



REPÚBLICA DEMOCRÁTICA DE TIMOR-LESTE

MINISTÉRIO DA SAÚDE
Gabinete do Ministro da Saúde

Ref. No : MS/POP/03/98

24 April 2003

TO

All NGOs in Health Sector in Timor-Leste
All UN UN Agencies in Timor-Leste
Central Pharmacy, Dili

Dear Sir,

Sub: Guidelines on "Drug Donation"

Enclosed please find a copy of the guidelines for Donation of Drugs (Guideline No.001/MS/03 dated 31 March 2003) prepared by the Ministry of Health, Timor-Leste. These guidelines would safeguard and protect the interests of the people of Timor-Leste, as several cases of donation of spurious and inferior quality of drugs have been noticed in the past. The guidelines are being sent for favour of your information and necessary action.

I take this opportunity to recognize and appreciate the assistance provided by your organization.

With kind regards,

Yours sincerely,

Dr Rui Maria de Araujo
Minister for Health

cc: Vice Minister for Health
All Districts, Hospitals and Institutions with in the Minister of Health



REPÚBLICA DEMOCRÁTICA DE TIMOR-LESTE

MINISTÉRIO DA SAÚDE

Gabinete do Ministro da Saúde

Guideline No. 001/MS/03

31 March 2003

DRUGS DONATION

The Ministry of Health has prepared following guidelines for Donation of Drugs in order to safeguard and protect the interests of the people of Democratic Republic of Timor-Leste. This step has been taken after learning that part of drugs donated are of inferior quality and at times spurious and not in the overall interest of the consumers of this country. These Guidelines are an update of an older version published by the Division of Health Services, Social Affairs Department, East Timor Transitional Administration under UNTAET dated 11 October 2000.

I. Selection of drugs

1. All drug donations should be based on an expressed need and be relevant to the disease pattern in Timor-Leste. Drugs should not be sent without the prior consent by the recipient.
2. All donated drugs or their generic equivalents should be approved for use in Timor-Leste and appear on the national list of essential drugs unless specifically requested otherwise by the recipient.
3. The presentation, strength and formulation of donated drugs should, as much as possible, be similar to those of drugs commonly used in Timor-Leste.

II. Quality assurance and shelf-life

1. All donated drugs should be obtained from a reliable source and comply with quality standards in both the donor country and Timor-Leste. The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce should be used.
2. No drugs should be donated that have been issued to patients and then returned to a pharmacy or elsewhere, or given to health professional as free samples.

3. 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 quality 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 date of the drugs be communicated to the recipient well in advance.

III. Presentation, packing and labeling

1. All drugs should be labeled in a language that is easily understood by health professionals in Timor-Leste; the label on each individual container should at least contain the International Non-proprietary Name (INN) or generic name, batch number, dosage form, strength, name of manufacturer, quantity in the container, storage condition and expiry date.
2. As much as possible, donated drugs should be presented in larger quantity units and hospital packs.
3. All drugs donations should be packed in accordance with international shipping regulation, and be accompanied by 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 condition. The weight per carton should not exceed 50 kilograms. Drugs should not be mixed with other supplies in the same carton.

IV. Information and management

1. Recipients should be informed of all drugs donations that are being considered, prepared or actually under way.
2. 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.

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.



Dr Rui Maria de Araujo
Minister for Health