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Press Office

Press release

Information on suspected side effects of nationally authorised medicines now available through a single website

EMA encourages patients to report suspected side effects

As of today, European citizens can obtain information on suspected side effects, also known as suspected adverse drug reactions, of an additional 1,700 active substances contained in medicines approved in the European Union (EU) through a website maintained by the European Medicines Agency (EMA), www.adrreports.eu.

The website launched in 2012 previously only contained information on suspected side effects reported with centrally authorised medicines. Its expansion now also allows the public to access the relevant information for medicines approved by national authorities in the EU.

Suspected side effects are reported by patients, consumers and healthcare professionals. These reports are suspected but not necessarily established side effects. They may not be related to or caused by the medicine.

National medicines regulatory authorities or pharmaceutical companies that hold the marketing authorisation for the medicine concerned are obliged to transmit these reports electronically to EudraVigilance, the European database of suspected side effects reported with medicines authorised in the European Economic Area (EEA). The information made available through the public website comes directly from EudraVigilance.

Spontaneous reports of suspected side effects provide regulatory authorities with important information which is used to monitor the safety of a medicine. Throughout a medicine's lifecycle, regulatory authorities analyse all reports together with all other available information on the medicines, to make sure that their benefits remain greater than their risks and to optimise their safe and effective use. Each report available on the public website pulls together the total number of individual suspected side effects reports submitted to EudraVigilance. These aggregated data can be viewed by age group, sex, type of suspected side effect and outcome.

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How to report side effects?

The EMA has published a leaflet in all official EU languages to encourage patients to report side effects. These reports help 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.

Therefore, the European pharmacovigilance legislation has introduced the possibility for patients to report side effects directly to the authorities in all EU Member States. The leaflet explains how patients can report side effects and includes contact details for all Member States.

After the legislation entered into force in July 2012, the number of side effects reported directly from patients to national regulatory authorities or pharmaceutical companies within the EEA has increased significantly. In the second year of operation of the legislation, EudraVigilance received 35,600 patient reports compared to 21,600 in the year preceding the legislation. This is in addition to reports received from healthcare professionals.

Notes

- This press release, together with all related documents, is available on the Agency's website.
- The leaflet on how to report side effects is available for the Agency's website and on www.adrreports.eu
- The figure of 1,700 active substances represents a major subset of all active substances contained in nationally authorised medicines in the EU. Roll-out of public access to suspected side effects related to all medicines available in the EU will occur gradually over the next few years.
- More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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