

Joining the WHO Programme for International Drug Monitoring (PIDM)

The WHO Programme for International Drug Monitoring (PIDM) provides a forum for WHO Member States (including their territories and areas, as appropriate) to collaborate in pharmacovigilance.

The administration of the WHO PIDM is shared: in accordance with an agreement concluded between WHO and the Government of Sweden, WHO headquarters, Geneva, is responsible for managing policy issues while the operational responsibility rests with Uppsala Monitoring Centre (UMC).

To join the Programme, the following requirements must be met:

1. General acquaintance with the methodology of spontaneous reporting

An applicant wishing to join the PIDM must have, in place, a programme for the collection of individual case safety reports (ICSRs). The 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/area or all sectors of the health-care system.

2. A National Centre for the safety monitoring of medicines and/or vaccines* must be designated and recognized by the Ministry of Health (or equivalent)

Each member in the WHO PIDM is represented by a National Centre* authorized by the competent health authority. The administrative affiliation of the National Centre* varies between members. In most cases, the National Centre* is part of the national drug regulatory authority (or equivalent) but it may also be affiliated to a university, a hospital department or may 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 PIDM is its global database of ICSRs submitted by the participating members. ICSRs collected by the applicant/PIDM member must be submitted to the WHO PIDM in a defined format. Before being admitted to the WHO PIDM the National Centre* has to demonstrate that they are capable of submitting data in the required format, as defined in the guidelines issued by UMC. A new member is accepted in the WHO PIDM provided that ICSRs submitted to the WHO global database by the member may be freely available for analysis according to policy determined by the WHO. (Patient and reporter identity are not recorded in the WHO global database).

*National Centre or other relevant public health institution if the application is submitted by a territory or area.

Practical procedure for joining the WHO Programme for International Drug Monitoring (PIDM)

- A. A formal application to be admitted as a member of the WHO PIDM should be sent to WHO headquarters, Geneva, by the competent health authority. The application should identify the institution and responsible person representing the country (or the territory/area) as a National Centre* in the WHO PIDM. An applicant will be regarded as an Associate Member from the time the formal membership application is accepted. Associate Members enjoy most of the services provided to full members.
- B. A sample of at least 20 ICSRs collected in the pharmacovigilance programme should be submitted to UMC. Reporting instructions may be obtained from 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 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 UMC. The applicant will subsequently receive a confirmation from WHO headquarters of its admittance to the WHO PIDM.

Additional measures to be taken to facilitate collaboration: UMC's 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 mentioned in the ICSRs. Whenever new editions of the formulary are issued, one copy should be made available to UMC. If a suitable National Drug Formulary or equivalent does not exist, relevant drug information should be submitted according to some other routine agreed with UMC staff. Collaboration between the National Centre* and 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 UMC or if one of UMC's staff members is invited to visit the National Centre*.

For further information, please contact:

World Health Organization

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