



**EUROPEAN COMMISSION**

**PRESS RELEASE**

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## **Pharmaceuticals: New symbol ▼ to identify medicines undergoing additional monitoring**

An inverted triangle will shortly appear on the inside leaflet of certain medicinal products on the EU market, following a legal act adopted by the European Commission today.

The symbol will allow patients and health care professionals to easily identify medicinal products that are undergoing **additional monitoring**, and its accompanying text will encourage them to report unexpected adverse reactions through national reporting systems.

Tonio Borg, European Commissioner for Health and Consumer Policy said: *"The symbol is easy to recognise for patients and healthcare professionals. It will help to obtain more and better information from them on possible side effects of a medicine which then can be thoroughly analysed. Stronger involvement of patients in the reporting on side effects is an integral part of Europe's pharmacovigilance system and – once in place - the new symbol will contribute to strengthen what is already one of the most advanced systems in the world."*

From September 2013, the symbol will be used to identify these pharmaceutical products that are subject to additional monitoring:

- All medicinal products authorised after 1 January 2011 that contain a new active substance
- Biological medicinal products, such as vaccines or plasma derived products, authorised after 1 January 2011
- Products for which certain additional information is required post-authorisation, or for which authorisation is subject to conditions or restrictions on their safe and effective use.

## Background

Once a medicinal product has been authorised in the Union and placed on the market, its **safety is monitored throughout its entire lifespan** to ensure that, in case of adverse reactions that present an unacceptable level of risk under normal conditions of use, it is rapidly withdrawn from the market. This is done through the EU system of **pharmacovigilance**.

The EU pharmacovigilance system is one of the most advanced and comprehensive systems in the world ensuring a high level of public health protection throughout the Union. [EU pharmacovigilance legislation](#) underwent a major review that led to the adoption of new legislation in 2010 to strengthen and rationalise the system for monitoring the safety of medicines on the European market and improves patient safety and public health through better prevention, detection and assessment of adverse reactions to medicines. The **Regulation adopted today is an Implementing Act of this legislation**.

For more information on pharmacovigilance:

[http://ec.europa.eu/health/human-use/pharmacovigilance/index\\_en.htm](http://ec.europa.eu/health/human-use/pharmacovigilance/index_en.htm)

Commissioner Borg's website:

[http://ec.europa.eu/commission\\_2010-2014/borg/index\\_en.htm](http://ec.europa.eu/commission_2010-2014/borg/index_en.htm)

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