WHO Department of Essential Drugs and Medicines Policy
Quality Assurance and Safety: Medicines

ADVISORY COMMITTEE ON SAFETY OF MEDICINAL PRODUCTS[1]
Terms of Reference

Functions

The Advisory Committee on Safety of Medicinal Products shall provide advice to the Director-General and as appropriate through him to the Collaborating Centre for International Drug Monitoring (*the* Uppsala Monitoring Centre), and to the Member States of WHO, on pharmacovigilance policy and issues related to the safety and effectiveness of medicinal products. It shall perform this function by providing advice to the WHO secretariat on general and specific issues related to pharmacovigilance that:

1. are important to national or international programmes and have the potential to affect them adversely if not resolved;
2. cannot be met by structures and/or institutions and/or systems that are already available;
3. respond to identified needs of a country that may be beyond the capability of country or countries themselves; such responses should be made within an appropriate timeframe, taking into account any existing information and the urgency of the issue; and/or
4. are likely to have policy implications for countries and to meet policy needs including policy needs throughout WHO (the latter includes the conduct of and future developments in pharmacovigilance in all programmes throughout WHO);
5. will advance and promote the future developments of pharmacovigilance as a discipline.

The Committee shall respond through WHO to national regulatory authorities and to national programmes, notably public health programmes, on highly technical or scientific issues where the implications are controversial, and on policy and research issues where these may be problematic. The Advisory Committee in its work shall also serve to further the principles and scope of pharmacoepidemiology to promote communication in this field, and to encourage training and capacity building in countries where there is little activity in the field of pharmacovigilance. It shall have the authority to solicit background information, resources permitting, data and research that may have bearing on its activities.

Composition

The Advisory Committee shall be composed of 12 members drawn from the WHO Expert Advisory Panels for Drug Evaluation and for Drug Policies and Management, and, where appropriate and in consultation with the relevant cluster, from other expert advisory panels. Advisory Committee members are selected by the Director-General

[1]For the purposes of this Committee a medicinal product includes drugs, blood products and other biologicals, and herbal medicines. Vaccines are under the umbrella of the Steering Committee on Immunization Safety.

to represent a wide range of geographical and professional backgrounds, including clinical pharmacology, pharmacovigilance, pharmacoepidemiology, clinical medicine, drug regulation, international public health and risk-assessment. All members shall serve in their personal capacities for an initial period of two years renewable for further terms. Rotation of the members is advisable in order to have fresh input to the Committee. In addition the Committee shall invite expertise for specific issues as necessary from individuals representing UN organizations, professional associations in related fields and other partner agencies who shall attend the meeting in the capacity of observers.

Operation

The Advisory Committee shall meet at least once a year. Additional meetings including teleconferences and videoconferences will be held on an ad hoc basis. Contact between meetings should be facilitated electronically. PSM/QSM shall provide the secretariat support to the Advisory Committee. The Advisory Committee shall elect a Chairperson, and a Rapporteur for each meeting from among its members.

The Advisory Committee shall operate in a transparent manner by wide consultation. WHO shall decide on the extent to which the reports or recommendations of the Committee shall be published. It shall also prepare reports on specific issues that may be published as required on an ad hoc basis and/or in the WHO Pharmaceuticals Newsletter as appropriate. An annual report outlining priority needs in the safety of monitoring of medicinal products shall also be prepared.

The Regulations for Expert Advisory Panels and Committees shall apply *mutatis mutandis* to the operation of the Advisory Committee except as otherwise provided herein.