POLIO GLOBAL ERADICATION INITIATIVE

MONOVALENT ORAL POLIO VACCINE TYPE 2 (mOPV2) VACCINE REQUEST FORM

for the response to
type 2 vaccine-derived poliovirus (VDPV2) and
type 2 wild poliovirus (WPV2)

Version 2, Dec 2016

World Health Organization

Introduction

Following global withdrawal of oral polio vaccine type 2 (OPV2) from national immunization programmes, a confirmed type 2 event will be considered a public health emergency of international concern (PHEIC). The World Health Organization (WHO), in collaboration with the United Nations Children's Fund (UNICEF) Supply Division and vaccine manufacturers, has established a stockpile of mOPV2 that can be provided rapidly to Member States following detection of a poliovirus type 2. In line with the guidelines for a type 2 outbreak response in this protocol, countries should file this request form for mOPV2 for supplementary immunization activities (SIA). The Eradication Outbreak Management Group (EOMG) will review the request and make recommendations to the Director Polio who will advise the WHO Director-General to authorize the release of mOPV2.

In most situations, detection of a type 2 vaccine-derived poliovirus (VDPV2) or type 2 wild poliovirus (WPV2) will initially require a small-scale rapid vaccination response using mOPV2 within 14 days of receiving the laboratory sequencing results. The scope, the number of doses and the vaccine type required for further supplementary immunization activities SIAs will depend on local risk factors and additional field and laboratory investigations. (See "Responding to a poliovirus event and outbreak: SOP for poliovirus type 2"[1] . In order to ensure an efficient and rapid process, the vaccine will be requested in two stages:

- **Stage 1 covers only mOPV2 required for the first round of supplementary immunization activities (SIA)** and should be filed with WHO within 24 hours of receiving the validated sequencing results.
- **Stage 2 covers mOPV2 requirements for all further planned SIAs rounds** and should be filed with WHO only after conducting further inves-tigation, final classification of the isolate if necessary, and completed response plan. Aim to submit this stage 2 request by day 14 following receipt of the sequencing results. If IPV is required as part of the outbreak response plan, please use the separate request form for IPV, syringes and safety boxes.

The signed vaccine request form and required documentation should be sent to:

the Advisory Group of the Eradication Outbreak Management Group on mOPV2 Provision Secretariat
at:
20 Avenue Appia, 1211
Geneva 27, Switzerland
Fax: + 41 22 791 4198
Email: mOPV2Request@who.int
CC: WHO country office, UNICEF Supply Division (aghazieh@unicef.org; aottosen@unicef.org)

[1] Responding to a poliovirus event and outbreak- Standard Operating Procedures (SOPs). http://polioeradication.org/tools-and-library/field-resources-for-polio-eradicators/gpei-tools-protocols-and-guidelines/

Checklist

1. Request form completed and signed	Yes ☐	
2. Vaccine acceptance letter signed and attached	Yes ☐	Pending ☐
3. Laboratory reports initial case (stage 1)	Yes ☐	Pending ☐
4. Field investigation reports	Yes ☐	Pending ☐
5. Laboratory reports of additional cases (stage 2)	Yes ☐	Pending ☐
6. Immunization response plan	Yes ☐	Pending ☐
7. Authorization from the national regulatory authority or ministry of health to import and use mOPV2	Yes ☐	Pending ☐
8. If pending, then expected date of receiving formal acceptance	___/____/____	
9. Risk assessment report	Yes ☐	Pending ☐
10. Map with dots representing the location of the case(s) or site of environmental sampling	Yes ☐	Pending ☐

11. Other (specify):

Notice for recipient countries of mOPV2

WHO use and release of mOPV2

WHO will prioritize the requests for vaccines from the global mOPV2 stockpile based on the recommendations of the Advisory Group on mOPV2 provision composed of Eradication and the Outbreak Management Group (EOMG) members and independents experts. The decision and the Advisory Group on mOPV2 provision recommendation will be based on epidemiological considerations, the laboratory information provided, the total number of doses requested from WHO, the total number of doses in the WHO mOPV2 stockpile, and the prioritization of the requests received by WHO based on countries' needs. In this regard, it should be noted that the submission of this request form does not automatically mean that WHO will supply any vaccine to the requesting country, or that WHO will supply the quan- tities requested, or that WHO will supply the vaccine by the requested delivery date. The decision whether to supply any vaccine to the country, and in which quantities, will be taken by the WHO Director-General in its sole discretion based on the recommendations of the Advisory Group on mOPV2 provision and the above-mentioned considerations. Details regarding any supply of vaccine, including the quantities and logistics, such as anticipated delivery timelines and destinations, will be communicated by WHO to the government at the contact details indicated in this request form. **The minister of health must complete and sign the *vaccine request form,*** then return the completed signed request form along with the required *acceptance letter authorizing the importation and use of mOPV2* (see below).

Country acceptance to authorize importation and use of mOPV2

mOPV2 has been prequalified by WHO and approved by a stringent national regulatory authority with jurisdiction over the facility where the vaccine has been manufactured. mOPV2 is intended for emergency use as a response to a type 2 outbreak or event following tOPV withdrawal, and has not been licensed in the country. Countries that are experiencing a type 2 outbreak or event, and that are requesting for the release of mOPV2 supply from the global mOPV2 stockpile, are strongly advised to authorize the importation based on WHO pre-qualification and/or provide an emergency waiver for use of the vaccine for the emergency response. Any delays in authorizing its importation and use will delay the procurement and delivery of the vaccine to the country, thereby delaying the required 14 day outbreak response in line with the GPEI SOPs for Responding to poliovirus event and outbreak. To enable UNICEF to issue a purchase order to the manufacturer, the country must submit a letter to authorize importation and use of the vaccine. In Annex A is provided a template letter which should be completed and copied on a Ministry of Health letterhead. **This acceptance letter for authorization to import and use mOPV2 must be signed by a designate person in the ministry of health or national regulatory authority.**

UNICEF will provide this letter to the manufacturer to initiate packing of the goods and clear the vaccine consignment for dispatch. The letter to authorize the manufacturer to send the vaccine must be provided at the time of submission of the duly signed and filled vaccine request form to avoid delays to supply the vaccine in order to start the first round of supplementary immunization activities within 14 days.

Waiver for special shipping documentation and/or pre-inspection requirements

In order to meet delivery timelines to the country, the supplier will only include the standard list of documents required for international vaccine shipment: the packing list, shipping invoice, and standard lot release certificate provided by the national regulatory authority of the producing country. Countries are requested to waive non-standard documentation requirements (such as original certificates of origin, consular legalisation and stamps in specific colors), as well as pre-inspection requirements. Should a country continue to require additional, non-standard documentation, provided that the manufacturer is able and willing to provide such additional documents, or pre-inspection, then the country accepts the responsibility for any delays in delivery of the vaccine.

Physical inspection of consignment after delivery

Physical inspection and verification of the mOPV2 consignment shall be made by the consignee named in this request form and/or its designated authorized representative, using the vaccine arrival report (VAR) accompanying the shipment. The VAR should be returned within 24 hours after delivery to ensure timely action if the consignment does not conform to the requirements. If the consignee, in consultation with the WHO country office, reasonably determines that, in terms of the aspects set out in the VAR, all or part of the vaccine consignment does not conform to the requirements, the consignee shall immediately notify WHO and UNICEF of the non-conformity.

General information

Date of the request: stage 1:

Date of the request: stage 2:

Country:

Outbreak-affected region/state:

Outbreak-affected areas (towns/districts):

Extended area with high-risk subpopulation region/state:

Extended area with high-risk subpopulation (towns/districts):

Requesting government ministry/department:

Contact details of focal people in requesting government ministry/department (name, telephone, email):

NAME | PHONE | EMAIL

Name and title of the person who fills this form:

NAME | TITLE

Signature of person who completes this form:

Consignee in the country	
Consignee organization*	
Contact name	
Telephone	
Fax	
Email	
Address	
PO box	
Town	
Country	

* The government will be responsible for handling the rapid importation and customs clearance of the vaccine into the country, unless UNICEF is exceptionally named in the purchase order as the consignee for customs clearance purposes.

Vaccination plan and vaccine supplies requirements

Notice: See GPEI SOPs Responding to a poliovirus event and outbreak to determine the type of vaccine, size of target population and number of supplementary immunization activities recommended for each situation.

1- First stage of vaccine deployment in case of type 2 detection (first supplementary immunization activity): SIA round 1 in rapid-response area (starting date __/__/__)

- Immunization plan for SIA round 1

Province	District	City/town/locality	Target age group	Target population (number)

- mOPV2 requirement for SIA round 1

Total target population (number)	Number of doses	Wastage factor	Total mOPV2 doses
	1	1.15*	

* If different wastage factor is used please provide supportive document e.g.vaccine wastage studies or monitoring exercise conducted in selected provinces/districts

[2] Responding to a poliovirus event and outbreak- Standard Operating Procedures (SOPs). http://polioeradication.org/tools-and-library/field-resources-for-polio-eradicators/gpei-tools-protocols-and-guidelines/

2- Second stage of vaccine deployment after type 2 detection (all additional supplementary immunization activities): SIA round 2 in outbreak-affected area (starting date __ /__ /____)

- Immunization plan for SIA 2

Province	District	City/town/locality	Target age group	Target population (number)
Outbreak-affected area (includes rapid-response area plus surroundings)				
Total				
Extended area with high-risk subpopulation (if required – see Protocol, Figure 3a–b)				
Total				

- mOPV2 requirement for SIA 2 in outbreak-affected area

Target population (number)	Wastage factor	Total mOPV2 doses
	1.15	

3- SIA round 3 (starting date __ /__ /____)

- Immunization plan for SIA round 3

Province	District	City/town/locality	Target age group	Target population (number)

- mOPV2 requirement for SIA round 3

Target population (number)	Wastage factor	Total mOPV2 doses
	1.15	

4- SIA round 4 (starting date __ /__ /____)

- Immunization plan for SIA round 4

Province	District	City/town/locality	Target age group	Target population (number)

- mOPV2 requirement for SIA round 4

Target population (number)	Wastage factor	Total mOPV2 doses
	1.15	

5- SIA round 5 (starting date __ /__ /____)

- Immunization plan for SIA round 5

Province	District	City/town/locality	Target age group	Target population (number)

- mOPV2 requirement for SIA round 5

Target population (number)	Wastage factor	Total mOPV2 doses
	1.15	

Case identification and laboratory investigation reporting

1- First stage of vaccine deployment in case of type 2 detection (SIA 1)

- Laboratory reporting for human specimens

Address of laboratory for virus isolation:

TEL

FAX

Name of responsible person:

Email:

If different, address of laboratory for sequencing:

TEL

FAX

Name of responsible person:

Email:

- Case identification

Province: District:

EPID no.	Patient name	Village/locality	Gender		Date of birth DD/MM/YYYY	Age (months)	Total doses of OPV	Total doses of IPV received	Date of paralysis onset	Date of last stool collection samples
			M	F						

- Laboratory report

Province: District:

EPID no.	Specimen ID	Source				Polio type 2 category					Nucleotide Changes	EPID no. Of VDPV Closest match	Comment
		AFP	Contact	Healthy	Other	Pending classification	cVDPV2	aVDPV	iVDPV2	WPV2			

- Reporting laboratory for environmental sample

Address of laboratory for virus isolation:

TEL

FAX

Name of responsible person:

Email:

- Laboratory report

Environmental sample site code	Environmental sample collection site name	EPID no.	Specimen ID	Date collected (DD/MM/YY)	VDPV2 category					Nucleotide changes	Date of classification (DD/MM/YY)	EPID no. of VDPV closest match	Comment
					Pending classification	cVDPV2	aVDPV	iVDPV2	WPV2				

2- Second stage of vaccine deployment in case of type 2 detection SIA 2–4+ (additional information obtained since stage 1 request)

- Case identification

Province: | District:

EPID no.	Patient name	Village/locality	Gender		Date of birth DD/MM/YYYY	Age (months)	Total doses of OPV	Total doses of IPV received	Date of paralysis onset	Date of last stool collection samples
			M	F						

- Reporting laboratory for human sample(s)

Address of laboratory for virus isolation:

TEL | FAX

Name of responsible person: | Email:

If different, address of laboratory for sequencing:

TEL

FAX

Name of responsible person:

Email:

- Laboratory report

Province:

District:

EPID no.	Specimen ID	Source				VDPV2 Category					Nucleotide Changes	EPID no. of VDPV closest match	Comment
		AFP	Contact	Healthy	Other	Pending classification	cVDPV2	aVDPV	iVDPV2	WPV2			

- Reporting laboratory for environmental sample(s)

Address of laboratory for virus isolation:

TEL

FAX

Name of responsible person:

Email:

- Laboratory investigation reporting of environmental sample(s)

Environ-mental sample site code	Environ-mental sample collec-tion site name	EPID no.	Speci-men ID	Date collected (DD/MM/YY)	VDPV2 category					Nucleotide changes	Date of classification (DD/MM/YY)	EPID no. of VDPV closest match	Comment
					Pending classification	cVDPV2	aVDPV	iVDPV2	WPV2				

Risk assessment

DPT3 coverage at ***national level*** in past three years:

2013	2014	2015

DPT3 coverage in ***affected district*** in past three years:

2013	2014	2015

Below, characteristics of the currently ***affected district*** (or subnational level):

High birth rate:	Yes ☐	No ☐	NA ☐
Population density:	Urban ☐	Rural ☐	Mixed ☐

Date last polio SIA: (dd/mm/yyyy):

Target age:

Vaccine used (check all that apply): tOPV ☐ bOPV ☐ IPV ☐ mOPV2 ☐

Total target population (number):

Estimated population coverage: %

Other population characteristics in the ***affected district***:

Refugee camps: Yes ☐ No ☐ NA ☐

Ongoing conflict: Yes ☐ No ☐ NA ☐

Displaced population: Yes ☐ No ☐ NA ☐

History of immunization refusals: Yes ☐ No ☐ NA ☐

Recent clusters of adverse events following immunization: Yes ☐ No ☐ NA ☐

Large population movements across borders: Yes ☐ No ☐ NA ☐

Others (please specify):

Terms and conditions

The government accepts and agrees that the supply of vaccine from the WHO mOPV2 stockpile will be subject to the following terms and conditions:

i. Your government represents and warrants that mOPV2 (hereinafter also "the vaccine") has been authorized by your government for importation and use in humans in the control of an outbreak or event of poliovirus type 2 in your country.

ii. The vaccine is being supplied to the government exclusively for emergency use under the control of the government, to respond to a WHO-confirmed outbreak of type 2 poliovirus in the country and reported as a public health emergency of international concern. In this connection, the government confirms that it has full knowledge of the known side-effects of the vaccine.[1]

iii. The vaccine has been licensed by a stringent national regulatory authority in the country of manufacturing and has been prequalified by WHO.[2,3] Specifically, the manufacturer of the vaccine has warranted and represented to WHO and UNICEF that for the duration of its shelf-life, the vaccine has been manufactured in accordance with current good manufacturing practices and conforms to the specifications approved by a functional regulatory authority with jurisdiction over the facility where the vaccine has been manufactured; and is of even quality, free from faults and defects in design, material, manufacture and technique.

iv. Except as explicitly otherwise provided herein, the government of the country shall be solely responsible for, and accepts, any and all liability for the use of the vaccine. Specifically, the government of the country agrees to indemnify, defend and hold harmless WHO and UNICEF as well as their officers, employees and agents, for any and all costs, expenses and claims of any kind arising from, as a result of, or in connection with the supply, distribution and/or use of the vaccine in the country, by or on behalf of the government or otherwise.

v. It is understood and agreed that neither WHO, UNICEF nor the manufacturer will accept any liability or responsibility whatsoever for the use of the vaccine in the country if the vaccine has not been authorized by your government for such use.

vi. To the extent that these terms and conditions limit potential liabilities associated with the supplies of the vaccine by or on behalf of WHO and UNICEF, the government expressly acknowledges that these terms and conditions are for the benefit of WHO and for the benefit of UNICEF, and, therefore, that these terms and conditions create benefits and rights that are directly enforceable not only by WHO, but also by UNICEF on its own behalf (as third-party beneficiary to the terms of this request form).

vii. Ownership of, and risk of damage to and loss of, the vaccine will transfer to the government upon availability of the vaccine FCA Brussels Airport for loading by the UNICEF designated freight forwarder; however, UNICEF will take out insurance covering the value of the goods during the transport to the recipient country. The government will be responsible for handling the rapid importation and customs clearance of the vaccine into the country (unless it has exceptionally been agreed that UNICEF will handle such importation and customs clearance). The government will also be responsible for the physical inspection of the vaccine quantity, using the vaccine arrival report (VAR) [4] accompanying the shipment, within 24 hours after delivery in the country, adhering to the terms set out in the section "Important notice" of the request form. The government will then be responsible for arranging for any subsequent storage and transportation of the vaccine (under appropriate conditions, including compliance with cold chain requirements[5]) and ensure its rapid delivery and administration to patients.

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1. WHO vaccine reaction rates information sheets. Geneva: World Health Organization; 2016 (http://www.who.int/vaccine_safety/initiative/tools/vaccinfosheets/en/).

2. Vaccine PQ. Geneva: World Health Organization; 2016 (http://www.who.int/immunization_standards/vaccine_quality/ vq_index/en/).

viii. The government agrees and will ensure that:
- the vaccine supplied hereunder will not be used for any purpose other than as provided in this request form;
- the vaccine supplied hereunder will only be provided to people in the country who have been prioritized in accordance with the country's outbreak response plan;
- the vaccine supplied hereunder will not be exported or otherwise made available for use outside the country;
- the vaccine supplied hereunder will be properly managed and stored during an outbreak response;
- any remaining open and unopened vial will be securely disposed of in compliance with WHO guidelines on safe disposal of OPV type 2.[6]

ix. In addition, bearing in mind that the aforesaid quantity is being provided to the government free of charge, the government will ensure that the vaccine supplied by WHO will not be sold but will only be provided to the targeted population in the country free of charge.

x. The labelling and inner packaging of the vaccine, as well as leaflets and outer packaging, may be in English and/or other languages. The packaging and insert leaflets will not be specially translated or adapted to meet certain specifications or requirements by countries outside of the standard packaging and insert leaflets.

xi. The government explicitly accepts and agrees with the use of standard packaging, labelling and leaflets as described above. The government will distribute any relevant leaflets to health-care professionals who administer the vaccine.

xii. The government confirms that it shall ensure that all health-care practitioners and others administering the vaccine to the population of the country:
- are fully aware of, understand and will ensure adherence to all recommendations for the proper handling, administration and use of the vaccine as contained in the above- mentioned leaflets and the attached information package;
- implement surveillance of adverse events following immunization as contained in "Global manual on surveillance of adverse events following immunization";[7]
- will have put into place a recall procedure as described in "Annex 5: good distribution practices for pharmaceutical products";[8]
- will inform all people to whom the vaccine may be administered of all possible safety concerns to which the vaccine may give rise, including its possible side-effects and known adverse events.

xiii. Your government agrees to notify WHO, in writing, as soon as reasonably possible, of any information received by it on the occurrence of any serious adverse events, an unexpectedly high occurrence of adverse events and any significant safety information with respect to the use of the vaccine. Your government agrees to transmit such information by mail to the World Health Organization, Department of Global Vaccine Safety, 20 Avenue Appia, 1211 Geneva 27, Switzerland, and via email to vaccsalert@who.int.

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3. The purpose of the United Nations prequalification assessment is to provide assurance that candidate vaccines meet WHO recommendations on quality, safety and efficacy, including compliance with WHO's recommended standards for good manufacturing practices and good clinical practice; and that candidate vaccines meet the operational packaging and presentation specifications of the relevant United Nations agency. The aim is to ensure that vaccines provided through the United Nations for use in national immunization services in different countries are safe, effective and suitable for the target populations at the recommended immunization schedules and with appropriate concomitant products (WHO Expert Committee on Biological Standardization. Sixty-first report. WHO Technical Report Series 978. Geneva: World Health Organization; 2013).

4. See http://www.unicef.org/supply/files/VAR_English-with_VaxAlert_and_Qtag_instr.pdf.

5. Vaccines and biologicals: ensuring the quality of vaccines at country level. Geneva: World Health Organization; 2002 (http://apps.who.int/iris/bitstream/10665/67824/1/WHO_V-B_02.16_eng.pdf).

6. Guidance for implementing the switch. Geneva: World Health Organization; 2015 (http://www.who.int/immunization/diseases/poliomyelitis/endgame_objective2/oral_polio_vaccine/implementation/en/).

xiv. Neither WHO nor any direct or indirect supplier of the vaccine to WHO or the country (including but not limited to the manufacturer and/or UNICEF) will be liable or held responsible for any delay or failure in the supply of the vaccine as a result of force majeure or act by government or other authorities that may prevent or restrict WHO and/or any (direct or indirect) supplier of the vaccine to WHO or the country (including but not limited to the manufacturer and/or UNICEF) in supplying and delivering the vaccine, or that may preclude or restrict the free movement of the vaccine to the agreed site of delivery. In addition, neither WHO nor any (direct or indirect) supplier of the vaccine to WHO or the country (including but not limited to the manufacturer and/or UNICEF) will be liable or held responsible for closure of airlines, airports, borders or other elements of the transportation system that may limit the free movement of goods within or between countries

xv. Any matter relating to the interpretation and application of this request form, which is not covered by its terms, will be resolved by reference to the laws of France, excluding the conflict of law rules.

xvi. All disputes relating to the interpretation or application of the present request form that cannot be resolved amicably will be finally settled by arbitration to be conducted in accordance with the Rules of Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with said Rules. The language of arbitration shall be English. The place of arbitration shall be agreed by mutual consent of the parties, or, in the absence thereof, shall be Paris, France. The parties shall accept the arbitral award as the final and binding adjudication of their dispute. It is understood and agreed that except for the enforcement of any arbitral award as aforesaid, nothing contained in this request form will be deemed to submit the government to any national court jurisdiction

xvii. It is further agreed and understood that:

- the terms and conditions contained in this request form are not aimed at establishing an international treaty, are not subject to international law and are not intended to give rise to any rights or obligations at international law;
- nothing in this request form shall be deemed to constitute a waiver of any privileges or immunities enjoyed by WHO and/or UNICEF, and/or as submitting WHO and/or UNICEF to any national court jurisdiction.

xviii. The government agrees that any supply of vaccines and other materials, as well as any other support and assistance that may be provided by WHO to the country in furtherance of this request form, will be provided in accordance with the terms of the agreement for technical advisory cooperation or assistance concluded with the government

The terms and conditions contained in this request form are irrevocable and cannot be amended or changed, except by mutual agreement of the government and WHO, including UNICEF, in so far as the benefits and rights of UNICEF in this request form are concerned.

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7. Global manual on surveillance of adverse events following immunization. Geneva: World Health Organization; 2014 (http://www.who.int/vaccine_safety/publications/Global_Manual_on_Surveillance_of_AEFI.pdf)

8. Annex 5: good distribution practices for pharmaceutical products. WHO Technical Report Series 957. Geneva: World Health Organization; 2010 (http://www.who.int/medicines/areas/quality_safety/quality_assurance/ GoodDistributionPracticesTRS957Annex5.pdf)

Annex A: template acceptance letter

[*insert letterhead of the competent authority (ministry of health) or national regulatory authority*]

[Note: countries should not specify the number of doses in this acceptance letter otherwise suppliers will need to round down the quantities due to the supplier regulatory requirement]

***Date**:*____/____/____

***Subject**:* acceptance letter for authorizing of the importation and use of mOPV2

On behalf of the government of_____[*country*], I hereby confirm the government's acceptance of and agreement with the terms and conditions of the mOPV2 vaccine request form for response to a type 2 vaccine-derived poliovirus (VDPV2) and wild poliovirus (WPV2).

I confirm that the mOPV2 vaccine manufactured by GlaxoSmithKline Biologicals in Belgium, and licensed by the Belgian National Regulatory Authority, and prequalified by WHO, is authorized for importing by the government of_____[*country*] for use in humans for the rapid control/prevention of poliovirus type 2.

This letter is to confirm the acceptance of and authorization for the importation and use of the mOPV2 vaccine from GlaxoSmithKline Biologicals in the country to respond to the current outbreak of polio type 2, and that provision has been made for the rapid custom clearance of the vaccine and immunization-related supplies into the country allowing for mass immunization campaigns to be promptly implemented.

Best regards,

Signed: _____

Name: _____

Title: _____

[*minister or designate with delegated authority to sign for the minister*]

Date: _____

Annex B: guiding notes to fill the request form

1- Checklist

Before sending the requisition to WHO headquarters, make sure you have all the documents to support the requisition. This checklist is to help to inventory all the documents attached to the requisition. For the stage 1 request, if the full field investigation, immunization response plan and risk assessment have not yet been completed, tick "pending".

2- General information

The vaccine request form will be filled in two stages:

Stage 1

Once GPLN ITD and sequencing results are available, a rapid response must be initiated within 14 days using mOPV2 for a minimum target population of 500 000 people in the affected area. In case of VDPV2, the ministry of health does not need to wait for further field assessment or laboratory investigation to confirm a cVDPV2, iVDPV2 or VDPV2. If the isolate is a WPV2, the vaccines and immunization-related supplies can be ordered for both stages at once after the initial rapid assessment conducted by the rapid response team shows there is evidence of individual excretion (for an environmental sample) and/or evidence of no exposure to wild virus in a laboratory or production facility (acute flaccid paralysis/human case or positive evidence of virus excretion). Please enter the date of completion in the form for stage 1.

Stage 2

Upon the availability of further field investigation and laboratory data (including GPLN ITD and sequencing results from additional contacts, and immunoglobulin testing) to enable final classification of the VDPV2 isolate, the stage 2 request form can be completed for VDPV2. By the time the first round of supplementary immunization activity starts (within 14 days following initial GPLN results), the government should be able to complete stage 2 of the form in order to receive the vaccine on time to conduct round 2 and subsequent rounds. (Note: the second round is expected to start within 30 days following the initial GPLN ITD and sequencing results.) Please enter the date the requisition form for stage 2 is completed. If both stages can be filled with results of initial GPLN ITD and sequencing, then write down the same date.

3- Consignee in the country

The consignee organization is the ministry of health or other responsible ministry (unless UNICEF is exceptionally named in the purchase order as the consignee). It will be the responsibility of the consignee to make provision for the payment of the value-added tax (VAT) or have a tax waiver in place in order to avoid delays in clearing the vaccine.

In signing this form, the ministry of health or other responsible ministry should have a confirmation that the vaccine will be cleared rapidly through customs once the consignment is in the country. A formal acceptance letter for the mOPV2 vaccine signed by the competent authority in the recipient country should be attached to the request form. Annex A provides a template of acceptance letter for mOPV2. Without this letter, the manufacturer will not accept to dispatch the vaccine. It is therefore very important to have this letter signed at the time the request form is sent to WHO to avoid delays of the vaccine delivery and to start implementing the first round of supplementary immunization activities.

4- Vaccine and immunization supplies requirements

Stage 1

The requisition for the supplementary immunization activity round 1 rapid response round should reach WHO headquarters within 48 hours after GPLN ITD and sequencing results are available. Please enter the planned start date of the first round of supplementary immunization activities.

Stage 2

Enter the mOPV2 requirements for each of the subsequent supplementary immunization activities as appropriate. The wastage factor for mOPV2 is 1.15. If you want to use another wastage factor, please provide justification, such as vaccine wastage studies or monitoring exercise in selected areas.

5- Case identification and laboratory investigation

The tables for human sample and environmental samples are the same in stages 1 and 2.

Paragraph A: case identification

Make sure all information for the identification of the case is filled in the table, including the name of the province and the district.

Paragraph B: laboratory reporting for human samples

If ITD and sequencing are not conducted in the same laboratory, then enter the details of the laboratory that performed virus isolation and the details of the laboratory that performed the sequencing. Headquarters may need to contact each laboratory for further enquiry. It is there- fore important to record all the contact details of the responsible people for each laboratory.

When filling the data in the table, use "–" when data are not available or applicable. In doing so, you confirm the data are not yet available or are not applicable rather than being a missing data entry.

If you fill the column labelled "EPID no. of the closest match" with an EPID number, the government confirms circulation of VDPV2 and therefore the government should be able to complete stages 1 and 2 of the vaccine request form. If you are expending further findings of field assessment to confirm circulation of the virus, do not wait and send the requisition stage 1.

Paragraph C: laboratory reporting for environmental sample

Write down the full address of the laboratory and contact details of the person for further enquiry if needed. Make sure all the column is filled with relevant data or "–" when not avail- able or applicable for each sample. Complete laboratory reports must be attached and sent along with the form.

6- Risk assessment

This part of the requisition form is to be filled once the field assessment has been conducted and is available, usually within 14 days following the laboratory notification of type 2 polio- virus isolate sequencing results. Provide information as completely as possible and attach the field assessment report to be sent along with the request form.


EVERY
LAST
CHILD