Guidelines
for
Donation of Medical Products 2025

Health Intervention and Technology Assessment Division
Department of Health Services
Ministry of Health

Version history

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Contents

1 Introduction

The Ministry of Health (MoH), Royal Government of Bhutan (RGoB), welcomes the appropriate donations of medicines and medical devices from national and international partners to strengthen the national health system and improve health outcomes for the population.

Donations shall be made in accordance with this guideline, which is aligned with internationally recognised principles for quality, safety, appropriateness and coordination of medical product donations, including those set out in World Health Organization (WHO) guidance on medicine and medical device donations. These international principles emphasise that donations should benefit the recipient to the greatest extent possible, be based on expressed need, and respect the authority and regulatory frameworks of the recipient country.

This guideline provides a clear, transparent and regulated framework to ensure that all donated medical products:

a) are based on an expressed need and agreed between the donor and the MoH;

b) comply with national regulatory and quality standards; and

c) contribute effectively and safely to the health system without imposing undue burden on the recipient.

2 Scope

These guidelines establish the requirements and procedures for the donation of health products to the Ministry of Health (MoH) of Bhutan and healthcare centres by national and international donors. They apply to all stakeholders involved in the donation, acceptance, importation, quality assurance, distribution, utilisation and monitoring of donated medical products, including but not limited to medicines, vaccines, medical devices, consumables, and medical equipment.

The purpose of this document is to ensure that all donated medical products are managed in a manner that upholds quality, safety, effectiveness, and appropriateness and are aligned with national health system needs and priorities, consistent with internationally recognised good donation practices.

3 Objectives

The objectives of these guidelines are to:

a) Streamline the process for managing donations of medical products to healthcare centres and the national health system, enhancing transparency, predictability and accountability in donation practices;

b) Define the roles and responsibilities of donors, the MoH and relevant authorities involved in the donation lifecycle, supporting coordinated action and effective oversight;

c) Ensure that all donated medical products are suitable for the Bhutanese health system, conform to national regulatory and quality requirements, and contribute safely and effectively to healthcare services without imposing undue burden on the recipient; and

d) Promote donations based on expressed needs, with products selected and accepted only after agreement between the donor and the MoH, reflecting national health priorities and resource capacity.

4 Normative references

The following normative documents contain provisions that, through reference in this guideline, constitute essential requirements. For dated references, only the edition cited applies. For undated references, the latest edition of the document (including amendments) applies.

a) Bhutan Medicine Rules and Regulations;

b) National Essential Medicines List (NEML); and

c) National Medical Devices List (NMDL).

5 Terms and definitions

For the purposes of these guidelines, the following terms and definitions apply:

5.1 Consumables

Disposable medical supplies for one-time use that are customarily used for a medical purpose and are not functional beyond a single use.

5.2 Donor

An institution or individual proposing to provide health products without financial consideration.

5.3 Import authorisation

An official document issued by the Bhutan Food and Drug Authority (BFDA) permitting the importation of medical products into the country.

5.4 Medical device

Any instrument, apparatus, implement, machine or related article intended by the manufacturer for use in the prevention, diagnosis, treatment, monitoring or alleviation of disease or injury.

5.5 Medical equipment

Medical devices that require calibration, maintenance, repair, training, and formal installation to operate safely and effectively.

5.6 Medical product

Any product used for medical purposes, including medicines, vaccines, medical devices, biological products and combinations thereof.

5.7 National Essential Medicines List

The list of essential medicines approved by the Ministry of Health, Bhutan, for use within the national healthcare system, reflecting priority healthcare needs.

5.8 National Medical Devices List

The list of medical devices approved by the Ministry of Health, Bhutan, based on national health priorities and the capacity to manage and use such devices.

5.9 Quality assurance documentation

Certificates, analysis reports, product registration authorisations and conformity evidence demonstrating compliance with applicable quality standards in both donor and recipient jurisdictions.

5.10 Recipient

The Ministry of Health or an entity authorised by the Ministry to receive donated medical products.

5.11 Shelf life

The period from manufacturing to the end of the period during which the product remains within approved specifications under defined storage conditions.

5.12 Obsolete

A product that is outdated due to technological advances or no longer meets performance requirements.

5.13 Packing list

Shipment document prepared by the consignor that provides an itemised inventory of the contents of a shipment, showing detailed information for each package such as description of goods, quantity, net and gross weights, dimensions and identification of packages. It is used to verify that the physical shipment corresponds to the approved donation and accompanying documentation and to facilitate customs clearance, logistics handling and receipt verification by the consignee and relevant authorities.

5.14 Pro forma invoice

Preliminary document issued by a donor before the delivery of goods, which describes the items to be shipped, their quantities, prices, terms of sale and other relevant details. It is provided in advance of a final commercial invoice to inform the recipient and relevant authorities of the expected contents and values of a shipment. The document may be used to help arrange import licensing, customs clearance and logistical planning, and to record agreed terms between parties prior to shipment.

5.15 Recall

An action taken to remove or correct a marketed product that is defective or potentially harmful.

6 Acronyms

BFDA	Bhutan Food and Drug Authority
BMRR	Bhutan Medicines Rules and Regulations
CE	Conformité Européene
DBME	Department of Biomedical Engineering
DHS	Department of Health Services
DMP	Department of Health Services
eBMSIS	Electronic Bhutan Medical Supplies and Inventory System
IEC	International Electrotechnical Commission
ISO	International Organization for Standardisation
MoH	Ministry of Health
NEML	National Essential Medicine List
NMDL	National Medical Devices List
RGoB	Royal Government of Bhutan
WHO	World Health Organization

7 Principles

This guidelines is underpinned by the following principles, consistent with internationally accepted good practices:

7.1 Recipient-centric needs

Donations shall be based on an expressed need as determined and endorsed by the MoH. Unsolicited donations shall be discouraged and shall only be considered if they meet documented national needs.

7.2 Respect for authority

Donations shall respect the policies, regulatory requirements and administrative frameworks of the MoH and relevant agencies.

7.3 Quality and safety

Products of substandard quality, banned, recalled, obsolete, refurbished without approved reconditioning evidence or otherwise unsafe shall not be accepted.

7.4 Communication and coordination

All stages of the donation lifecycle shall involve active communication between the donor and MoH, with written agreements prior to shipment.

7.5 Transparency and documentation

All donations shall be supported by complete documentation, including quality assurance certificates, packing lists and relevant documents.

8 General requirements

8.1 Designation of recipient and routing

8.1.1 All donations of medical products shall be officially routed through and approved by the MoH prior to shipment, importation, receipt, distribution or utilisation. Donated products intended for healthcare centres shall not be directly delivered to individual centres without formal authorisation from the MoH.

8.1.2 Donations will be accepted only if they correspond to documented national needs and priorities, including essential medicines and medical device lists or justifiable therapeutic needs endorsed by MoH. Requests shall be confirmed in writing before acceptance.

8.2 Review and conformity to National standards

8.2.1 The Department of Health Services (DHS) shall assess whether proposed donated products conform with applicable national standards, regulatory requirements and health system needs, including product registration or exemption as required by the Bhutan Food and Drug Authority (BFDA).

8.2.2 Products that are expired, outdated, obsolete, unserviceable, previously used, or refurbished without approved reconditioning evidence shall not be accepted under any circumstances.

8.2.3 The specifications, formulation, strength, presentation and quantity of donated products shall be agreed between the donor and MoH prior to shipment and documented in formal correspondence.

8.3 Implementation and procedural routing

8.3.1 Upon approval of a donation, the donor and the Department of Medical Products (DMP) shall process the donation, ensuring compliance with import, storage, distribution and monitoring requirements.

8.3.2 The DMP shall coordinate with the donor, BFDA and other relevant authorities for import authorisation, quality inspection, clearance, distribution and monitoring of donated products.

8.3.3 Donors shall provide a *pro forma invoice* for the medical products to the DMP at least 30 calendar days before the planned shipment date to facilitate timely processing of import authorisation and logistics planning.

8.4 Costs and financial responsibilities

8.4.1 All costs associated with a donation, including shipment, importation, warehousing, customs clearance, local distribution, quality inspections, training (if applicable), and disposal of rejected products, shall be agreed in advance and documented in writing between the donor and MoH.

8.5 Product packaging, labelling and documentation

8.5.1 Donated products must meet labelling and packaging requirements consistent wiith international best practices for safe use and supply chain management. Labels shall be provided in English and include key information such as the product's generic/INN name, strength, batch/lot number, manufacturer, storage conditions, expiry date, and instructions for use where applicable.

8.5.2 All medical products shall be packaged and shipped in accordance with international packing and shipping standards to preserve quality and integrity throughout transport and storage. Packaging shall be robust, secure and suitable for the mode of transport selected.

8.5.3 Shipments shall be accompanied by a detailed packing list that specifies the contents of each package, including product description, quantity, batch/lot numbers, expiry dates, weights, shipment unit identifiers and any special handling or storage conditions.

8.5.4 Products requiring temperature control shall be clearly labelled with their specific temperature requirements and shipped with appropriate temperature monitoring devices to ensure compliance with specified conditions during transport.

8.6 Quality inspection and acceptance

8.6.1 The DMP shall facilitate quality inspection and verification upon receipt to ensure that the donated products match approved specifications and documentation.

8.6.2 Products that fail the quality inspection shall not be accepted and shall be returned or re-exported at the donor's expense. Such rejected items shall not enter the national supply chain.

8.7 Inventory registration and tracking

8.7.1 All donated products that are accepted and received or installed at a healthcare centre shall be entered in the electronic Bhutan Medical Supplies and Inventory System (eBMSIS), including detailed records of batch/lot numbers, expiry dates, storage location and utilisation tracking.

9 Specific requirements by product category

9.1 Medicines and vaccines

9.1.1 Donations of medicines and vaccines shall conform to the National Essential Medicines List (NEML) of Bhutan or be specifically justified based on therapeutic need and endorsed by the MoH.

9.1.2 All donated medicines and vaccines shall have a minimum remaining shelf life of 70 % of their total shelf life at the time of receipt. For products whose total shelf life is less than 12 months, the donated quantities shall be divided into two separate lots, or otherwise arranged, as agreed in writing between the donor and the MoH.

9.1.3 Prescribing information and storage requirements shall accompany all donated medicines and vaccines. Labels shall be in English and comply with labelling requirements, including the international non-proprietary name (INN), batch/lot number, dosage form, strength, manufacturer and expiry date.

9.1.4 Donated medicines and vaccines shall be obtained from quality-assured sources and comply with quality standards acceptable in both donor and recipient jurisdictions.

9.2 Medical equipment

9.2.1 Donated medical equipment shall be fully functional upon arrival and include all essential accessories, consumables and working materials necessary for proper operation, as agreed between the donor and MoH.

9.2.2 Donated equipment and medical devices shall be supplied with consumables and accessories sufficient to support a minimum of 12 months of normal operation for each healthcare centre, unless a different operational period is agreed in writing between the donor and recipient. The provision shall include, but not be limited to, reagents, spare parts, operational supplies and other ancillary items necessary for safe and effective use.

9.2.3 Donors shall provide all user manuals, installation guides and service documentation in English.

9.2.4 Donated equipment shall meet the manufacturer's safety and performance specifications and, where applicable, conform to internationally recognised standards such as those of the International Organization for Standardisation (ISO),

Conformité Européene (CE) and International Electrotechnical Commission (IEC) or equivalent regulatory frameworks.

9.2.5 Donors shall support the installation, commissioning and operational training for complex and high-end equipment. Training shall be provided to end-users and maintenance staff to ensure safe and effective use.

9.2.6 Where donors agree to fund maintenance over a defined period, the donor and the Department of Biomedical Engineering (DBME) shall formalise a maintenance agreement detailing roles, responsibilities, service levels, spare parts provisioning, calibration schedules, and associated costs.

9.3 Consumables

9.3.1 Donated consumables and single-use medical supplies shall be supplied with clear expiry dates and shall not include used or reprocessed items unless they have been properly sterilised and shown to meet applicable safety standards.

9.3.2 Consumables intended for use with specific devices shall match the brand and model specifications of the recipient's equipment.

9.3.3 All donated consumables shall have a minimum remaining shelf life of 70 % of their total shelf life at the time of receipt. For products whose total shelf life is less than 12 months, the donated quantities shall be divided into two separate lots or otherwise arranged, as agreed in writing between the donor and the MoH.

9.3.4 Donated consumables shall be stored and transported in strict accordance with the manufacturer's labelled instructions for storage, handling and transport, taking into account specified environmental conditions.

9.4 Packaging, temperature control and transportation

9.4.1 All donated products, including medicines, vaccines, devices and consumables, shall be packed in compliance with international shipping standards to ensure product integrity during transportation and handling.

9.4.2 Products requiring temperature control shall be clearly labelled with their specific storage and transport conditions and shipped with temperature monitoring devices to record and demonstrate compliance throughout transit.

10 Roles and responsibilities

10.1 Donor

10.1.1 Ensure that the proposed donation is aligned with the expressed needs of the MoH and conforms to the agreed specifications, quantities and timelines.

10.1.2 Organise logistics and transport from the point of origin to the port of entry in Bhutan in accordance with the agreed plan, including temperature control where applicable and advance notification of arrival details.

10.1.3 Provide evidence that the donated products meet internationally accepted standards and are not subject to bans, recalls or regulatory restrictions.

10.1.4 For donated equipment and devices, coordinate with the MoH for installation support, user training, and operational guidance to ensure safe, effective use. This includes supplying manuals and service documentation in English language.

10.2 Department of Health Services

10.2.1 Review donation proposals for alignment with national health priorities and compliance with relevant standards, including the National Essential Medicines List (NEML), the National Medical Devices List (NMDL), and applicable regulatory criteria. Based on this review, DHS shall formally approve or reject donation proposals and shall document the rationale for each decision.

10.2.2 Facilitate communication between the donor and other departments throughout the donation lifecycle, and maintain records of decisions, outcomes, stock status, and any issues encountered.

10.3 Department of Medical Products

10.3.1 Coordinate with relevant agencies for import authorizations, customs clearance, and logistical arrangements upon shipment arrival.

10.3.2 Arrange and manage logistics, transport, and warehousing of donated products within Bhutan, ensuring compliance with standards for handling and storage.

10.3.3 Oversee quality inspection and distribution of donated products to ensure products are safe, functional, and appropriately utilized within the health system.

10.3.4 Distribute accepted donated products to healthcare centers in accordance with the distribution order.

10.3.5 Maintain an up-to-date inventory of all donations, including product details, inspection outcomes, distribution records, and utilization monitoring.

10.4 Bhutan Food and Drug Authority

10.4.1 Process and issue import authorizations for donated medical products in accordance with national regulatory requirements.

10.4.2 Confirm that donated products comply with applicable national regulations, including registration status or exemptions, labeling standards, and quality requirements prior to entry.

10.5 Department of Biomedical Engineering

10.5.1 Oversee the safe installation, calibration, and commissioning of donated equipment and devices at designated healthcare centers in line with manufacturer specifications.

10.5.2 Support planning for ongoing maintenance, servicing, and spare parts availability, including documentation of responsibilities if donor-funded maintenance is provided.

10.5.3 Ensure that end-users and healthcare centre technicians receive appropriate training and technical support to operate and manage equipment safely.

10.6 Recipient healthcare centres

10.6.1 Verify the quantity, physical condition and documentation of donated products against the packing list and other shipment documents upon arrival.

10.6.2 Record all accepted donated products in the inventory management system with detailed traces of batch/lot numbers, expiry dates and storage location.

10.6.3 Ensure storage, handling and use of donated products follow manufacturer requirements and applicable guidelines.

11 Reference

a) World Health Organization (2011). Guidelines for Medicine Donations, Revised 3rd Edition. World Health Organization, Geneva.

b) World Health Organization (2024). Medical Device Donations: Considerations for Solicitation and Provision, 2nd Edition.

c) Partnership for Quality Medical Donations (PQMD). PQMD Guidelines for Quality Medical Product Donations.

d) ISO 13485:2016 .Medical Devices – Quality Management Systems - Requirements for Regulatory Purposes.

12 Annexures

Annexure 1: Operational conditions for donated equipment

All medical equipment donated should conform to the following voltage specifications and operational environmental conditions:

Voltage of AC supply

a) For single-phase equipment: 230V ± 6%, 50Hz ± 1%

b) For three-phase equipment: 400V ± 6%, 50Hz ± 1%

**For sensitive medical equipment like laboratory analysers and ultrasound imaging systems, online UPS or UPS with stabiliser should be supplied. Further, X-ray imaging systems suhould be supplied with servo-voltage stabilisers.*

Operational environmental conditions

a) Temperature: 5 - 40°C

b) Relative humidity: 4 to <90%

c) Altitude: 200 - 3000m

d) Atmospheric pressure: 500 - 800 mmHg

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