

Accessing Affordable and Timely Supply of Vaccines for use in Humanitarian Emergencies: the Humanitarian Mechanism

WHO Working Document

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Background:

People affected by emergencies, epidemics and other humanitarian crises are typically the most vulnerable, already facing a range of obstacles in meeting their basic needs. In order to reduce vaccine-preventable disease-related (VPDs) morbidity and mortality amongst crisis-affected populations, in 2013 WHO published its guidance, *Vaccination in Acute Humanitarian Emergencies: a Framework for Decision Making*.¹ The framework has been used in select contexts, and a revision is underway to update the guidance and develop supporting tools.²

Despite the available technical guidance, experience from partners showed that a key barrier to protecting crisis-affected populations from VPDs was affordable and timely access to vaccines.³ In June 2016, Médecins Sans Frontières (MSF) and the World Health Organization (WHO) organized a meeting on timely supply of affordable vaccines in humanitarian emergencies which established working groups to advance progress on this matter.⁴ In October 2016, WHO convened a follow up meeting to gather input on their revised technical guidelines and present work completed by the working groups established during the June meeting.⁵ One of the working groups proposed a mechanism for accessing affordable and timely supply of vaccines for use in humanitarian emergencies: the Humanitarian Mechanism. Following those discussions, the mechanism is now jointly launched by WHO, UNICEF, MSF and Save the Children.

The Humanitarian Mechanism sets forth requirements for vaccine supply in emergencies, elements for effective and efficient vaccine procurement in emergencies, and a modality for management of requests aligned with the mechanism. The main aim is to facilitate timely access to affordable supply for entities such as Civil Society Organizations, Governments or UN Agencies who are procuring on behalf of populations facing humanitarian emergencies who otherwise do not have access to affordable vaccines. The mechanism's principles are aligned with the WHO & UNICEF Joint Statement on donations (2011).⁶

¹ *Vaccination in Acute Humanitarian Emergencies: a Framework for Decision Making*. <http://goo.gl/F92hJw>

² Estimated completion: Q2 2017.

³ Meeting of the Strategic Advisory Group of Experts on immunization, October 2015 – Conclusions and recommendations, <http://www.who.int/wer/2015/wer9050.pdf?ua=1>

⁴ Please contact MSF or WHO for meeting report on *Vaccinating in Humanitarian Emergencies: Identifying challenges and resolving barriers to timely supply of affordable vaccines in humanitarian crisis situations*. June 20, 2016.

⁵ Please contact WHO for meeting report on *Meeting on Vaccination in Humanitarian Emergency Situations*. October 10-11, 2016.

⁶ http://www.who.int/immunization/hpv/plan/who_unicef_joint_statement_on_vaccine_donations_who_unicef_2011.pdf

This Terms of Reference outlines the Humanitarian Mechanism, and the commitments made to date by suppliers (Annex III).⁷ It is hoped that more suppliers will join this effort in making commitments to offer their lowest global vaccine prices to governments and/or organizations serving the needs of people caught in humanitarian emergencies. It should be noted that other mechanisms already exist for accessing supply of certain vaccines where risk of disease is considered high, such as the International Coordination Group for meningococcal vaccine, oral cholera vaccine and yellow fever vaccine,⁸ or at lowest market prices for some vaccines through UNICEF procurement on behalf of populations facing humanitarian emergencies.⁹

It is acknowledged that while this mechanism will aim to facilitate timely access to affordable vaccines in humanitarian crises, the challenge remains for many Middle Income Countries (MICs) to introduce life-saving vaccines in their routine immunization programs also due to price barriers. Partners are engaged in various efforts with vaccine manufacturers to achieve affordable, sustainable vaccine prices for MICs beyond humanitarian emergencies and this mechanism.¹⁰

Principles of the Humanitarian Mechanism:

- Ensure timely and affordable access to vaccine supply for humanitarian emergencies
- Align with WHO's guidance, *Vaccination in acute humanitarian emergencies: A framework for decision making* (hereafter referred to as the "Framework")
- Enhance granting of lowest price to procuring entity while avoiding interference with commercial strategy of companies
- Enable any entity with procurement capacity to purchase vaccines directly from the manufacturer for speed and efficiency
- Promote information and transparency of manufacturers' price offers for humanitarian emergencies and predictability of process

Main features of the Humanitarian Mechanism:

- 1) Promotion of manufacturer supply commitments:** The mechanism partners call for affordable prices for all antigens to entities vaccinating in humanitarian emergencies. Through the mechanism, price offers made publicly are recorded and published, including their terms and conditions as indicated by suppliers.
- 2) Management and coordination of requests:** Through the mechanism, management and coordination of requests will take place to:
 - Ensure there are no duplicate requests to access supply offers;
 - Ensure rapid notification of all relevant parties;

⁷ In September and November 2016, GSK and Pfizer, respectively, made commitments to offer the lowest global price for their pneumococcal conjugate vaccines (PCV) to non-governmental organizations (NGOs) and UN agencies for use in humanitarian emergencies.⁷ Details on these commitments are enclosed below.

⁸ International Coordinating Group (ICG) on Vaccine Provision: <http://www.who.int/csr/disease/icg/qa/en/>

⁹ Lowest market prices for vaccines are available for most vaccines (see Annex X) to respond to humanitarian emergencies through UNICEF Supply Division. For further information on access to vaccines through UNICEF Supply Division, please send your queries to psid@unicef.org

¹⁰ http://www.who.int/immunization/programmes_systems/sustainability/mic_strategy/en/.

- Provide an opportunity to collect data on demand in order to inform future forecasts of vaccine needs for humanitarian emergencies, acknowledging the inherent difficulty in forecasting for unpredictable situations.
- 3) **Beneficiary entities request access to supply through the mechanism by interacting with the Verification Body** (see detailed ToRs in Annex I) – at these email addresses: CASTILLA ECHENIQUE, Jorge: castillaj@who.int, LAMUNU, Margaret Orunya: lamunum@who.int, COSTA, Alejandro Javier costaa@who.int. The Verification Body verifies that requests for supply meet requirements of offers within two (2) working days via email. Feedback on requests for additional information or rejection is required.
 - 4) **Procurement of vaccines:** Entities with the capacity to self-procure can do so directly from the manufacturer (through a direct agreement established with the manufacturer), whereby other entities can use procurement services such as UNICEF Supply Division.
 - 5) **Annual monitoring of offers' use and potential adjustments to mechanism modus operandi:** Through its operations the mechanism will collect information on demand for vaccines in emergency contexts and potential challenges to use of supply offers. Information will be reviewed annually to ensure the mechanism objectives are met.

Some of these features are detailed further in Annex I.

Period in effect:

The mechanism will begin operations commencing 1st May 2017. After 12 months of operation, a discussion will be convened by the mechanism's partners with manufacturers to determine whether the objectives of the mechanism are being met and any change in its structure required. A mid-point review of demand will be organized.

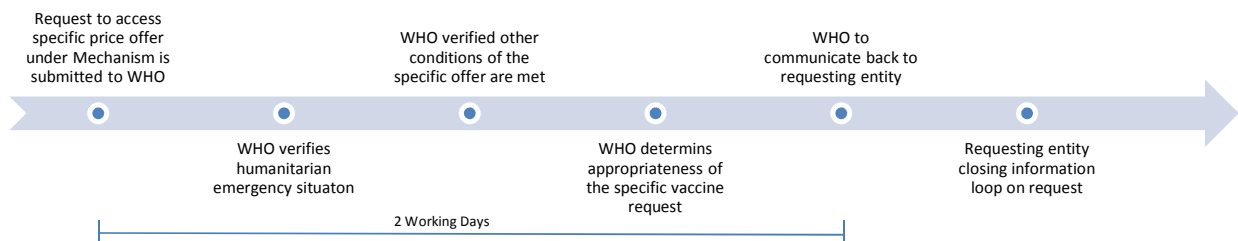
Roles & responsibilities:

1. WHO will lead implementation of the mechanism by i) documenting manufacturer commitments to the mechanism (IVB); ii) managing and coordinating requests for access to vaccines (WHE); iii) acting as the Verification Body (WHE in collaboration with IVB); iv) leading the annual monitoring of the mechanism implementation in collaboration with mechanism partners (IVB in collaboration with WHE).
2. UNICEF SD will develop contractual agreements based on the offers made by suppliers through their tendering processes. CSOs or other UN agencies may use UNICEF SD procurement services.
3. CSOs that will procure directly from the manufacturer will develop contractual agreements based on the offers made by suppliers through their usual supply and procurement processes.

Annex I – Humanitarian mechanism process in detail

Aligned with the WHO Framework which outlines steps for determining use of which vaccines in various emergency contexts, the below process will be followed.

- 1) Price offers under the Humanitarian Mechanism should be made to WHO (IVB) at cernuschit@who.int. WHO will publish all offers on its website here: http://www.who.int/immunization/programmes_systems/sustainability/en/
- 2) Requests for vaccine use should be submitted to these email addresses Castilla Echenique Jorge castillaj@who.int, Lamunu Margaret Orunya lamunum@who.int, Costa Alejandro Javier costaa@who.int, Diana Chang Blanc changblancd@who.int, cernuschit@who.int at WHO, using the *Template* provided in Annex II.
- 3) WHO WHE will review and determine within 2 working days if the request meets conditions of the relevant supply offer. All requests will need to meet the following verifications: i) verification of humanitarian emergency situation; ii) determination of appropriateness of the specific vaccine request – see below for more information. Feedback on requests for additional information or rejection is required.
- 4) WHO will notify the requesting entity, the manufacturer and mechanism partners (at E.Diggie@savethechildren.org.uk, K.Mathieson@savethechildren.org.uk, ymomeni@unicef.org, hdeehan@unicef.org, Kate.Elder@newyork.msf.org, Tanja.ducomble@geneva.msf.org, cernuschit@who.int, changblancd@who.int) of compliance or non-compliance (within 2 working days);
 - a. For entities procuring directly from suppliers, supply and delivery arrangements will be made directly in accordance with any contractual agreements between the parties.
 - b. For entities procuring through UNICEF SD, UNICEF SD will commence procurement services through standard mechanisms (Instruction for requests for access to vaccine through UNICEF https://www.unicef.org/supply/index_purchasing.html).
 - c. If requests are not validated, WHO will send information on the reason to all partners.
- 5) The requesting entity will provide a feedback to WHO – same addresses as above - on receipt and use of vaccines to complete the information loop and inform annual monitoring of the mechanism use.



Verification of humanitarian emergency situation:

A humanitarian emergency is defined in WHO's Framework as the occurrence of one or more of the following conditions, due to any reason (natural, man-made or a combination thereof). Emergencies are often WHO/UNICEF graded emergencies, but there may be occasions when the humanitarian emergency is not graded. The below definition is believed to encompass the large majority of

potential scenarios, but there may be cases in which data and available information are imprecise, incomplete or controversial; in such instances, application of the definition should err on the side of caution, i.e. it is preferable to assume that an emergency is taking place.

- 1) Sudden unplanned displacement of a large proportion of the population away from the community of habitual residence and into any settlement (refugee or internally displaced persons' camps; host community; urban areas; other uninhabited areas), within the same country or across international borders.
- 2) Direct exposure of the civilian, non-combatant population to new or exacerbated and sustained episodes of armed conflict resulting in risk factors including, reduced access to health care, disrupted water and sanitation, food insecurity, etc.
- 3) Consistent and reliable evidence from food security and/or nutritional indicators suggesting that a sudden deterioration of nutritional status is impending or has already occurred, above and beyond known seasonal fluctuations or situations of chronic poor nutritional status and/or food insecurity.
- 4) Natural or industrial (including nuclear) disaster resulting in temporary homelessness, disruption to critical public services (e.g. health care, water and sanitation, food deliveries, etc.), increased risk of injury and/or exposure to adverse weather conditions for a large proportion of the population.
- 5) Sudden breakdown of critical administrative and management functions, within the public and/or private sector, due to any reason, resulting in large scale disruption of public health and related services (e.g. water and sanitation, housing).

For WHO WHE's verification (Castilla Echenique Jorge or replacement), at least one of the following criteria will be used to determine if a humanitarian emergency is occurring:

1. UNICEF or WHO or OCHA graded emergency
2. Humanitarian response plan is in place (OCHA)
3. Establishment of an Immunization Task Force (WHO IVB will be consulted for this info)
4. Acknowledgment by a national or local health authority of an emergency
5. If none of the above is met, the requesting entity should outline the conditions entailed in the emergency for WHO HQ's review in consultation with mechanism members; common sense should prevail. In this case, verification may take a longer period of time.

Determination of appropriateness of the specific vaccine request:

WHO Headquarters, Immunization, Vaccines and Biologicals (Diana Chang Blanc or replacement) will determine the appropriateness of the vaccine request based on compliance with the WHO Framework for Vaccination in Humanitarian Emergencies. Appropriateness will be established by reviewing the information provided as per the Template below.

Of note, final responsibility for an answer on compliance within two (2) working days rests with WHO/WHE (Castilla Echenique Jorge or replacement).

Annex II - Template for submitting requests to WHO to access supply offers

Date

Organization

Name/contact of focal point for submission

Country of activity

Vaccine(s) & product(s) to be used

Confirmation of process followed to reach agreement with local health authorities and/or relevant immunization parties (the Immunization Task Force, if there is one) on vaccination activity in application of the WHO Framework for vaccination in humanitarian emergencies. If available, submit the report of Framework use.

Proposed vaccination activity

- Project location
- Target population (age group, total number)
- Vaccination schedule
- Total number of doses required
- Timeline of vaccination/Start date of vaccination
- Brief information on context and strategy for vaccine delivery (type of emergency, timeline of activity, schedule to be used, delivery strategy)
- Justification for vaccine use (epidemiological data, risk factors accordance as per availability of this information)

Vaccine to be procured directly from manufacturer or through UNICEF Supply Division

If specific target population or other condition apply to supply offer being accessed, additional specific information needs to be provided.

Annex III - Current supply offers & related verification conditions

Pneumococcal Conjugate Vaccines (PCV):

GlaxoSmithKline

In September 2016, GSK was the first company to commit to a humanitarian price for civil society organizations serving the vaccination needs of refugee and internally displaced people (IDPs). GSK's commitment is initially for its PCV, Synflorix, at the lowest global price of US\$ 3.05/dose. GSK's commitment is for its multi-dose vial presentation of Synflorix as used for deliveries of Synflorix to UNICEF for use in immunisation programmes supported by Gavi. Currently this is a two-dose vial presentation.

<http://us.gsk.com/en-us/media/press-releases/2016/gsk-sets-out-further-steps-to-address-emerging-global-health-security-challenges/>

Contacts: an.x.vermeersch@gsk.com, guy.m.pickles@gsk.com

Pfizer

In November 2016, Pfizer committed to a humanitarian price for civil society organizations serving the vaccination needs of people caught in humanitarian emergencies. Pfizer's commitment is for its new multi-dose vial (MDV) presentation of PCV, Prevenar 13, at the lowest global price of US\$ 3.10/dose. Pfizer additionally pledged to donate all sales proceeds for the first year of the program to humanitarian groups.

http://www.pfizer.com/news/press-release/press-release-detail/pfizer_announces_major_expansion_of_humanitarian_assistance_program

Contacts: JulieM.Jenson@pfizer.com, John.Roberts@pfizer.com

Both GSK and Pfizer have made their offer to non-governmental organizations (NGOs)/civil society organizations (CSOs) and UN agencies.

In order to ensure that a request is submitted by an NGO/CSO, WHO in collaboration with UNICEF will ensure that requesting NGOs/CSOs:

- Are a member of Global Health Cluster (HC) or HC observer status; or
- Are registered with their home national authority as having met all of the conditions of a not-for-profit health organization; and
- Procure their vaccine via UNICEF Supply Division.

If the NGO/CSO does not meet the above conditions, a desk audit will be performed by WHO or UNICEF in consultation with local entities (e.g. if established, the Immunization Task Force) to determine status and appropriateness of request in the local context. This will be completed within one (1) week.

For GSK's supply, the presence of refugees or displaced populations (internally or from other countries) will also be verified by WHO/WHE.

Annex III – Vaccines provided by UNICEF in Humanitarian Emergencies with arrangements for non-Gavi Markets

Vaccines currently under UNICEF Long Term Agreements	DTwP-Hib-HepB-Pentavalent	Same or similar price level to Gavi supported countries has been accessed
	BCG	
	MMR (LZ)	
	JE	
	DT/DPT/HepB	
	TT/Td	
Emergency/outbreak response vaccine (contractual agreements for emergency response and/or stockpile)	OPV/mOPV	Managed through GPEI
	IPV	
	Measles/MR	Managed in collaboration with MRI
	Yellow Fever & Meningitis	Managed through ICG for outbreak response
	Oral Cholera Vaccine	Managed through ICG for outbreak response & through the GTFCC for preventive campaign