



GUIDELINES
for
**Donations of Medicines
Medical Supplies
and Equipment**
to
The Republic of Fiji Islands



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GUIDELINES FOR DONATIONS OF MEDICINES AND MEDICAL SUPPLIES

Status of the Guidelines:

The Fiji Guidelines for donations of medicines and medical supplies are underpinned by the National Medicinal Products Policy (NMPP) of Fiji.

Under the NMPP a person must not deliver into the Fiji Islands any medicine or other medical supplies by way of donation unless the Government of the Fiji Islands has requested the donation; and prior to the importation or delivery, an approval has been granted for the donation in writing, by the Chief Pharmacist. Consignments without the necessary documentation will not be accepted.

Donations that arrive without appropriate permission and documentation will automatically be confiscated and refused entry to Fiji by the Customs Authorities.

In addition, the Director of FPBSC, in collaboration with the relevant National Program Managers (EMA, LMU, Laboratory, Dental) is authorised to refuse the Customs Authority clearance of donations that arrive unannounced and do not fit the criteria for donations to Fiji.

Important Points

- Organisations, including Churches, working in Fiji may not donate their excess medicines from the stock for their own use to health services. These organisations must take care to avoid importing excess medicines to minimize waste. Disposal of any waste is their own responsibility but must be in accordance with the NMPP.
- All approved donations must be directed to the Fiji Pharmaceutical and Biomedical Services Centre (FPBSC), not to individual health services.
- Provincial Councils are aware of this policy and will intercept and donations that arrive in remote locations.
- A Register and records are kept of donors who have contravened the Fiji policy on donations.

PREFACE

These guidelines are based on the international Guidelines for Drug Donations developed by the World Health Organisation (WHO) and major international agencies in 1999 and reviewed in 2011¹ and Guidelines for Equipment Donations originally developed in 1997² ³. The WHO's guidelines reflect a consensus between the major UN agencies and other major international agencies active in humanitarian emergency relief.

These guidelines aim to improve the quality of medicines and equipment donations to Fiji.

It shall be the responsibility of the MoHMS to ensure that all relevant stakeholders, including foreign diplomatic missions, are notified of the policy on donated medical equipment and consumables. In instances where a donor contacts a health facility or a clinician directly, it will be the responsible of the latter to direct the donor to the Director of FPBSC for information about conditions for donations of supplies for Fiji.

The core principles are the same for medicines, medical supplies, consumable and equipment.

¹ http://whqlibdoc.who.int/publications/2011/9789241501989_eng.pdf

² http://www.drugdonations.org/eng/richtlijnen/eng_guidelinesequipmentdon.pdf

³ http://www.who.int/hac/techguidance/pht/1_equipment%20donatiombuletin82WHO.pdf

CORE PRINCIPLES

- A donation is intended to assist the recipient. Donations should not be sent unless they have been requested. Donations should be based on an expressed need. Donor-initiated donations where the recipients' advice has not been sought are unhelpful.
- Donations must support essential medicines policies and medical systems. Respect must be given for the authority of the recipient and the receiving country's administrative arrangements including national standard treatment guidelines and essential medicines lists and equipment policies.
- There should be no double standards. If the quality of an item is not acceptable in the country of origin, it is unacceptable as a donation. Medicines and consumables should have 18 months remaining shelf-life on arrival at the destination. Equipment that cannot be used or repaired in the country of origin is unlikely to be helpful in the recipient country and the collection and redistribution of patients' unused medicines is not permitted.
- In most cases a financial contribution is more appropriate than donations in kind. It allows the recipient to prioritise needs and goods can often be accessed locally or from appropriate procuring agencies at a fraction of the cost of their transport from another country.

Why are guidelines needed?

Scenarios associated with medicines and equipment donations range from acute emergencies to non-emergency development programs. Although there are differences between these scenarios, there are basic rules for an appropriate response that apply to all.

This policy describes the process for the acceptance of donated medical supplies and equipment to ensure that it is appropriate to Fiji's clinical needs and conforms to specified standards set by the Ministry of Health (MoHMS).

Fiji, like many other developing countries, faces difficulties in trying to meet its needs for its healthcare system. It has therefore welcomed appropriate donations of medical supplies and equipment and related consumables from various charitable and non-governmental organisations and individuals.

Though these donations have been welcomed, many times donations have led to difficulties in service provision and are found idle in health facilities or have had to be destroyed for the following reasons:

How can donations cause problems?

Problems with medicines and medical supplies

- Fiji like most developing countries has a national essential medicines list generated by the National Standard Treatment Guidelines covering major health problems. Training programs for health personnel focus on the correct use of these medicines. Such developments need support. Donated medicines outside these national systems can frustrate and undermine the national medicine policy which aims to secure reliable supplies of appropriate good quality essential medicines and to promote standard treatment guidelines as a tool to encourage rational medicine use.

- There are also problems with the quality of donated medicines; donation of expired medicines being a common practice as well as medicines with a short shelf-life. This practice is not acceptable. If the quality of a medicine is not suitable for use in the country of origin, it is not suitable for donation to an overseas country.
- Apart from the issues of the quality of the products, eg expired/damaged medicines, and the relevance of the medicines to the situation, logistical difficulties can also arise. These difficulties are associated with sorting, storage and distribution which may waste valuable human and financial resources. In addition, transport costs from the country of origin may be higher than the value of the medicines, and a financial contribution can be much more helpful.

Problems with medical equipment

Examples of issues:

- a. Equipment is unserviceable
- b. Equipment is not a standard requirement in the health system and remains in storage cluttering the space until it can be destroyed.
- c. Equipment is not a standard item/model and would incur additional costs to operate and maintain it
- d. Necessary consumables, accessories, reagents, etc required to operate the equipment are not included
- e. Equipment is at the end of its life cycle and/or no longer supported by the manufacturer
- f. Spare parts are not available
- g. No user and service manual is available
- h. Not suitable for the environment it has been donated for
- i. Wrong voltage and frequency
- j. The user is not aware of how to operate the equipment
- k. Technicians are unaware of how to maintain and service the equipment

Furthermore, there are some associated cost issues that need consideration due to budgetary implications. For example, some additional equipment has substantial running costs, which are not able to be budgeted or met by the MoHMS. Where inclusion of the donated equipment is not already planned by the MoHMS those additional costs are also not provided for.

Finally, some donated equipment may require substantial investment in installation costs and unless the MoHMS is able and has planned to meet those installation costs, or unless the installation is financed by the donor, it may mean that the donated equipment cannot be used for a significant period. This too needs to be considered by both the donor and the MoHMS.

GUIDELINES FOR DONATIONS OF MEDICINES

CONDITIONS FOR DONATING MEDICINES

If approval has been granted for donating medicines the following conditions apply:

Pre-Donation Requirements:

Responsibility of Recipient

It shall be the responsibility of the Essential Medicines Authority, in collaboration with National Medicines and Therapeutics Committee; and the Disaster Management Committee when relevant, to justify the need for the medicines being requested or being offered and make the following points clear:

Selection of medicines

All medicine donations should be based exactly on the expressed need.

1. A written request should be obtained from a competent authority in the recipient country. In the case of Fiji, the donation will be according to a request signed by the Director of the FPBSC.
 - The donated medicines should NOT be directed to an individual or to a specific health facility. They must be directed to the Fiji Pharmaceutical and Biomedical Services Centre for appropriate storage and distribution
 - Medicines should not be sent without prior clearance by the recipient.
 - The Fiji Pharmaceutical and Biomedical Services Centre when receiving the medicines will be required to acknowledge receipt of the donated medicines.

The above provisions exclude donor-driven donations, or donations which arrive unannounced and unwanted. It encourages the people of Fiji to specify their needs, and empowers them to refuse unwanted gifts.

2. All donated medicines must be on the Fiji Essential Medicines List and in response to a specific exceptional need expressed by the authorised officer of the Fiji Pharmaceutical and Biomedical Services.
3. The presentation and strength of donated medicines should be similar to those commonly used in Fiji.

Quality and shelf-life

4. All donated medicines should comply with quality standards in both the donor and recipient country, ie the Republic of Fiji Islands. This provision prevents double standards. For example, donations of unused medicines (returned medicines from patients or doctors' free samples), which would not be acceptable for use in the donor country must not be donated to another country.
5. All donated medicines should have a remaining shelf-life of at least eighteen months after the arrival in the recipient country, ie the Republic of Fiji Islands.

Presentation, packing and labelling

6. All medicines should be labelled in English. The label should contain at least the International Non-proprietary Name (generic name), dosage form, strength, name of manufacturer, storage conditions and expiry date.

Product Information and Consumer Product Information (where available) should be included for each of the medicines sent.

7. As much as possible, donated medicines should be presented in larger quantity units that suit the distribution system and work-flow in Fiji.

Export and transport of medicines donations

8. All medicine donations should be packed in strong outer cartons and be accompanied by a detailed packing list which should specify the contents of each carton by generic name, quantity and expiry date. Cartons should be numbered and the contents of each carton listed in detail in the accompanying documents. In addition, the contents of cartons should be marked on the outside of cartons. Medicines should never be packed together with non-medicine items.

Preparation for consignment of goods must be undertaken in close cooperation with the recipient (the FPBSC) to determine the transport and clearance arrangements, documents needed by the recipient and the Customs Authorities, and the costs that need to be met by the donor. The FPBSC will require advance details of the content of the shipment and its time of arrival. In most cases international transport, customs warehousing, clearance costs and internal transport will need to be paid by the donor. However, in some cases the recipient is able to cover the cost of clearance and internal transport. Donating agencies should make their own arrangements to comply with these customs documentation requirements at all dispatch, transit and entry points.

Where unsolicited donations are received, the recipient should not be required to pay the costs of clearance. In addition, waste disposal is a major problem in Fiji and must not be exacerbated by the need to dispose of unnecessary, unsolicited donated products.

Value of medicines donations

9. In the recipient country the declared value of a medicine donation should be based on 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.

Note: Vaccine Donations

The donation of vaccines is not appropriate because of the logistical problems associated with transport and storage. Donations of money for purchasing vaccines is more helpful. Donations for vaccine purchase should only be directed to the Coordinator of the Expanded Program on Immunisation (EPI), Ministry of Health, Republic of Fiji Islands.

GUIDELINES FOR DONATIONS OF MEDICAL EQUIPMENT AND CONSUMABLES

Donation Process:

The purpose of this process is to clearly define the roles and responsibilities of both the donor and the MoHMS and is aimed at trying to ensure that equipment and consumable products received are useful and can be well integrated into the health system in Fiji. Consumables including products for laboratory and dental use will only be donated according to the detailed specifications of the recipient.

Pre-Donation Requirements:

Biomedical Equipment

1. Biomedical Equipment - Responsibility of Recipient

It shall be the responsibility of the Secretary of the National Biomedical Committee and the National Clinical Product Committee to justify the need for the medical equipment and consumables (eg dressings, appliances, bedding and linen, sutures, needles and syringes, gloves, spare parts, etc) being requested for or being offered and shall take into account the following:

- a. Status of existing resources (physical, financial, human).
- b. For equipment, any additional costs which will arise, such as additional staff, reagents and other chemicals and consumables, maintenance and general running costs.
- c. Any additional capital investment required, such as installation costs.
- d. Where intended medical equipment will be utilised.
- e. How the intended donation[s] will address the identified need.
- f. Demonstration of sustainability including:-
 - I. the availability of skilled and qualified health workers to operate and maintain the equipment;
 - II. whether it will be replaced at the end of its useful 'life' and how that capital investment will be planned.
- g. Where applicable, the Ministry of Health shall identify to the donor the standard model it requires based on the current model in use. The standards are developed by the respective Clinical Services Networks (CSNs) of the MoHMS and shall be revised and/or amended by the CSNs as and when appropriate in accordance with recognized standards set by the International Organisation for Standardisation (ISO) and the International Electro technical Commission (IEC). Should the offer of equipment be from the donor, the authority to accept the equipment and model will be the Director of FPBSC after consultation with the relevant program manager.

2. Biomedical Equipment - Responsibility of Donor

Where the potential donor is notified, it is the responsibility of the donor to contact FPBSC through the Director to formalise the donation process before making any shipments. It shall be the responsibility of the potential donor to make a critical evaluation of the intended medical equipment to be donated. The donor shall ensure that:

- a. The donated equipment is fully operational and that all the essential accessories and parts are available for immediate use of equipment.

- b. The donated equipment is of the standard model required by the MoHMS. In the event the standard model requested for by the MoHMS is not available due to unforeseen circumstances, any change[s] of standards thereafter will be done after prior agreement has been reached between the Director, in consultation with the relevant Program Manager, and the donor.
- c. Consumables and accessories for operation of equipment are supplied for 18 months of normal operation
- d. Consumables, accessories and parts are available from manufacturer for at least 3 – 5 yrs.
- e. All relevant documentation such as a check list, operating and service manuals and any training aids are available.
- f. The operating and service manuals and all other relevant documentation are available in English.
- g. Equipment is tested and passed the safety and performance tests by a competent biomedical engineer or a biomedical service organisation as per manufacturer' s specifications prior to shipment.

In accordance with the principle of effective communication as set out under Good Donation Practice (refer to Clause 1 of Principles of Donations on Page 2, ***all potential donors must have prior written approval from the Director of FPBSC after his collaboration with the relevant National Program Managers (EMA, LMU, Laboratory, Dental as appropriate).***

3. Prioritising Equipment Donations

As a general rule, the MoHMS shall give first priority to receiving donations of replacement equipment, over donations of additional equipment. It is unlikely that the MoHMS will be able to plan to finance the replacement of all essential equipment when it reaches the end of its useful 'life'. So, unless such equipment is no longer required its replacement should always take priority over any and all additional equipment. This rule should equally apply to donations of equipment as it should to MoHMS equipment purchases.

4. Support

It shall be the responsibility of the donor to ensure there shall be sales support for all donated equipment for a minimum of three years. This support should include spare parts, consumables and accessories (reusable or disposable), support for troubleshooting and repair and maintenance assistance.

5. Obsolescence

Obsolete equipment – or equipment for which replacement parts are unavailable – will not be donated to Fiji unless under conditions where MoHMS has agreed to do so for reasons which will benefit the health facilities and has specifically requested such equipment in writing. In such cases, equipment donated will be clearly marked for the identified reason and location for donation, together with all other necessary documentation.

6. Training

It shall be the responsibility of the Ministry of Health to ensure that any specialised training that may be required for the operation and/or servicing of donated equipment is undertaken prior to the arrival of the equipment in question.

In the instance of difficulty in organising training for operators and maintenance personnel the MoHMS may seek the assistance of the donor to suggest alternatives.

Once training requirements have been satisfactorily met the MoHMS shall inform the donor that the equipment may be packed for shipping.

7. Assembly, Packaging and Shipping:

The donor shall be responsible for the assembly, packaging and shipping of the donated equipment and shall ensure the following:

- Any radioactive sources need to be removed and packaged separately, safely and properly and appropriately marked and labelled.
- Fluids are to be drained and packaged safely and appropriately marked and labelled.
- Fragile parts are packaged with great care and appropriately marked and labelled.

Donated Equipment: Installation, Commissioning and Maintenance

The MoHMS Fixed Asset Management Manual sets out procedures for the installation, commissioning and maintenance of medical equipment. In cases where there are special technical installation requirements, installation shall be in accordance with the instructions received from the donor and shall be done by a biomedical engineer.

The donor shall preferably be responsible for the installation and related costs and commissioning of the donated equipment. However, in the case where a donor agency is willing to meet installation costs for the equipment being donated, the MoHMS shall ensure that all relevant documentation relating to installation costs of the donated equipment shall be made readily available to the donor agency.

The equipment shall then be commissioned by trained personnel in accordance with normal, standard principles for all health care services practice, prior to clinical use. This procedure shall include verification of proper and safe operation of the equipment.

The MoHMS shall be responsible to have a program in place to accommodate periodic inspection, maintenance and costs and calibration of the equipment that will enable the donated equipment to be maintained in a safe, operating environment to ensure maximum use of its lifetime span.

In the event where a donor agency is willing to provide funding to meet maintenance costs for a specified duration, the MoHMS and the donor agency shall draw up a maintenance agreement that clearly specifies the arrangements, roles and responsibilities of each party.

Follow-Up Evaluation:

The MoHMS and the donor should have a process to assess and evaluate the effectiveness of the donated equipment and its impact on service provision.

Unserviceable Equipment:

The standard procedures for the writing off and disposal of all fixed assets, whether donated or not, are defined in the Fiji Public Service Financial and Stores Regulations and also in the Ministry' s Fixed Asset Management Manual.

It shall be the responsibility of the Head of Department to initiate the writing off and disposal of unserviceable equipment in a timely manner. Under no circumstances must a write-off and disposal be unreasonably delayed, as this would lead to false records in the Fixed Asset Register and a failure to account correctly in the Financial Ledgers, all of which would attract fully justified and serious Audit criticism.

GUIDELINES FOR DONATIONS OF CONSUMABLES

Consumables - Responsibility of Recipient

- For consumables, provide detailed description including all specifications such as quantities, quality standards, size, numbers of items required, etc., in line with the National Essential Consumables List.

Consumables - Responsibility of Donor

- Consumables, including laboratory and dental consumables, must comply with the specification of the recipient.
- Consumables and accessories for operation of equipment are supplied for 18 months of normal operation.

Customs Clearance:

The MoHMS shall be responsible for the clearance of approved donated equipment, including materials for use of churches, from the Customs Department; and related transportation from the port of entry to FPBSC and there-after to the health facility where the equipment shall be installed and used. The FPBSC may not be by-passed.

All documentation related to the donated equipment shall be requested by the MoHMS prior to its shipment.

All consignments that arrive at any port of entry in Fiji bearing the markings and designated as 'Donated Equipment and/or Consumables' without a written approval from the MoHMS **shall not be accepted into the country**. In accordance with policy, the MoHMS shall ensure that Customs Officers at all ports of entry are aware of the policy on donated equipment.

Disposal of these unaccepted items shall be dealt with in accordance with existing procedures and regulations of the Customs Department.

REFERENCES

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Guidelines for the donation of medical equipment. Royal Australian College of Surgeons
[MEMPP donation guideline.pdf](#)