Helpline facility to assist reporting of adverse drug reactions in India

Vivekanandan Kalaiselvan, Prabhakar Mishra, Gyanendra N Singh

We wish to draw colleagues’ attention to the launch of a helpline facility for health-care professionals and the public – especially those in rural areas – to report adverse drug reactions to the Indian Pharmacopoeia Commission (IPC). In 2010, the Ministry of Health and Family Welfare, Government of India, launched the nationwide Pharmacovigilance Programme of India (PvPI) to monitor the safety of medicines. IPC, an autonomous institution, established under the Ministry of Health and Family Welfare, Government of India, Ghaziabad, has been functioning as the National Coordination Centre (NCC) for PvPI since April 15th 2011. The main responsibility of the NCC is to monitor adverse reactions to medicines observed in the Indian population and to develop and maintain its own pharmacovigilance database. Adverse drug reaction monitoring centres (AMCs) have been set up across the country by the PvPI; there are currently 150 of these centres, which monitor the adverse drug reactions and report to the NCC. This system allows health-care professionals to report any adverse drug reactions in their areas of work, but may not bridge the gap between general public and NCC.

Therefore, to extend the PvPI to remote areas and to give scope for health-care professionals in corporate hospitals, tertiary hospitals and private clinics, as well as patients, to report adverse drug reactions directly to NCC, a toll-free helpline (1800 180 3024) has been set up by the NCC. This facility, which was launched on 11 October 2013, provides assistance in reporting adverse reactions associated with the use of medicines, with the aim of ensuring patient safety. Essential information, such as what to report, how to report, where to report, etc. is provided on the helpline by a dedicated pharmacist during working hours (Monday to Friday 09:00 to 17:00); outside these hours, callers may leave a message on an interactive voice response system. Health-care professionals and non-health-care professionals can use the helpline to report both serious and non-serious adverse reactions related to any medicinal product, including drugs, vaccines, medical devices, blood products, nutritional/dietary supplements and herbal products. The person reporting is asked whether he or she is a health-care professional, non-health-care professional or patient. Patients/consumers only are also required to provide their name, address and contact details.

The reported information is passed on to the respective AMCs for validation and assessment of causality. It is then entered into VigiFlow, a web-based individual case safety report management system that was specifically designed for use by national centres in the World Health Organization (WHO)-Uppsala Monitoring Centre for International Drug Monitoring. This facility has been upgraded by introduction of an SMS service to acknowledge the reports of adverse drug reactions received through the toll-free helpline. This will enable the NCC to send SMS acknowledgement and feedback to all those reporting adverse drug reactions, which will make the service more user friendly and build confidence for all stakeholders of PvPI.

The helpline is an important and useful tool for direct reporting of suspected adverse drug reactions by hospital pharmacists/clinicians from all types of hospitals, as well as private clinics and nursing homes. Provision of the helpline service contributes to the quality of care provided by the NCC and provides benefits to the national database.

REFERENCES


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