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Patient Health Protection

2011 EudraVigilance-Human Annual Report

Explanatory note

The European Medicines Agency plays a key role in the monitoring of the safety of medicines in the European Union (EU). The Agency's main responsibilities in this area include: supporting the coordination of the European pharmacovigilance system; providing information on the safe and effective use of medicines; and managing and maintaining EudraVigilance, the EU information system designed to manage information on safety reports of medicines.

More information on the Agency's work in supporting the European pharmacovigilance system is available on the EMA website.

The European Medicines Agency continuously monitors the safety of medicines for human use authorised in accordance with Regulation (EC) No 726/2004. So-called safety signals may emerge from the sources the Agency screens as part of its safety monitoring. These sources include spontaneous reports held in EudraVigilance (more information on EudraVigilance can be found here), clinical studies and the scientific literature.

A safety signal is information on a new or incompletely documented adverse event that is potentially caused by a medicine and that warrants further investigation[1]. A signal is not a confirmation for a causal relationship with the medicine. The adverse event could be a symptom of another illness or caused by another medicine taken by the patient. The evaluation of safety signals is a routine part of pharmacovigilance and is essential to ensuring that regulatory authorities have the most up-to-date information on a medicine's benefits and risks.

During 2011, EudraVigilance data were analysed at least every month for all centrally authorised medicines. For some medicines this was done more frequently, at least every two weeks. In general, medicines are monitored at least every two weeks if they contain one or more new active substances authorised within the last two years, if they have been authorised in a new patient population within the last two years, if there is a potential safety concern with the medicine or if safety information is limited due to low patient exposure. For details about this process, please refer to SOP/H/3065 - Periodic signal detection for centrally authorised products based on reaction monitoring reports.

[1] A signal is 'information that arises from one or multiple sources (including observation and experiments), which suggests a new potentially causal association or a new aspect of a known association, between an intervention and an event or set of related events, either adverse or beneficial, that is judged to be of sufficient likelihood to justify verificatory action' *(source: Report of the CIOMS working group VIII, Practical Aspects of Signal Detection in Pharmacovigilance, Geneva 2010)*.

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Following the December 2009 Management Board meeting, the Agency introduced a different way of reporting to the Board on the implementation of the EudraVigilance system for medicines for human use, with the primary focus being on how EudraVigilance contributes to the conduct of pharmacovigilance in the EU. In addition, the Agency has continued to provide information on the more technical aspects of the EudraVigilance implementation. In order to increase transparency, the Agency published the annual reports for the years 2009 and 2010.

The present report includes for the first time details on each validated signal which was communicated to CHMP (Committee on Human Medicinal Products) rapporteurs in 2011, as regards product/active substance, nature of the issue and regulatory action/outcome. Details on progress in signal management in the EU and details of requests for information or documents from EudraVigilance are also included. This is followed by an overview of the status of implementation of EudraVigilance-Human.

The Agency would like to highlight that identification of a potential safety signal should not be interpreted as meaning that the medicine or the active substance causes the observed effect or is unsafe to use. Only a detailed evaluation and scientific assessment of all available data allows for robust conclusions to be drawn on the benefits and risks of a medicine. If the risk is confirmed or considered likely to be associated with the medicinal product, regulatory action may be necessary and this usually takes the form of an update of the summary of product characteristics (SmPC) and the package leaflet. Only in a small fraction of cases does a signal lead to safety concerns requiring action beyond labelling, e.g. changes to the Risk Management Plan, restriction of use to populations in which the benefit-risk balance remains positive, gathering further data from additional sources (observational studies, registries, etc.) to better understand the risk etc.

The Agency would like to emphasize that prescribers should not change their practice based on the list of signals included in this report. The European Medicines Agency publishes patient safety information when it recommends major changes to the authorisation of a medicine. These can be viewed on the patient safety page. National medicines regulatory authorities also publish patient safety information related to medicines authorised in their respective countries. See the list of national medicines regulatory authorities in the EEA for contact information.

Likewise, patients should not stop or change medication that has been prescribed for them without prior consultation with a healthcare professional. Any concerns related to a medicine should always be discussed with a doctor or pharmacist. The European Medicines Agency cannot advise individual patients on their treatment or condition.