

III. 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 Drugs¹ that are included in the UN list of emergency relief items recommended for use in acute emergencies.²

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'³ 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. An 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 quantity and remaining shelf-life allow for proper administration prior to expiration. 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.

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. It is important that the recipient official responsible for acceptance of the donation is fully aware of the quantities of drugs being donated, as overstocking may lead to wastage. The argument that short-dated products can be donated in the case of acute emergencies, because they will be used rapidly, is incorrect. In emergency situations the systems for