

Joining the WHO Programme for International Drug Monitoring

The WHO Programme for International Drug Monitoring provides a forum for WHO member states to collaborate in pharmacovigilance. The administration of the WHO Programme is shared. In accordance with an agreement between WHO and the Government of Sweden, WHO Headquarters, Geneva, is responsible for policy issues while the operational responsibility rests with the Uppsala Monitoring Centre.

Considering the sensitive nature of the data being collected within the Programme, countries contributing such data to the scheme have agreed on certain requirements that should be complied with by countries wishing to join. Collaborating with WHO, being an organization for co-operation between member states, also requires a certain administrative structure in the pharmacovigilance activity. The basic requirements are:

1. General acquaintance with the methodology of spontaneous monitoring

A country joining the WHO Programme must have a programme for collection of individual case safety reports (ICSRs) in place. The national programme should have reasonable funding to ensure continuity of operations and access to appropriate staffing and technical facilities. By operating the programme the managerial staff will acquire the necessary competence needed to interpret information coming from spontaneous adverse reaction monitoring systems. The activities of the national system do not necessarily have to cover the whole country or all sectors of the health-care system.

2. A National Centre for Drug Monitoring must be designated and recognized by the Ministry of Health (or equivalent)

Only WHO member states can join the WHO Drug Monitoring Programme. Each state is represented by a National Centre authorized by the competent national health authority. The administrative affiliation of the National Centre varies between countries. In most cases the National Centre is part of the national drug regulatory authority but it may also be affiliated to a university institution, a hospital department or be integrated with a drug information or poison information service. A central technical advisory committee with expertise to evaluate reports and advise on suitable action is desirable.

3. Technical competence to fulfil reporting requirements to WHO

The main asset of the WHO Drug Monitoring Programme is its database of adverse reaction case reports submitted by the participating countries. Case reports collected in the national drug monitoring programme must be submitted to the WHO Programme in a defined format. Before being admitted to the international scheme the National Centre has to demonstrate that it is capable of submitting data in the required format, as defined in the guidelines issued by the UMC.

A new country is accepted in the Programme provided that individual case safety reports submitted to the WHO database from that country may be freely available for analysis by any investigator, according to policy determined by the WHO. (Patient and reporter identity is not recorded in the WHO database).

Practical procedure for joining the WHO Drug Monitoring Programme

A. A formal application to be admitted as a member of the WHO Drug Monitoring Programme should be sent to WHO Headquarters, Geneva, by the competent health authority of the country.

The application should identify the institution and responsible person representing the country as a National Centre in the WHO Programme.

A country will be regarded as an Associate Member Country from the time the formal membership application is received. Associate Members Countries enjoy most of the services provided to full member countries.

B. A sample of at least 20 ICSRs collected in the national pharmacovigilance programme should be submitted to the UMC. Reporting instructions may be obtained from the UMC. *Please note:* This step may be taken simultaneously or even before a formal application is sent to WHO Headquarters.

The sample reports will be subjected to a check for technical compatibility with the reporting requirements by the UMC staff. Any deviation will be reported back to the National Centre. When compatibility of the reports is ensured, WHO Headquarters will be notified by the UMC. The applying country will subsequently receive a confirmation from WHO Headquarters of its admittance to the Programme.

Additional measures to be taken to facilitate collaboration

The UMC staff need to have access to an up-to-date version of the National Drug Formulary or equivalent in Latin text, in order to identify drug names occurring in the adverse drug reaction reports. Whenever new editions of the formulary are issued, one copy should be made available to the UMC. If a suitable National Drug Formulary does not exist, relevant drug information should be submitted according to some other routine agreed with the UMC staff.

Collaboration between the National Centre and the UMC is greatly facilitated if personal contacts can be established at an early stage. It is thus favourable if a representative of the National Centre can spend some time at the UMC or if one of the UMC staff members is invited to visit the National Centre.

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