

Guidelines for Drug Donations

Selection of drugs

- 1. All drug donations should be based on an expressed need and be relevant to the disease pattern in the recipient country. Drugs should not be sent without prior consent by the recipient.**

Justification and explanation

This provision stresses the point that it is the prime responsibility of the recipients to specify their needs. It is intended to prevent unsolicited donations, and donations which arrive unannounced and unwanted. It also empowers the recipients to refuse unwanted gifts.

Possible exceptions

In acute emergencies the need for prior consent by the recipient may be waived, provided the drugs are amongst those from the WHO Model List of Essential Drugs that are included in the UN list of emergency relief items recommended for use in acute emergencies.

- 2. All donated drugs or their generic equivalents should be approved for use in the recipient country and appear on the national list of essential drugs, or, if a national list is not available, on the WHO Model List of Essential Drugs, unless specifically requested otherwise by the recipient.**

Justification and explanation

This provision is intended to ensure that drug donations comply with national drug policies and essential drugs programmes. It aims at maximizing the positive impact of the donation, and prevents the donation of drugs which are unnecessary and/or unknown in the recipient country.

Possible exceptions

An exception can be made for drugs needed in sudden outbreaks of uncommon or newly emerging diseases, since such drugs may not be approved for use in the recipient country.

- 3. The presentation, strength and formulation of donated drugs should, as much as possible, be similar to those commonly used in the recipient country.**

Justification and explanation

Most staff working at different health care levels in the recipient country have been trained to use a certain formulation and dosage schedule and cannot constantly change their treatment practices. Moreover, they often have insufficient training in performing the necessary dosage calculations required for such changes.

Quality assurance and shelf-life

- 4. All donated drugs should be obtained from a reliable source and comply with quality standards in both donor and recipient country. The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce 51 should be used.**

Justification and explanation

This provision prevents double standards: drugs of unacceptable quality in the donor country should not be donated to other countries. Donated drugs should be authorized for sale in the country of origin, and manufactured in accordance with international standards of Good Manufacturing Practice (GMP).

Possible exceptions

In acute emergencies the use of the WHO Certification Scheme may not be practical. However, if it is not used, a justification should be given by the donor. When donors provide funds to purchase drugs from local producers, those which comply with national standards should not be excluded on the sole grounds that they do not meet quality standards of the donor country.

- 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.**

Justification and explanation

Patients return unused drugs to a pharmacy to ensure their safe disposal; the same applies to drug samples that have been received by health workers. In most countries it is not allowed to issue such drugs to other patients, because their quality cannot be guaranteed. For this reason returned drugs should not be donated either. In addition to quality issues, returned drugs are very difficult to manage at the receiving end because of broken packages and small quantities involved.

- 6. After arrival in the recipient country all donated drugs should have a remaining shelf-life of at least one year.**

Justification and explanation

In many recipient countries, and especially under emergency situations, there are logistical problems. Very often the regular drug distribution system has limited possibilities for immediate distribution. Regular distribution through different storage levels (e.g. central store, provincial store, district hospital) may take six to nine months. This provision especially prevents the donation of drugs just before their expiry as in most cases such drugs would only reach the patient after expiry.

Possible exceptions

An exception should be made for drugs with a total shelf-life of less than two years, in which

case at least one-third of the shelf-life should remain. An exception can also be made for direct donations to specific health facilities, provided the responsible professional at the receiving end is aware of the shelf-life and the remaining shelf-life allows for proper administration prior to expiration. In all cases it is important that the date of arrival be communicated to the recipient well in advance.

Presentation, packing and labelling

- 7. All drugs should be labelled in a language that is easily understood by health professionals in the recipient country; the label on each individual container should at least contain the International Nonproprietary Name (INN, or generic name), batch number, dosage form, strength, name of manufacturer, quantity in the container, storage conditions and expiry date.**

Justification and explanation

All donated drugs, including those under brand name, should be labelled also with their INN or the official generic name. Most training programmes are based on the use of generic names. Receiving drugs under different and often unknown brand names and without the INN is confusing for health workers and can even be dangerous for patients. In case of injections, the route of administration should be indicated.

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

Justification and explanation

Large quantity packs are cheaper, less bulky to transport and conform better with public sector supply systems in most developing countries. This provision also prevents the donation of drugs in sample packages, which are impractical to manage. In precarious situations, the donation of paediatric syrups and mixtures may be inappropriate because of logistical problems and their potential misuse.

- 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.**

Justification and explanation

This provision is intended to facilitate the administration, storage and distribution of donations in emergency situations, as the identification and management of unmarked boxes with mixed

drugs is very time and labour intensive. This provision specifically discourages donations of small quantities of mixed drugs. The maximum weight of 50 kg ensures that each carton can be handled without special equipment.

Information and management

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

Justification and explanation

Many drug donations arrive unannounced. Detailed advance information on all drug donations is essential to enable the recipient to plan for the receipt of the donation and to coordinate the donation with other sources of supply. The information should at least include: the type and quantities of donated drugs including their International Nonproprietary Name (INN or generic name), strength, dosage form, manufacturer and expiry date; reference to earlier correspondence (for example, the letter of consent by the recipient); the expected date of arrival and port of entry; and the identity and contact address of the donor.

- 11. In the recipient country the declared value of a drug donation should be based upon the wholesale price of its generic equivalent in the recipient country, or, if such information is not available, on the wholesale world-market price for its generic equivalent.**

Justification and explanation

This provision is needed in the recipient country to prevent drug donations being priced according to the retail price of the product in the donor country, which may lead to elevated overhead cost for import tax, port clearance, and handling in the recipient country. It may also result in a corresponding decrease in the public sector drug budget in the recipient country.

Possible exception

In case of patented drugs (for which there is no generic equivalent) the wholesale price of the nearest therapeutic equivalent could be taken as a reference.

- 12. Costs 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.**

Justification and explanation

This provision prevents the recipient from being forced to spend effort and money on the clearance and transport of unannounced consignments of unwanted items, and also enables the recipient to review the list of donated items at an early stage.