

CHAPTER 8 RISK COMMUNICATION, EDUCATION AND TRAINING

Overview

8.1 This chapter provides an overview of the existing framework of risk communication on drug safety, including education and training; and presents the Review Committee's findings and recommendations on the enhanced measures for effective risk communication.

Existing Framework of Risk Communication

8.2. Risk communication is a process of exchange of risk information among all stakeholders in order to make them aware of the risks identified, and ensure the risk assessment results are clearly received and understood. In respect of drug safety, stakeholders include the whole drug industry and its practitioners, healthcare professionals in both the public and private sectors, patients and the general public.

8.3 The risk communication strategy of DH on drug safety is an integral part of the post-market control of drugs. Risks are divided into two levels: those related to drug safety and those related to the safe use of drugs.

Risks related to Drug Safety

8.4 DH has implemented various measures to identify and assess the potential hazards of registered drugs, including the drug surveillance programme, adverse drug reaction reporting programme, toxicovigilance programme, intelligence obtained through monitoring of overseas authorities, and drug incident reports in the media and from the patients.

8.5 Hazards on drug safety can be a quality defect affecting one or all batches of the product, presence of an undeclared drug substance in the product or a newly-discovered side effect. Upon receipt of the hazard report, DH would assess the risk and impact of the hazard, and then use the appropriate means to disseminate the drug recall message to the public. Dissemination channels include issue of press statements, holding of press conferences, distribution of information leaflets to the public, announcements of public interest in electronic media, etc., depending on the gravity of case.

8.6 Doctors and pharmacists are important stakeholders along the line of risk communication due to their services provided to the public. DH would therefore issue letters about drug incidents and product recalls to doctors, pharmacists and their professional associations, as well as private and public hospitals. The general public could then also receive the message during their encounter with these healthcare professionals.

Risks related to Safe Use of Drugs

8.7 On the perspective of safe use of drugs, HA and healthcare professionals have been playing an active role. Information about drug indication, side effects, contra-indications, drug interaction, etc. is disseminated to patients during doctor consultations and counselling to patients at pharmacies.

8.8 As a registration body for drugs, DH publishes certain essential registration information on the electronic compendium of registered drugs on its website. The primary objective is to facilitate healthcare professionals to check whether a drug is registered or not.

Education and Training Programmes for the Pharmaceutical Industry

8.9 DH conducts regular education and training programmes to the pharmaceutical industry. Topics covered include information on various traders' licences, information on registered drugs on the website of DH, classification of drugs, requirements for drug registration, requirements for approval of change of particulars of registered drugs, undesirable medical advertising, etc.

8.10 After the drug incidents in March 2009, DH organized a number of seminars for the management of different levels of the drug supply chain including manufacturers, wholesalers and importers/exporters to remind them of the required standards under the GMP and all the legal and licensing requirements, as well as the importance of internal audit and corporate governance during the drug manufacturing process.

Findings and Recommendations

8.11 The Review Committee identifies a number of areas for improvement in the existing framework for risk communication, and makes the recommendations as outlined in the following paragraphs.

Setting Up of a Dedicated Team in DH for Education and Training

8.12 The Review Committee finds that apart from DH, HA, Consumer Council and some pharmaceutical associations have been organizing various public education programmes on drug safety, yet there is no co-ordination among these programmes, leading to duplication of efforts.

8.13 The Review Committee **recommends** that DH sets up a dedicated, multi-disciplinary team for education and training. The team should collaborate with and co-ordinate efforts of the academia, Consumer Council and relevant professional bodies in the provision of education and training programmes on drug safety. Other functions of the team should include –

- (a) drawing up guidelines and protocols for hazard identification and risk communication in the manufacturing process;
- (b) performing risk assessment in response to any incident related to drug manufacturing and recommending risk communication actions accordingly;
- (c) assisting training institutions to organize educational and training activities for the pharmaceutical industry; and
- (d) producing education and training materials.

Organization of More Training Programmes with Focus on Quality Control

8.14 The Review Committee notes that the focus of training programmes organized by DH prior to the drug incidents in March 2009 was on drug registration requirements, and the target group was the management of manufacturers, wholesalers and importers/exporters.

8.15 The Review Committee **recommends** that DH should continue to organize seminars with additional focus on quality control. In addition to the management at different levels of the drug supply chain, DH should also organize continuous training programmes for front-line staff, including manufacturing workers and workers involved in handling of drugs at the importer, wholesaler and retailer levels. Training content should cover checking of supplies, appropriate drug storage conditions, stock control, keeping of records, etc.

Enhancement of the Content of “Compendium of Pharmaceutical Products” on DH Website

8.16 The Review Committee notes that DH's electronic compendium of registered pharmaceutical products currently only includes the product brand-name, the active ingredients, the product registration number and the name and address of the registrant. This scope of information does not meet the rising demand of users. The Review Committee also finds that some drug information is not user-friendly. For instance, the list of pharmaceutical products is available in English only.

8.17 The Review Committee **recommends** that the content of the compendium be enhanced to provide more information for the general public, healthcare professionals and the drug industry, including product classification (i.e. Part I or Part II Poison or non-poison), whether the product has to be prescribed by doctors only, Chinese name of product if available, images of approved packaging, address of the manufacturer, country where the product is manufactured, product registration expiry date, etc. Any product recall and approved changes to registered particulars of drugs should also be highlighted in the compendium to alert the general public.

Setting Up of a Designated Website to promote Drug Safety

8.18 The Review Committee observes that, in spite of its wide public health implications, there is no designated website of DH on the subject of drug safety, and information on the subject is scattered in different parts of DH website. This is not convenient for the public to access useful drug information.

8.19 The Review Committee **recommends** DH to set up a designated website on drug safety to provide a better platform for information dissemination and exchange, while the revamped electronic compendium of pharmaceutical products as well as other information related to the work of DH pharmaceutical service should also be migrated to this designated website. The information database should be enriched to provide more patient-oriented advice, drug alerts and other useful drug information to the public, the pharmaceutical industry and the healthcare professionals. The revamped website should be more user-friendly, facilitating the public's quick search of information. Hyperlinks to websites of relevant professional bodies and organizations should also be included. The Review Committee further **recommends** that DH establishes a focus group comprising user representatives from the Consumer Council, public and private hospitals, community pharmacists, patient groups, etc. to work out the prototype of the enhanced website and its contents.

Enhancement of Drug Information accompanying Dispensed Medicines

8.20 The Review Committee finds that except for the basic information on frequency and method of use of drug, drug information for medicines dispensed to patients at hospitals and clinics is rather limited.

8.21 The Review Committee **recommends** that more information on drugs and patient-oriented advice, such as uses, side effects and precautions, be provided when dispensing drugs to patients at hospitals or clinics, either on the drug label or in an accompanying leaflet to educate the public on safe use of the drug concerned.