EUROPEAN MEDICINES AGENCY
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Press Office

Press release

European Medicines Agency publishes initial list of medicines under additional monitoring

The European Medicines Agency has published today the initial list of medicines that are subject to additional monitoring. This represents an important deliverable of the new European pharmacovigilance legislation. These medicines will have to display an inverted back triangle in their package leaflet and in the information for healthcare professionals called the summary of product characteristics (SmPC), together with a short sentence explaining what the triangle means.

All medicines on the European Union (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.

Reporting suspected adverse reactions is an important way to gather more information on medicines on the market. Regulatory authorities look at 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.

Medicines that are subject to additional monitoring are:

- medicines authorised after 1 January 2011 that contain a new active substance;
- biological medicines for which there is limited post-marketing experience;
- medicines with a conditional approval or approved under exceptional circumstances;
- medicines for which the marketing-authorisation holder is required to carry out a post-authorisation safety study (PASS).

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

A medicine can be included on this list when it is approved for the first time or at any time during its lifecycle. It remains under additional monitoring for five years or until the PRAC decides to remove it

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from the list usually because studies have further established the safety profile of the product concerned. The complete additional-monitoring list will be 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.

Implementation plan

The inverted black triangle will start appearing in the package leaflet and SmPC of the medicines concerned from the autumn of 2013.

Marketing-authorisation holders of medicines on the list are required to update the product information to include the new black symbol and explanatory text using the latest version of the product-information templates. They should start to include new information in the product information during the course of 2013.

- For new medicines, the Agency encourages marketing-authorisation applicants to start using the new product-information template if an opinion from the Committee for Medicinal Products for Human Use (CHMP) is expected in May 2013. Any new medicine on the list authorised after 1 September 2013 will include the black symbol in the package leaflet and the summary of product characteristics when it is placed on the EU market.
- For medicines that are already authorised, marketing-authorisation holders are encouraged to use the new template at the next regulatory procedure affecting the product information. If there are no such procedures, companies should submit a type-IA_{IN} variation no later than 31 December 2013.

An implementation plan outlines the exact regulatory process and timeline the companies need to follow to comply with these new requirements.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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