



Guideline for the Donation of Medical Products

February 2018

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Target Audience: MJF Health Team, MJF Board, VCH staff, Vanuatu MoH, Members of Public

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Document Date: February 2018

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Preface

Vila Central Hospital, Vanuatu, relies significantly of the donation of medical devices for its function. The Melanie Jewson Foundation is committed to supporting Vila Central Hospital through the ethical and responsible donation of medical equipment.

Acknowledgements

This document is built primarily on the foundation provided by the WHO document '*Medical device donations: Considerations for solicitation and provision*' (1), and the PQMD document '*PQMD guidelines for quality medical product donations*' (2). Both of these documents were intended for the purpose of adaptation for use by NGOs and charities, such as the MJF.

Abbreviations and Definitions

Consumables – Non-durable medical supplies that are usually disposable in nature; cannot withstand repeated use by more than one individual. They are primary and customarily used to serve a medical purpose, and may be ordered or prescribed by a physician. Examples include gloves, syringes and needles.

Consumer Products – Items in this category are available for consumers to purchase over the counter and include bandages, hygiene products and linen.

Durable Medical Equipment (DME) – Non-expendable articles used for medical care which can withstand repeated use. Examples of durable medical equipment include, but are not limited to, hospital beds, wheelchairs and IV poles.

Medical Equipment – A medical tool requiring calibration, maintenance, repair, user training and decommissioning – activities usually managed by clinical engineers. Medical equipment is used for the specific purposes of diagnosis and/or treatment of disease or injury. Examples include, monitors, pumps and incubators.

MJF – Melanie Jewson Foundation

MoH – Ministry of Health

VCH – Vila Central Hospital

1. Needs Assessment

A needs assessment is a systematic process for determining and addressing needs, or 'gaps' between existing conditions and desired ones. Here, it is a strategic part of the planning process, aimed at identifying, defining and prioritising requirements with regard to medical devices. A thorough needs assessment would include the potential impact on the service delivery within the health system of Vanuatu, and should take into account the overall objectives of VCH and MJF, long-term plans of use and human resources development.

A needs assessment should be conducted prior to making **every** donation. This should be conducted in thorough collaboration with VCH staff members, including clinical heads of departments, biomedical engineering and maintenance staff, as well as the Vanuatu MoH, to perform a thorough assessment of:

- 1.1. Health Need: including an analysis of the nature of the health need, the impact on the local population and the amount of time the health need is anticipated to impact the affected population.
- 1.2. Medical Equipment: an analysis of why this requested piece of equipment is necessary, how it will be used, why it is superior to currently available options and how it will meet the requested demand.
- 1.3. Consumables / Durable Medical Equipment: why these consumables / DME are required and how they will be used. When consumables / DME are being donated to support a specific piece of equipment, they need to meet the manufacturer's specifications in order to ensure compatibility.
- 1.4. Quantity: the quantity donated should fit the documented need in order to prevent/reduce waste, fraud and misappropriation or environmental problems.
- 1.5. Impact: how the donated equipment/consumable item is expected to impact the affected population, over what timeframe, in what way, and to how many people.
- 1.6. Capacity: does VCH have the capacity and facility to handle the equipment/consumable item. Factors to consider include, but are not limited to, avail-

able and appropriate space, electrical and pneumatic power, heating, ventilation and air conditioning.

- 1.7.Human Resources: is there trained personnel available to install, operate, maintain, calibrate and repair the device.
- 1.8.Ancillary equipment: is the donating piece accompanied by all necessary ancillary equipment?
- 1.9.Option appraisal: should there be more identified need than the MJF has capacity to fulfil, options should be selected according to how the needs are prioritised, the likely impact of the option, and the availability of resources.
 - 1.9.1.Prioritisation should be according to national and international policy as determined by the Vanuatu MoH.
 - 1.9.2.The aim is to give first priority to actions that will have the highest positive impact on the delivery of services, with the minimal use of resources:

Finances / Resources Required	Likely Impact of Change	
	Low	High
Low	Soft target: wait	Win: Go!
High	Refrain or wait	Challenging: wait

2. Appropriateness of the Donation

Ensuring the appropriateness of the donation is among the most important steps in any donation process. If the donated equipment is not appropriate it can create an additional burden for VCH, and potentially impede progress.

2.1.General

- 2.1.1.A donation should only be made based on an expressed need, by VCH or Vanuatu MoH (Requirements set out in Section 1).
- 2.1.2.A donation should be relevant to the health needs of the VCH community.
- 2.1.3.The product being considered for donation should be reviewed and approved by VCH/MoH prior to shipping.
- 2.1.4.The donated product should be culturally appropriate for the VCH community.

2.2.Medical Equipment

- 2.2.1. The MJF should conduct an assessment to ensure that VCH has the capacity to properly install, house, operate and service the equipment intended for donation.
- 2.2.2. Prior to donation, the MJF and VCH should work together to determine what, if any negative effects may occur as a result of donation, for example, financial burden.
- 2.2.3. The MJF should ensure that VCH is aware of all necessary ancillary equipment, ongoing supplies needed and utilities necessary to support the device prior to the donation being made.

2.3. Consumables / Durable Medical Equipment / Consumer Products

- 2.3.1. Prior to donation, the MJF and VCH should work together to ensure that the items for donation are of the appropriate product type, quantity, size, material etc to address the health needs of the population.
- 2.3.2. No expired consumables should ever be shipped. Country specific expiry guidelines should be followed at all times, unless written approval or exemption has been obtained. Expired consumer products may be donated, if acceptable within local practice or guidelines.

3. Quality

It is important to ensure that donations are of a high quality, and that steps have been taken to ensure that quality is maintained. There should be no double standard in quality. If an item is unacceptable in Australia, then it is also unacceptable for donation to Vanuatu.

3.1. General

- 3.1.1. Quality is of foremost importance. All donated products should be obtained from a quality ensured source and meet all quality standards, both in Australia and Vanuatu.
- 3.1.2. In order to demonstrate quality, documentation should accompany each shipment, eg Certificate of Compliance or Manufacturing
- 3.1.3. Adverse events should be documented in writing, sent to the MJF board, and investigated appropriately.
- 3.1.4. In the event of a recall being placed on the product, the MJF is responsible either for the update to new specifications, or the removal of the donated product.

3.2. Medical Equipment

- 3.2.1. The MJF and VCH should communicate to assess the advantages and disadvantages of new equipment versus used and refurbished equipment prior to donation.

- 3.2.2. All documentation including operating and service manuals, with parts list, should be included in the donation, in English or Bislama.
- 3.2.3. Prior to making the donation, the MJF is responsible for ensuring that the equipment is fully operational at the system and sub-system levels, and has all essential accessories and supplies.
- 3.2.4. Equipment should comply with all regulation standards in Vanuatu.
- 3.2.5. Equipment should meet all the manufacturer's existing safety and performance specifications. Where the equipment has been refurbished it should be done so to the original manufacturer's standards.
- 3.2.6. Ideally, equipment should have a period of technical assistance provided by the manufacturer/refurbisher, and access to spare parts and accessories.

3.3. Consumables / Durable Medical Equipment

- 3.3.1. The MJF should ensure that all consumables / DME being donated meet the quality standards, both in Vanuatu and Australia.
- 3.3.2. The medical and inventory staff at VCH should be involved in the ordering process, if possible, to ensure the usability of the donation.
- 3.3.3. All applicable laws and regulations in relation to expiration dating for disposable medical consumables / DME should be followed.
- 3.3.4. Unsterilised, expired or re-sterilised single use medical items, including equipment and implantable devices are not to be shipped without prior written approval from VCH.

3.4. Consumer Products

- 3.4.1. The MJF should ensure that all consumables / DME being donated meet the quality standards, both in Vanuatu and Australia.
- 3.4.2. The medical and inventory staff at VCH should be involved in the ordering process, if possible, to ensure the usability of the donation.
- 3.4.3. Consumer products with expiration dates less than 12 months should not be shipped without prior written acceptance from VCH, and an agreement that the product will be utilised before the expiry date, or properly destroyed.

4. Logistics

Proper steps must be taken, both by MJF and VCH to ensure that the product remains the highest quality and arrives as efficiently as possible. This should be done in accordance with the MJF's MOU with the Vanuatu MoH.

4.1. Packaging

4.1.1. Prior to shipping, the MJF should take all necessary steps and precautions to ensure the safe transport of the product so that it arrives in Port Vila undamaged.

4.2.Storage

4.2.1. Arrangements for any necessary storage should be made prior to shipping, and a clear understanding reached of who is responsible for paying for said storage.

4.2.2. Storage areas should be dry, well ventilated, well-lit and out of direct sunlight.

4.3.Shipping and Transportations

4.3.1. The MJF will work with a freight forwarder or directly for shipping lines and will prepare and collect all appropriate documentation prior to shipment.

4.3.2. The MJF is responsible for ensuring custom's clearance, and maintaining a current MOU with the Vanuatu MoH/Custom's Office for this purpose.

4.3.3. Prior to shipping, the MJF is responsible for ensuring that all components of the donated equipment (eg lithium batteries, IT equipment) are acceptable for import to Vanuatu, and that all regulatory and compliance hurdles have been met.

4.3.4. Costs of transportation should be addressed in advance by the MJF/VCH. Arrangements to pay required duties should be made prior to shipping, or Duty Free Clearance Status should be ensured prior to the shipment arriving.

4.3.5. The shipping documents should be clear, correct and contain all essential data and information required. They should include Bill of Landing, Shipping Notification, Packing List, Commercial Invoice and Donation Letter.

4.3.6. Prior to any donation being made, the MJF should perform due diligence to ensure that the donated products are not diverted for export, commercial sale, or into illicit channels.

4.3.7. Upon arrival of the shipment to the final destination, the donation should be inspected for any damage that may have occurred during shipping. If damage has occurred, the product should be disposed of in the appropriate manner.

5. Maintenance

Ongoing maintenance costs can represent a significant burden on VCH, and the MJF aims to minimise the ongoing financial impact of its donations, to ensure that they remain functional and viable long term.

- 5.1. Where there are ongoing requirements for specific consumable items to enable the functioning of a piece of medical equipment, for example, ECG paper, the MJF will determine a long term agreement with VCH prior to donation. Depending on individual circumstance this may include VCH taking over ongoing costs or MJF providing ongoing supplies for an agreed upon period of time.
- 5.2. Donated equipment should have at least two year's technical assistance, and access to spare parts and accessories. Prior to donation, the MJF and VCH will determine an approach to maintenance and spare parts purchase.

6. Disposal

Ensuring the proper disposal of unused or expired products is an important aspect of any donation plan to minimise environmental and health hazards. Destruction processes and documentation requirements should be agreed upon by the MJF and VCH prior to donation, and should take into account Vanuatu's guidelines.

- 6.1. VCH and MJF will agree upon who will pay for the eventual destruction of the medical product.
- 6.2. Outline local practices regarding the requirements of minimally accepted destruction practices, including required proofs.
- 6.3. Determine a hierarchy of concern regarding the destruction of a product, to ensure that the product is not saleable on the black market or cause undue health or environmental risks.

7. Monitoring and Evaluation

Evaluation is an important step to ensure that donated products are being used properly, as stipulated in an agreement. It is also vital to understand how well the various aspects of the specific donation worked, so that the appropriate changes can be made in the future, and ensure that the MJF's funds are being allocated in the most effective way in the future.

- 7.1. The MJF and VCH will agree in advance on what product and patient documentation will be kept updated on site for a reasonable amount of time.
- 7.2. The MJF will periodically evaluate donations to measure their impact.

7.3. The MJF, VCH and Vanuatu MoH should have a plan in place to review the donation program in order to learn from its successes and challenges.

7.4. When appropriate, reports and recommendations on post-donation evaluations should be disseminated to the general public to share lessons learned and progress made.

8. Emergencies

The MJF currently does not operate within the sphere of disaster relief. We are committed to providing long-term support to the VCH, aimed on facilitating their usual daily practice.

9. Pharmaceuticals

The MJF currently does not donate pharmaceutical or medicinal products of any kind.

References

1. WHO (2011), Medical device donations: considerations for solicitation and provision. Available from: http://www.who.int/medical_devices/management_use/manage_donations/en/ Accessed 15 September 2017
2. PQMD (2017), PQMD guidelines for quality medical product donations. Available from: <http://www.pqmd.org/pillars/donation-guidelines/> Accessed 15 September 2017