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Medicinal Products

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Pharmacovigilance: xEVMPD notifications for art. 14 products

ECHAMP position

The pharmacovigilance obligations as defined in title IX (Pharmacovigilance) of Directive 2001/83/EC requires marketing authorization holders (MAH) to register with EMA's EudraVigilance database for the electronic data interchange of pharmacovigilance information. The registration process is a prerequisite for the electronic reporting of Individual Case Safety Reports (ICSRs). Detailed product information has to be deposited in the so-called Article 57 database. Applying the format of the eXtended EudraVigilance Product Report Message (XEVPRM) and the use of the xEVMPD data entry tool (EVWEB) in line with EMA's business rules are mandatory.

In accordance with Article 16(3) of Directive 2001/83/EC, the pharmacovigilance requirements shall apply to homeopathic medicinal products, with the exception of homeopathic medicinal products registered further to the special, simplified registration procedure under Article 14(1) of Directive 2001/83/EC.

Therefore, in accordance with the legislation, there are no reporting obligations for suspected adverse reactions for holders of simplified registrations concerning homeopathic medicinal products.
However, obligations exist based on national rules, e.g. in Germany. The provisions of section 63c German Medicines Act (AMG) setting out all **obligations on documentation and reporting ICSRs** are directed equally towards Marketing Authorization Holders and all other pharmaceutical entrepreneurs placing a medicinal product on the market. **Homeopathic registration procedures are expressly stated**, whereby, according to German law, the notification of Individual Case Safety Reports (ICSRs) must be continued transmitted to the NCA. This group did not need to fill EMA's Data Entry Tool (EVWEB) in the past, as the product details are available at the national competent authority's (NCA) data repository.
The MAH was obliged to collect ICSRs from the NCA's website in a monthly cycle. The goal was to get notice of ICSRs directly sent by doctors, health care professionals or patients.

Six months after the European Medicines Agency has announced that the EudraVigilance database has achieved full functionality for reporting and analysing suspected adverse reactions all reports have to be submitted in a centralized form. As a result, the German legislator has given up its national obligation to provide adverse reaction reports of registered or approved products for pharmaceutical companies in a database (§ 62 Abs. 3 S. 1).

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The continuation of this commitment by the companies should now be generated through regular research in the EudraVigilance Data Analysis System (EVDAS). In fact, the EVDAS line listing report does list cases received in EudraVigilance at this time, received by Post-Authorisation Module (EVPM) or from NCA independently. It is foreseen to replace the xEVMPD data format by the ISO IDMP format and integrate these data into the SPOR data management services. Based on these data (xEVMPD/IDMP) EMA / registration holders would become able to recite verbatim drug and substance information reported in ICSRs against Article 57 medicinal product information. With regard to technical conditions for this necessity we are afraid that in future the registration holder will be obliged to enter the medicinal products and their substances in question in the database referred to in Article 57 (xEVMPD). An obligation which is not required for simplified registered products by the directive.

Conclusion

This obligation can't be accepted because the legal basis is lacking and the workload is an imposition on the entrepreneurs concerned. Moreover, the necessity to report ICSRs of registered homeopathic medicinal products is limited to only a few member states. More pragmatic solutions are necessary as e. g. the BfArM could continue the service to post ICSRs on its website for this product group, because the national authority itself still receives information under national law.