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Press Office

Press release

European Medicines Agency publishes a video explaining the concept of medicines under additional monitoring

A back triangle will start appearing on product information this autumn to encourage reporting of suspected adverse reactions

The European Medicines Agency has published a video and a factsheet in all official European Union (EU) languages today explaining the meaning of the black triangle, which is now starting to appear in the product information of certain authorised medicines in the EU. The black triangle has recently been introduced in the EU as part of the concept of medicines under additional monitoring and is an important deliverable of the new European pharmacovigilance legislation.

Medicines under additional monitoring are being monitored particularly closely by European regulatory authorities. Their package leaflet and the information for healthcare professionals, called the summary of product characteristics (SmPC), have to display an inverted back triangle together with a short sentence that reads:

▼ This medicinal product is subject to additional monitoring.

The back triangle will start appearing on the product information of medicines that are subject to additional monitoring more and more over the next few months, including in the printed package leaflet that comes with the medicine.

All medicines on the EU market are carefully monitored. If a medicine is labelled with the inverted black triangle, it does not mean that it is unsafe; the purpose of the symbol is to actively encourage healthcare professionals and patients to report any suspected adverse reactions observed with the medicine, either because the medicine is new to the market or because there is a limitation to the data available on its safety.

Regulatory authorities continuously collect information to monitor real-life experience with medicines. Reporting suspected adverse reactions is an important way to gather more information on medicines on the market. In a real-life setting, where a larger and more diverse group of patients use the medicines, less common side effects may be observed. Regulatory authorities look at all reports of adverse reactions, 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 to optimise safe and effective use.

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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), authorised in the EU after 1 January 2011;
- 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, based on a decision by the Agency's Pharmacovigilance Risk Assessment Committee (PRAC).

The list of medicines under additional monitoring is reviewed every month by the PRAC and published on the Agency's website, where additional information on additional monitoring can also be found in all EU languages.

Notes

1. This press release, together with all related documents, is available on the Agency's website at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/09/news_detail_001900.jsp&mid=WC0b01ac058004d5c1.
2. The video and other information materials are available at: http://www.ema.europa.eu/ema/index.jsp?curl=/pages/special_topics/general/general_content_000586.jsp.
3. More information on additional monitoring of medicines is available at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/document_listing/document_listing_000365.jsp&mid=WC0b01ac058067bfff.
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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