

National pharmacovigilance programme

Safety and efficacy are the two major concerns about any drug. While the efficacy of a drug can be detected with relative ease, the same cannot be said about safety because the adverse effect of a drug may be uncommon but very serious and many patients may be affected or subjected to a potential risk before the relationship with the drug is established. This gave birth to a new branch of pharmacology called pharmacovigilance. By definition, pharmacovigilance is *"the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems. Recently, its concerns have been widened to include herbals, traditional and complementary medicines, blood products, biologicals, medical devices and vaccines"* (WHO, 2002). It is fast emerging as an important approach for the early detection of unwanted effects of the drugs and to take appropriate regulatory actions if necessary. This may ensure the safer use of drugs.

The Uppsala Monitoring Centre (UMC, WHO), Sweden is maintaining the international database of adverse drug reaction (ADR) reports received from several National Centres. In September 2005, the database had 3.5 million adverse drug reaction reports and 78 countries were participating in this programme. Vigibase online (web based) system is used for submission of ADR reports. Although, India is participating in this programme, its contribution to UMC database is very little. This is essentially due to the absence of a vibrant ADR monitoring system and also the lack of a reporting culture among health care workers.

Appreciating the importance and benefits of pharmacovigilance, Central Drugs Standard Control Organization (CDSCO), Ministry of Health and Family Welfare, Govt. of India launched the National Pharmacovigilance Programme (NPP) in November, 2004. It is largely based on the recommendations made in the WHO document titled "Safety Monitoring of Medicinal Products – Guidelines for Setting Up and Running a Pharmacovigilance Centre".

The immediate aim of NPP is to foster the culture of ADR notification by health care workers. Subsequently, it seeks to generate broad based ADR data on the Indian population and share this with UMC, WHO database. This would ensure optimum safety of drug products in the Indian market.

Under this programme, the whole country is divided into zones and regions for operational efficiency. CDSCO, New Delhi is at the top of the hierarchy followed by two zonal pharmacovigilance centres viz, Seth GS Medical College, Mumbai and AIIMS, New Delhi. There are 5 regional

pharmacovigilance centers located at Kolkata (*IPGMR-SSKM Hospitals*), Mumbai (*TN Medical College & BYL Nair Charitable Hospital*), Nagpur (*Indira Gandhi Medical College*), New Delhi (*Lady Hardinge Medical College*) and Pondicherry (*JIPMER*). Twenty eight peripheral centers, spread country-wide, are attached to their nearest peripheral centres.

ADR reports can be sent only by health care workers (doctors including dentists, nurses, pharmacists) to any one of the nearest pharmacovigilance centre. The full list of centres is available at CDSCO web site (www.cdsc.nic.in). Some centres like JIPMER, Pondicherry (www.jipmer.edu) and AIMS, Kochi (www.aimshospital.org) have web based facility for ADR reporting. ADR reports sent by lay public are not acceptable. Data received at the peripheral centres are forwarded to the respective regional centers which will carry out the causality analysis. This information will be forwarded to the zonal centres. From there the data will be forwarded to the CDSCO and UMC database.

The functioning of NPP is to be periodically reviewed by the National Pharmacovigilance Advisory Committee" - a 16 member committee appointed by the Govt. of India. The committee will also evaluate the pharmacovigilance data received from various centres and recommend possible regulatory measures.

ADR monitoring programmes are not new to India. In 1982, five centres were established by Drug Controller General of India for nationwide monitoring of ADR. In 1987, ICMR had collected about 58,000 ADR cases through its multi-institutional study but they all stopped functioning after few years due to several reasons such as insufficient funds, lack of enthusiasm etc. The present programme may be successful since this has been structured taking into consideration the past deficiencies. Three interactive workshops were conducted by CDSCO/WHO for training the participants of the programme. Further, the World Bank has committed to provide US\$1,00,000 for this project. The success of this programme depends on the continuous active support by CDSCO and the dedicated work of the pharmacovigilance centres.

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