PQMD™

The Partnership for Quality Medical Donations

PQMD GUIDELINES FOR QUALITY MEDICAL PRODUCT DONATIONS

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PQMD GUIDELINES

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In the mid-to-late 1990s, there was growing concern that donations of medical products were actually damaging the viability of host country healthcare programs. Despite much evidence of well-managed donation programs, there was increasing evidence that situations of natural disasters and wars created opportunity to dump unwanted, expired, even dangerous products into those environments. Global health interests were concerned that efforts to build universal formularies to manage pharmaceuticals in developing countries were being undermined by the shipment of brand-name products, expired products, "garbage bags" containing a disparity of sample drugs in two-tablet packaging. The World Health Organization, joined by the World Council of Churches and others called for the establishment of international guidelines and protocols for the delivery of donated medical products.

In 1999, a small group of American pharmaceutical manufacturers and non-profit organizations realized the importance of joining the discussion. They committed themselves to a process to create Guidelines that would reflect the best efforts of their programs and would also address concerns of the global health community. That informal, pioneering group that became known as "The Partnership for Quality Medical Donations, Inc.,(PQMD)". PQMD has taken seriously the importance of a Guidance Document to inform and guide the practices of organizations that engage in medical product and service donations.. In the intervening seventeen years, PQMD has demonstrated a continuing commitment to improve and implement "Guidelines" to manage donated medical products and the performance of those who participate in this industry.

This 2016 edition of the PQMD Guidelines, approved by the members of the PQMD Board of Directors on April 7, 2016, reflects the base of knowledge, experience and expectations of the membership for how medical product donations should be carried out. It is our hope that other organizations will join with the PQMD member companies and non-profit organizations in using these Guidelines to guide and inform their work in supplying donated medical products that address needs being experienced by partners, in their own countries and globally.

Randall Weiss
Board Chair

Elizabeth J Ashbourne
Executive Director

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OVERVIEW

In 1999, against a backdrop of inappropriate medical product donations and the WHO publication of their Inter-agency Guidelines to ensure appropriate and effective donations, an informed alliance of non-governmental organizations (NGOs) and Pharmaceutical and Medical Device companies incorporated. The goal of Partnership for Quality Medical Donations (PQMD) is to support adherence to and implementation of the WHO Guidelines and continue to encourage/develop appropriate and effective medical donations.

PQMD became the first U.S. organization to endorse and contribute to the WHO Inter-agency Guidelines on Drug Donations, and sponsored the first systematic assessment of Pharmaceutical donations conducted by the Harvard School of Public Health.

In response to the recommendations which came from the Harvard assessment, and working with Temple University, PQMD published The Seven Key Components in the Comprehensive Management of Medical Product Donations. These Guidelines provided some practical advice for organizations considering the management of medical donations in a manner consistent with the WHO Guidelines on Drug Donations.

In 2011, PQMD worked to update the Seven Components and make them into a more detailed document to align with general donation practices. PQMD was, and remains, the only organization to tackle a comprehensive overview of product donations across pharmaceuticals, medical devices, medical equipment, consumables and consumer products. We feel that through our diverse membership of Donor Companies and NGO partners we have a broad level of understanding of the issues with donations of these types.

As we continue to expand our knowledge, and as the global health environment continues to change, we felt it was time to again review and revise our Guidelines. This version is more detailed, and includes new classes of equipment, and new issues to be faced. At the heart of the document, however, is the reliance on long standing partnerships. A truly successful donation program must rely on trust, knowledge, and familiarity with programs, products, and global health trends. Donations cannot be made without due consideration of a number of topics – some of which are highlighted herein.

We also acknowledge that the world is changing fast, and other organizations involved in global health work are developing more detailed guidelines. We present with this version other standards/guidelines known to us in the reference section.

Finally, we acknowledge that this document is not all inclusive. Based on the nature of our membership, we are focused on product which is donated from an original manufacturer directly to an NGO partner. Medical surplus product, product salvaged from a health care facility, previously kitted product which is being redistributed or refurbished equipment being redeployed from any source, is not included in these Guideline. Nor is there an in depth discussion of tariffs, customs, etc.

Definitions

Bill of Lading/Airway Bill - A document issued by a carrier that lists goods being shipped and specifies the terms of their transport. Alternately – A legal document between the carrier of goods and the shipper that details the type, quantity, destination and receiver of the goods being shipped. This document should accompany the goods and be signed by the carrier, shipper and receiver as receipt of transport.

Certificate of Donation (Free of Charge Invoice) - This document is a customs declaration used to clearly state that the goods being transferred are being donated from the consigner to the consignee. The document is generated by the organization exporting the goods internationally. It is used by the importing country to calculate tariffs, and includes details of the goods and the parties involved in the shipment.

Company – The company/manufacturer that is the original owner of the item being donated.

Consumables - Non-durable medical supplies that are usually disposable in nature; cannot withstand repeated use by more than one individual; are primarily and customarily used to serve a medical purpose; generally are not useful to a person in the absence of illness or injury; may be ordered and/or prescribed by a physician. Examples of medical supplies include, but are not limited to, gloves, oxygen, and syringes.

Consumer Products – Items in this category are available for consumers to purchase over the counter (OTC - without a prescription) and include bandages, medicines not requiring a prescription, hygiene products, etc.

Consignee – A party (usually a buyer) named by the consignor (usually a seller) in transportation documents as the party to whose order a consignment will be delivered at the port of destination. The consignee is considered to be the owner of the consignment for the purpose of filing the customs declaration, and for paying duties and taxes. Formal ownership of the consignment, however, transfers to the consignee only upon payment of the seller's invoice in full.

Distributing Partner - Any organization that receives the donation on its way from the **Donor** to the patient. Organizations that could fall into this category include, but are not limited to, governmental agency (ies), NGOs, hospitals, clinics, etc. Each **Distributing Partner** is accountable, in regards to tracking, management and compliance, to the **Donor.**

Donor – The organization who offers the product for donation to a **Distributing Partner.** This could include, but is not limited to, Companies or NGOs. All **Distributing Partners** should be held accountable to the **DONOR** in regards to tracking and management of the donated product.

Drug Supply Chain Security Act (DSCSA) – The Drug Quality and Security Act (DQSA), was signed into law by President Obama on November 27, 2013. Title II of DQSA, the Drug Supply Chain Security Act, outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States.

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

Gift in Kind (GIK) – Also referred to as in-kind donations, a kind of charitable giving in which, instead of gifts of money to buy needed goods and services, the gifts are actually the goods and services themselves.

Medical Device- An article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose.

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 treatment of disease or rehabilitation following disease or injury; it can be used either alone or in combination with any accessory, consumable, or other piece of medical equipment. Examples of Medical Equipment include, but are not limited to, endoscopic generators, autoclaves, monitors, pumps, respirators, and incubators. Medical equipment does not include implantable, disposable or single-use medical devices.

NGO - A Non-Governmental Organization. A non-governmental organization (**NGO**) is any non-profit, voluntary citizens' group which is organized on a local, national or international level.

Packing List - Itemized list of articles usually included in each shipping package, giving the quantity, description, and weight of the contents. Prepared by the shipper and sent to the consignee for accurate tallying of the delivered goods. Also called bill of parcels, packing slip, or unpacking note.

Patient – The individual or individuals that are receiving medical treatment.

Pharmaceutical/Biopharmaceutical - A compound/biological agent manufactured for use as a medicinal drug. The terms, in this document, are used interchangeably.

Section I.

This section deals with the structure of organizations, how they operate, and how they interact with other organizations.

1. Governance

1.1. **Companies** and **NGOs** should have a documented Gift in Kind (GIK) standard operating policy and procedures.

1.2. **Companies** and **NGOs** should have a person on staff with responsibility and oversight for GIK donations.

1.3. **NGOs** should be registered with the appropriate governmental authority as a non-profit corporation with a tax exempt designation as a 501(c)3 for US or equivalent as appropriate for international laws.

1.4. **Companies and NGO**s should have bylaws that are reviewed and updated on a regular basis, as determined to be adequate by the board of directors.

1.5. **Companies and NGOs** should be governed by a duly appointed or elected board of directors that is mandated by organizational bylaws.

2. Finance

2.1 U.S. based **Companies** and **NGOs** should comply with Generally Accepted Accounting Principles (GAAP.) Non-U.S. Based **Companies** and **NGOs** should comply with standards as appropriate for their country.

2.2 **Companies** and **NGOs** should have a financial statement that is audited annually, or as required by law.

2.3 **Companies** and **NGOs** should recognize the Financial Accounting Standards Board (FASB) as the accounting standards setter for organizations located and/or operating in the United States. International organizations shall recognize their country's equivalent.

2.4 **NGOs** should file an IRS 990 tax return in the U.S. or international equivalent when applicable by law.

3. Policies

3.1 **Companies** and **NGOs** should not offer or accept donations of a product for which there is no specific programmatic need. *See section 6 Appropriateness of the Donation*.

3.2 **Companies** and **NGOs** should be in compliance with regulations such as the Foreign Corrupt Practices Act (FCPA), Health Care Compliance regulations, Office of Foreign Assets Control (OFAC), the Drug Supply Chain Security Act (DSCSA), or international equivalents as required by law.

3.3 **NGOs** should have a policy in place to ensure that if a service fee is charged when donating product, the fee does not exceed the expense incurred to source, administer, process, warehouse, manage and handle the GIK provided.

3.4 **Companies** and **NGOs** should have a policy and/or procedure in place for selecting and evaluating the **Distributing Partner**.

3.5 **Companies** and **NGOs** should have a policy and/or practice in place to ensure each donation complies with the PQMD Donation Guidelines.

3.6 Companies and **NGOs** should have a written conflict of interest policy that is applicable to all organizational employees and volunteers.

4. Organizational Evaluation

4.1 **Companies** and **NGOs** should have a current strategy that outlines their operational goals for product donations.

4.2 **Companies** and **NGOs** should develop criteria against which to evaluate the effectiveness of programs that integrate GIK, and complete said evaluation on a regular schedule, as appropriate.

4.3 **Companies** and **NGOs** should evaluate their partners to ensure that partnership objectives are being met. This evaluation shall be conducted on an ongoing basis for the purpose of determining the benefit of future partnerships.

5. General Assessment (Partner and Location)

5.1 Country and Regional Assessment

5.1.1 Geographic Region: When conducting a needs assessment the **Donor** should take the following geographic factors into account: the area's location, accessibility, climatic conditions, and security status.

5.1.2 Population Characteristics: When conducting a needs assessment, it is important for the **Donor** to take the following population characteristics into account: demographics and socioeconomic status.

5.1.3 Local Government: Prior to beginning work in-country, **Donors,** guided by local expertise, should have a clear understanding of the rules, regulations, and receptivity of the local government to foreign aid agencies.

5.1.4 Health Care Infrastructure: Prior to beginning work in a country, **Donors** should have a clear understanding of the local healthcare infrastructure, including location and capacity of nearby health facilities, and other **NGOs** working in the area, and its receptivity to outside support.

5.1.5 Medical Culture and Traditional Health Practices: Prior to working in a country, it is important for **Donors**, guided by local expertise, to understand the medical culture, beliefs and traditional health practices of the local population.

5.2 In-Country Partner:

5.2.1 Communication: Before working with a **Distributing Partner**, the **Donor** needs to determine what will be the most effective modes of communication. This determination will be based on factors including existing infrastructure, ease of access to technology, and facility location.

5.2.2 Mission: When determining whether or not to work with a new **Distributing Partner**, the **Donor** should determine if the missions of the two organizations align.

5.2.3 Human Resources**:** The **Donor** should obtain appropriate information on the **Distributing Partner's** staff capacity and qualifications that directly determine the ability of the **Distributing Partner** to effectively handle and distribute the donation.

5.2.4 Facility: The **Donor** should obtain appropriate information on the **Distributing Partner's** facility that directly determines their capacity to effectively handle, store and distribute the donation. This would include but is not limited to warehouse and/or storage capacity, climate control, and clinic capacity. *See section 9 Logistics*

5.2.5 Contact Information: The **Donor** needs to maintain an updated contact list (with **Distributing Partner'**s information) that can be accessed if any issues arise.

5.2.6 Sale of Donated Product**:** Prior to making a donation, the **Donor** must be certain that the **Distributing Partner** has the proper policies and procedures in place to prevent GIK product from being sold, either intentionally or by unintentional mixing with products designated for purchase.

5.2.7 End-Use Transfer: 5.2.7 End-Use Transfer: The **Donor** must track donation to the **Distributing Partner,** to ensure the product is handled and stored properly, used by trained personnel, maintained as required, or destroyed.

5.3 Logistics Assessment: Prior to working in a country, **Donors** need to assess the logistics capabilities of that country in order to identify any potential problems or difficulties. Items to consider may include the transportation network, customs/MOH rules and regulations, import laws, and local shipping and storage capacity. *See logistics section for additional logistics information.*

Section II

Section II addresses the specific steps taken during the donation process. The areas covered in this section are; Needs Assessment, Donation Appropriateness, Quality, Logistics, Disposal, Emergency, Monitoring and Evaluation, and Valuation.

6. Needs Assessment (non-disaster)

A needs assessment is a systematic process for determining and addressing needs or "gaps" between current conditions and desired conditions or "wants". The discrepancy between the current condition and wanted condition should be measured to appropriately identify the need. The need can be a desire to improve current performance or to correct a deficiency.

A needs assessment is part of the planning process often used for improvement in individuals, education/training, organizations, or communities. By clearly identifying the problem, resources can be directed towards developing and implementing a feasible and applicable solution. Gathering appropriate and sufficient data informs the process of developing an effective program that will address the group's needs and wants.

6.1 General

6.1.1 Nature of the Health Need: When conducting a needs assessment, **Companies** and **NGOs** should take the following factors into account: nature of the health need, impact on the local population, and the amount of time the health event is anticipated to impact the affected population.

6.1.2 Quantities donated should fit the documented need in order to prevent/reduce waste, fraud, and misappropriation or environmental problems.

6.1.3 Disposal is a key item for consideration in all cases of donations. It is key, therefore, that the **Distributing Partner** have a plan for disposal in line with the requirements set out in **Section 10 – Disposal**.

6.2 Pharmaceutical

6.2.1 Prior to the donation of any pharmaceuticals, **Companies** and **NGOs** should determine if the product being sent matches the expressed need and is appropriate for treating the affected population.

6.2.2 Prior to the donation of any pharmaceuticals, **Companies** and **NGOs** should determine if the **Distributing Partner** has the proper storage facilities for the product. This includes adequate space, lighting, fire protection, shelving, dispensary/security, and climate control.

6.2.3 When conducting a needs assessment, **Companies** and **NGOs** should determine if the **Distributing Partner** has appropriately trained medical professionals for prescribing, handling and dispensing of pharmaceuticals prior to any donation being made.

6.2.4 Prior to donating pharmaceuticals to a country, a **Donor** should know and follow all rules and regulations governing donated medicines in that country. This can include but is not limited to what drugs are registered for use in the country, what appears on the country's list of essential medicines, and any national standard treatment and language labeling guidelines.

6.3 Medical Device and Equipment

6.3.1 Prior to donating any piece of medical equipment the donating **Company** and **NGOs** should work with the **Distributing Partner** to create an analysis of why the requested equipment is necessary, how it will be used, why it is superior to currently available local diagnostic and/or treatment options, and how it will meet the requested demand.

6.3.2 Prior to donating a piece of medical equipment the **Donor** must assess the **Distributing Partner's** facility and capacity to handle the equipment. Important factors to consider include but are not limited to available and appropriate space, electrical and pneumatic power, heating, ventilation, and air conditioning.

6.3.3 Before a piece of medical equipment is sent the **Donor** must determine if the **Distributing Partner** has staff that is properly trained to install, operate, maintain, calibrate and repair the device.

6.3.4 If donating a piece of equipment that is not accompanied by all necessary ancillary equipment, the **Donor** should determine if it is locally available and feasible for the **Distributing Partner** to procure.

6.3.5 When items are being donated to support a specific piece of equipment, the **Donor** should be aware of the manufacture's specification for that exact piece of equipment, in order to ensure compatibility.

6.4 Durable Medical Equipment

6.4.1 Prior to donating any piece of durable medical equipment the **Donor** should work with the **Distributing Partner** to create an analysis of why the requested equipment is necessary, how it will be used, why it is superior to currently available local options, and how it will meet the requested demand.

6.4.2 Prior to donating a piece of durable medical equipment the **Donor** should assess the **Distributing Partner's** facility and capacity to handle the equipment.

6.5 Consumables

6.5.1 **Donors** should determine if the **Distributing Partner** has the appropriately trained personnel necessary to properly manage the medical consumables being donated.

6.5.2 When consumables are being donated to support a specific piece of equipment, the **Donor** should be aware of the manufacturer's specification for that exact piece of equipment, in order to ensure compatibility.

6.6 Consumer Products

6.6.1 Prior to the donation of any over the counter/consumer products, **Donors** should determine if the product being sent matches the expressed need and is appropriate for treating the affected population.
6.6.2 Prior to the donation of any consumer products, **Donors** should determine if the **Distributing Partner** has the proper storage facilities for the product. This includes adequate space, lighting, fire protection, shelving, dispensary/security, and climate control.
6.6.3 When conducting a needs assessment, **Donors** should determine if the **Distributing Partner** has appropriate personnel for handling and dispensing of products prior to any donation being made.

7. Appropriateness of the Donation

Ensuring the appropriateness of a donation is one of the most important steps in any donation process. If a donation is not appropriate it can create additional burden for the **Distributing Partner** and in disaster situations, it can actually impede recovery efforts. The guidelines below outline important steps that can be taken to help ensure that a donation is appropriate for the situation and **Distributing Partner** population.

7.1 General

7.1.1 A donation should only be made based on an expressed need, and specifically requested by the **Distributing Partner**.
7.1.2 A donation should be relevant and appropriate to the health needs of the target population.
7.1.3 Product being considered for donation should be reviewed and approved by the **Distributing Partner** prior to shipping, including quantities to be received and expiry dating.
7.1.4 Donated product should be culturally appropriate for the target population and the **Distributing Partner**.
7.1.5 Disposal is a key item for consideration in all cases of donations. It is key, therefore, that the Distributing Partner have a plan for disposal in line with the requirements set out in Section 10. Disposal.

7.2 Pharmaceuticals

7.2.1 Donated medicines or their generic equivalent must be approved for in-country use and/or on the national list of essential medicines or national treatment guidelines, unless approval is received from relevant authorities.
7.2.2 Donated medicines should fit strength, dosage, and formulation for treatment of target population.
7.2.3 Prior to donation, the **Donor** should ensure **Distributing Partner** has or will have all necessary equipment and consumables needed for proper use and disposal of specific medicine, such as sharps for injectables.
7.2.4 No expired product should ever be shipped. Country specific expiry guidelines should be followed at all times, unless written approval or exemption has been obtained.
7.2.5 Thought should be given to the declared value of the product (i.e. the market value in the donor country rather than the world market price). If the declared value is too high, it may result in high import taxes and overhead costs for storage and distribution. In some cases the total handling costs

(duties, storage, transport) are higher than the actual value of the medicines, or the medicine might be procured locally for less costs.

7.2.6 Donations of medicines for chronic conditions, including medicines that are required for lifelong treatment, should be strongly evaluated as unexpected discontinuation of these medicines can have severe results – for example, the disease may become recurrent, or resistance to the medicine may develop. At the start of a long-term donation program, a plan should be prepared on how to phase out a donation, as well as how to determine effectiveness and efficacy of the donation.

7.3 Medical Device, Equipment and Durable Medical Equipment

7.3.1 The **Donor** should conduct an assessment to ensure the facility has the capacity to properly install, house, operate and service the equipment.

7.3.2 The **Donor** will coordinate with the **Distributing Partner** to determine the best geographic location for medical equipment that will ensure effective patient access and use. Things to consider include catchment area, target population, regional disease area, **Distributing Partner's** area of influence, readiness to absorb technology, and potential impact on morbidity and mortality in the region.

7.3.3 The **Donor** and **Distributing Partner** should assess the advantages and disadvantages of new equipment versus used and refurbished prior to any donation. I.e. **Distributing Partner** may not have the capacity to operate a newer piece of equipment based on facility infrastructure or if future repair of equipment would be cost prohibitive.

7.3.4 Prior to the donation of a piece of medical equipment the **Donor** should work with the **Distributing Partner** to determine what if any negative effects may occur as a result. For instance, will the operation and maintenance of the equipment cause financial burden for the facility. Another important factor to consider is the impact the donation may have on the surrounding community, such as putting an existing locally operated facility out of business.

7.3.5 **Donor** should take care to include all vital supplies along with the equipment to ensure proper use and maintenance. The recommended quantity of supplies should cover two years of normal use in the market. Consideration should be given as to provision of supplies – to ensure shipment of supplies matches the ability of the **Distributing Partner** to store, mange, and secure the volume to be provided (i.e perhaps supplies should be shipped quarterly to allow storage and management of expiry). Supplies should include, but are not limited to, operational manuals, service manuals, accessories, consumables, reagents and spare parts. Some supplies which require specialized shipping might be best sourced locally, if possible (lithium batteries, reagents, etc.).

7.4 Consumables

7.4.1 Prior to the donation of any medical consumables the **Donor** should work with the **Distributing Partner** to ensure that the items are of the appropriate product type, quantity, size, material etc. to address the health needs of the target population.

7.4.2 No expired product should ever be shipped. Country specific expiry guidelines should be followed at all times, unless written approval or exemption has been obtained.

7.5 Consumer Products

7.5.1 Donated medicines or generic equivalent must be approved for in-country use and/or on the national list of essential medicines or national treatment guidelines unless approval is received from relevant authorities.

7.5.2 The Donor should also determine if the active ingredients in the consumer products being donated are culturally acceptable in the **Distributing Partner'**s country.

7.5.3 Prior to the donation of any consumer products, the **Donor** should work with the **Distributing Partner** to ensure that the items are of the appropriate product type, quantity, size, material etc. to address the health needs of the target population.

7.5.4 No expired product should ever be shipped. Country specific expiry guidelines should be followed at all times, unless written approval or exemption has been obtained.

7.5.5 Thought should be given to the declared value of the product (i.e. the market value in the donor country rather than the world market price). If the declared value is too high, it may result in high import taxes and overhead costs for storage and distribution. In some cases the total handling costs (duties, storage, transport) are higher than the actual value of the products, or the products might be procured locally for less costs.

8. Quality

Quality is an important thing to consider when planning a donation. It is important that the product be of high quality, and that steps be taken to ensure that quality is maintained. There should be no double standard in quality. If the quality of an item is unacceptable in the **Company's** country, it is also unacceptable as a donation. It is also important that the donation not exceed the amount needed by the **Distributing Partner,** which could create an additional burden for them in terms of storage and disposal.

8.1 General

8.1.1 The quality of the product must be of the foremost priority. All donated products should be obtained from a quality ensured source and meet all quality standards in both the **Company** and **Distributing Partner** countries.

8.1.2 In order to demonstrate product quality, appropriate documentation should accompany each shipment. Supporting quality documents may include a Certificate of Compliance, Manufacturing, or Analysis.

8.1.3 An adverse event reporting procedure should be documented and roles and responsibilities clearly understood.

8.2 Pharmaceuticals

8.2.1 The product's generic name should appear on all packaging and shipping documents, along with other relevant information, e.g. quantity, expiration date, lot and control numbers, and storage/temperature requirements.

8.2.2 Pharmaceuticals with expiration dates less than 12 months dating should not be shipped without prior written acceptance from the **Distributing Partner**, and an agreement that the product will be utilized before expiry or properly destroyed. The documentation should be signed by the person at the **Distributing Partner** organization who is responsible for the management of the donation, and should include a definition of 'properly destroyed' as well as outline who is responsible for payment and management of destruction (refer to Section 10. Disposal).

8.2.3 All pharmaceuticals must include prescribing information (i.e. product insert) in a language easily understood by the **Distributing Partner**.

8.2.4 It is NOT acceptable to donate unused medicines that were issued to patients or that were issued as free samples to health professionals. These medicines should be properly destroyed and must NOT be donated.

8.2.5 An established process should be understood by the **Distributing Partner** for reporting any patient adverse events. Process shall be outlined between **NGO** and **Company**, and communicated to **Distributing Partner** accordingly.

8.2.6 In the event of a recall or withdrawal of a donated product by the **Company** or medicines regulatory authority (i.e. FDA (U.S.), MHRA (UK), etc.), the donating company will notify the **NGO** of said recall, who will work closely with the **Company** to implement the recall per the required protocols. The **NGO** should collect all recalled products from **Distributing Partners**, hospitals, MOH, etc. and provide all documentation which verifies the collection and destruction of said product. Refer to Section 10. Disposal.

8.2.7 The **NGO** and **Company** should incorporate the developing requirements of the **Drug Supply Chain Security Act (DSCSA)** into all transactions. This should include, at a minimum, lot-level traceability and verification of products and transactions. Initially, this documentation will be provided on paper, but **Company** will endeavor to incorporate electronic data as quickly as possible.

8.3 Medical Device, Equipment and Durable Medical Equipment

8.3.1 All documentation including operating and service manuals, with parts list, should be included in the donation and in a language easily understood by the **Distributing Partner**.

8.3.2 Prior to making a donation the **Donor** will ensure that the equipment is fully operational at the system and sub-system levels, and has all essential accessories and supplies.

8.3.3 The **Donor** should ensure that the **Distributing Partner** is aware of all necessary ancillary equipment, ongoing supplies needed and utilities necessary to support the device, prior to the donation being made.

8.3.4 Equipment should not be donated if it is not approved by the appropriate regulatory body for use in the **Distributing Partner** country.

8.3.5 It is the responsibility of the **Donor** to identify donated equipment that has been recalled or placed under a hazard alert, and to ensure that it is either updated to the new specifications or disposed of in the correct manner (refer to Section 10. Disposal). In addition, equipment should not be donated if

it is subject to a recall or hazard alert from the manufacturer, unless it has been updated to meet the new requirements.

8.3.6 The donated equipment should meet all of the manufacturer's existing safety and performance specifications. In addition, when necessary the donated item should also meet standards set by international agencies including the International Organization for Standardization (ISO) and the International Electro Technical Commission (IEC).

8.3.7 Equipment should not be donated if spare parts, accessories, and technical assistance are no longer available for the particular product, or if it is expected to be discontinued in the next two years.

8.3.8 Used equipment should be decontaminated and sterilized prior to packaging and shipping.

8.4 Consumables

8.4.1 The **Donor** should ensure that the consumable being donated meets all quality standards in both the **Company** and **Distributing Partner** countries.

8.4.2 The medical and inventory staff at the **Distributing Partner** organization who will be using and handling the product should be involved in the ordering process, if possible, to ensure usability of donation.

8.4.3 All applicable laws and regulations in relation to expiration dating for disposable medical consumables should be followed.

8.4.4 In the event of a recall, it is the responsibility of the **Donor** to communicate and coordinate appropriate handling and disposal of the product with the **Distributing Partner (refer to Section 10. Disposal)**.

8.5 Consumer Products

8.5.1 The quality of the product must be of the foremost priority. All donated products should be obtained from a quality ensured source and meet all quality standards in both the Donor and Distributing Partner countries.

8.5.2 Consumer Products with expiration dates less than 12 months dating should not be shipped without prior written acceptance from the Distributing Partner, and an agreement that the product will be utilized before expiry or properly destroyed. The documentation should be signed by the person at the Distributing Partner organization who is responsible for the management of the donation, and should include a definition of 'properly destroyed' as well as outline who is responsible for payment and management of destruction.

8.5.3 In order to demonstrate product quality, appropriate documentation should accompany each shipment. Supporting quality documents may include a Certificate of Compliance, Manufacturing, or Analysis.

8.5.4 An adverse event reporting procedure should be documented and roles and responsibilities clearly understood.

8.5.5 Disposal is a key item for consideration in all cases of donations. It is key, therefore, that the Distributing Partner have a plan for disposal in line with the requirements set out in Section 10. Disposal.

9. Logistics

It is extremely important that the proper steps are taken both in the country of origin and the **Distributing Partner** country to ensure the product maintains the highest quality and arrives as efficiently as possible. Having a strong in-country relationship/partnership with the Ministry of Health, Customs Office, in-country Distributing Partner, a shipping broker and possibly the Ministry of Finance will improve your transportation/logistics process.

Packaging and storage can be some of the most complicated aspects of GIK logistics. Access to high quality medical products can be compromised when proper packaging/storage procedures aren't followed. It is important that all persons involved in the packaging and transportation of product/equipment be knowledgeable about shipping guidelines as well as the field conditions at the end destination.

9.1 General

9.1.1 Packaging

9.1.1.1 Cases, bagged or boxed units should be small and light enough to be managed by hand, if possible.

9.1.1.2 Packaging should be appropriate for the climatic conditions encountered in the **Distributing Partner** country.

9.1.1.3 Protective packaging should take account of the mode of transportation chosen, e.g. glass syringes and bottles should be packed to avoid breakage.

9.1.1.4 Labeling and packaging should be in a language easily understood by most health care professionals in the **Distributing Partner** country.

9.1.1.5 Packaging should be sealed securely to prevent opening in transit and ideally be designed to show evidence of tampering.

9.1.2 Storage

9.1.2.1 Arrangements for any necessary storage should be made prior to shipping, including if applicable, the warehouses of the **NGO**(s), **Distributing Partners**, freight forwarders, and in-transit layovers.

9.1.2.2 Storage areas should be dry, well ventilated, well lit, out of direct sunlight. Products requiring storage under defined conditions (such as temperature, light or humidity) should be stored in compliance with their instructions.

9.1.2.3 Prior to shipping any product the **Donor** should confirm that the **Distributing Partner** has properly trained staff to manage storage and warehouse facilities.

9.1.2.4 There should be a system of stock usage based on expiration date to ensure appropriate stock rotation (FEFO -first expiry/first out). Products beyond their expiry date or shelf life should be separated from usable stock. Expired products cannot be sold or supplied and arrangements need to be made for their destruction. Refer to section *10. Disposal.*

9.1.3 Shipping & Transportation

9.1.3.1 The **Donor** will work with a freight forwarder or directly with shipping lines for transportation and will prepare and collect all appropriate documentation prior to shipment.

9.1.3.2 The means of transportation should be appropriate to the circumstances of the donation, whether by air, sea or ground, taking costs and time into consideration.

9.1.3.3 Customs Clearance can be a difficult process to manage given governmental changes and ambiguities. It is key that the **Donor** has the process established prior to making the donation to insure timely clearance, and that the **Distributing Partner** understand that process in order to manage it.

9.1.3.4 Costs of transportation should be addressed in advance by the **Donor/Distributing Partner**. Arrangements to pay required duties should be made prior to shipping, or Duty Free Clearance Status should be obtained before shipment arrives in country.

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

9.1.3.6 Shipping should be in accordance with the **Distributing Partner** country's policies, examples could include customs, insurance, pallet regulations, etc.

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

9.1.3.8 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. *See 10. Disposal.*

9.1.3.9 The **Distributing Partner** should provide the **Donor** with verification of receipt upon acceptance of the donation, including date, count, and condition.

9.2 Pharmaceuticals

9.2.1 Packaging

9.2.1.1 The **Donor** should ensure pharmaceutical donations are packed in accordance with all international shipping requirements. Each shipment should be accompanied by a detailed packing list.

9.2.1.2 Products requiring temperature protection should be clearly labeled with temperature requirements and shipped separately from products not requiring temperature protection.

9.2.1.3 Maintenance of temperature protection should be confirmed and documented. If control thermometers are included in the packaging, there should be prior agreement between the **Company**, **NGO**, and **Distributing Partner**s regarding how and when they are to be read and analyzed, and the actions taken if there is an excursion. Clear instructions regarding those expectations should be included with the control thermometers.

9.2.1.4 The expiry date should be clearly labeled on all primary packaging.

9.2.2 Storage

9.2.2.1 Prior to shipment the **Donor** should ensure the **Distributing Partner** has a secure facility to store the product.

9.2.2.2 Drugs and vaccines should be stored apart from other goods and under the conditions specified by the manufacturer on the label to avoid deterioration by light, moisture or temperature.

9.2.2.3 Temperature and/or humidity should be monitored and recorded periodically. Records should be reviewed regularly.

9.2.2.4 When specific temperature storage conditions are required (i.e. Controlled room temperature, refrigeration, freezing), storage areas should be equipped with temperature recorders or other devices that will indicate when the specific temperature range has not been maintained. Ideally an alarm will indicate an excursion, and remediating action can be taken immediately. Alarms should run on a separate power supply or have backup systems during a power failure.

9.2.3 Shipping & Transportation

9.2.3.1 When considering the appropriate means of transportation for items requiring temperature protection, the **Donor** should take into account the duration of time that a shipment will spend in transport. Additional allowance should be made for unplanned layovers and customs delays.

9.3 Medical Device, Equipment and Durable Medical Equipment

9.3.1 Packaging

9.3.1.1 Prior to packaging the **Donor** should ensure that all necessary steps and precautions have been taken to ensure safe transport and that the device arrives at the destination undamaged. **Donor** should also verify that all items (lithium batteries, IT equipment, etc.) are acceptable for import to the destination country, and that all regulatory and compliance hurdles have been removed.

9.3.1.2 The **Donor** should ensure that all accessories, cables, and other items required for operation are included in the packaging prior to shipment. **Donor** should also ensure all operations, installation and maintenance manuals are provided to allow appropriate and proper operation of the product.

9.4 Consumables

9.4.1 Packaging

9.4.1.1 The expiry date should be clearly labeled and remain as originally printed on all individual packaging.

9.4.1.2 Consumables should be packed in boxes that protect the integrity of the product and are suitable for transportation.

9.4.2 Storage

9.4.2.1 Medical Consumables should ideally be stored and maintained in their original manufactured packaging, whenever possible. It is critical that the integrity of the product should not be compromised even if you are taking out of the packaging.

9.4.2.2 In the case of kitted products, the process should be managed under quality supervision according to internationally accepted formularies. The highest value is to use manufactured packaging to prevent the indiscriminant consolidating of items to the detriment of quality care.

9.5 Consumer Products

9.5.1 Packaging

9.5.1.1 The Donor should ensure product donations are packed in accordance with all international shipping requirements. Each shipment should be accompanied by a detailed packing list.

9.5.1.2 The expiry date should be clearly labeled on all primary packaging.

9.5.2 Storage

9.5.2.1 Prior to shipment the **Donor** should ensure the Distributing Partner has a secure facility to store the product.

10. Disposal

Ensuring the proper disposal of unused or expired products is an important aspect of any donation plan. Product that is improperly disposed of can pose significant environmental and health hazards. When pharmaceuticals are not properly destroyed, they pose a serious environmental risk and can pollute the local ground water. When medical waste is not handled properly it can pose a serious health risk to the surrounding human and animal population. It is in the best interest of **Donors** and **Distributing Partners** to have a thoughtful conversation about destruction parameters before an offer is made. Destruction process and documentation requirements shall be agreed upon between Company and NGO prior to any destruction of product, and shall take into account NGO/In Country Guidelines/SOPs, as well as local regulations. The conversation should include consideration of the following:

10.1 Determine who will pay for destruction, including any transport, fees, etc. This will likely vary depending on where the product to be destroyed is located (home country of donor, Distributing Partner country).

10.2 Outline the requirements around minimally accepted destruction practices, and minimal ‘proof’ of destruction (witness, photos, etc.).

10.3 Detail whether product is required to be reimported for destruction by the donor.

10.4 Understand what the acceptable local practices are for destruction. Are these acceptable to the donor? (Should product or packaging be rendered unusable/unreadable prior to destruction, etc.?)

10.5 Outline any specific environmental concerns which would dictate one destruction method over another.

10.6 Determine whether the product in question can be recycled in any way.

10.7 Determine whether the process for managing product to be destroyed differs between expired product and recalled product.

10.8 Outline what parties are required to be involved in the destruction decision process.

10.9 Determine a hierarchy of concern regarding destruction – is the key to insure product is not saleable on the black market or manage environmental impacts via varying destruction methods. This discussion will aid in choosing an appropriate destruction method.

11. Emergency

Even in an emergency situation, a needs assessment must be completed to ensure that appropriate products are provided. In some cases, a needs assessment is more critical in an emergency situation, as there is less ability of Distributing Partners to manage donations in light of other more acute concerns. By clearly identifying the problem, resources can be directed towards developing and implementing a feasible and applicable solution. Gathering appropriate and sufficient data informs the process of developing an effective program that will address the group's needs and wants.

11.1 Assessment

11.1.1 Prior to making a donation the **Donor** should determine whether the local government is accepting outside assistance. Every effort should be made to coordinate response efforts with local authorities.

11.1.2 The **Donor** should have an expedited plan for qualifying new partners during an emergency.

11.1.3 Prior to making a donation a **Distributing Partner** should be identified who is qualified to receive, manage, and distribute the donation.

11.1.4 During an emergency it is important to determine how and where other **NGOs** or international agencies are responding, in order to reduce duplication of effort.

11.1.5 The **Donor** should be aware of any potential security concerns.

11.1.6 The **Donor** should engage local partners and/or government officials in the assessment process.

11.1.7 Donations should only include products that have been specifically requested by the identified qualified local partner(s).

11.2 Quality

11.2.1 During a disaster product donations should be held to the same quality standards as in non-disaster situations.

11.2.2 Donated products should meet quality assurance requirements in the originating and **Distributing Partner** countries.

11.3 Logistics

11.3.1 The **Donor** should coordinate in-country logistics with **Distributing Partner** prior to a donation being sent.

12. Monitoring and Evaluation

Evaluation is an important step in any donation process. Monitoring and evaluation are required to ensure that donated products and medical equipment are being used properly, as stipulated in an agreement. It is vital to understand how well the various aspects of the program or specific donation worked, so that the appropriate changes can be made in the future. In addition, understanding a program's impact will ensure that resources are allocated in the most effective way in the future.

12.1 General

12.1.1 The **Donor** and **Distributing Partner** should agree in advance on what product and patient documentation will be kept on site for a reasonable amount of time and update regularly.

12.1.2 **Companies**, **NGOs** and **Distributing Partners** should evaluate donations periodically to measure their impact.

12.1.3 The **Donor** and **Distributing Partner** should have a plan in place to review the donation program in order to learn from its successes and challenges.

12.1.4 When appropriate, reports and recommendations on post donation evaluations should be made available in order to share lessons learned, as well as progress made.

12.2 Pharmaceuticals

12.2.1 Evaluations should include site inspections. Inspections by the **Donor** or other in country agency may include but are not limited to storage facilities, security measures, dispensary procedures and record keeping.

12.2.2 Program dispensary records should be reviewed on a regular basis to check for discrepancies and ensure that no diversion or other inappropriate activities have taken place.

13. Valuation

13.1 An organization's valuation framework should be compliant with generally accepted accounting principles.

13.1.1 An organization's valuation framework should be internally consistent in application.

13.1.2 Financial reviews should be conducted to ensure compliance with generally accepted accounting principles.

13.2 An organization's valuation framework should be clear and transparent.

13.2.1 A concise description of the valuation framework should be available to the public upon request.

13.2.2 Audited financial statements should be available upon request.

13.3 An organization's process used to determine product or service values should be explicitly documented through written practices and procedures.

13.3.1 The organization should maintain regular internal documentation demonstrating compliance with its practices or procedures.

13.4 Valuation frameworks for products or services should use methods that are practical and reasonable.

13.4.1 The value should accurately reflect the attributes of the products or services.

13.4.2 Product or service values should be determined by verifiable, active market data where available.

Section III

14. Reference Documents

14.1 WHO Guidelines for Medicine Donations, revised 2010. This 3rd edition of Guidelines for medicine donations has been developed by the World Health Organization (WHO) in cooperation with major international agencies active in humanitarian relief and development assistance. The guidelines are intended to improve the quality of medicine donations in international development assistance and emergency aid. Good medicine donation practice is of interest to both donors and Distributing Partners.
http://www.who.int/medicines/publications/med_donationsguide2011/en/index.html

14.2 "Making it Work: A toolkit for medical equipment donations to low-resource settings". This new resource has been developed by the Tropical Health & Education Trust (THET) to provide practical guidance to individuals and organizations planning to donate medical equipment overseas. It will assist people to evaluate whether or not to donate medical equipment in the first place, and if they decide to proceed, how to do so effectively. It is available to download online, alongside a series of a series of videos which highlight the critical issue of medical equipment donations, as well as what THET is doing to support partnerships to improve the maintenance and management of equipment overseas. Find out more at www.thet.org

14.3 World Medicines Situation Report -
http://www.who.int/medicines/areas/policy/world_medicines_situation/en/index.html

14.4 Guidelines for Disposal of Unwanted Pharmaceuticals in and After an Emergency
http://www.who.int/water_sanitation_health/medicalwaste/unwantpharm.pdf

14.5 EMERGO Group – A resource site for Medical Device and IVD Professionals
http://www.emergogroup.com/resources

14.6 WHO Certification scheme on the quality of pharmaceutical products moving in international commerce
http://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/en/

14.7 Medical Device Donations: Considerations for Solicitation and Provision, June 2011 - One of WHO's strategic objectives is to "ensure improved access, quality and use of medical products and technologies." To meet these objectives, WHO and partners have been working towards devising an agenda, an action plan, tools and guidelines to increase access to appropriate medical devices. This document is part of a series of reference documents being developed for use at the country level. This documents are intended for use by biomedical engineers, health managers, donors, nongovernmental organizations and academic institutions involved in health technology at the district, national, regional or global levels.
http://whqlibdoc.who.int/publications/2011/9789241501408_eng.pdf?ua=1

14.8 Drug Supply Chain Security Act (DSCSA) - Title II of the Drug Quality and Security Act of 2013

The Drug Quality and Security Act (DQSA), was signed into law by President Obama on November 27, 2013. Title II of DQSA, the Drug Supply Chain Security Act, outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States.
http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm376829.htm

14.9 WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce - The Scheme is an administrative instrument that requires each participating Member State, upon application by a commercially interested party, to attest to the competent authority of another participating Member State that: a specific product is authorized to be placed on the market within its jurisdiction or, if it is not thus authorized, the reason why that authorization has not been accorded; the plant in which it is produced is subject to inspections at suitable intervals to establish that the manufacturer conforms to GMP as recommended by WHO; and all submitted product information, including labelling, is currently authorized in the certifying country.
http://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/guidelines/en/

HISTORICAL RECORD

Version	Date	Author	Description of/Reason for Change
1	February 2014	Kim Keller - Chair	Revision in total
2	April 2015	Kim Keller - Chair	Clarifications around Destruction
3	November 2015	Kim Keller – Chair	DSCSA addition/Destruction additions
4A	March 2016	Kim Keller - Chair	Definition clarifications – Board Review
5	April 2026	Kim Keller - Chair	Board approval 2016