

Introduction

Drug Act was promulgated in Nepal in 1978 with the main objective of making safe, effective and quality medicines available to all in affordable price. Medicines available via commercial channel are required to comply these requirements. However, many consignments of donated drugs do not comply with the national requirements. This guideline has been issued to receive the drugs needed and avoid receiving drugs that are unsolicited, so that the donor's desire to help in need is fulfilled and scarce resource is not wasted in total, logistic and disposal management of unsolicited supplies. The guideline is adopted from 'Guidelines for Drug Donations, second edition, 1999' published by WHO (WHO/EDM/PAR/99.4; <http://www.who.int/dap/edmguidelines.html>). Necessary changes have been made to suit local situation. For detailed information one can refer to aforementioned document.

Guidelines

1. All drug donations should be based on expressed need and be relevant to the disease pattern in Nepal. Drugs should not be sent without prior consent by the recipient. Drugs banned or not in use in Nepal should not be sent.
2. All donated drugs or their generic equivalents should be approved for use in Nepal and appear on the National List of Essential Drugs-Nepal, 2002 (<http://www.dda.gov.np>), unless specifically requested otherwise by the recipient. A recipient is Ministry of Health and Population (MOHP) in emergency situation and MOH or legally registered organization in normal situation.
3. The presentation, strength and formulation of donated drugs should, as much as possible, be similar to those of drugs commonly used in Nepal.
4. All donated drugs should be obtained from a reliable source and comply with quality standards in both donor country and Nepal. The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce should be used.

5. No drugs should be donated that have been issued to patients and then returned to a pharmacy or elsewhere, or were given to health professionals as free samples.

6. After arrival in Nepal all donated drugs should have a remaining shelf-life of at least one year. In case the shelf-life of the product when manufactured is less than two years, half of the period should be remaining (For example a product having shelf-life of eighteen months should have remaining shelf-life of nine months on arrival in Nepal.) The exception may be made for direct donations to specific health facilities, provided that: the responsible professional at the receiving end acknowledges that (s)he is aware of the shelf-life; and that the quality and remaining shelf-life allow for proper administration prior to expiration, but the remaining shelf-life should not be less than six months in any case. In all cases it is important that the date of arrival and the expiry dates of the drugs be communicated to the recipient well in advance.

7. All drugs should be labeled in English; the label on each individual container should be at least contain the International Nonproprietary Name (INN) or generic name, batch number, dosage form, strength, name of the manufacturer, quantity in the container, storage conditions and expiry date.

8. As much as possible, donated drugs should be presented in larger quantity units and hospital packs.

9. All drug donations should be packed in accordance with international shipping regulations, and be accompanied by a detailed packing list which specifies the contents of each numbered carton by INN, dosage form, quantity, batch number, expiry date, volume, weight and any special storage conditions. The weight per carton should not exceed 50 kilograms. Drugs should not be mixed with other supplies in the same carton.

10. Recipient should be informed of all drug donations that are being considered, prepared or actually under way.

11. The declared value of a drug donation will be based upon the wholesale price of its generic equivalent in Nepal, or, if such information is not available, on the wholesale world-market price or its generic equivalent.

12. Cost of international and local transport, warehousing, port clearance and appropriate storage and handling should be paid by the donor agency, unless specifically agreed otherwise with the recipient in advance. A fee of Nepalese Rupees 300 per product in every consignment is charged by the Department of Drug Administration as per the Drug Act for issuing letter of recommendation to import the drug. It should be made clear whether this fee would be paid by the donor or the recipient.

13. For further detail or clarification, please contact: Government of Nepal, Ministry of Health and Population, Department of Drug Administration, Madan Bhandari Path, Bijulibazar, Kathmandu, Nepal. Tel. +977 1 4780227;+977 1 4780432; Fax. +977 1 4780572; e-mail : dda@healthnet.org.np; web-site: www.dda.gov.np

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