DOI: ABDC/2012/4572:0023

Book Review

Misc. Section

Safety Monitoring Of Medicinal Products Reporting System For The General Public

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I have been closely associated with initiating and sustaining pharmacovigilance activities in two medical schools in Nepal, a small developing country in South Asia. In Nepal like in many other countries the major method of reporting adverse drug reactions (ADRs) is spontaneous reporting by health professionals. I have been always interested in reporting of ADRs by consumers both as a means to empower consumers and overcome the drawbacks of traditional reporting systems.

Consumer ADR reporting is widely practiced in developed nations like Australia, Canada, Sweden, Netherlands, United States and United Kingdom among others. Studies also have been conducted on consumer reporting in Malaysia and a pilot reporting program has been conducted. Recently the World Health Organization (WHO) has published a booklet to help different countries set up a national system for reporting consumer ADRs. The booklet recommends consumer reporting to be set up within existing national systems of ADR reporting. Consumer reporting is designed to supplement rather than replace reporting by health professionals. The booklet is divided into nine sections with certain sections having a number of subsections.

The first section deals with the need for consumer reporting. As a member of a pharmacovigilance center in a teaching hospital I am aware of the extent under-reporting which can be partly overcome using consumer reports. Consumer reports may be more effective with medicines used for chronic illness, complementary and alternative medicines and over-the-counter (OTC) medicines. The third section deals with starting a consumer reporting program. Consumer reporting should ride piggyback on an existing spontaneous reporting system. Reporting of adverse reactions to medicines is the focus of the fourth section. The form recommended to be used is similar to the one used in reporting by health workers with a few changes. Patient reports tend to be more narrative and rich in content and may need more space for documentation. Special issues in reporting form the basis of the fifth section. How to stimulate reporting by consumers and medical confirmation of reports are important issues. How consumers should report ADRs and to whom and how to ensure quality of reports in developing nations could be major challenges.

Communication with consumers and providing feedback to them about their reports and information about medicines is important. We had seen this was an important issue in Pokhara with health workers and pharmacovigilance activities were combined with drug information services. Section 7 deals with assessment of case reports which is similar to the process followed with reports from health workers. Relationship with other parties including consumer organizations, regulatory authorities, pharmaceutical companies, professional organizations, WHO, the national pharmacovigilance center and the media is the thrust area of section 9. The glossary of terms is useful and I liked the examples of consumer reporting forms from the Netherlands and Sweden shown in the Annex.

The handbook can serve as a starting step for setting up a consumer reporting program. I would have liked the booklet to mention sources of additional reading as I am sure the information mentioned in the booklet would not be sufficient by itself to set up and run a program. A list of references is provided and who to contact for further information is also mentioned. A contact e-mail address would have been helpful. I also feel books for consumers especially in developing nations in consumer ADR reporting are important so that they know about ADR reporting, how to report and why they should report ADRs.

The booklet would serve as a useful basic introduction to the subject and would be of interest to those interested in consumer reporting though the language may be technical for non-specialist readers.

About the handbook:

World Health Organization: Safety monitoring of medicinal products Reporting system for the general public. 2012. ISBN 978 92 4 150319 8.

Can be freely downloaded from:

http://www.who.int/medicines/areas/quality_safety/safety_efficacy/EMP_ConsumerReporting_web_v2.pdf.

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FINANCIAL OR OTHER COMPETING INTERESTS:
None.

Date Of Submission: **May 23, 2012**
Date Of Peer Review: **Jun 05, 2012**
Date Of Acceptance: **Jun 06, 2012**
Date Of Publishing: **Jun 25, 2012**