EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 May 2012
EMA/258738/2012
Press Office

Press release

European Medicines Agency boosts EU transparency with online publication of suspected side effect reports

Member States and the Agency release data on medicines in compliance with EudraVigilance access policy

The European Medicines Agency has today begun publishing suspected side effect reports for medicines authorised in the European Economic Area (EEA) on a new public website: www.adrreports.eu. The reports come directly from the European Union (EU) medicines safety database EudraVigilance, and are one of the many types of data used by regulators to monitor the benefits and risks of a medicine once authorised. The launch of the new website is part of the Agency's continuing efforts to ensure EU regulatory processes are transparent and open and is a key step in the implementation of the EudraVigilance access policy.

The information published today relates to approximately 650 medicines and active substances authorised through the centralised procedure, which is managed by the Agency. Information on the website is presented in the form of a single report per medicine or active substance. Each report pulls together the total number of individual suspected side effect reports submitted to EudraVigilance by Member States and marketing authorisation holders. These aggregated data can be viewed by age group, sex, type of suspected side effect and by outcome. Within a year the Agency aims to additionally publish suspected side effect reports for common drug substances used in nationally authorised medicines.

A side effect (also known as an adverse drug reaction) includes side effects arising from use of a medicine within the terms of the marketing authorisation as well as from use outside the terms of the marketing authorisation, including overdose, misuse, abuse and medication errors, and those associated with occupational exposure.

All information on the website relates to suspected side effects. Suspected side effects may not be related to or caused by the medicine, and as a result, the published information cannot be used to determine the likelihood of experiencing a side effect or as an indication that a medicine is harmful**.** All users of the website are asked to read and accept a disclaimer explaining how to understand the information before they view a web report.

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Medicines are an important part of modern healthcare, providing effective treatments for many diseases and conditions. For a medicine to be authorised for use in the EU the benefits of the medicine must always outweigh the risks.

Today's launch also highlights the importance of side effect reporting and pharmacovigilance in safeguarding public health within the European Union. Side-effect reporting is a key element in ensuring the detection of new or changing safety issues, and the Agency continues to further strengthen its work with partners and stakeholders across Europe to ensure a robust system for safety signal detection.

In June, the Agency will launch the website in the remaining 22 official EU languages.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The European database of suspected adverse drug reaction reports: http://www.adrreports.eu
3. Patients, consumers and healthcare professionals report suspected side effects to either the national medicines regulatory authority or the pharmaceutical company that holds the marketing authorisation for the medicine. These reports are then transmitted electronically to EudraVigilance. The Agency, on behalf of European Member States, is responsible for the development, maintenance and coordination of EudraVigilance.
4. Pharmaceutical companies that hold the marketing authorisation for a medicine in the EEA are also legally required to submit to EudraVigilance all reports of suspected unexpected adverse reactions that are serious and that occurred in a third country (non-EEA) where they hold a marketing authorisation. The web reports present information on suspected side effects that have occurred in both the EEA and outside the EEA.
5. A web report does not include reports from studies (e.g. clinical trial, non-interventional study) or other types of reports (i.e. they only include spontaneous reports).
6. Web reports can only be viewed with Adobe Reader 10.x and Adobe FlashPlayer 10.2.
7. Frequently asked questions and a short guide on how to interpret web reports are available.
8. The Management Board of the European Medicines Agency approved the EudraVigilance Access Policy in December 2010. The EudraVigilance Access Policy describes how stakeholders, such as national medicines regulatory authorities in EEA countries, healthcare professionals, patients and consumers, as well as marketing authorisation holders and research organisations, can access information on suspected side effects submitted electronically to EudraVigilance.
9. More information on the 2010 pharmacovigilance legislation can be found on the Agency's website.
10. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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