

DRAFT PRODUCT DONATIONS POLICY (update of CRQS A15-01)

1.2 Purpose

The purpose of this policy is to define minimum requirements for the contribution of Abbott products to Private Voluntary Organizations (PVOs), Non-Governmental Organizations (NGOs), institutions or government organizations for distribution domestically and internationally.

1.3 Scope

This policy applies to all contributions of Abbott products. All divisions, affiliates and divisional or corporate administered programs must comply with the requirements of this policy. This policy does not cover nor supersede tax regulations or Corporate Tax Division instructions regarding the deductibility of production contributions, any legal requirements of the recipient country or any international regulations regarding product contributions.

1.4 Implementation

Implementation is in accordance with Effective By Date.

1.5 Responsibilities

Function	Responsibility
Division Materials Management (Planning, Logistics, etc.)	Identifying products eligible for donation, and coordinating the shipping of product. Coordinating these activities with Global Citizenship and Policy staff that manage the product donations process. Also responsible for coordinating English overlabel activities with appropriate parties.
Division Quality Assurance	Assuring all non-conforming and products intended for ex-US distribution are acceptable for donation. Facilitate English overlabel approval process.
Corporate Tax Division	Providing guidance to assure compliance with current tax law and to ensure maximum tax benefit.
Division Accounting	The submission of Schedule II and Charity Schedule II (if applicable) documents to the Corporate Tax Division and Charity Schedule II documents to the Corporate Product Donations Coordinator.
Global Citizenship and Policy	The overall Corporate, coordination and administration of product donation program; which includes affiliates and Abbott distribution organizations (e.g. Ross, ALOG, NOLA, Breda), audit/assessment of new charitable organizations, approval of charitable organizations, consideration of the World Health Organization, emergency relief efforts. Keeping documentation on all donations, including Memorandums, monthly product donation

	receipt and distribution reports from charitable organizations, distributing Schedule IIs to charitable donations on a quarterly basis, and preparing monthly reports on product donations to senior management.
Global Product Protection	Take action with collaboration of appropriate functional teams to identify the source of donated product in all cases where diversion is suspected or confirmed.
Medical	Approve donations of all non-conforming products from a safety and efficacy standpoint.
Overlabeling Sites	Implement overlabeling activities per Abbott Materials Management direction, for products destined for donation. Pharma and nutritional overlabeling site must be certified per ANI Overlabeling Policy 03-08-2.
Regulatory Affairs	Review donations of all products intended for all markets, and approve all label overlays.
Corporate Regulatory Quality Science	Shall review for final approval of all non-conforming product, all donations from affiliates, and monitor compliance to this policy.

2.0 Definitions

Term	Definition
Approved Inventory (AP Status)	Product that has completed the QA review process and is considered acceptable for distribution.
Certified Overlabeling Sites	Affiliates or HUBs that are qualified to perform overlabeling activities for pharma and nutritional products.
Charitable Organization	A non-profit hospital, health care entity, institution, organization, foundation, association or corporation that has been granted an exemption under section 501 (c)(3) of the Internal revenue Code of 1954, as amended.
Contribution	Refers to “gift-in-kind” or the donation of products.
Controlled Substance	A substance placed by federal law into one of five schedules (I, II, III, IV, V). This placement is based upon the substance’s medical use, potential for abuse and safety or dependence liability.
Dating	The amount of time prior to the manufacturer’s stated expiration on a given product.
Exception Report (ER)	A report used to document a potential nonconformity, nonconformity, or deviation.
Expiration Date	The date established by the manufacturer and

	printed on the package after which the quality of the product and its related efficacy and safety are not guaranteed and after which the product should not be used.
Memorandum	A form that must be completed (sections I-IV) and submitted to Product Donations Coordinator/PM for all product donations prior to commitment to charitable organization but after product has been identified (List#, Lot#, etc).
Non-conforming Product	Any product that does not meet its required specifications (e.g. low-fill, unacceptable level of ingredient(s)) for intended market.
Non-Governmental Organization/Private Voluntary Organization (NGO/PVO)	Non-governmental organizations or private voluntary organizations that receive healthcare products and distribute them to those in need.
Public Health Consultancy	An Abbott approved organization responsible for managing requests for charitable contributions, particularly those related to least developed countries as defined by the United Nations.
Regular Shelf Stock	Finished products that are actively marketed at the time of contribution.
Returned Goods	Products returned to Abbott control by a customer or other source.
Sample	A unit (a packet, card, blister pack, bottle, container or other single package) comprised of one or more dosage units of a prescription drug sample, intended by the manufacturer or distributor to be provided by a licensed practitioner to a patient in an unbroken or unopened condition.
Schedule II/Charity Schedule II	An internal accounting and tax document used to track product contributions.
Short-Dated (Product)	The date at which product is not routinely acceptable for shipping due to its approaching expiration date.
Un-inspected Product	Product that has not gone through QA process.
World Health Organization (WHO)	The World Health Organization is a United Nations specialized agency for health that has as its objective, the attainment by all people of the highest possible level of health.
WHO International Code of Marketing of Breast-milk Substitutes	The aim of the Code is to contribute to the provision of safe and adequate nutrition for infants, by the protection and promotion of breast-feeding, and by ensuring the proper use of breast-milk substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution.

3.0 Requirements

3.1 Product Eligibility

3.1.1 General Requirements

- Products eligible for donation are:
 - Regular shelf stock products
 - Returned goods that are in their original, unopened package, show no signs of abuse, tampering or inappropriate storage that might affect product efficacy, and comply with requirements outlined within CRQS Policy A11-02. For products requiring unique storage conditions, such as refrigeration, a determination that returned goods were maintained under appropriate conditions while outside of Abbott's control must be made prior to contribution.
 - Other products, if approved by Global Citizenship and Policy department, appropriate Quality and Regulatory Center of Excellence and the recipient PVO or NGO, may be donated.
- Products manufactured by Abbott that are marketed by or with another company may be donated only with the approval of that company. The marketing division's Quality Assurance group will obtain this approval
- Every Product donation must be accompanied by a completed Memorandum addressed to Quality and Regulatory Center of Excellence, that includes description of the product(s), status of the product (Approved Status or Non-conforming/un-inspected), the reason(s) for donation request, restrictions and appropriate signatures.

3.1.2 Specific Requirements

- Drugs
 - Samples can be donated directly to a charitable organization. Written acceptance letter by a licensed practitioner on behalf of the charitable organization to the Product Donations Manager must be received prior to donation. Sample must comply with requirements of 21 CFR 203 (PDMA) and have the approval of the Vice President for the Quality & Regulatory Center of Excellence – Drugs prior to consideration by the Corporate Product Contributions Coordinator.
 - Donation of returned or salvaged drug product must comply with applicable FDA regulatory requirements and CRQS Policy A11-02
 - Donation of finished dosage form bulk products is not allowed unless packaged into configurations that are supported by product stability data.
 - Controlled substances must be shipped from Abbott Distribution Centers through normal and approved channels for a controlled drug. All donations must comply with the Controlled Substances Act (CSA) as well as applicable requirements of the FDA and DEA.

- Chronic, life-saving drugs (e.g. Kaletra) or lifestyle drugs (e.g. Reductil/Meridia) are NOT eligible for donation
 - Drug donations should adhere to guidelines established by the World Health Organization
 - The Vice President for the Quality and Regulatory Center of Excellence – Drugs, Corporate Product Contributions Coordinator and the recipient PVO/NGO shall approve exceptions, in writing and prior to shipment
 - Diagnostics/Devices
 - All diagnostics/devices are eligible for donation with the exception of vascular stents and nutritional devices
 - Any diagnostic/device tracking or post market surveillance obligations that Abbott may have also applies to donated diagnostics/devices
 - Nutritional
 - All nutritional products are candidates for contribution with the exception of the items listed below. These items may, however, be candidates for donation at the discretion of management.
 - Ready-To-Hang (All)
 - Private Label (All)
 - Disease Specific - non-retail (AlitraQ, Juven, Nepro, NutriFocus, Optimental, Oxepa, Perative, Pivot, ProSure, Pulmocare)
 - Glass containers (All)
 - Metabolics (EleCare, Human Milk Fortifier, NaturalCare, NeoSure, ProviMin, RCF, RMFS, Special Care)
 - Infant formula is eligible for donation in compliance with Abbott's infant formula policy (attached)
- 3.1.3 Contributions destined for country of intended use
- Any product that is considered for a charitable contribution shall:
 - Fulfill requirements as outlined by Memorandum
 - Have at least 2 months remaining shelf life if donated to a foodbank or other organization approved by GC&P
 - US distribution:
 - Fulfill the requirements of the Federal Food, Drug and Cosmetic Act (FDCA) at the time of the contribution and 180 days prior to the date of the contribution in order to be eligible for any tax benefit
 - Be in inventory to qualify for any additional tax incentive as defined by the Internal Revenue Code. For example, samples are not eligible for additional tax benefits above and beyond product cost.
 - Affiliate in-country distribution:
 - Is in compliance with the requirements, laws and policies of the country
 - Hurricane/Disaster Response

- Procedure must comply with the **Hurricane/Disaster Policy (attached)**
 - Product must have 12-18 months remaining shelf life, as per WHO Guidelines
- 3.1.4 Contributions not destined for country of intended use
- It is the joint responsibility of Global Citizenship and Policy, Division Materials Management, Division Quality Assurance, Division Regulatory Affairs, Global Product Protection, Division Medical and CRQS to ensure export donations are in conformance with receiving countrys' donation process. In general, products can be donated if they:
 - Meet the specifications of the foreign recipient
 - Are not in conflict with the laws/policies of the recipient country
 - Are not sold or offered for sale in domestic commerce
 - Have at least 6 months remaining shelf life
 - Exception made for contributions made to U.S-based charitable organizations for Medical Missions/Medical Outreach Programs, where minimum remaining shelf life required is 2 months
 - Disaster Relief
 - Products in inventory are eligible for donation either from affiliate in country of disaster or from HQ
 - Products must have 12-18 months remaining shelf life as per WHO guidelines
 - Products requests must be made to Abbott in writing by a charitable organization and if applicable, be accompanied by a written request from the local organization in country of disaster
- 3.2 Procedure – Refer to Process Flow Diagrams in Appendix X
- The Product Donations Coordinator or Program Manager must approve all charitable organizations and donations, including those by the Divisions, Business Units, international locations and affiliates prior to the commitment of any product donation.
 - At any time, the Product Donations Coordinator or Program Manager may designate product in approved inventory status from any of the affiliates, business units, HUBs to be donated for disaster relief efforts, corporate programs or mission programs.
 - Memorandums (see appendix) must be completed and submitted to the Corporate Product Donations Coordinator or Program Manager for every product donation. They must be completed by the unit requesting to donate and submitted once the product donation has been approved and specific product identified. Computer print-outs are acceptable but must include all of the product information required.
 - For contributions destined for country of intended use, products in approved inventory (AP) status may be designated for charitable contribution without additional Quality Assurance approvals provided the eligibility requirements outlined in 3.1.1 are met.

- Any suspected product donation diversion should be reported immediately to the Product Donations Coordinator or Program Manager, who will collaborate with Global Product Protection to determine source of product leak.

3.2.1 All products manufactured within the US

1. For all donation requests made directly from a charitable organization:
 - Division, Business Unit, Affiliate or HUB-driven requests
 - Donation requests from pre-approved charitable organizations must be sent to the Product Donations Coordinator or Program Manager along with the completed Memorandum. This must be done prior to shipment of product.
 - Division, Business Unit, Affiliate or HUB will be responsible for all communication with the charitable organization and coordinating procurement of product for all of their own product donation initiatives.
 - Once product is shipped to charitable organization, Division, Business Unit, Affiliate or HUB is responsible for obtaining from charitable organization, proof of product receipt and for submitting appropriate paperwork for tax purposes. Nothing more is required.
 - Corporate Product Donations Coordinator or Program Manager-driven requests
 - The Product Donations Coordinator or Program Manager will coordinate with the appropriate Division Materials Management to procure requested product.
 - The Product Donations Coordinator or Program Manager will notify approved charitable organizations of material availability and provide information on remaining dating, any limitations to product quality or condition and any restrictions on use.
 - The Product Donations Coordinator or Program Manager must complete the Memorandum and keep a copy for the files.
1. For all other donations:
 - The appropriate Division Materials Management group will report the availability of eligible products and submit a completed Memorandum (sections I-IV) to the Product Donations Coordinator or Program Manager.
 - For products that are non-conforming, the following additional criteria shall be met to qualify as a charitable contribution:
 - Division Quality Assurance, Division Regulatory Affairs, Division Medical and CRQS must approve the Exception Report certifying that the product is acceptable for donation purposes from a product safety, standard, and efficacy perspective.

- Section I – IV of the Memorandum must be completed, which identifies the product name, list number, lot number, non-conformance description, number of units, expiration date, and restrictions for use (if applicable). A copy of the approved Exception Report must be attached to the Memorandum and routed for approval signatures to the Division VP Quality Assurance and the VP of the Quality & Regulatory Center of Excellence.
 - The Product Donations Coordinator or Program Manager will notify approved charitable organizations of material availability and provide information on remaining dating, any limitations to product quality or condition and any restrictions on use.
 - Once the accepting charitable organization is identified by the Product Donations Coordinator or Program Manager, the charitable organization will sign section V of the Memorandum, acknowledging the listed product(s) as detailed throughout the Memorandum.
2. The Product Donations Coordinator or Program Manager will notify either:
 - For US donations: Division and Regional DM or
 - For international donations: the appropriate Regional Commercial Director and General Manager of intended recipient country, and Global Product Protection
 3. For international-destined product donations only, while notification is taking place, Division's Material Management must obtain an additional Divisional Regulatory approval prior to shipment. After instructions have been received from the Product Donations Coordinator or Program Manager, the division will prepare the shipping documents and no-charge invoice identifying the list number, lot number and quantity of products contributed and ship the contribution by normal procedures.
 3. For U.S.-destined product donations, the Product Donations Coordinator or Program Manager notifies Division's Material Management to prepare for shipping of the products. An accounting journal entry will be made to the appropriate expense account to relieve inventory or credit returned goods for the cost of products. A copy of the journal entry must be attached to the Schedule II when forwarded to Corporate Accounting D-344.
 4. Accounting Division submits Schedule II and Charity Schedule II documents (if applicable) to Corporate Tax Division and Charity Schedule II documents to the Corporate Product Donations Coordinator/Program Manager. A summary of all product donations should be prepared in the month of the contribution using a Schedule II form. This summary must show product list number, lot number, product description, expiration date, quantity, standard factory cost and the selling price for each product. The selling price to be used will be the lowest quantity discount price indicated

from the pricing schedule. In the case of infant formula, the average selling price may be used.

5. The Corporate Product Donations Coordinator or Program Manager must send the Schedule IIs to the charitable organization(s) for their approval and signature once every quarter. The charitable organization must be instructed to return the signed Schedule II(s) to Abbott's Tax Division once every quarter (all Schedule IIs must be returned by January 15 of the following fiscal year).
6. Charitable organization provides written confirmation of receipt to Abbott. The confirmation shall include product description, expiration date, lot number and quantity received. Every quarter, the charitable organization is responsible for

3.2.2 All products manufactured outside of the US

1. For all donation requests made directly from a charitable organization:
 - Affiliate or HUB-driven requests
 - Approved charitable organizations and subsequent donation requests must be sent to the Product Donations Coordinator or Program Manager along with the completed Memorandum. This must be done prior to shipment of product.
 - Affiliates and HUBs will be responsible for coordinating procurement of product for all of their own product donation initiatives.
 - Corporate Product Donations Coordinator or Program Manager-driven requests
 - The Product Donations Coordinator or Program Manager will coordinate with the appropriate Commercial Director.
 - The Product Donations Coordinator or Program Manager must complete the Memorandum and keep a copy for the files.
1. For all other donations:
 - The appropriate Division Materials Management group will report the availability of eligible products and submit a completed Memorandum (sections I-IV) to the appropriate Regional Commercial Director
 - For products that are non-conforming, the following additional criteria shall be met to qualify as a charitable contribution:
 - Division Quality Assurance, Division Regulatory Affairs, Division Medical and CRQS must approve the Exception Report certifying that the product is acceptable for donation purposes from a product safety, standard, and efficacy perspective.
 - A section I – V of the Memorandum must be completed, which identifies the product name, list number, lot number, non-conformance description, number of units, expiration date, and restrictions for use (if applicable). A copy of the

- approved Exception Report must be attached to the Memorandum and routed for approval signatures to the Division VP Quality Assurance and the VP of the Quality & Regulatory Center of Excellence. Both documents are submitted to appropriate Commercial Director.
2. Either the Commercial Director or the General Manager will contact the Product Donations Coordinator or Program Manager to make them aware of available products for donation.
 3. The Product Donations Coordinator or Program Manager will notify approved charitable organizations of material availability and provide information on remaining dating, any limitations to product quality or condition and any restrictions on use.
 4. Once the accepting charitable organization is identified by the Product Donations Coordinator or Program Manager, the organization will sign section V of the Memorandum, acknowledging the listed product(s) as detailed throughout the Memorandum.
 5. The Product Donations Coordinator or Program Manager will notify either:
 - a. For US donations: Division and Regional DM or
 - b. For international donations: the appropriate Regional Commercial Director and General Manager of intended recipient country, and Global Product Protection
 6. While notification is taking place, Division's Material Management must notify Divisional Regulatory.
 7. For non-English product labels requiring overlabeling in English to be eligible for donation, additional steps are required. Division Material's Management is responsible for coordinating and obtaining documents required per ANI Overlabeling Policy 03-08-2.
 - a. Initiate request for Label Request Approval (LRA)
 - b. Labeling Division to outsource English translation of label.
 - c. Submit the following to ANI QA for Divisional Regulatory approval
 - i. pdf of product label
 - ii. complete English translation of product label
 - iii. pdf of proposed English overlabel
 - d. Coordinate overlabeling activities with certified overlabeling site per ANI Overlabeling Policy 03-08-2.
 8. Once overlabel is approved, forward approval documentation to Product Donations Coordinator.
 9. After instruction from the Division Material's Management have been received from the Product Donations Coordinator or Program Manager, the division/site will prepare the shipping documents and no-charge invoice identifying the list number, lot number and quantity of products contributed and ship the contribution by normal procedures.
 10. Charitable organization provides written confirmation of receipt to Abbott. The confirmation shall include product description, expiration date, lot number and quantity received. The recipient may utilize the charity Schedule II for this purpose.

3.3 Charitable organization Eligibility and Requirements

- Only charitable organizations that hold 501 c (3) status and are a public foundation according to the IRS or other organizations that have been approved by Global Citizenship and Policy and the Corporate Tax Division will be eligible for domestic and international donations. The approved organizations must also indicate that the donated product will be used solely for the care of the ill, needy or infants in accordance with that organization's exempt purpose and its mission.
- Other organizations that work with an Abbott approved public health consultancy are eligible for donations provided they meet the requirements set forth by the specific product contribution program.
- The Product Donations Coordinator, Program Manager or public health consultancy shall audit or assess an organization's ability to meet the following elements:
 - Capabilities with regard to safety, storage, distribution and tracking of product
 - Ability to provide product status reports of local partner use activity (including any of their sub-recipients) or product destruction

4.0 Document Information

- 4.1 Attachments
- 4.2 Governing Documents
- 4.3 Reference Documents
- 4.4 Description of Change
- 4.5 Distribution
- 4.6 Signature Block

Approver Name	Signature Date	Approver Functional Area
S. Moody/J. Hinders		Initiator Subject Matter Expert
John Wolfinger		DVP CRQS QCOE
J. Hughes		DVP Quality Operations
TBD		DVP Medical
Patricia Scaman		DVP Regulatory DVP ADD DVP GDC
Scott Roe		MPG