EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 April 2013
EMA/244682/2013

Medicines under additional monitoring

The European Union (EU) has introduced a new process to label medicines that are being monitored particularly closely by regulatory authorities. These medicines are described as being under 'additional monitoring'.

Medicines under additional monitoring have a black inverted triangle displayed in their package leaflet and in the information for healthcare professionals called the summary of product characteristics, together with a short sentence explaining what the triangle means:

▼ This medicinal product is subject to additional monitoring.

The black triangle will be used in all EU Member States to identify medicines under additional monitoring. It 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.

What does the black triangle mean?

All medicines are carefully monitored after they are placed on the EU market. If a medicine is labelled with the black triangle, this means that it is being **monitored even more intensively** than other medicines. This is generally because there is less information available on it than on other medicines, for example because it is new to the market or there is limited data on its long-term use. It does not mean that the medicine is unsafe.

Additional monitoring status is always applied to a medicine in the following cases:

- it contains a new active substance authorised in the EU after 1 January 2011;
- it is a biological medicine, such as a vaccine or a medicine derived from plasma (blood), for which there is limited post-marketing experience;
- 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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7129
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

Other medicines can also be placed under additional monitoring, based on a decision by the European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC).

European list of additionally monitored medicines

A European **list of medicines under additional monitoring** is available. The European Medicines Agency first published this list in April 2013, and it is 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 life cycle. A medicine remains under additional monitoring for five years or until the PRAC decides to remove it from the list.

There may be a delay between the decision to add or remove a medicine from this list and the time when the updated package leaflet comes into circulation. This is because it takes some time for the updated package leaflet to gradually substitute older stock already on the EU market.

The up-to-date list of medicines under additional monitoring can always be found on the European Medicines Agency's website and is also published by the national medicines regulatory authorities in the EU Member States. The list is reviewed every month.

For more information, see the list of medicines under additional monitoring:
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/04/WC500142453.pdf

Why are medicines monitored after they are approved?

European regulatory authorities decide to authorise medicines after assessing their **benefits and risks** based on the results of clinical trials.

Only medicines whose benefits have been shown to be greater than their risks can reach the market. This ensures that patients can access the treatments they need without being exposed to unacceptable side effects.

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 commercial use.

Information is continuously collected after a medicine is placed on the market to monitor real-life experience with the product. European regulatory authorities closely monitor this information to make sure that the benefits of medicines continue to outweigh their risks.

The same monitoring methods are used across the EU so that European regulatory authorities can share the information gathered in individual EU countries. 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.

Reporting side effects

Reporting **suspected side effects** is an important way to gather more information on medicines on the market. Regulatory authorities look at reports of side effects alongside all the information they

already have to make sure that the benefits of medicines remain greater than their risks and to take any necessary action.

Patients and healthcare professionals are encouraged to report suspected side effects seen with any medicine. Under the new pharmacovigilance legislation, patients have the right to report suspected side effects directly to the national medicines regulatory authorities in their country if they wish. Information on how to do this must be given in each medicine's package leaflet and summary of product characteristics.

The black triangle makes it possible to quickly identify medicines that are subject to additional monitoring. Patients and healthcare professionals are strongly encouraged to report any suspected side effects with medicines displaying the black triangle, so that any new emerging information can be analysed efficiently.

Introduction of the new European system

The concept of additional monitoring and the black symbol were introduced by new EU laws on the safety-monitoring of medicines, called the **pharmacovigilance legislation**, which started to come into effect in 2012.

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 substitute older stock on the EU market.

If educational materials are distributed to patients and healthcare professionals about a medicine subject to additional monitoring, these will contain information on its additional monitoring status.

The up-to-date list of medicines under additional monitoring can always be found on the European Medicines Agency's website and is also published by the national medicines regulatory authorities in the EU Member States. The list is reviewed every month.