PQMD
Partnership for Quality Medical Donations

Guidelines for Quality Medical Product Donations 2023

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PQMD GUIDELINES

Revision of October 2023

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 significant efforts to ensure well-managed donation programs, there was also increasing evidence that situations of natural disasters and wars created opportunities to dump unwanted, expired, even dangerous products into the affected areas. 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 global pharmaceutical manufacturers and non-profit organizations realized the importance of being part of the thought leadership on the future of donations practices. They committed themselves to an iterative process to create Guidelines that would reflect the best efforts of their programs, build and evolve year-on-year based on best practices, and would also address concerns of the global health community about capacity gaps, safety, and efficacy. As more organizations contributed their expertise to the discussion and content of the Guidelines, the need for a more formal group emerged, which is today the “Partnership for Quality Medical Donations, Inc., (PQMD).” Since that time, PQMD regularly updates their guidance, accommodating as possible, all the prevailing industry and regulatory changes and challenges. PQMD has demonstrated a continuing commitment to improve and implement the “Guidelines” to inform, guide and manage donated medical products and to assist the performance of those who participate in this industry. Additionally, these guidelines reflect the growing opportunity to ensure that donations are a short-term remedy for urgent or unexpected circumstances and are integrated into support for resilient and sustainable health systems and contribute to access to quality healthcare for all.

This 2023 edition of the PQMD Guidelines, approved by the members of the PQMD Board of Directors on December 6, 2023 reflects the base of knowledge, experience and expectations of the membership for how medical product donations should be carried out. This document also provides links to other complementary materials and organizations, that are also focused on quality donations! It is our hope that others will join with the PQMD membership in using these Guidelines to inform their work in supplying critical donated medical products, devices and services to those in need across the globe.

Chris Skopec
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. One of the goals 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 believe this document must be a living one, so our commitment is to make annual updates to include the latest thinking and requirements. At the heart of the document is our continued 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 welcome any comments or questions about the information provided herein. We are all practitioners, and in a state of continuous improvement. We welcome the opportunity to have this document serve as an opening for communication as we continue to improve the quality of the donation practices in the industry.

Definitions

Adverse Event – An adverse event may be defined as a medical occurrence in a patient or consumer temporarily associated with the use of a medical product, but not necessarily related (205 WHO Guidelines).

Bill of Lading or Airway Bill – A document issued by a carrier that lists goods being shipped and specifies the terms of their transport. Alternatively – 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.

Bonded Warehouse – A temporary customs-controlled warehouse for storing commodities that have not cleared customs. Products can only exit the bonded warehouse by customs clearance (that allows products to enter the commerce of the country) or through in-bond transportation (products are transported but not in the commerce of the country) to another bonded warehouse or to exit the country.

Certificate of Analysis (COA): A document signed by an authorized representative of a manufacturer describing specifications for and testing conditions and testing methods applied to a product and the results of the testing that confirms a product meets its product specification.

Certificate of Conformity (or Conformance): A document issued by an authorized party (manufacturer or independent laboratory) that states the product meets the required standards or specifications.

Certificate of Donation or 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.

Certificate of Origin (COO): A document certifying that goods in a particular shipment are wholly obtained, produced, manufactured or processed in a particular country. A COOs is a declaration by an exporter and used to satisfy customs or trade requirements.

Cold Chain Distribution & Storage: Transportation system that maintains a temperature-controlled environment inside an insulated enclosure with appropriate cooling mechanism, or an actively powered system that uses electricity or other energy source to maintain a temperature-controlled environment inside an insulated enclosure under thermostatic regulation (e.g., cold room, refrigerator, temperature-controlled truck, refrigerated ocean or air container).

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; are generally 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), i.e., without a prescription, and include bandages, medicines not requiring a prescription, hygiene products, etc.

Customs Clearance – Is the official process through which customs authorities or government agencies allow goods, products, or merchandise to enter or leave a country's borders. It involves a series of procedures and documentation to ensure that the items being imported or exported comply with the relevant laws, regulations, and tariffs of the importing or exporting country.

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 the owner of the consignment to file the customs declaration and pay duties and taxes. Formal ownership of the consignment, however, transfers to the consignee only upon payment of the seller's invoice in full.

Dangerous Goods (DG) - A dangerous good, also known as a hazardous material or hazmat, is any material that poses a risk to human health, property or the environment during transportation. This can include everything from hand sanitizers to batteries. The movement of these is highly regulated and the shipper is responsible for compliance with DG regulations, classification, packaging, marking & labeling, and documentation.

Data loggers - Temperature data loggers can record the environmental temperature or the temperature of the product itself, recording the time along with the temperature reading. Transport Validation for Pharmaceutical Products. A validation protocol should be written before starting the validation process. It is observed that a 20% increase in temperature can reduce the efficiency of drug up to 25% those are stored at 2-8°C. Every drug has a unique relationship between the temperature and reduction in its efficiency.

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, wholesalers, local importers of record, brokers etc. Each **Distributing Partner** is accountable, regarding tracking, management, and compliance, to the **Donor.**

Donor – The organization that 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** regarding tracking and management of the donated product.

Drug Supply Chain Security Act (DSCSA) – The **DSCSA** is a US regulation managed by the US FDA, which regulates the distribution of prescription drugs in the United States. **DSCSA** creates a single national standard and closed supply chain in the US for every actor in the supply chain from manufacturers, wholesalers, distributors, transporters, and dispensers. As a US-based entity, PQMD includes this requirement in these Guidelines as an example of traceability requirements, which may be deemed globally necessary in the future.

Durable Medical Equipment (DME) – Nonexpendable articles used for medical care that 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]

EUA- Emergency Use authorization. – The US FDA authorizes unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN (chemical, biological, radiological and nuclear) threat agents when certain criteria are met, including there are no adequate, approved, and available alternatives.

Freight Forwarder – A person or a company who engages in the business of organizing and coordinating shipments on behalf of individuals or business by contracting with one or more carriers to transport the goods.

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 the goods and services themselves.

Incoterms – Widely-used terms of sale, are a set of 11 internationally recognized rules which define the responsibilities of sellers and buyers. Incoterms specify who is responsible for paying for and managing the shipment, insurance, documentation, customs clearance, and other logistical activities.

Please refer to Appendix 1 for definition of all incoterms.

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.

> **Class I** devices are not intended to help support or sustain life or be substantially important in preventing impairment to human health and may not present an

unreasonable risk of illness or injury. Examples of Class I devices include elastic bandages, examination gloves, and hand-held surgical instruments.

Class II devices are held to a higher level of assurance than Class I devices and are designed to perform as indicated without causing injury or harm to patient or user. Examples of Class II devices include sutures, endoscopy devices, acupuncture needles, powered wheelchairs, infusion pumps, air purifiers, and surgical drapes.

Class III devices are usually those that support or sustain human life, are of substantial importance in preventing impairment of human health, or present a potential, unreasonable risk of illness or injury. Examples of Class III devices that currently require a premarket notification include implantable pacemaker, pulse generators, HIV diagnostic tests, automated external defibrillators, and endosseous implants.

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.

Other – 'Other', as seen in the Donor Cascade below, references a **Donor** other than a manufacturer, e.g., health care facility, individual, retailer, wholesaler, distributor.

Off-Label use - means any use that is not included in the cleared "indications for use". Please refer to local market

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.

Product – Any Pharmaceutical, Biopharmaceutical, Medical Device, DME, Medical Equipment, Consumable, or Consumer Product, or any combination, as appropriate.

Recall – A recall is when a product (Pharmaceutical, Consumer, Medical Device) is removed from the market, or a correction is made to the product because it is either defective or potentially harmful (Class I, II or III). Sometimes a company discovers a problem and recalls a product on its own. Other times a company recalls a product after the relevant regulatory authority raises concerns, e.g., FDA in the US or MHRA in the UK.

Time- and temperature-sensitive pharmaceutical products (TTSPP) – Any pharmaceutical good or product which, when not stored or transported within predefined environmental conditions and/or within predefined time limits, is degraded to the extent that it no longer performs as originally intended.

Temperature excursion – An excursion event in which a TTSPP is exposed to temperatures outside the range(s) prescribed for storage and/or transport. Temperature ranges for storage and transport may be the same or different; they are determined by the product manufacturer, based on stability data.

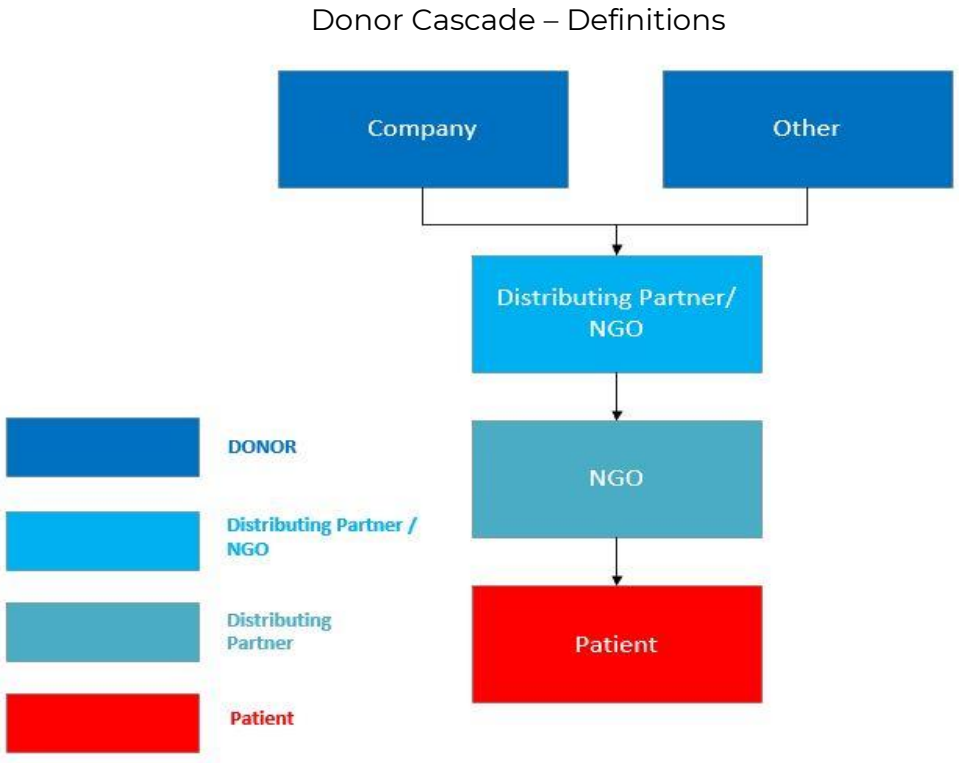


Figure 1 Donor Cascade (see definition of "Other")

Section I.

1. Required Minimum Standards (RMS) for Medical Donations

1.1 Do not ship donations that are not wanted by the recipient organization; ensure there is a need.

1.2 Do not donate or ship expired stock.

1.3 Donated product is to not be sold on - it must be distributed free of charge.

1.4 Donated product should have an expiration date of 12 months or more. Product with less than 12 months to expiration can be donated with Field approval provided the **Distributing Partner** is aware of the product expiry *prior to* the donation, and there is an agreement between the **Donor** and **Distributing Partner** that the product can be utilized. Country specific expiry guidelines and regulations should be followed at all times, unless approval per the above has been obtained.

1.5 Prior to making or accepting a donation make sure there is a contract or formal agreement in place that reflects clear and common understanding and responsibility for the following:

- Financial terms.
- Specific product and quantities, batch numbers and expiry dates.
- Policies and procedures for product complaints, adverse event reporting, safety and security requirements, (i.e., cold-chain, versus ambient shipping, product stability and tracking).
- Product disposal, proof of destruction and product recall.
- Monitoring and evaluation requirements.

Section II.

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 (SOP)

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 U.S. or equivalent as appropriate for international law.

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 as mandated by organizational by-laws.

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 U.S. 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.

2.5 **Companies** and **NGOs** should report on their total donations annually, or as required 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. *Refer 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), EU Falsified Medicines Directive (FMD) 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.

3.7 It is recommended **Companies** and **NGOs** have procurement policies that include the purchase of services in support of medical product donations.

3.8 **Companies** can donate product to **NGOs**, patient assistance programs, access to medicine and affordability programs that are not within the scope of these guidelines as permissible by local laws. Neither party will give, promise to give, or authorise the giving of anything of value to any government official, health care professional or person affiliated with a health care organisation to obtain or retain business or secure an improper advantage by the Donor Company. Donations are never used as an incentive or reward for any past, present or future willingness to purchase, prescribe, sell, supply, administer, or recommend any product sold by the Company.

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.

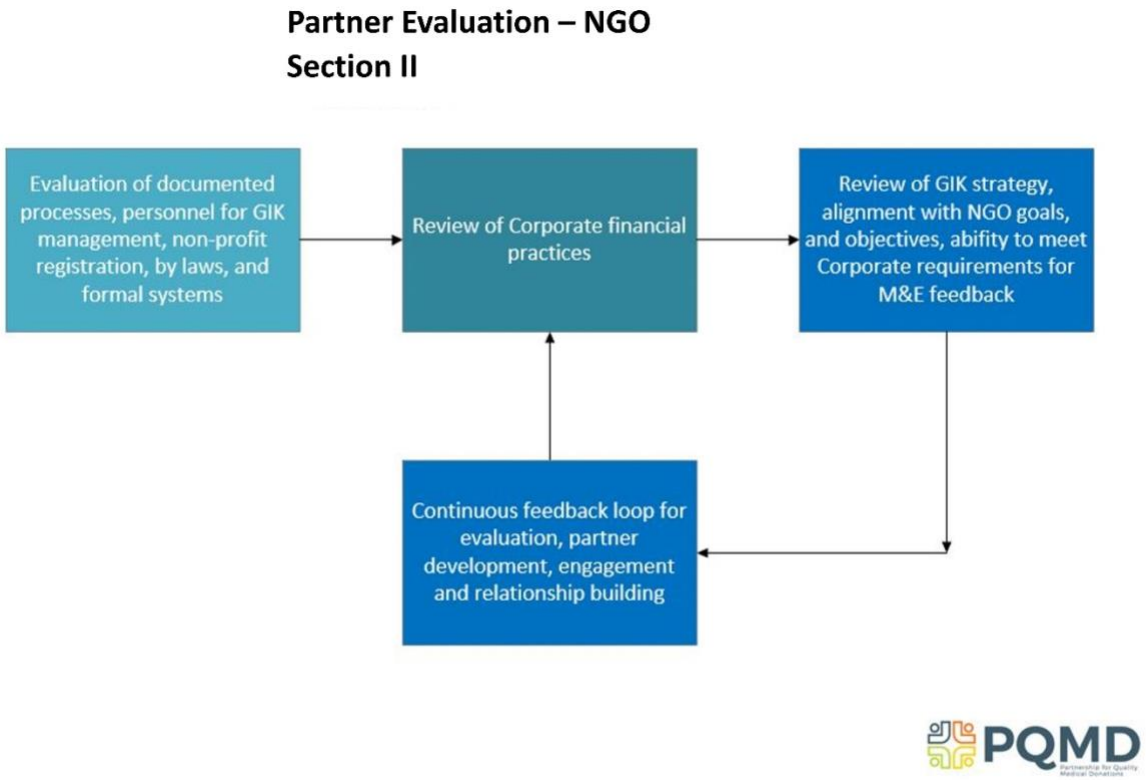


Figure 2 Partner Evaluation - NGO

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, the training and knowledge of its local physicians, 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: On going channels of communications between the Donors and Distributing Partner are essential to facilitating medical donations. 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, clinic capacity, and security. *Refer 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 (inventory management process, and internal audits) 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: 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, customs duties and customs clearance times, and local shipping and storage capacity (including proper facilities for cold chain storage of medicines pending customs clearance). *Refer Section 9 Logistics.*

Section III.

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, 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 When conducting a needs assessment, **Companies** and **NGOs** should take into account the nature of the health need, including 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 vital, therefore, that the **Distributing Partner** have a plan for disposal in line with the requirements set out in Section 10 Disposal.

6.2 Pharmaceutical and Medical Device (Class II and Class III)

6.2.1 Prior to the donation of any **Pharmaceuticals** or **Medical Devices**, **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 or medical devices (class II and class III), **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 products prior to any donation being made.

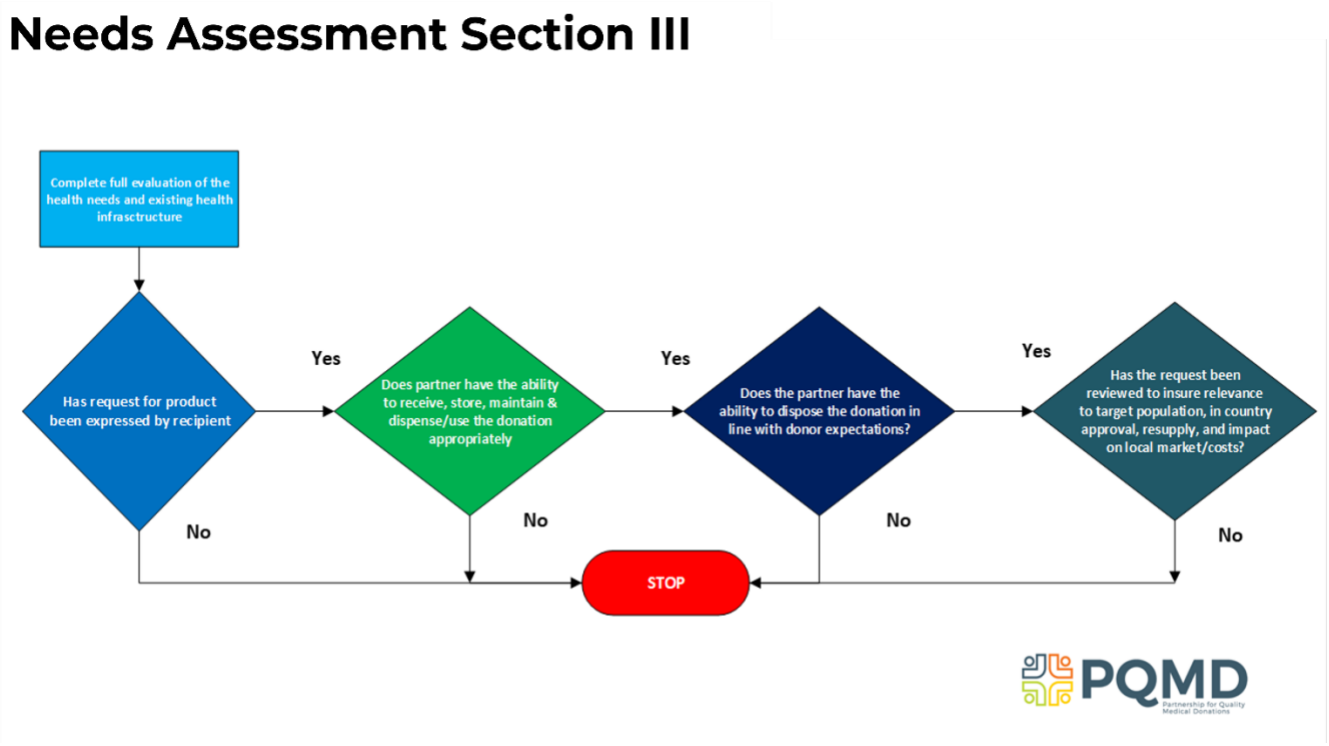


Figure 3 Needs Assessment

6.2.4 Prior to donating **Pharmaceuticals** or **Medical Devices** to a country, a **Donor** should know and follow all rules and regulations governing donated medical products in that country. This can include, but is not limited to, what products 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 (Class I), Durable Medical Equipment and Medical Equipment

6.3.1 Donors should complete a site assessment, or a detailed checklist/questionnaire, prior to offering any device/equipment to ensure all parties understand the support needed for the donation. Considerations to be included in the assessment include electricity (frequency, local voltages, power plug type) and surge protection to protect against power surges, even when facilities are fed from

generators. It is recommended that correct plug adapters and transformers always be provided/attached to eliminate risk.

6.3.2 Before a product is sent, the **Donor** must determine if the **Distributing Partner** has staff that is professionally trained to install, operate, maintain, calibrate, and repair the product.

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

6.3.4 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 Consumables

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

6.4.2 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.

6.5 Consumer Products

6.5.1 Prior to the donation of any consumer products, **Donors** should determine if the product being sent matches the expressed need and is appropriate for treating the affected population.

6.5.2 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.

6.5.3 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 as determined by medical professionals or MOH as communicated 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** and authorized for import 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 or bio equivalent must be approved for in-country use and/or on the national list of essential medicines or national treatment guidelines, unless prior 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 containers for injectables.
7.2.4 No expired product should ever be shipped. Product with less than 12 months to expiration can be donated with Field approval provided the **Distributing Partner** is aware of the product expiry *prior to* the donation, and there is an agreement between the **Donor** and **Distributing Partner** that the product can be utilized. Country specific expiry guidelines and regulations should be followed at all times, unless approval per the above 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 cost.
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. At the start of any donation program, a thoughtful patient treatment plan should be agreed upon between the **Donor** and **Distributing Partner**. This includes determining length of the donation program, its effectiveness and efficacy, as well as consideration for the program's discontinuation.

7.3 Medical Device (class I, II, and III), Medical Equipment and Durable Medical Equipment

7.3.1 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.

7.3.2 The **Donor** and **Distributing Partner** should assess the advantages and disadvantages of new equipment versus used and refurbished prior to any donation. For example, the **Distributing Partner** may not have the capacity to operate a newer piece of equipment based on facility infrastructure, or technical support capabilities.

7.3.3 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 key 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.

7.3.4 **Donor** should take care to include all vital supplies along with the equipment to ensure proper use and maintenance. The recommended quantity of supplies (reagents, for example) should be provided to 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, manage, and secure the volume to be provided (i.e., supplies may 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. Supplies that require specialized shipping might be best sourced locally, if possible (e.g., lithium batteries, reagents, etc.). At a minimum, local supply chain processes should be evaluated for continued support when **Donor** support ends. Corporate donors should consider including a customer service agreement as part of the donation to ensure technical support is available.

7.3.5 Prior to shipping or transfer to **Distributing Partner**, the **Donor** should purge any patient information from devices or equipment.

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 consumable should ever be shipped. Consumables with less than 12 months to expiration can be donated with Field approval provided the **Distributing**

Partner is aware of the consumable expiry *prior to* the donation, and there is an agreement between the **Donor** and **Distributing Partner** that the consumable can be utilized. Country specific expiry guidelines and regulations should be followed at all times, unless approval per the above 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 consumer products should ever be shipped. Product with less than 12 months to expiration can be donated with Field approval provided the **Distributing Partner** is aware of the consumer product expiry *prior to* the donation, and there is an agreement between the **Donor** and **Distributing Partner** that the consumer product can be utilized. Country specific expiry guidelines should be followed at all times, unless approval per the above 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 cost. *Refer Section 13 Valuation*.

7.6 Off Label Use

7.6.1 **Distributing Partners** should only consider donations specified for off label usage if there are no other available treatment options and the in-country medical regulations or accepted practice recognize/approve the treatment with off label usage.

8. Quality

Quality is important 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 **Donor's** country, it is also unacceptable as a donation outside the donor country. 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. Quality considerations apply to all categories of products and encompass a range of activities from temperature-controlled shipping and all related components to reviewing calibration and validation certificates.

8.1.2 **Donors** should have a supplier assurance program in place when sourcing products from suppliers other than direct manufacturers.

8.1.3 In order to demonstrate product quality and authenticity, appropriate documentation should accompany each shipment. Supporting quality documents may include a Certificate of Compliance, Manufacturing, or Analysis (DSCSA Requirements). It is strongly recommended to request certification documents and test reports to ensure authenticity and avoid counterfeit or substandard products. **Donors** and **Distributing Partners** should communicate directly with manufacturers to validate authenticity of products.

8.1.4 **Donors** should ship products according to manufacturer or country requirements to ensure product integrity stability, safety, and quality are maintained.

8.1.5 An **adverse event** reporting policy should document agreed upon procedures, roles, and responsibilities. The established policy should include, but may not be limited to, a defined reporting timeframe, process for assigning priority and severity of each adverse event category, as well as detailed documentation of reporting procedures and adverse event collection criteria. In addition, the policy should outline which contractual party (e.g., **Donor (Company/NGO)** or **Distributing Partner**) is responsible for **adverse event** training, reporting, adherence to local laws and regulations, as well as mandatory requirements for manufacturers, importers, and device user facilities in countries where the **Donor (Company/NGO)** or **Distributing Partner** operate.

8.1.6 An established **recall** reporting process should document agreed upon processes, roles responsibilities, and should be focused on patient safety at all levels. The process shall be outlined between **Donor (Company/NGO),** shall include criteria related to identification of **recall**, communications, data requirements, product collection and management (including destruction, as applicable), costs, timelines, etc., and shall be communicated to the **Distributing Partner** accordingly.

8.2 Pharmaceuticals and Medical Device (Class II and III)

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 No expired product or medical device should ever be shipped. Product or medical devices with less than 12 months to expiration can be donated with Field approval provided the **Distributing Partner** is aware of the product or medical device expiry *prior to* the donation, and there is an agreement between the **Donor** and **Distributing Partner** that the product or medical device can be utilized. Country specific expiry guidelines and regulations should be followed at all times, unless approval per the above has been obtained.
8.2.3 All products must include prescribing information (i.e. product insert) in a language easily understood by the **Distributing Partner**.

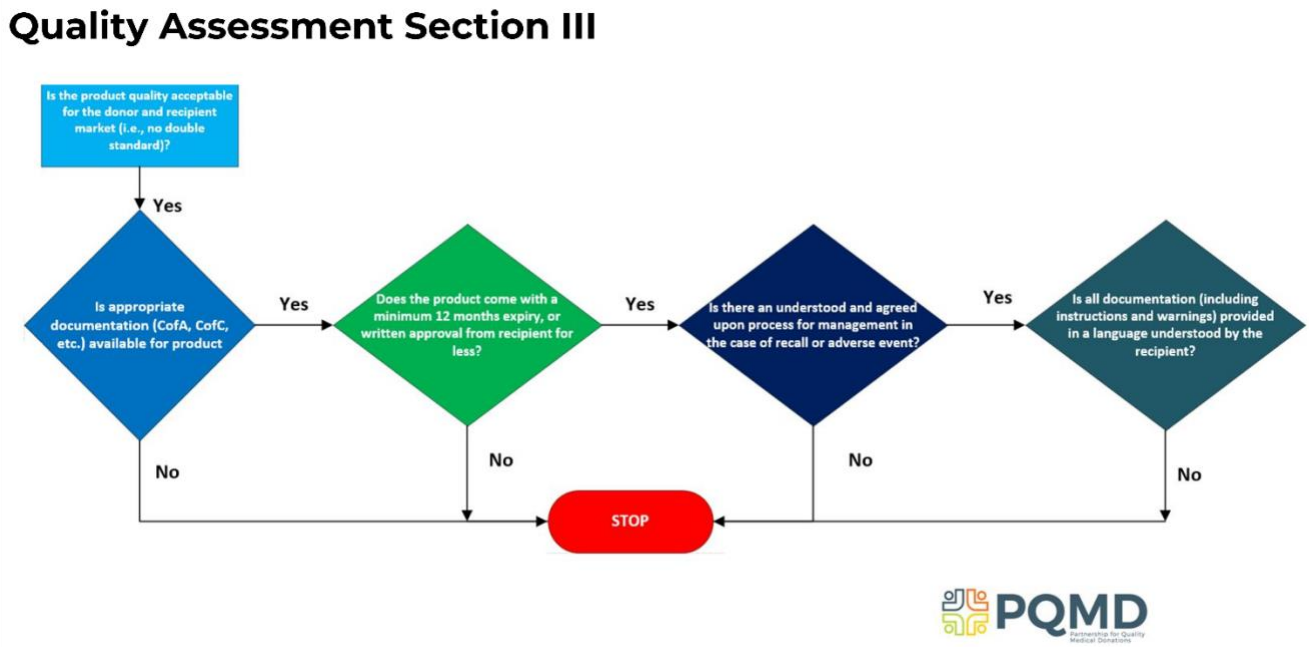


Figure 4 Quality Assessment

8.2.4 It is NOT acceptable to donate unused products that have been outside of the control of the **Donor (Company/NGO)** where the **Donor (Company/NGO)** is unable to verify that proper product storage and handling conditions have been maintained (i.e. product that has left the regulated supply chain). These products should be properly destroyed with appropriate destruction certification detailing quantity and batch numbers and must NOT be donated. *Refer Section 10 Disposal.*

8.2.5 In the US, the **NGO** and **Company** should incorporate the developing requirements of the **Drug Supply Chain Security Act (DSCSA)** and EU Falsified Medicines Directive (FMD) 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. For more information, specific deadlines, and to read the act itself visit: https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/

8.3 Medical Device (Class I), Medical 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 product 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 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 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.

8.3.5 The donated product 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).

8.3.6 **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.

8.3.7 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.

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

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. It is a good idea to plan from the destination backwards. Unless you've shipped to that country before or in the past few months, try to become familiar with the customs clearance process at your destination. Many steps will depend on the consignee's status in their country.

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 are not followed. It is important that all people involved in the packaging and transportation of product/equipment be knowledgeable about shipping guidelines as well as the field conditions at the end destination.

In the spirit of the UN 2030 Agenda and SDG 13, **Donors** and **Distributing Partners** should consider tracking the impact of carbon emissions in particular as it relates to humanitarian aid and relief to vulnerable populations impacted by climate change.
https://www.un.org/en/climatechange/science/key-findings

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.
9.1.1.6 – Dangerous Goods (DG) Labeling – **IMPORTANT** - Transport labels for dangerous goods must be clearly printed on or affixed to the surface of the package in a location other than the bottom and near the shipping marking, as they inform how to transport, handle and store dangerous goods.
The National Code of Federal Regulations lists nine classes of dangerous goods and dangerous goods class labels:

Explosives: An explosive is any substance or device that is either designed to explode, such as by rapidly releasing gas or heat, or has an internal chemical reaction that makes it explosive. There are six divisions of explosives. Common explosives include fireworks, gun powder, ammunition and airbag inflators and modules.

Gases: There are three divisions of gases. The first division, flammable gases, is any gas that will ignite at a concentration of 13% or less in air. These gases also have a flammable range of at least 12%. Examples of the first division include camp stoves, propane tanks and spray cosmetics. The second division comprises non-flammable, non-toxic compressed gases like fire extinguishers, carbon dioxide and nitrogen. The third division includes poisonous gases, such as hydrogen sulfide or hydrogen cyanide, that are toxic to humans in transportation.

Flammable liquids: A liquid is flammable or combustible when it has a flashpoint less than 60° C (140° F) or has a flashpoint at or above 37.8° C (100° F) like gasoline, camp fuels, paint or ethanol.

Flammable solids: The fourth classification of dangerous goods, flammable solids, are combustible during ignition in normal conditions. There are four divisions of flammable solids. The first includes self-reactive, thermally

unstable materials and those that are combustible through friction, such as matches. The second is spontaneously combustible materials like activated carbon, coal and rags with residues from oil or paint. The third includes materials that are flammable or emit a flammable gas when wet, like lithium, magnesium or aluminum powder.

Oxidizing substances and organic peroxides: Oxidizing materials readily give off oxygen or other oxidizing substances or chemically react to oxidize combustible materials. There are two divisions, oxidizing substances like hydrogen peroxide, fluorine or oxygen generators and cylinders, and organic peroxides like accelerators, resins or acetone peroxide.

Poisons and infectious substances: There are two divisions of toxic substances, poisons and infectious substances. Poisonous materials are so toxic to humans that they are hazardous during transportation due to oral, dermal or inhalation toxicity. Examples include arsenic, pesticides and some medicines. Infectious substances are items like used needles or blood samples that could potentially contain a pathogen and spread diseases like HIV or Hepatitis B.

Radioactive materials: Radioactive materials like radioactive medicines, X-ray machines or smoke alarms are unstable and release radionuclides during decay.

Corrosives: Corrosives are highly reactive substances like most acids, wet and NiCad batteries and mercury thermometers that chemically cause damage to human tissue.

Miscellaneous hazardous materials: This classification includes all other hazardous materials that may be hazardous to human health or the environment but do not fall under one of the previous categories. Examples include dry ice, engines, lithium batteries and ammonium nitrate fertilizers.

9.1.2 Optimizing the use of space/capacity: Optimizing space/capacity for all modes of transport can lead to reduced climate change impact and freight cost savings. To facilitate more environmentally and economically sustainable supply chain practices, procurement and logistics staff can:

- Require suppliers to optimize space on a per-load or per shipment basis.
- Identify opportunities during purchasing to build a full container/truck load.
- Identify opportunities for cargo consolidation with improved planning and consolidation.

- Identify opportunities with packaging to reduce the dunnage weight and space demands if such reduction does not compromise cargo integrity during transport and storage.

9.1.3 Storage

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

9.1.3.2 Storage areas should have enough capacity and space to accept donations, be dry, well ventilated, well lit, and out of direct sunlight. To prevent product deterioration or infestation, products should not be stored on the floor or against walls or near food storage areas. Products requiring storage under defined conditions (such as temperature, light, or humidity) should be stored in compliance with their instructions and/or label requirements.

9.1.3.3 If bonded warehouses are utilized at the port or for through country transit such facilities should meet the appropriate storage requirements for pharmaceutical and medical products to maintain product quality.

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

9.1.3.4 There should be a system of stock usage based on expiration date to ensure appropriate stock rotation, i.e., first expiry, first out (FEFO). Products beyond their expiry date or shelf life should be labelled or marked as unusable and removed and quarantined from usable stock. Expired products cannot be sold or supplied and arrangements need to be made for their destruction. *Refer Section 10 Disposal*.

9.1.4 Medical Product Registration: Distributing partners planning to receive pharmaceuticals, consumable medical supplies, and medical equipment should engage local ministries of health or other regulatory authorities to determine if there are registration requirements prior to import. Requirements could include dosages, labelling, product packaging, leaflets, instructions, and language requirements. This could affect import licensing if needed on a per shipment basis.

9.1.5 Shipping & Transportation

9.1.5.1 The **Donor** and **Distributing Partner** should agree on the shipping arrangements (who ships the products) and the corresponding responsibilities.

9.1.5.2 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. *See Quality 8.1.3*. Lead times should be considered in acquiring the shipping documents.

9.1.5.3 The means of transportation should be appropriate to the donation's circumstances, whether by air, sea, or ground, considering cost and time.

9.1.5.4 Insurance for ocean (maritime insurance) and air transport should be considered to reduce risks during transport. Considerations to obtain insurance should include the following:

- Through country transit risks
- Costs of insurance as determined by insurable value (on shipping paperwork or otherwise)
- Risks the Donor or Distributing Partner (who is arranging shipping) would like covered or is willing to accept.

9.1.5.5 Customs Clearance can be a complicated process to manage given governmental changes and ambiguities. It is key that the **Donor** has the process established prior to making the donation to ensure timely clearance, and that the **Distributing Partner** understands that process to manage it. The **Distributing Partner** should engage a customs house broker in the destination country to determine import requirements and make contacts and develop a network in the destination country, **Distributing Partners** should inquire into the following issues:

- What name or designation is best to receive the shipment? Which entity available to you has the optimal legal status, name value, duty and tax free status for your shipment? Make sure you spell it right, and indicate the full address, email, and phone/fax numbers.
- What is the best cargo description to use on the shipping documentation, to minimize duties and taxes, and to afford speedy customs clearance?
- Are there any specific clauses that need to be attached to the description? For example, “Imported under duty exemption franchise no. 7”; “Donation for humanitarian aid”; “Not for resale”
- Do you recommend a particular customs value that will likely be acceptable, and will minimize the basis of taxes and duties, if exemptions are not obtained or are voided?
- Does the consignee have the appropriate import permits for medical products?
- Which documents need to be provided by the sender to expedite clearance? (Original Bills of Lading, Declaration of Value, Packing Lists, Letter of Donation, Certificates of Origin, Phytosanitary Certificates, Fumigation Certificates, Certificates of Analysis, etc.)
- Does the consignee (receiving party) have a customs agent or “contact” in the customs house with whom they have become acquainted?

- Tax exemption is not guaranteed just because your consignee is a non-profit organization. Receiving tax exemption on an import is granted by the country's revenue authority. Every country has its own process for tax exemption. Some countries only grant exemptions on a per shipment (per bill of lading) basis while others can grant exemptions for a certain period or up to a certain value. Most important to keep in mind is that some countries, especially in times of financial distress, may not provide tax exemption at all.
- If bonded transportation through a country prior to destination is required, all customs formalities must be managed and coordinated to facilitate the transportation and the customs clearance at destination (border clearance or clearance at named destination port).

9.1.5.6 Cost of transportation should be addressed in advance of shipping 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. Consider the logistics and customs situation. Does your consignee have the appropriate budget for typical local charges, including but not limited to:

- Port charges
- Customs agent
- Duties and taxes (including VAT or excise taxes), including import fees
- Local delivery to the final door from the place of customs clearance: a rail terminal, discharge port, border crossing, etc.
- Cargo handling at the warehouse (unloading and stowage)
- Bonded transportation and warehousing for through country transit.
- Maritime insurance.
- Carbon emissions costs and carbon credit offsets.

Now that you have considered your shipment from the perspective of the destination, make your plans in the US accordingly, with regards to documentation, contents, packaging, budget, etc.

9.1.5.7 The shipping documents should be clear, correct, and contain all essential data (such as country of origin, harmonized schedule number 9802.20.000, ECCN – Export Commodity Classification Numbers), a valuation – customs, fair market as deemed appropriate) and information required to satisfy regulatory requirements for export and import. They should include an Import/Export License (if applicable),Bill of Lading, Shipping Instructions/Notification, Detailed Packing List, Commercial Invoice, and Donation letter, and any Certificates of Origin, Dangerous Goods Declaration and Certificates of Analysis/Conformity. If multiple modes of transportation used (i.e aircraft and then trucking to destination), the shipping documents listing the products and values should match.

- Import/Export Licenses serve as formal authorizations for the export and import of goods.
- Export licenses may be required in cases of sanctioned countries including US Exports as they relate to the Office of Foreign Assets Control (OFAC). More information on countries and persons that are sanctioned can be found here.
- Import licenses are required in almost all countries and are usually managed by the local revenue authority. A consignee should be registered as an importer prior to planning your shipment details. If you are importing pharmaceuticals or consumables, the import license likely needs to be approved by the Ministry of Health as well as the local Revenue Authority.

Shipping Instructions:
To begin, you'll need to gather the names, addresses, telephone and fax numbers of the:

- Shipper or exporter of record: likely your organization.
- Consolidation point: where the cargo will be gathered and load made ready.
- Consignee: receiving party at destination.
- Notify Party (if present): an agent, organization, or associate who may represent the consignee at the destination.

Be precise! Avoid nicknames and abbreviations, as this information will appear on the official shipping documentation.

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

- Determine the amount of free time available for cargo arriving at the port in case of delays to avoid demurrage, storage, detention, and other related charges.
- Determine if the cargo is subject to any pre-inspection requirements.
- Determine if the cargo requires a Cargo Tracking Note (mostly required for imports to African countries).
- Engage with a freight forwarder to determine appropriate handling and transportation process and requirements for dangerous goods.

9.1.5.7 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.
9.1.5.8 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 quality of the product should be assessed to determine the disposition of the product and may require consultation with the donor. Any product requiring disposal should be disposed of appropriately. *See 10. Disposal*.

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

9.1.5.10 Any entity receiving temperature-controlled products should verify the data loggers to validate product was transported at the specified temperatures along the end-to-end supply chain.

9.1.5.11 The **Distributing Partner** should plan transportation to other warehouses or distribution points and use appropriate transportation and equipment in consideration of environmental factors (such as thermal pallet covers for transit that potentially exposes products to direct sunlight) that could affect products.

9.1.5.12 Unintended Consequences of Failure to Plan Logistics:

- Inability to clear customs duty/tax free.
- Delays in getting aid/relief products to intended recipients.
- Accumulation of exorbitant storage, demurrage, port/airport storage fees.
- Ultimate forfeiture or destruction of cargo for failure to timely clear cargo through customs.
- Failure to obtain transportation (maritime for ocean, air cargo) insurance could lead to exorbitant costs should a contingency or "Act of God" arise that damages or destroys the ocean vessel or aircraft.
- Holidays at destination could delay unloading of cargo or leave a stranded carrier without a way to unload.

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 Drug **Supply Chain Security Act (DSCSA**) compliance is required to transact any prescription drug movement in the US supply chain, including product donations. The DSCSA does not include devices, consumer products, or other consumables. For more information, specific deadlines, and to read the act itself visit: https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/

9.2.1.3 Products requiring temperature protection should be clearly labeled as appropriate with temperature requirements or “Fragile”, as needed. Temperature controlled products should be considered for separate shipping from other products.

9.2.1.4 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.

9.2.1.5 The expiry date should be clearly labeled on all primary and secondary 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 Facilities should be temperature mapped and regular recalibration of systems should be in place. Temperature and/or humidity should be monitored and recorded periodically. Cooling units should be subject to a regular maintenance program and 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, Medical Equipment and Durable Medical Equipment

9.3.1 Packaging

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

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 on all primary and secondary 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 it 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 indiscriminate 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 with available space to receive the shipment.

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 product destruction and shall consider NGO/In Country Guidelines/SOPs, and 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 vary depending on where the product to be destroyed is located, such as the home country of the donor or Distributing Partner country.

10.2 Outline the requirements around minimally accepted destruction practices and minimal 'proof' of destruction, such as 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 and prioritize concerns, such as whether the product or packaging be rendered unusable/unreadable prior to destruction.

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. Priority might be given to ensure products cannot be resold on the black market and to minimize environmental impacts due to destruction methods. This discussion will aid in choosing an appropriate destruction method.

10.10 Ensure a certificate of destruction is obtained and submitted to **Donor** and/or other stakeholders.

11. Emergency Disaster Responses

Even in an emergency, a needs assessment must be completed to ensure 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 donating, a **Distributing Partner** should be identified who is qualified to receive, manage, and distribute the donation.

11.1.4 During an emergency disaster response it is important to determine how and where other **NGOs** or international agencies are responding, 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).

11.1.8 The **Distributing Partner** should work with a local Customs Broker to determine if there have been any changes to import requirements and communicate any needed documentation or certification back to the **Donor.**

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. This includes but is not limited to providing accurate documentation, complying with local and international shipping regulations (Dangerous Goods, Customs Regulations, etc.) It is important to note that these regulations must be adhered to even during a disaster or emergency situation.

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.

As noted in the PQMD Resource Guide for Evaluating Medical Donations, "program monitoring and evaluating the impact of medical donation programs can help organizations make the business case for the provision of aid within their organizations and/or with donors. Strengthening organizations' ability to conduct monitoring and evaluations is a necessary step towards highlighting the value and impact of medical donation programs." This section touches on a few key points – for a more detailed evaluation resource, please go to www.pqmd.org for the full report.

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.
13.2.3 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.

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

13.3.1 In collaboration with PQMD, InterAction and other interested parties, a recommended methodology for the valuation of pharmaceutical products and a list of valuation resources may be found online at www.pqmd.org

13.4 **Donors** and **Distributing Partners** should weigh the considerations around the bookable value of products versus customs value and insurable values.

Section IV.

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.
https://apps.who.int/iris/rest/bitstreams/53172/retrieve

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 http://www.thet.org/health-partnership-scheme/resources/publications-old/making-it-work-a-toolkit-for-medical-equipment-donations-to-low-resource-settings

14.3 The Sphere Handbook: Humanitarian Charter and Minimum Standards in Humanitarian Response. The Sphere Handbook is one of the most widely known and internationally recognized sets of common principles and universal minimum standards for the delivery of quality humanitarian response. Because it is not owned by any one humanitarian organization, the Sphere Handbook enjoys broad acceptance y the humanitarian sector as a whole. http://www.sphereproject.org/handbook

14.4 The PQMD Resource Guide for Evaluating Medical Donations provides a recommended framework for evaluating medical donation programs; provide technical guidance on the principles and methods of good monitoring and evaluation practices; promote and strengthen the use of common terminologies and methods in order to facilitate assessment of the collective impact of donation programs; and facilitate the acquisition of high quality ate and information to feedback for current and future program design of quality medical donation programs.
http://www.pqmd.org/

14.5 World Medicines Situation Report. This third edition of the World Medicines Situation Report brings together in one place new data on key topics relating to the pharmaceutical sector, and updates the 1988 and 2004 reports. Current efforts to document and improve sharing of information have paved the way to accessing information that was not possible a decade ago, such as disaggregated data on pharmaceutical expenditures, consumption, drug prices and insights on policies and impacts on improving access to medicines. The aim of this publication is to gather relevant information comprehensively in a single site and publication.
http://www.who.int/medicines/areas/policy/world_medicines_situation/en/index.html

14.6 Guidelines for Disposal of Unwanted Pharmaceuticals in and After an Emergency. During conflicts and natural disasters large quantities of pharmaceuticals are often donated as part of humanitarian assistance. Undoubtedly many of the pharmaceuticals save lives and alleviate suffering, but some donations given by well-meaning but uninformed people may cause problems. Pharmaceuticals may arrive past or near their expiry date, may be inappropriate for the needs. Donated pharmaceuticals with a long shelf-life may be mismanaged. Staff and storage space may be lacking and the pharmaceutical management system in disarray. These disposal guidelines are based on a report on the safe disposal of unwanted and unusable drugs in Mostar, which had accumulated during the war in Bosnia and Herzegovina.
https://www.who.int/water_sanitation_health/medicalwaste/unwantpharm.pdf

14.7 EMERGO Group – A resource site for Medical Device and IVD Professionals
https://www.emergobyul.com/resources

14.8 WHO Certification scheme on the quality of pharmaceutical products moving in international commerce. The model certificates shown in this web site conform to the format recommended by the World Health Organization. Although the contents of the model certificates are consistent throughout the Scheme, certificates issued by different national authorities may have a different format and occasionally different wording. The national regulatory authority of the exporting country should be able to provide more specific information. When any doubt arises about the status or validity of a certificate, the competent authority in the importing country should request a copy directly from the certifying authority, as provided for under section 4.9 of the guidelines.
http://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/en/

14.9 WHO Technical Specification for Medical Devices: In countries there is a significant need for counselling regarding minimum specifications and requirements that should be considered before starting a process of purchase or donation of medical devices. Having this type of specification allows improved access to medical devices of high quality, safety, and efficacy, as well as planning adequately the financial, infrastructure and human resources, among others, to be considered in the implementation, functioning, and decommissioning of the devices. WHO technical specification (TS) for medical devices can provide guidelines in procurement and acquisition process of medical devices.

https://www.who.int/medical_devices/management_use/mde_tech_spec/en/

14.10 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.
https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/title-ii-drug-quality-and-security-act

14.11 The Code of Conduct for the International Red Cross and Red Crescent Movement and Non-Governmental Organizations (NGOs) in Disaster Relief. The Code of Conduct lays down ten points of principle which all humanitarian actors should adhere to in their disaster response work, and goes on to describe the relationships that agencies working in disasters should seek with donor governments, host governments and the UN System.
https://media.ifrc.org/ifrc/who-we-are/the-movement/code-of-conduct/

14.12 InterAction-PQMD Valuation Methodology Recommendations. The methodology outlined in this guide, and list of valuation resources, are designed to assist NGOs in determining the financial valuation of donated pharmaceutical products received in pursuit of their missions.
https://www.interaction.org/documents/interactions-pharmaceutical-recommended-methodology-decision-tree-and-pricing-inputs-catalog/

14.13 UN Sustainable Development Goals (SDGs) are "urgent call for action by all countries – developed and developing – in a global partnership" to "improve health and education, reduce inequality, and spur economic growth" as strategies for ending poverty while addressing the challenges of climate change.
https://sdgs.un.org/goals

14.14 PQMD Guidelines at a Glance. Shorthand summary of PQMD Guidelines.
Insert link to Guidelines at a Glance on PQMD COP website.

Section V.

15. NGO & Corporate Checklist

PQMD members can complete this self-assessment checklist on an annual basis to test their organizations, as well as the guidelines, to ensure both are keeping up with industry trends. The online version can be found on the PQMD site: **Assessment Checklist**.

NGO & Corporate Checklist - PQMD Standard			
Documentation and Internal Compliance	**YES**	**NO**	**N/A**
Do you have documented SOPs to support GIK			
Do you audit or monitor these SOPs?			
Is this information considered confidential or proprietary?			
At what frequency are they reviewed?			
Do you have a written Conflict of Interest Policy as part of your internal compliance documentation?			
Do you have staff whose job description includes GIK compliance (e.g. accountability for maintaining documentation, monitoring, and reporting)?			
Are you a 501(c) 3, international non-profit, or do you have local authority to run a charity?			
Do you have documentation to support your charity status?			
Do you have approved organizations bylaws which drive your governance?			
Do you comply with GAAP or locally recognized guidelines?			
Do you recognize the Financial Accounting Standards Board (FASB) as the accounting standards setter, or INGO locally recognized equivalent?			
Do you file an IRS form 990, or local INGO equivalent annually?			
Do you adhere to the Foreign Corrupt Practices Act (FCPA), or local International Non-Government Organization (INGO equivalent)?			
Do you follow requirements set forth under Health Care Compliance regulations (HCC), or local INGO equivalent?			
Do you work with the US Treasury Department agencies dealing with BIS and OFAC, or local equivalent?			

NGO & Corporate Checklist - PQMD Standard Continued			
Product Donation Processes	**YES**	**NO**	**N/A**
Do you follow Good Distribution Practices (GDP)?			
Do you conduct a needs assessment to confirm that donations of products, devices, or equipment match the needs and limitations of the facility and country?			
Does this assessment include (Please check all that apply): -appropriate fit with the local healthcare infrastructure and government MOH? -review of recipient country restrictions and regulations? -a product sustainability assessment (continuity of care for a patient, either continuous support or enough for a full round of therapy per patient)? -a device and equipment sustainability assessment (i.e. consumable, spare parts and repair services)? -confirmation of storage and security capabilities? -confirmation of destruction and notification of destruction process? If so, can you provide a high-level summary of key criteria used in this assessment?			
Do you have an internal process to assess, approve or decline unsolicited offers for donation?			
Do you have formal measurement and evaluation (M&E) process to validate your donation program outcomes? If so, does this process include M&E metrics for review by your organization/partners? If so, does your organization use these metrics for continuous improvement?			
As a product recipient, do you request a financial contribution or service fee to cover (e.g., administrative overhead, inventory management, or product destructions) from your Corporate Donor? If so, are these service fees auditable to your partners?			
Regardless, do you ever charge a product recipient or beneficiary for donated product? If so, in what cases?			
Which of the following do you include with your product, device, or equipment donations? Detailed packing list; pro forma invoice; donation letter; COA; COO			

Section VI.

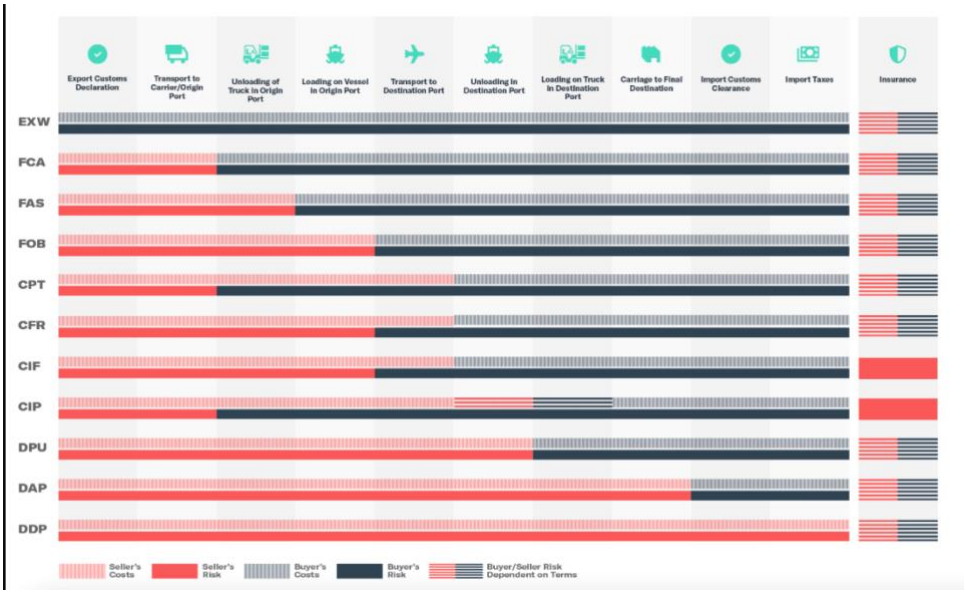
Appendix 1

The seven Incoterms® 2020 rules for any mode(s) of transport are:

- **EXW** – Ex Works (insert place of delivery) - This type of term indicates that the seller is responsible for making the goods available at their premises, and the buyer is responsible for collecting them from there. The seller does not have to bear any costs or risks associated with transporting the goods, as this is all the responsibility of the buyer.
- **FCA** - Free Carrier (Insert named place of delivery) - This type of term indicates that the seller is responsible for delivering the goods, cleared for export, and packaged, to a named location. The buyer is responsible for arranging and paying for carriage and insurance from now on.
- **CPT** - Carriage Paid to (insert place of destination) This is used when the seller agrees to pay for all costs associated with the transport of goods up to a specified destination. The risk and costs associated with any further transport from that point onwards is then passed onto the buyer. This type of Incoterm is most often used in cases where the goods are delivered directly to the buyer's door.
- CIP - Carriage and Insurance Paid To (insert place of destination) requires the seller to pay for all costs associated with transporting goods up to a specified destination and for any associated insurance costs. The risk and responsibility for any further transport from that point onwards is then passed onto the buyer. This type of Incoterm is most often used when goods are shipped by air or sea.
- **DAP** – Delivered at Place (insert named place of destination) This indicates that the seller is responsible for delivering the goods at a named place, cleared for importation, but not unloaded from any form of transport. The buyer then takes on responsibility for unloading costs from this point onwards.
- **DPU** – Delivered at Place Unloaded (insert of place of destination) This requires the seller to deliver goods to a specified destination but does not require them to assume responsibility for any additional costs such as customs duties or taxes. The buyer then assumes the risk and responsibility for unloading the goods at their end.
- **DDP** – Delivered Duty Paid (Insert place of destination). This requires the seller to be responsible for all costs associated with delivering goods to a named destination, including any customs duties or taxes. The buyer is then responsible for unloading the goods at their end.

The four Incoterms® 2020 rules for Sea and Inland Waterway Transport are:

- **FAS** – Free Alongside Ship (insert name of port of loading) In this term, the seller must deliver the goods alongside a named vessel at the port of shipment. The buyer is responsible for loading, carriage, and insurance costs from this point onwards.
- **FOB** – Free on Board (insert named port of loading) In this term, the seller must deliver the goods on board a named vessel at the port of shipment. The buyer then takes over responsibility for loading, carriage, and insurance costs from this point onwards.
- **CFR** – Cost and Freight (insert named port of destination) This term is similar to CIF in that the seller pays for all costs related to loading, carriage, and insurance up until delivery at a named port of destination. However, here it is assumed that the risk passes onto the buyer once shipment has been made.
- **CIF** - Cost Insurance and Freight (insert named port of destination) Here, the seller must deliver the goods to a named port of destination and pay for all associated costs including loading, carriage and insurance up to that point. The buyer then takes on responsibility for unloading the goods at their end.



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 2016	Kim Keller - Chair	Board approval 2016
5A	January 2017	Kim Keller – Chair	Flow Charts/Check lists – Board Review
6	April 2017	Kim Keller – Chair	Board Approval 2017
6b	November 2018	Kim Keller - Chair	EC Review
7	February 2018	Kim Keller – Chair	EC Approval
8	February 2019	Ann K Novakowski – Chair	Revisions for added clarity
9	June 2021	Marcia Roeder	EC Review
10	November 2023	Lydia Amartey-Williams	EC Approval