Kenya Becomes 98th Full Member of the WHO Programme for International Drug Monitoring

Kenya has been awarded as the 98th membership to the WHO Programme for International Drug Monitoring.

Through a letter dated 4th May 2010, signed by Dr. Lembit Rägo, Coordinator, Quality Assurance and Safety: Medicines, Essential Medicines and Pharmaceutical Policies of the World Health Organization (WHO), he confirmed that Kenya was the 98th full member with immediate effect. "WHO considers this Programme a vital network in promoting Pharmacovigilance throughout the world" he adds.

The WHO Programme for International Drug Monitoring was set up in 1968 as a consequence of the so-called "Thalidomide tragedy". It was discovered that Thalidomide could cause limb deformities if ingested by mothers during pregnancy became the modern starting point of a science focusing on patient problems caused by the use of medicines. This science and activities associated with it is now most commonly called **PHARMACOVIGILANCE**.

The Programme provides a forum for WHO member states to collaborate in the monitoring of drug safety. Within the Programme, individual case reports of suspected adverse drug reactions are collected and stored in a common database, presently containing over 5 million case reports. In each of the countries participating in the Programme, the government has designated a National Centre for pharmacovigilance.

The WHO Programme, which was established in 1968, consists of a network of the National Centres, WHO Headquarters, Geneva and the WHO Collaborating Centre for International Drug Monitoring, the Uppsala Monitoring Centre, in Uppsala, Sweden. As of May 2010, 98 countries had joined the WHO Drug Monitoring Programme, and in addition, 32 'associate members' were awaiting compatibility between the national and international reporting formats.

Functions of the WHO Programme for International Drug Monitoring include:

- Identification and analysis of **new adverse reaction signals** from the case report information submitted to the National Centres, and sent from them to the WHO ICSR database. A data-mining approach (BCPNN) is used at the UMC to support the clinical analysis made by a panel of signal reviewers
- Provision of the **WHO database as a reference source** for signal strengthening and ad hoc investigations. Web-based search facilities and customized services are available
- **Information exchange** between WHO and National Centres, mainly through 'Vigimed', an e-mail information exchange system
- Publication of **periodical newsletters**, (WHO Pharmaceuticals Newsletter and Uppsala Reports), **guidelines and books** in the pharmacovigilance and risk management area

- Supply of **tools for management of clinical information** including adverse drug reaction case reports. The main products are the WHO Drug Dictionary and the WHO Adverse Reaction Terminology
- Provision of **training and consultancy support** to National Centres and countries establishing pharmacovigilance systems
- Computer **software for case report management** designed to suit the needs of National Centres (VigiFlow)
- Annual **meetings for representatives of National Centres** at which scientific and organizational matters are discussed
- **Methodological research** for the development of pharmacovigilance as a science.

The Programme has become a global network of pharmacovigilance centres in over 120 countries around the world. In each participating country the Ministry responsible for Health has appointed a National Centre for Pharmacovigilance responsible for maintaining contacts with WHO on issues related to medicines safety. **In Kenya, the National Pharmacovigilance Centre located at the Pharmacy and Poisons Board, the Medicines Regulatory Authority in Kenya, located along Lenana Road, Nairobi.**

The Uppsala Monitoring Centre (UMC), the WHO Collaborating Centre for International Drug Monitoring is located in Uppsala, Sweden and manages a database of Individual Case Safety Reports (ICSRs) received from the national centres worldwide. Currently, the database called VigiBase, contains around 5 million ICSRs in which medicines, including vaccines and biologicals, have been suspected of contributing to an adverse reaction in the exposed patient.

The Department of Pharmacovigilance is grateful to all of you who have supported the activities in Kenya by sending Suspected Adverse Drug Reaction reports, Poor Quality Medicines Complaints and supporting in other ways. You are encouraged to continue reporting to ensure patient safety.

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"You need not be certain…

Just be suspicious"

Report all suspected cases of ADRs and Poor Quality Medicines

Remember…