EUROPEAN MEDICINES AGENCY
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Press Office

Press release

Increasing access to reports on adverse reactions to medicines

Revised EudraVigilance access policy is adopted by EMA Management Board

The European Medicines Agency (EMA) will give increased access to reports on suspected adverse reactions to medicines authorised in the European Union (EU), while guaranteeing that personal data will be fully protected. This is the outcome of a revision of EudraVigilance Access policy, which was adopted by EMA's Management Board at its December 2015 meeting. The adoption followed a broad public consultation generating close to 400 comments which have been taken into account in the final policy.

EudraVigilance is the European database of all suspected adverse reactions reported with medicines authorised in the European Economic Area (EEA). Managed by EMA on behalf of the EU medicines regulatory network, EudraVigilance receives over one million adverse drug reaction (ADR) reports per year. The large datasets included in the database provide the backbone for the continuous safety monitoring of medicines in the EU.

The Agency has made data from EudraVigilance publically available since 2011. At the time, EMA defined levels of access to information on ADR reports for medicines in EudraVigilance per stakeholder group: for European regulators, for healthcare professionals, consumers and patients, for marketing-authorisation holders and for academia. Information from EudraVigilance on centrally authorised products and substances commonly used in medicines is available through a dedicated public website.

The revised policy takes into account the changes to the system of safety monitoring of medicines introduced by the pharmacovigilance legislation, such as new transparency provisions, the introduction of direct patient reporting across all EU Member States and a simplification of the reporting of adverse reaction reports for pharmaceutical companies.

Key changes include:

- The public will have access to more information, including line listings of the side effect reports and summary presentations for individual adverse reaction reports received in EudraVigilance. While ensuring that patients and those who have sent in reports of suspected side effects are not identifiable, this access represents a significant increase in transparency for the users of medicines;

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 8427 **Facsimile** +44 (0)20 3660 5555
E-mail press@ema.europa.eu **Website** www.ema.europa.eu

- Academia will be able to get extended access to data sets upon request in support of their research activities;
- The Uppsala Monitoring Centre (UMC) of the World Health Organization (WHO) will be added as a new stakeholder group who will be provided with individual case safety reports (ICSRs) originating from within the EEA;
- Medicines regulatory authorities in countries outside the EEA will be provided with data, in line with the WHO dataset, upon request;
- Marketing-authorisation holders of medicines authorised in the EU will be given enhanced access to reports related to their medicines in support of their signal detection and other pharmacovigilance obligations.

These changes will come into effect in the third quarter of 2017 in parallel with EMA implementing a series of technical improvements to the EudraVigilance system.

Data transfer agreement with WHO

To allow the transfer of data on suspected adverse reactions occurring in the EEA, EMA and the WHO concluded an agreement earlier this month. The data will be transferred electronically to WHO's UMC on a daily basis. The start of this data transfer in 2017 will follow the introduction of the new reporting rules within the EEA which take effect after a successful audit of the improved EudraVigilance system.

The transferred reports on suspected adverse reactions occurring in the EEA will contribute to VigiBase, the WHO Global Individual Case Safety Report database, on behalf of the WHO Programme on International Drug Monitoring. Better global knowledge on the safety of medicines will also help to promote the safe use of medicines for the benefit of patients worldwide.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The exchange of letters between the WHO, the UMC and EMA took place earlier this month in application of Regulation (EC) 726/2004, requiring the Agency to make available promptly all suspected adverse reaction reports occurring in the EU to the WHO.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

Contact our press officers

Monika Benstetter

Tel. +44 (0)20 3660 8427

E-mail: press@ema.europa.eu

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