines subject to EU-wide additional monitoring

This document provides information about the Black Triangle scheme – a system to identify medicines that are being monitored particularly closely by regulatory authorities.

Contents

Medicines under additional monitoring

Medicines that are being monitored particularly closely by regulatory authorities in the European Union (EU) are described as being under 'additional monitoring'. Medicines under additional monitoring will have an inverted Black Triangle displayed in their patient information leaflet and in the information for healthcare professionals called the summary of product characteristics, together with a short sentence:

> ▼ This medicinal product is subject to additional monitoring.

Although the Black Triangle has been in place in the UK for many years to signify medicines that are subject to intensive monitoring, it will now be used in all EU Member States and the list has been agreed Europe-wide. For the first time in EU countries, the Black Triangle will start appearing in the package leaflets of the medicines concerned from the autumn of 2013. It will not appear on the outer packaging or labelling of medicines.

Summary of Product Characteristics wording

For medicinal products subject to additional monitoring ONLY:

The black symbol and the statements should only appear preceding section 1. The black symbol shall be a black inverted equilateral triangle: the symbol shall be proportional to the font size of the subsequent standardised text and in any case each side of the triangle shall have a minimum length of 5 mm. For the purpose of preparing the product information annexes please use the black triangle as presented in the template.

> ▼ 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.

For ALL medicinal products the following sub-heading should appear at the end of section 4.8

> **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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

Patient Information Leaflet wording

For medicinal products subject to additional monitoring ONLY:
The black symbol and the statements should only appear immediately after the declaration of the name of the medicine. The black symbol shall be a black inverted equilateral triangle: the symbol shall be proportional to the font size of the subsequent standardised text and in any case each side of the triangle shall have a minimum length of 5 mm. For the purpose of preparing the product information annexes please use the black triangle as presented in the template.

> ▼ 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.

For ALL medicinal products the following sub-heading should appear at the end of section 4

> **Reporting of side effects**
> If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard
> By reporting side effects you can help provide more information on the safety of this medicine.

What are Black Triangle medicines (▼)?

Medicines regulatory authorities such as the MHRA license medicines after rigorous assessment of evidence including clinical trial data to ensure medicines meet required standards of safety, quality and efficacy. Clinical trials involve a relatively small number of patients for a limited period of time. Patients in clinical trials are carefully selected and followed up very closely under controlled conditions. In a real-life setting, a larger and more diverse group of patients will use the medicine; they may have other diseases; and they may be taking other medicines. Some less common side effects may only occur once a medicine has been used for a long time by a large number of people. It is therefore vital that the safety of all medicines continues to be monitored while they are in use.

Information is continuously collected after a medicine is placed on the market to monitor real-life experience with the product. The MHRA closely monitors this information, alongside other regulators, to make sure that the benefits of medicines continue to outweigh their risks. The same monitoring methods are used across the EU so that information gathered in individual countries can be shared. This provides a wealth of knowledge for regulators to rely upon when making decisions, and enables them to act quickly to ensure patient safety when required, such as providing warnings to patients and healthcare professionals or restricting the way a medicine is used.

In the UK the Commission on Human Medicines (CHM) and the MHRA encourages the reporting of all suspected adverse reactions (side effects) to newer drugs and vaccines, which are denoted by the Black Triangle symbol ▼. This symbol appears next to the name of a relevant product:

- in the British National Formulary (BNF)
- in the British National Formulary for Children (BNFC)
- in Monthly Index of Medical Specialties (MIMS)
- in the Association of the British Pharmaceutical Industry (ABPI) Medicines Compendium
- on advertising material
- in Drug Safety Update
- Summaries of Product Characteristics and Patient Information Leaflets - starting to appear from Autumn 2013

Why is a Black Triangle assigned to a medicine (▼)?

All medicines are carefully monitored after they are placed on the market. If a medicine carried the Black Triangle symbol, this means that it is subject to intensive monitoring. This is because we have relatively limited information about their safety from clinical trials as these trials generally involve only small numbers of eligible patients who take the medicine for a relatively short period of time. Patients in clinical trials may not be fully representative of those who will use the medicine when it is marketed. The Black Triangle symbol does not mean that the medicine is unsafe.

A Black Triangle (additional monitoring status) is always assigned to a medicine if:

- it contains a new active substance; new medicines or vaccines authorised on or after January 2011 are assigned a Black Triangle
- it is a biological medicine, such as a vaccine or a medicine derived from plasma (blood);

- it has been given a conditional approval (where the company that markets the medicine must provide more data about it) or approved under exceptional circumstances (where there are specific reasons why the company cannot provide a comprehensive set of data);
- the company that markets the medicine is required to carry out additional studies: for instance, to provide more data on long-term use of the medicine, or on a rare side effect seen during clinical trials.

Other medicines can also be placed under additional monitoring, on request from the MHRA or other regulators if the request is then approved by the European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC) (external link). Medicines will be typically assigned a Black Triangle for a period of five years. Medicines may continue to have a Black Triangle if this is requested by regulators taking into account the time needed to complete the obligations place on a medicine marketing authorisation. A medicine previously removed from the list may be reinstated if new conditions related to monitoring of risks and benefits of a medicine are imposed after the granting of the marketing authorisation.

List of Black Triangle (additionally monitored) medicines

A European list of medicines under additional monitoring has been published by the European Medicines Agency. It was first published in April 2013, and will be reviewed every month by the PRAC.
A medicine can be included on this list when it is approved for the first time or at any time during its lifecycle. A medicine remains under additional monitoring usually for five years or until the PRAC are satisfied that it can be removed from the list. There may be a delay between the decision to add or remove a medicine from this list and the time when its updated package leaflet (displaying the Black Triangle or not, respectively) comes into circulation. This is because it takes some time for the updated package leaflet to gradually replace older stock already on the EU market.
The up-to-date list of medicines under additional monitoring is published each month on the MHRA website. For more information, see the list of medicines under additional monitoring.

Reporting suspected adverse drug reactions to a Black Triangle medicine (▼)?

Reporting suspected side effects is an important way to gather more information about medicines on the market. Regulatory authorities look at reports of side effects alongside all other information available to make sure that the benefits of medicines remain greater than their risks, and to take any necessary action.

For health professionals and patients
The MHRA requests that all suspected reactions to Black Triangle medicines are reported to the Yellow Card Scheme so that any new emerging information can be analysed. To report a Yellow Card please visit www.mhra.gov.uk/yellowcard.

For the pharmaceutical industry
For the reporting of adverse reactions associated with Black Triangle medicines marketed by a particular company, the same rules apply for all medicines. The general requirements for managing products subject to additional monitoring is detailed in the Good Vigilance Practice module X additional monitoring (external link).

For information on reporting requirements for the pharmaceutical industry please see the Questions and Answers page under the New Pharmacovigilance Legislation webpage.

Transition to the European-wide Black Triangle (additional monitoring) system

The Black Triangle Scheme for intensive monitoring of medicines has run for many years in the UK, but the concept of additional monitoring and the black symbol were introduced EU-wide by new EU laws on the safety-monitoring of medicines, called the pharmacovigilance legislation, which came into effect in 2012.
From 25 April 2013 medicines under additional monitoring indicated by the Black Triangle will be published in an EU-wide list. There will be requirements for Patient Information Leaflets and Summaries of Product Characteristics to include information about the Black Triangle and reporting of adverse drug reactions.
Any new medicine authorised after 1 September 2013 which is subject to additional monitoring will include the black symbol in the package leaflet and the summary of product characteristics when it is placed on the EU market.
The legislation affects medicines authorised in the EU after 1 January 2011. Therefore, there will be a transition period for medicines authorised between January 2011 and August 2013 while their updated package leaflets gradually replace older stock.
Any materials distributed to patients and healthcare professionals about a medicine subject to additional monitoring, will contain information on its additional monitoring status.

For questions and answers in relation to the new pharmacovigilance legislation, the Black Triangle Scheme and additional monitoring please visit the additional monitoring section of our website.

The Black Triangle (▼) on advertising material

Material for distribution to healthcare professionals and patients should include the Black Triangle status and should make all efforts to encourage reporting of adverse reactions. The wording provided above for the SPC may be used to achieve this. Specifications for the Black Triangle symbol can be found in the ABPI Code of Practice for the Pharmaceutical Industry (external link).

Patient support material wording

Specifications for the Black Triangle and adverse drug reaction reporting text can be found in the ABPI Code of Practice for the Pharmaceutical Industry (external link).

List of Black Triangle medicines (under additional monitoring)

The latest lists of Black Triangle (additional monitoring) medicines are available on the European Medicines Agency website (external link).

Contact

For specific Black Triangle enquiries please contact us at: blacktriangle@mhra.gsi.gov.uk