



FIP Statement of Principle

GOOD PRACTICE IN DONATIONS OF MEDICINES

This statement was adopted by the Council of the International Pharmaceutical Federation (FIP) at its Council meeting in Vancouver on 5th September 1997

Preface:

This statement is intended for pharmacists and others to use in donor countries (countries from which donated medicines are obtained). More extensive advice for those working in recipient countries (countries where donated medicines are to be used) can be found in a WHO document entitled *Guidelines for Drug Donations (WHO/DAP/96.2)* issued in May 1996.

Introduction:

(1) This statement aims to improve the quality of medicine donations, not to hinder them. It is intended to serve as a basis for national guidelines, to be reviewed, adapted and implemented by national pharmaceutical associations in giving advice to pharmacists, agencies involved in the donation of medicines and government departments.

There are many different scenarios for the donation of medicines. They may take place in acute emergencies or as part of development aid in non-emergency situations. There are many basic rules for an appropriate donation that apply to all scenarios.

Medicines are an essential element in international humanitarian relief efforts.

(2) There are many examples of donations of medicines that cause problems instead of being helpful.

Examples of such problems include:

- (a) Donated medicines are often not relevant for the emergency situation,*
- (b) Many donated medicines arrive unsorted and labelled in a language which is not easily understood,*
- (c) The quality of the donated medicines does not always comply with standards in the donor country,*
- (d) Medicines may be donated in the wrong quantities,*
- (e) The common but mistaken belief is that, in an acute emergency, any type of medicine is better than none at all,*

- (f) *A general lack of communication between the donor and the recipient may lead to many unnecessary donations. This is unfortunate because in disaster situations and war zones inappropriate donations of medicines create an extra workload in sorting, storage and distribution and can easily overstretch the capacity of scarce human resources and transport facilities.*
- (g) *Donating unused medicines returned to a pharmacy for safe disposal, or free samples given to health professionals are examples of double standards because in most countries their use would not be permitted due to concerns about quality. For this reason this type of donation is forbidden in an increasing number of countries and is generally discouraged.*

(3) This Statement gives guidance because:

- (a) Donors intend well, but often do not realise the possible inconveniences and unwanted consequences at the receiving end.*
- (b) Donor and recipient may not communicate effectively.*
- (c) Medicine needs may vary between countries and from situation to situation.*
- (d) The donation of medicines must be based on a sound analysis of the needs, and their selection and distribution must fit within existing health policies and administrative systems.*
- (e) Unsolicited and unnecessary donations of medicines are wasteful and should not occur.*
- (f) The quality requirements for medicines are different from other donated items, such as food and clothing. Medicines can be harmful if misused, they need to be identified easily through labels and written information, they may expire, and they may have to be destroyed in a professional way.*

Taking into account this introduction and these definitions, it is the policy of FIP that:

Pharmacists should be involved, either directly or by advising others, in the arrangements for donations of medicines and should seek to ensure that the following four principles are complied with

1. Donated medicines should benefit the recipient to the maximum extent possible. This implies that all donations should be based on an expressed need and that unsolicited medicine donations are to be discouraged.
2. A donation of medicines should only take place with full respect for the wishes and authority of the recipient, and be supportive of existing government health policies and administrative arrangements.
3. There should be no double standards in quality. If the quality of an item is unacceptable in the donor country, it is also unacceptable as a donation.
4. There should be effective communication between the donor and the recipient. Donations should never be sent unannounced

In order to comply with these principles the following additional guidance is given:

- (a) All donated medicines, or their generic equivalents, should be approved for use in the recipient country.
- (b) The presentation, strength and formulation of donated medicines should, as much as possible, be similar to those commonly used in the recipient country.
- (c) All donated medicines should be obtained from a reliable source and comply with quality standards in both donor and recipient country. As a minimum standard all medicines should be manufactured in accordance with Good Manufacturing Practice. This should be confirmed by use of the WHO Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce.
- (d) No medicines 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.
- (e) All donated medicines should have an appropriate shelf life. Normally a shelf life should be at least one year from the time of arrival in the recipient country. Where a shorter shelf life is appropriate then the donor is responsible for ensuring that the health professional at the receiving end is aware of the shelf life, the remaining shelf life allows for the proper administration of the medicine and that the date of arrival is communicated to the recipient well in advance.
- (f) All medicines should be labelled in a language that is understood by health professionals in the recipient country. The label on each individual container must include the generic name (whenever possible the international non-proprietary name - INN - or the national non-proprietary name), batch number, dosage form, strength, name of manufacture, quantity in the container, storage conditions and expiry.
- (g) As much as possible, donated medicines should be presented in larger quantity units and hospital packs that can be easily subdivided.
- (h) All donated medicines 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. The packing list should contain the same information as the label on each individual container (see f. above). The weight per carton should not exceed 50 kilograms. Medicines should not be mixed with other supplies in the same carton.
- (i) Recipients should be informed of all donations of medicines that are being considered or prepared and of progress when actually in transit.