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Pharmacovigilance Activities in Nepal

We read with great interest the article by Olsson et al.[1] published in a recent issue of *Drug Safety*. The authors have clearly identified certain barriers and challenges in strengthening pharmacovigilance programmes in developing countries. We hereby share our experiences with the recently developed National Pharmacovigilance Programme in Nepal.

Nearly two-thirds of the drugs in Nepal are imported from foreign countries and the country has limited capacity in terms of drug manufacturing. Prior to marketing a drug, the Department of Drug Administration (DDA), the national drug regulatory authority, evaluates the drug thoroughly and then approves it on the basis of data available from other countries. In the past, the DDA has banned several drugs, such as amidopyrine (aminophenazone), phenacetin, clioquinol, analgin (metamizole [dipyrone]), amphetamine, chlorphentermine, oxyphenbutazone, methaqualone, phenylbutazone, santonin, sulphaguanidine and meprobamate, in order to ensure medicine safety. In addition, registration of products such as gatifloxacin, cyclo-oxygenase 2 inhibitors, etc., was denied due to safety concerns. However, no system existed to monitor adverse drug reactions (ADRs) within the country.

Recognizing the importance and benefits of pharmacovigilance as an important tool towards safety monitoring and rational use of medicines, the Government of Nepal initiated the pharmacovigilance programme in 2002. The Government decided to become a member of the WHO Programme for International Drug Monitoring in October 2004 and nominated the DDA as the national centre. Nepal was given full membership of the WHO programme in July 2006. Following membership, the DDA has established four regional centres that report ADRs to the DDA. These regional centres are located at the Manipal Teaching Hospital, Pokhara; Tribhuvan University Teaching Hospital, Kathmandu; Nepal Medical College Hospital, Kathmandu; and KIST Medical College, Lalitpur. The regional centres report the ADRs to the national centre via the web-based system for ADR management, 'Vigiflow'. The first two centres were set up in 2004 and 2006, respectively, and the third and the fourth centres were established during 2007 and 2008, respectively.

The Manipal Teaching Hospital was the pioneer in starting pharmacovigilance in Nepal. Since its inception, the centre has received a total of 355 ADR reports from the hospital (September 2004 to August 2005: 98; September 2005 to August 2006: 38; September 2006 to August 2007: 45; September 2007 to February 2008: 174). The ADR reporting forms are placed in the wards, outpatient departments and the Drug Information Center (DIC) of the hospital. Doctors, nurses and pharmacists report ADRs, if any occur, to the pharmacovigilance cell, a unit of the DIC of the hospital.

Activities of the Pharmacovigilance Centre at the Tribhuvan University Teaching Hospital are coordinated by the Drug Information Unit of the Clinical Pharmacology Department. The centre regularly reports the ADRs to the national centre. To date, 50 ADRs have been reported to the national centre.

Pharmacovigilance activities at the Nepal Medical College Hospital were initiated voluntarily by the Department of Clinical Pharmacology in July 2007. When the centre was started, the ADR reporting form was given to the doctors of all clinical departments of the hospital. The ADR reports are then sent to the DDA. The centre has received 11 ADR reports, the majority of which are from the Dermatology Department, followed by the Paediatrics Department.

At KIST Medical College, pharmacovigilance activities were started with the encouragement and support of the hospital's Medicine and Therapeutics Committee in July 2008. The department of Clinical Pharmacology and Therapeutics runs the programme with support from other departments. All faculty members and house officers from clinical science departments are encouraged to report adverse reactions. As of 3 February 2009, a total of 29 ADRs have been reported from various departments. The majority of reports (23 of 29) are from the Medicine Department but there are also reports from other departments, such as Paediatrics, Gynaecology and Radiology. This regional centre has already started reporting ADRs to the national centre.

The DDA is the designated focal point (national centre) for ADR monitoring in Nepal to liaise with the Uppsala Monitoring Centre (UMC). The main objective of the pharmacovigilance programme in the DDA is to establish a system of regular reporting and surveillance of ADRs, and keep ADR reporting operational. Starting with 8 ADR reports in 2004, the national database now contains approximately 323 ADR reports. Altogether, 278 ADR reports have been sent to the UMC from the national centre. In 2007, 69 ADR reports were sent to the UMC, and in 2008, of 206 ADR reports received, 169 were sent to the UMC. The ADR database shows an increasing tendency of reporting over time.

As the national center for pharmacovigilance activities, the DDA co-ordinates the programme. A standard ADR reporting form has been developed by the DDA based on the requirements of the UMC. Information on ADR reporting is regularly included in the 'Drug Bulletin of Nepal' published by the DDA. Health professionals working in participating hospitals benefit from the pharmacovigilance system in relation to research, publications and studies related to ADRs. Through collaboration with the UMC, Nepal has also been able to contribute to the global database by sharing information with the UMC. This programme, although in its initial phase, has provided a good platform for promoting the culture of ADR reporting in health professionals and for encouraging them to be vigilant. The DDA has been working towards the addition of more teaching hospitals for ADR reporting so as to strengthen the pharmacovigilance programme. The revised National Medicine Policy 2009 (draft)[2] has also recognized the need for a pharmacovigilance programme in Nepal and has aimed for implementation of the programme for effective postmarketing surveillance and ADR reporting to ensure ongoing assessment of the medicine.

In spite of progress made in the short span of 6 years, the current pharmacovigilance programme has a few limitations, such as financial constraints, lack of adequate manpower and training. In order to strengthen pharmacovigilance, several measures need to be taken, such as creation of awareness among healthcare professionals and the general public, expanding pharmacovigilance to community settings, conducting training programmes for health professionals, and incorporating pharmacovigilance topics into the curriculum of doctors, nurses and pharmacists, etc. Although there are limitations and challenges, the current pharmacovigilance programme has been successful in developing a reporting culture among healthcare professionals in the country. The DDA should take adequate steps to strengthen this programme into a fully developed pharmacovigilance system. If mature and well developed, the pharmacovigilance programme will certainly play an important role in ensuring drug safety in Nepal.

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References

1. Olsson S, Pal SN, Stergachis A, et al. Pharmacovigilance activities in 55 low- and middle-income countries: a questionnaire-based analysis. Drug Saf 2010; 33 (8): 689-703
2. National medicines policy 2009 (revised). Kathmandu: Department of Drug Administration, Ministry of Health and Population, 2009