

## HEALING HELP PHARMACEUTICAL DONATIONS PROGRAM

## 2018 Application and Agreement

CMMB distributes much needed medicines and supplies to locations worldwide in response to requests from partner NGOs, health facilities, or CMMB country offices. In addition, CMMB supports the efforts of volunteers who organize medical mission trips by providing them with medicines they can carry as they go about their work.

#### CMMB's Mission:

Inspired by the example of Jesus, Catholic Medical Mission Board works in partnership globally to deliver locally sustainable, quality health solutions to women, children, and their communities.

#### CMMB's Vision:

A world in which every human life is valued and health and human dignity are shared by all.

#### **CMMB's Core Values:**

*Collaboration:* To work in partnership for locally sustainable solutions *Love:* To embrace and be compassionate towards all people *Excellence:* To deliver sustainable, quality, and impactful results *Respect:* To act always with integrity and to value and honor the dignity of all

The following information is required by CMMB before a donation of pharmaceuticals or medical supplies can be provided to you and your organization. Once you have submitted the fully executed application/agreement form, with all the required supporting documents, it will go through CMMB's review and approval process to determine if we are able to assist your program/mission.

We must receive your request at least six weeks before your projected departure date or requested deliver date, in order to allow for adequate time for processing of the application and, if approved, for delivery of the donation. Incomplete applications cannot be processed.

#### Once the application is complete, please send along with supporting material to:

By Mail:		By Fax:	
	Catholic Medical Mission Board (CMMB)		(646) 638-1504
	Attention: Healing Help Team	By Email:	
	100 Wall St. 9 <sup>th</sup> Floor		donationrequests@cmmb.org
	New York, NY 10005		

## **Frequently Asked Questions:**

#### We have received donations from CMMB in the past, do I need to complete the application? Although my previous application looks different from this one, can I just submit it again?

- CMMB updates the application/agreement form annually, in order to keep up with everchanging requirements from donors, regulators, and oversight organizations and to ensure that in this dynamic environment we incorporate best practices with regard to in-kind stewardship, supply chain management, pharmaceutical and regulatory reporting, and monitoring and evaluation of our in-kind program impact.
- This document is both an application for assistance and an agreement to fulfill certain requirements before, during and after your program, should the application be approved and a donation offered.
- For these reasons, CMMB cannot accept earlier versions of the application form, nor can we accept incomplete or unsigned forms.
- New applications are available each year on October 1 and cover your same-country requests from the date CMMB approves the application through December 31 of the following year.
  - $\circ$  ~ The 2018 application is valid for programs and missions through December 31, 2018

#### What happens to my application after I submit it to CMMB?

- Once your application has been received, the information is reviewed and verified. If there are any questions or concerns with your application, you will be contacted for clarification or additional information.
- If your application is denied, you will receive a denial notification via email, which will indicate the reason you were turned down. Incomplete forms, requests without required supporting documents, outdated forms and short-dated requests (less than 6 weeks lead time) cannot be processed. If there is a possibility to correct and resubmit your request you will be advised of what steps you would need to take.
- If your application is approved, you will receive an approval notification via email, which will
  summarize next steps. Review the notification and contact CMMB with any questions. This email
  will contain an attached adverse event reporting guide. This brief training outlines the possible
  adverse events that could take place during the distribution of Healing Help donations in the field
  as well as suggested next steps and communication protocols between you and CMMB. The
  email will also include a form that you must sign and return to verify that the necessary members
  of your organization have read and understood the training.
- After approval, you will receive an offer with product in CMMB inventory which has been donated by manufacturers. You must reply to the offer (accept/decline/adjust) within 48 hours. When your shipment is prepared, shipping documents are sent to you, and the shipment leaves our distribution center. NOTE that since much of our donated product is short-dated, offer and subsequent shipments are sent as close to your departure/requested date of receipt as possible to maximize useful life of product in-country.

#### What are my obligations as a consignee organization?

- You are responsible for providing complete, accurate information about your organization and any organizations/facilities you are working with during the application process.
- You are responsible for obtaining required paperwork for duty free import and customs clearance, and unless otherwise agreed to IN WRITING, you are responsible for any costs for shipping to country, and transport in country, including any expenses related to demurrage, storage, inspection or clearance.
- You are responsible for the proper use and handling of all product donated to you.
- You are responsible for reporting to CMMB any issues that arise in relation to shipments you receive (detailed in the above-mentioned Adverse Event Reporting Guide).

- You are also responsible for post-shipment closeout with CMMB: returning shipping receipt, completing the field feedback report with photos if you captured any, filling out the line item distribution report, and providing a final participant roster.
- Also, following your trip, you will be responsible for completing the annual Foreign and Corrupt Practices Act certification for the calendar year.

## **Completing the Application**

The 2018 Healing Help application is broken up into three main parts:

- **Program Overview** (Pages 1-6) includes outline of application sections and steps required in order to be approved to receive donations of medicine and medical supplies.
- **Logistics Information** (Pages 7-16) captures details regarding the consignee's plans for transportation and distribution of the product donated by CMMB.
- **Agreements** (Pages 17-20) outlines the terms of compliance and confirms applicant commitment to adhere to terms and requirements for donation.
- Appendix (Pages 21-22) supporting documents and space for additional information

#### **Section A: Consignee Information**

For the purpose of this application, the applicant is the consignee; you are making the request for and taking responsibility for any donated product CMMB is able to provide to you. Unless otherwise indicated, all items in this section must be completed in full.

#### **Section B: Beneficiary Information**

For the purposes of this application, the beneficiary refers to the in-country organization(s) that will benefit from the donation made by CMMB. This section also provides a place to list the facility(ies) where your team will work. If you will be working in multiple facilities, you may use the chart following section B. *In addition, you must attach a dated proof of correspondence with an in-country partner or agency to verify that they plan to work with your organization.* 

#### Section C: Requested Product

Provide an itemized list of needed product (pharmaceuticals, medical supplies, hygiene items). If you need more space than what is provided, or if you have a list in another format that you would like to attach, please check the box indicating that your list is attached. CMMB does not regularly receive donations of medical equipment (machines, monitors); although you are free to request them, our ability to fill that part of your request is limited. While CMMB will make every effort to match the items on your list, because we rely on donated product, we cannot guarantee requested items will be supplied to you. In addition, the offer you receive from CMMB may include items not on your list, based on what we have available. You are free to accept or decline any amount of these items.

#### Section D: Health Practitioner Statement of Intent for Use of Medicines & Health Care Supplies

This section must be completed and signed by the licensed health care practitioner (HCP) who will be overseeing the dispensing of donated medicines and supplies. A copy of the license is requested but optional for U.S.-based practitioners, *but MUST be attached to the application if the certifying practitioner is licensed overseas.* The HCP's license must be valid for the duration of the time during which CMMB product will be dispensed. The type of product you are eligible to receive from CMMB is determined by the prescribing authority associated with the license of the listed overseeing HCP.

#### Section E: Transportation Plans

This is the information that identifies when product is needed, and where it is to be sent. It also determines what costs the consignee is able cover with regard to shipping product, and what partners or agencies they are using in connection with any donation they receive from CMMB. In some instances, CMMB will not be able to release product from our distribution center without first receiving copies of clearances or other approval documents from the government of your end-use country.

#### Section F: Roster of Participants for Mission Trip

This section provides a blank participant roster for short-term trips. Please be as accurate as possible. You will be able to update/provide the final roster in your post-trip reporting to reflect any last-minute additions or deletions from your roster, but the pre-trip roster will be a factor in product allocation for hand-carry requests.

#### Section G: Organizational Commitment to Comply with Donation Requirements\*

This section should be filled out by a member of the requesting organization (consignee) who has the authority to act on behalf of the organization since they will be agreeing to terms and conditions for the donation. Note that while we can accept final submission electronically either by fax or email, items that request as "signature" or "initial" MUST be written not typed. \*Failure to comply with these requirements during the trip will impact your future eligibility to receive donations from CMMB.

#### Section H: Certification of Intent to Comply with the Foreign and Corrupt Practices Act

As a U.S. organization working overseas, we are required to certify that our employees, partners and affiliates are compliant with the U.S. Foreign and Corrupt Practices Act of 1977. This section is the first step of a two-step process in which you first will verify that you understand and intend to comply with the requirements of the act before any product can be allocated; then, within three months of your mission, you will be sent a shipment summary of any product you received and the country and organizations to which it went and asked to verify that you did comply with FCPA regarding all shipments and locations during the prior year.

#### Appendix I: Summary of the Foreign and Corrupt Practices Act (FCPA)

This appendix provides a summary of the Act, its intention and your responsibility when doing business in a foreign country.

#### Is your application COMPLETE? What are the next steps?

See the checklist below to make sure that your application is complete and includes all the required documentation.

#### When you submit the application/agreement:

- □ All questions on the application have been answered (Sections A through H, inclusive).
- □ Verification of your organization's eligibility to receive donations is attached.

(IRS determination letter, parent organization verification of group participation, state charitable registration verification with EIN (not State Registration Number) clearly shown).

- □ Section B has been completed for EACH organization that will benefit from any donation you receive from CMMB or facility you will be working in (pages 9-11).
- □ You have included a dated correspondence with your in-country beneficiary to verify the proper logistics of the mission trip are in place.
- □ A list of requested products has been included (either embedded or as an attachment).
- □ A copy of the overseeing health care practitioner's valid license is attached. (Recommended for US practitioner, **required** for non-US practitioner).
- □ The FCPA summary (Appendix I) has been reviewed and the certification of intent to comply, and related information sheet (Section H) has been completed.
- □ Section F has been completed with a roster of those who will be travelling with the mission.
- □ The appropriate parties have signed and/or initialed all required locations.
- □ The entire application and all supporting documents have been submitted by email, fax or mail to the address/number listed on the cover of this document at least 6 weeks before the earlier of your requested donation receipt date or departure date.

#### You may receive a follow up call or email from CMMB:

- Please respond to the question as soon as possible, so that your application can be processed timely.
- Failure to provide additional information or clarification may result in your application being denied as incomplete.
- If your application is denied for any reason, you will be advised by email. If your application can be corrected or amended to allow for its approval, you will be given that opportunity if sufficient time remains to do so and still allow for timely delivery of donation to your location.

#### After you receive approval and the initial offer:

- Respond to donation offer with your intention to accept, decline, or amend the donation offered. Please do so as soon as possible and within 48 hours maximum so that items you are unable to use can be offered to others.
- □ If you have not already submitted them, obtain any approvals/clearance documents required to bring the donated shipment in-country.
- □ Inform CMMB when all approvals are in place, and shipment may occur; send copies of approval documents for our files.
- □ Read the Adverse Event Reporting Guide and return the signed agreement confirming that you and the pertinent members of your organization have read and understood it.

#### Verify when shipment is received:

- □ Sign, date and return the first receipt, "Shipment Received by Consignee," to CMMB upon arrival of the donation.
- □ Sign, date and return the final receipt, "Shipment Cleared in Country," to CMMB once the donation has cleared customs in the destination country.

#### <u>After your trip/mission/program:</u>

- □ Complete and return the attached field feedback form that details how the donation was used and the beneficiary population that it served.
- □ Provide photos of the donated product in use, and/or the patients being served.
- CMMB may use these photos to spotlight and publicize its Healing Help Program.
- □ Return the line item inventory report with values distributed for every product.
- □ Provide any missing information regarding your in-country partners, or the final participant roster, as needed.
- When you receive the year-end donation summary, complete the included Foreign and Corrupt Practices Act Annual Compliance Certification and return to CMMB.

#### Protocols for adverse events:

- Once you are approved, the approval email you receive will include a brief training on adverse event protocols.
- □ It is important that you review the different types of adverse events and understand them within the context of your beneficiary country/community.
- Before departure you must be familiar with the necessary lines of communication with CMMB in the case that any of these adverse events take place.

#### Planning a second request this year?

- IF the request is for the same organization and the same destination country in the covered calendar year, you need only fill out and return those sections that are changing. Situations that would require completion of each section include:
  - It will always be necessary for you to complete and submit *Section E: Transportation Plans*.
  - If you are traveling to a different location within the same beneficiary country, you will need to complete and submit another *Section B: Beneficiary Information.*
  - If you are requesting new products, you will need to complete and submit another *Section C: Requested Products.*
  - If you are travelling with a different group, you must submit a new *Section F: Roster of Participants.*
  - If you are including a new prescriber to assume authority for the donated product, you will need to complete and submit another Section D: Health Practitioner's Statement of Intent for Use of Medicines and Health Care Supplies.
  - **Sections A, G, and H** are continuous and do not need to be repeated unless traveling to a new destination country as stated below.
- IF the request is for the same organization and a DIFFERENT destination country, a new application is required.

CONSIGNEE ID#:

### Section A: Consignee Information

This section refers to you, the applicant, and the organization you represent. All fields are required unless otherwise noted.

#### 1. Name and contact information for organization

Please list the primary location of the organization requesting donation. In most cases this information should match your tax exempt/charitable registration information.

Name of Your Organization.		
Name of Chief Executive:		
Title/Position:		
Address:	Phone:	
City:	Fax:	
State:	Email:	
Zip Code:	Website:	
Country:		

#### 2. Name and contact information for applicant

2a. Please provide information about the person who is completing the application

Relationship to the Organiza	tion: Leadership 🗆	Staff 🗆	Volunteer 🗆	Consultant 🗆
Contact Name:				
Contact Title/Position:				
Contact Email:				
Secondary Contact:				
Contact Title/Position:				
Contact Email:				

**2b.** If you are at the primary (headquarters, corporate) location already listed above, check here and skip to question 3.

If you are at a satellite, chapter, off-site or other secondary location of the organization, complete the address information below.

Address:	Phone:	
City:	Fax:	
State:	Email:	
Zip Code:	Website:	
Country:		

#### 3. How do you derive your charitable status and eligibility to receive donations?

Please provide your employee identification number provided by the IRS: \_\_\_\_\_

3a. We are independently registered as a US 501 (c)(3) tax-exempt organization
Please provide us with a copy of the IRS letter ruling on your 501 (c)(3) status.

**3b.** We are a registered US 501 (c)(3) tax-exempt organization under a group ruling  $\Box$ 

including the		OUP ruling, please provi oof that you are part of		
-		n the state of		
<ul> <li>Please provide under what at</li> </ul>		ou are eligible to receiv	e donations from CM	MB, and
3d. Other (attach supp	•	nts)		
	-	g mission trips or mana	ging in-country prog	rams?
5. Does your organiza	tion have a relig	gious affiliation?		
		r reporting purposes oni	y. Religious affiliatior	1 does NOT
impact eligibility to re	-		, , , , , , , , , , , , , , , , , , , ,	
No:		Yes:		
I prefer not to answer	: 🗆	Please identi	fy:	<u>.</u>
6. <i>For SHORT TERM ('</i> 6a. How often do you		•		
Once a year $\Box$		Other		
			fy:	
7. How were you refe	rred to CMMB?	(Check all that apply)		
Mailing list:		Pharma company:	□ which?	
Personal reference:		Mission affiliation:	□ which?	
Internet:		Other:	□ describe	
You are a current con	signee (You have	e received a donation in	the <b>current calendar</b>	year) 🗆
		reviously received a don t donation (if known)	-	ut <b>NOT within</b>
8. Please provide 2 re	ferences for you	ur organization:		
a. Contact Person:		b. Contact Pe	rson:	
Organization		Organization		_

Organization:	Organization:
Phone number:	Phone number:
Email address:	Email address:
	Email address:

## Section B: Beneficiary Information

This section refers to the organization(s) and facility(ies) that you will be working with in-country. DO NOT list any information about US organizations, facilities, etc.

#### All fields are required unless otherwise noted.

<u>NOTE</u>: CMMB endeavors to assess the effects of its donated product. You will be asked to submit feedback after your mission to determine impact, so the below information is crucial.

# 9a. Name and contact information of the facility which will be the recipient of donation from CMMB (if there are multiple facilities, you may utilize the chart in appendix II):

Facility Name:			
Phone:	Fax:	 Email:	
Address:			
City:			
Country:			
GPS Coordinates (if kno			
Name of Overseeing O	rganization:	 	

*Please submit proof of correspondence (e.g. email) with your in-country beneficiary as documentation of logistical coordination between your organization and the/each in-country beneficiary. Ensure that this is dated as proof that it applies to the current mission request.* 

## b. Name, title, and contact information of the person responsible for the facility which will be the recipient of the donation from CMMB.

Name:			Title:	
Contact: (ema	il, fax a	nd/or phone)		
Clinic: 🗆	Dispe		lospital: 🗆	ט(ש) Regional/Referral Hospital: □ itable (faith-based): □
	•	•	•	itable (secular):
	•	•	• •	
		Mission/Pop-u	•	
If pop clinic, p	lease d	escribe the setting	3	
d. Indicate wh	at type	e of treatment the	e healthcare fac	ility provides/will be supported by
CMMB's dona	tion:			
Emergency		Surgery 🛛	Pediatrics 🗆	Dentistry 🛛
X-ray		Laboratory	OB/GYN □	Pharmacy
Orthopedics Other (list)		Hospice 🛛	рт/от 🛛	Nutrition

#### e. Indicate the hours of operation of the facility, if known.

f. List the number a	ind type of he	ealthcare work	ers at th	e facility/location.	
Medical Doctor	9	Surgeon			
Midwife	[	Nurse			
Pharmacist	[	Dentist			
Clinical officers	I	Lab technician			
Health workers	[	Non-medical			
Other					
<ul><li>g. What is the catch</li><li>h. What is the num</li><li># Adult Males:</li></ul>	ber of patien	ts seen at this	facility p	•	
# Children under 5		# Child	ren over	5 vears:	
i. Indicate the type	of populatio	n this facility s	erves:	Other (please describe)	
j. What are the mo population?	st common di	iseases or heal	th condi	tions that afflict the targeted	

k. Please give a detailed summary of the challenges faced by the healthcare facility.

I. In your opinion, how will Healing Help donations alleviate the challenges currently faced by the health facility.

m. Please indicate what other resources the facility/local organization needs to ensure sustainability and build its capacity to provide health services to the population.

n. Please list any other partners you are working with in the area.

o. Will you collaborate with the Ministry of Health in the recipient country?

Yes \_\_\_\_ No \_\_\_\_

p. Are there any details you want to provide about your organizations work in the beneficiary community?

## Section C: Requested Products

**10.** Please provide an itemized list with quantities of the products needed, including medicines, medical supplies, and consumer products.

- Please give the names of the products you are requesting, including international nonproprietary (INN) or generic name when possible.
- It is acceptable to list category in lieu of specific brand/product: Antacid, Antibiotic, Antifungal, Anthelminthic, Antihistamine, Antihypertensive, Hormonal, Ophthalmic, Respiratory, Topical, Analgesic, Antiviral, Cough/Cold, Diabetic, GI, Vitamins.
- Please provide information on any other requirements for product donations.
- Check here if you are attaching a separate list of requested products
   (Suggested if more space is needed)

Category	Product (INN)	Dosage/Strength	Quantity	Expiry
	1			

## <u>Section D: Health Practitioner's Statement of Intent for Use of Medicines</u> and Health Care Supplies

This section to be filled out by a licensed health care practitioner who will oversee the dispensing of donated medicines and supplies.

NOTE: Product offered for donation will be determined in accordance to the prescribing authority of the overseeing medical professional (i.e. if a non-prescribing HCP is listed below, only non-prescription products can be offered):

11. This is to certify that I take full responsibility for donated medicines and supplies to be used in mission work outside of the United States. In compliance with the Food, Drug, and Cosmetic Act, as amended, and IRS regulations, these medicines and supplies will not be returned to the United States, nor be sold or exchanged for other commodities or services. They will be used in treating the sick poor. If these supplies are lost, misplaced, or stolen prior to arriving at their ultimate destination, I will immediately report this in writing to CMMB. I will track and report any adverse medical events to CMMB immediately in accordance with the Adverse Event Reporting Guide.

Name of Practitioner:				
Signature of Practitioner:				
State/Country of License:				
License Number:				
Profession: (check one)				
Medical Doctor* 🛛				
(If specialist, please identify	specialty)		_	
Surgeon		Dentist		
Physician Assistant		Psychiatrist		
Nurse		Other		
NP/APN		(identify)		
Address:		Phone:		
City:		Fax:		
State:		Email:		
Zin Code:		Country*		

\* For US-licensed HCPs, a copy of the license is optional.

\*If the certifying HCP is NOT licensed in the US, a copy of the license spanning the dates of the program MUST be attached to the application.

## **Section E: Transportation Plans**

- Requesting that CMMB ship to you in a US location? Complete questions 13-17 AND 23.
- Requesting that CMMB ship to you at a NON-US location? Complete questions 13-23 (inclusive).

12. What are the data Departure/start data		program/missio	<b>n trip?</b> Return/er	date:	
(Check here if this re		te an ongoing n			
Check here if this re	equest suppor	rts an ongoing pi	ogram with no si	art date 🗆 )	
13. Date product is	requested to	arrive, if earlier	than or not tied	to a departure d	ate:
NOTE: This date stil	l must be six v	weeks or more fi	om the date the	application/agree	ement is
received by CMMB.					
14. Please provide	the contact in	oformation for w	vhere the donativ	n is to be sent (d	lonations
cannot be shipped				in is to be sent (o	
Name:		F	hone:		
Addresse:			ax:		
City:			Email:		
State:			Country:		
Zip:					
Yes:	organization	-		osts (End Ex/LIDS)	_
Portion: $\Box$	organization	able to pay doi	nestic snipping c	JSIS (FEU EX/UPS)	ŗ
Yes:	If you wi	sh us to direct bi	ll, account #		
17. Is the healthcar	• •	••••••			pay any of
the following expe		o the internatio	•	_	
Ocean shipment:	No:		Yes:		
Inland transportatio			Yes:		
Air transportation:	No:		Yes:		
18. Is the healthcar	e facility/ben	eficiary able to	receive donation	s duty free?	
No:		Yes:			

• If YES, please obtain a copy of that certificate from your in-country partner and send to CMMB once you are notified of application approval.

• We cannot ship until the duty-free import certificate is in place.

19. Name and contact information of the individual or agency that will act as consignee and assist the beneficiary facility in the clearance, receipt and delivery of this donation:

Name:	Phone:	
Agency:	Fax:	
Address:	Email:	
City/Town:	State/Region:	
Country:		
Secondary Contact:		
Name:	Phone:	
Agency:	Fax:	
Address:	Email:	
City/Town:	State/Region:	
Country:		

20. Give the details of the most convenient port of entry or airport for clearing the shipment through customs and for in-country transportation:

21. Do yo	u have an import cu	ustoms broker?	
No:		Yes:	
If YES, ple Name:	ase also provide the	e full name, address	and contac hone:
Name: Address:		F	
Name:		F	hone:

22. Please be aware that following shipment, additional expenses may arise related to demurrage, storage, inspection or clearance. Consignees are responsible for any such expenses.

## Section F: Mission Trip Roster (if applicable)

First Name	Last Name	License Type	Prescriber?	Mission Role	State/Country
			1		

## <u>Section G:</u> Organizational Commitment to Comply with Donation Requirements

In order to receive a donation of medicines and medical supplies from CMMB, you must acknowledge your agreement to comply with the following terms and conditions by reading each statement and signing your initials in the space provided.

- By signing and submitting this application/agreement to CMMB, and requesting a product donation on behalf of the organization named in Section A, you are representing that you have the authority to enter into an agreement on behalf of this organization.
- If the application is approved and a donation offer is made, by accepting the offer you are also granting permission for CMMB, with prior written notice, to audit/inspect the facility to which product is shipped and any downstream facility to which donated pharmaceutical product is brought or sent for distribution. Failure to comply with these requirements WILL impact your future eligibility to receive product from CMMB.

23. Name, position and signature of the representative of the applicant organization (consignee) acknowledging this agreement:

Name:	 Signature:	
Position:	 Date:	

- \_\_\_\_\_ I will insure that all CMMB medicines and medical supplies donated to my organization will be distributed free of charge and without discrimination of any nature, including but not limited to race, religion, gender, politics, nationality or geography.
- \_\_\_\_\_If a modest administrative fee for service is charged by my organization or the medical facility where services are performed, I will insure that this fee is not identified with CMMB, donors to CMMB, or the medicines or supplies provided to us by CMMB.
- \_\_\_\_\_I am fully aware of the laws involved in the import of pharmaceutical products to my beneficiary country(ies) and the plans for this trip will be compliant with these laws.
- \_\_\_\_\_I agree to incur any additional expenses related to demurrage, storage, inspection or clearance of the donation.
- \_\_\_\_\_I will not return any donation to the United States.
- \_\_\_\_\_I will not sell or exchange any donation for property or services.

- \_\_\_\_\_Neither I nor my organization have ever sold donated product, or charged a fee for donated product; in addition, neither I nor they have ever presented donated product for rebate, refund or chargeback either in the US or abroad.
- \_\_\_\_\_Neither I, my organization, my beneficiary organization, nor anyone involved in leadership of that organization is or has been identified on a US Office of Foreign Asset Control (OFAC) Sanctions List.
- \_\_\_\_\_I will immediately notify CMMB of any adverse logistics event regarding this donation including but not limited to diversion, loss, damage to, confiscation or destruction of products.
- \_\_\_\_\_I will immediately notify CMMB of any adverse medical events in relation to any donated product whether observed by me personally, or by other members of my organization, or reported to us by in-country counterparts, patients or their families. Further, I will confer with CMMB before making statements to media or regulatory bodies.
- \_\_\_\_\_I will confirm receipt of all donations by returning the shipment manifest and delivery receipt provided by CMMB with each donation.
- \_\_\_\_\_I will provide CMMB with a completed field feedback report, including photographs, reports, success stories, or program evaluations for each shipment received.
- \_\_\_\_\_I will provide CMMB with impact feedback, including a complete accounting of the distribution of all donated product using CMMB's Line-Item Distribution Report (provided at time of shipment).
- \_\_\_\_\_I will provide CMMB with an updated final Mission Trip Roster identifying licensed HCPs and participants who were directly involved in the dispensing of medicines donated to our organization.
- \_\_\_\_\_I will provide updated information to CMMB regarding in-country partners (e.g. contact persons, phone or email addresses or GPS coordinates), or additional beneficiaries or distribution locations, etc. to reflect any pending, missing or additional information gained in-country/on-site as soon as possible.
- \_\_\_\_\_I am aware that pharmaceutical products must be destroyed in accordance with local laws in the country where I will distribute this donated product. I will ensure that I and/or members of my organization travelling with the products know the local laws regarding disposal/destruction before departure. In the unexpected event that any pharmaceutical products or medical supplies must be destroyed after distribution to our beneficiary, we will ensure adherence to local regulations of the Ministry of Health, Ministry of Trade, and/or any other relevant authorities.

## <u>Section H:</u> Certification of Intent to Comply with the Foreign and Corrupt Practices Act

The undersigned, \_\_\_\_\_\_, in my capacity as \_\_\_\_\_ [POSITION] for

[NAME OF CHARITABLE ORGANIZATION] ("Charity") represent the following in connection with the requested in-kind donation of pharmaceutical products and medical supplies ("Contemplated Donation").

1)\_\_\_\_\_ I have reviewed this Certificate with the appropriate principals of Charity and have been duly authorized to execute this Certificate on behalf of Charity.

2)\_\_\_\_\_ I understand that U.S. law prohibits giving, promising or offering to give, or authorizing the giving of anything of value, including money payments, to a Foreign Official in order to obtain, retain or direct business or any other advantage to the Company or to any other person or corporate entity or to achieve any other improper purpose.

3) \_\_\_\_\_ I certify that the donation received was not in exchange for executing any commercial contracts with the underlying donor organization and that receipt of this donation was not made or in order to obtain, retain or direct business or any other advantage to the donor organization or to any other person or corporate entity or to achieve any other improper purpose.

4)\_\_\_\_\_ I understand that U.S. law prohibits giving, offering, or promising anything of value, including money payments, to any person or entity, including intermediaries and representatives, while knowing or having reason to know that all or any portion of such payment or thing of value will be offered, given or promised, directly or indirectly, by that person or entity for the purpose of influencing any act or decision of any Foreign Official.

5) \_\_\_\_\_ The Contemplated Donation is made for the charitable purpose intended and nothing more. All donated proceeds made in connection with the Contemplated Donation will be used for such charitable purpose. None of the donated proceeds will be transferred in any manner to any Foreign Official for any reason whatsoever. I understand that any transfer of the donated proceeds to any Foreign Official will result in the revocation of the charitable gift from the company.

6)\_\_\_\_\_ I shall notify the Company's representatives immediately if, at any time, I become aware of any past, current or future act resulting in an actual or potential conflict with or violation of any the above representations.

IN WITNESS WHEREOF, the undersigned has executed this Certificate on behalf of Charity as of the \_\_\_\_ day of \_\_\_\_\_\_, 20\_\_\_.

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## Additional applicant information for FCPA compliance review:

- A. Is this organization a government entity (non-US)? Yes/No
- B. Are any officials of the organization also government officials? Yes/No (if yes, list below)

Name	Title	Contact Information

- C. Do any of the listed individuals have regulatory authority over any United States medical supply companies, pharmaceutical companies or medical device companies? Yes/No (if yes, list US medical supply, pharmaceutical or medical device company/companies below)
- D. Have any of the listed individuals made any decisions to award contracts to any United States medical supply companies, pharmaceutical companies or medical device companies within the past 12 months, and/or is he/she expected to do so within the next 12 months? Yes/No

(If yes, list US medical supply, pharmaceutical or medical device company/companies below)

E. Was this donation requested by someone other than the applicant? Yes/No (If yes, please provide information about the requestor below)

Name	Position	Organization/Company		

F. Is this donation required by a contract? Yes/No(If yes, please attach a copy of the contract and identify the section requiring donation)

By signing this form, the entity making this request (applicant) represents that the request is a legitimate request for a charitable donation and it is not intended for funds or in-kind products to be used in any way that contravenes donor compliance policy or United States law.

Applicant Signature	: <u></u>
Applicant Name:	
Date of Request:	

#### Appendix I: Summary of the Foreign and Corrupt Practices Act (FCPA)

The U.S. Foreign Corrupt Practices Act of 1977 ("FCPA") is a criminal law of the United States ("U.S.") that prohibits U.S. companies, their agents, representatives and employees, from corruptly giving, offering, promising, or authorizing anything of value to foreign (non-U.S.) officials or foreign political parties, officials or candidates, for the purpose of influencing them to misuse their official capacity to obtain, keep, or direct business or gain any improper business advantage. In short, the FCPA prohibits the payment of bribes in order to win business or obtain any other benefit from the government.

The FCPA also prohibits misrepresentations in a company's books and records and requires that a company's books, records and accounts be maintained in reasonable detail accurately representing transactions or any payment.

In addition to prohibiting corrupt payments to foreign officials, the FCPA also forbids offering or paying anything of value to <u>any person or entity</u> (for example, a third-party) when it is known that all or part of the payment will be transmitted to a foreign official for the improper purposes mentioned above. Under the FCPA, a person will be considered to "know" that a prohibited payment is being or will be made when that person has actual knowledge of such payments, or consciously disregards facts and circumstances that should reasonably alert the person of the high probability that such payments have been made or will be made.

A violation of the FCPA occurs when an offer, promise or authorization of a corrupt payment (bribe) has been made. In other words, a violation can occur without an actual payment being made. Likewise, a violation can occur even if no benefit is ever received from the government.

A "Foreign Official" for purposes of the FCPA means any:

- non-U.S. government official (includes municipal, provincial, central, federal or any other level of government);
- officer or employee of a foreign government, or any department, agency, ministry or instrumentality thereof (includes executive, legislative, judicial or regulatory);
- person acting in an official capacity on behalf of a foreign government or any department, agency, ministry or instrumentality thereof;
- officer or employee of a company or business owned or controlled in whole or in part by a foreign (non-U.S.) government ("state owned enterprise");
- officer or employee of a public international organization such as the United Nations or World Bank;
- member of a royal family;
- foreign political party, member, or official thereof;
- candidate for foreign political office; and
- elected officials of foreign countries, civil servants and military personnel.

The term also includes the children, spouse or other close relatives of Foreign Officials.

"Anything of value" for purposes of the FCPA includes cash and cash equivalents such as unauthorized travel expenses, vacations, gifts, services, and lavish entertainment.

The FCPA applies to all United States companies and their subsidiaries world-wide, its employees and to all persons and entities, wherever located, acting on behalf of any US company or its subsidiaries, such as marketing representatives, distributors, consultants, and sales representatives.

Companies that violate the FCPA anti-bribery provisions may be subject to extensive financial penalties. Individual officers, directors, employees, marketing representatives, consultants or agents found to have willfully violated the FCPA may be fined and imprisoned for up to five years for each violation.

# Appendix II: Additional space to list facilities from section B if your organization is working with or distributing to multiple facilities.

Facility Name	Location	Facility Type	Maternal and Child Health Work? (Y/N)	Psychiatric Work? (Y/N)	Number of Patients per Year	Number of Staff