National policies for safety of medicines in the Asia Pacific region

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ABSTRACT

National medicines policies can aid the safe use of medicines by ensuring availability of quality products, appropriate information for prescribers and consumers, strengthening the national medicines regulatory capacity and improving access to expert advice and authoritative laboratory testing. We report the findings of a workshop on medicines safety, which focused on the Asia Pacific region. Participants noted that external support is needed for resource-poor countries and that national medicines policies should include surveillance on problems with medicines, rather than the more limited monitoring of adverse drug reactions. The latter approach may be the only sensible option in countries in the Asia Pacific with very small populations.

Key words: National medicines policy, pharmacovigilance, safe use of medicines

INTRODUCTION

In the years following the recognition of the teratogenic effects of thalidomide in 1961, individual countries established activities for the monitoring of suspected adverse reactions to medicines. The World Health Organization (WHO) defined an adverse reaction as: “A response which is noxious and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function.”¹ In May 2012, the Asia Pacific Conference on National Medicines Policies was held in Sydney, Australia; we report the findings of a conference workshop addressed the contemporary need to ensure communities’ access to safe and effective medicines.² In introducing this workshop, the convenors invited participants to regard the topic of safety of medicines as encompassing not only adverse effects but also other drug-related problems. This broader approach-termed “pharmacovigilance” – involves the detection, assessment, understanding and prevention of adverse effects or any other possible problems related to interventions, including herbal medicines, traditional and complementary medicines, blood products, biologicals, vaccines and, in some countries, medical devices.³ The convenors of the workshop were aware that, despite its increasing use in technical English, the term “pharmacovigilance” would not have been encountered by a significant proportion of the participants, thus time was devoted to introducing the term and explaining its history and current meaning.

The aims of the workshop were to examine the goals and scope of a national medicines safety programme that would form part of a national medicines policy; identify factors that can affect the safe use of medicines; describe activities that support the safe use of medicines; and identify difficulties in dealing with medicine safety problems in the Asia Pacific region.

The workshop identified the main sources of problems that might be reported about medicines:

- intentionally fraudulent (“counterfeit”) medicines and substandard medicines, including those with physical problems such as crumbling tablets.
- unexpected clinical problems with a medicine from a usually reliable source
- adverse reactions to medicines and
- biased or misleading information for prescribers and consumers that on occasions may be because of poor quality translation of information.
FACTORS THAT PROMOTE THE SAFE USE OF MEDICINES

Workshop participants identified various factors that mitigate problems and aid safe use. The first factor is access to medicines of appropriate quality, efficacy and safety, which is an objective of the supply aspect of a national medicines policy. Regulation of supply and monitoring of quality by a well-established national Medicines Regulatory Authority (MRA) as, for example in Japan, Malaysia and Singapore may be effective. However, a number of countries in the Asia Pacific region do not have a well-established or adequately resourced MRA. In these circumstances, adherence to a policy of purchasing WHO prequalified products should assist greatly. Unfortunately, not all needed medicines that are available are prequalified. In addition, it was noted that in Pacific Island countries products are encountered that do not meet pharmacopoeial standards or are suspected of not being bioequivalent to the innovator product. Actions to prevent the circulation of such products could be facilitated by setting up reporting systems that will include perceived problems with medicines.

Second, information should be available to both prescribers and consumers and should be accurate and unbiased. Misleading information for prescribers and dispensers may affect the many patients who rely on these professionals for advice about medicines. There is a need for written consumer information to be available in appropriate local languages coupled with awareness of problems where there are low literacy rates or consumers have limited capacity to interpret the information. Innovative means for providing information include web-based access to information about national reporting of adverse effects and telephone services that allow consumers to discuss aspects of their medicines, including adverse effects, with a pharmacist or other health-care professional. It was noted that in Pacific Island countries, there are no requirements for written patient information to be supplied and only WHO prequalified products usually have a package insert provided. These inserts are directed at prescribers and there is no consumer version.

Third, each country should have a programme for reporting of “problems with medicines”. Such programmes should not be limited to soliciting reports of suspected adverse reactions. For example, information on medicines that are suspected not to contain the appropriate pharmaceutical ingredients and queries about bioequivalence and bioavailability could be gathered and investigation initiated through a national reporting programme. When developed, reporting programmes should have mechanisms to deal with reporting from consumers as well as from health professionals. It is important to ensure that it is understood by health professionals and consumers that the purpose of reporting is not litigation or assigning blame but to optimize therapy with safer products. Workshop participants were informed about the work of the Malaysian National Patient Safety Council, which advises the Ministry of Health about national priority areas and strategies for patient safety and quality improvement in healthcare. Its activities include the reporting of medication errors.

Fourth, a well-resourced national MRA with a clear supporting legal basis is able to contribute to the safe use of medicines. Such an agency can undertake assessments of the information supporting the quality, safety and efficacy of medicines. This information can include evidence to support the bioequivalence of generic versions of a medicine to the innovator product. Although such an agency may not have extensive laboratory capacity, it may often have developed relationships with accredited national agencies in other countries. In some countries in the Asia Pacific region, however, there is no or only very limited regulatory capacity. Such countries have a need for assistance from regulatory agencies and experts in other countries in information interpretation and laboratory testing.

Participants noted that well-resourced regulatory agencies in the region, which are responsible for the registration process, now have requirements for the marketing companies to develop and follow risk management plans. These plans include postmarketing surveillance to be undertaken by the marketing authorization holder (supplying company) for a specified number of years and the reporting of a range of problems whenever they come to the company’s notice, including suspected adverse reactions, medication errors and instances of misuse of the product. In Malaysia, for example compliance by the company with the risk management plan is enforceable by the national regulatory agency.

NEEDS WHEN A PROBLEM IS DETECTED

The workshop identified the need for ready access to expert clinical or technical advice and to authoritative laboratory testing when a problem is detected, especially in resource-poor countries. The experience of Bhutan concerning problems with a pentavalent vaccine was described. Shortly after the vaccine, which was prequalified by WHO, was introduced in Bhutan in September 2009 the national health authorities were notified of five serious adverse events in infants, including four deaths. Because there was no local virological expertise, it was necessary to create a team of international experts to investigate. Furthermore, there was no designated testing facility in Bhutan and testing...
had to be carried out in another country. There can be extended time lags in the advisory and testing processes which may disrupt the supply chain and distribution for significant periods. Bhutan has now instituted an expert advisory group for medicines and vaccines. Use of the vaccine has been resumed.

For some countries with small populations and limited resources, the establishment of national expert groups is impossible. In some cases, these countries use WHO to identify and source expert clinical advice. It was suggested that assistance might be requested from the MRA in the country from where a problem medicine had been supplied. An alternative, especially for Pacific Island countries, could be the prospective establishment of a network of expert clinical and technical advisers in developed countries who could be consulted at short notice.

Rapid access to testing laboratories that are recognized as authoritative when a problem arises is also a frequent need. In practice, this usually means the laboratories of national MRAs in well-resourced countries. Access to testing may take time and, in some cases, be very expensive. Some resource-poor countries have turned to other laboratories such as in university departments to undertake testing at reduced cost. Unfortunately, supplier companies – including some multinational companies – have refused to accept the results of this testing, claiming that the laboratory is not accredited or recognized or has not carried out the testing at the appropriate standard. Such instances may lead to dispute, especially where there is a contractual requirement that the supplier reimburse the government when a product is shown to be defective.

**CONCLUSION**

The workshop participants concluded that to ensure safe use of medicines, a national medicines policy should include requirements for medicines of demonstrable quality, appropriate information for prescribers and consumers, a national medicines regulatory capacity and ready access to expert advice and to authoritative laboratory testing. The regulatory capacity and laboratory testing may require external support. Each country should have a method for the reporting of problems with medicines.

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**REFERENCES**


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