



The European Agency for the Evaluation of Medicinal Products
Human Medicines Evaluation Unit

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PRINCIPLES OF PROVIDING THE WORLD HEALTH ORGANIZATION WITH PHARMACOVIGILANCE INFORMATION

Background

As laid down in Article 25 of Council Regulation (EEC) No 2309/93, the EMEA shall collaborate with the World Health Organization (WHO) on international pharmacovigilance and shall submit promptly to WHO appropriate and adequate information regarding the measures taken in the European Union related to the marketing authorisations of centrally authorised medicinal products which may have a bearing on public health protection in third countries.

Therefore, the CPMP Pharmacovigilance Working Party discussed and agreed during its meeting on 13-14 January 1998 the principles of how to provide the WHO Headquarters in Geneva and the WHO Collaborating Centre for International Drug Monitoring in Uppsala with such pharmacovigilance information¹.

In addition, the Pharmacovigilance Working Party also agreed on the principles for the provision of pharmacovigilance information for non-centrally authorised medicinal products.

Agreed Principles

- **Adverse Drug Reaction Reports**

Adverse drug reactions (ADRs) occurring in the EU will be reported to the WHO Collaborating Centre for International Drug Monitoring by the Member State in whose territory the ADR has occurred. This applies to reports for centrally and non-centrally authorised medicinal products sent to the competent authorities either by health care professionals or by the marketing authorisation holders. ADRs occurring in Luxembourg will be transmitted to the WHO Centre by the French competent authority. ADRs occurring outside the EU will not be reported in order to avoid duplication at the WHO Centre and in particular to respect the information policies of third countries and their agreements with the WHO Centre.

- **Rapid Alerts**

Rapid alerts will be sent for non-centrally authorised medicinal products by the Member States and for centrally authorised products by the EMEA in agreement with the European Commission if definitive measures related to the marketing authorisations of medicinal products (restriction, variation, suspension, withdrawal) are implemented by the competent authority or if the rapid alert informs about a public statement (positive or negative) made by the competent authority.

¹ ADR reports will only be sent to Uppsala.

- **Infofaxes**

Infofaxes will not be sent as they deal with less urgent information usually at an early stage of investigation. This information is therefore in most cases pre-mature.

- **Other Pharmacovigilance Information for Centrally Authorised Products**

The EMEA will inform about any regulatory action concerning centrally authorised medicinal products in case of safety reasons once the Commission Decision is granted. The EMEA will also transmit any other public statements concerning centrally authorised medicinal products.

- **Outcomes of Referrals**

The EMEA will inform about the outcome of a referral procedure initiated in case of safety reasons once the Commission Decision is granted. The EMEA will also transmit any other public statements concerning such products.

- **CPMP Position Statements on Pharmacovigilance Issues**

The EMEA will transmit CPMP Position Statements on pharmacovigilance issues once they are released to the public.

In addition, Member States will provide further information for nationally authorised products according to their legislation and agreements.