**NOVEL MONOVALENT ORAL POLIO VACCINE TYPE 2 (nOPV2) VACCINE REQUEST FORM**

for the response to

type 2 vaccine-derived poliovirus (VDPV2) and type 2 wild poliovirus (WPV2)

Version 2, January 2024

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**Introduction**

Following global withdrawal of oral polio vaccine type 2 (OPV2) from national immunization programmes in 2016, a confirmed type 2 event will be considered a public health emergency. 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 poliovirus type 2-containing vaccine 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,[[1]](#footnote-1), [[2]](#footnote-2) countries should file this form to request WHO to release Novel Oral Polio Vaccine type 2 (nOPV2) to respond to Type 2 outbreak(s).

Requests for nOPV2 will be reviewed by the Outbreak Response and Preparedness Group (ORPG) of the Global Polio Eradication Initiative (GPEI), together with the relevant regional teams (from WHO and UNICEF). The GPEI/ORPG will make a recommendation to WHO’s Director of Polio Eradication, who will, in turn, advise WHO’s Director-General to authorize the release of nOPV2.

The signed request form for nOPV2 should be submitted to WHO Headquarters within 24 hours of receiving the approval of the scope of the round(s) and the decision by the WHO Director-General to release the vaccine. Any delay in submitting the signed request form may impact the vaccine delivery lead times, and a minimum of 10 working days should be allowed from time of submission (noting also that larger orders may take longer to deliver).

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

The GPEI/ORPG Secretariat

c/o World Health Organization

Department of Polio Eradication

20 Avenue Appia

1211 Geneva 27, Switzerland

Fax: + 41 22 791 4198

Email: [nOPV2Secretariat@who.int](mailto:mOPV2Secretariat@who.int)

CC: WHO country office, and UNICEF Supply Division (ilewis@unicef.org; aottosen@unicef.org; [aafsar@unicef.org](mailto:aafsar@unicef.org)) and the Global Stockpile Secretariat ([globalstockpile@who.int](mailto:globalstockpile@who.int)).

**General Information**

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| Date of the request: | |  | | | | |
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| Country: | |  | | | | |
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| Outbreak-affected region/state: | |  | | | | |
| Outbreak-affected areas (towns/districts): | | | | | | |
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| Extended area with high-risk  subpopulation region/state: | |  | | | | |
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| Extended area with high-risk  subpopulation (towns/districts): | |  | | | | |
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| Requesting government ministry/department: | |  | | | | |
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| Contact details of focal people in requesting government ministry/department  (name, telephone, email): | | | | | | |
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| NAME | | PHONE | | | | EMAIL |
| Name and title of the person who fills this form: | | | | | | |
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| NAME | | | | TITLE | | |  |

**Signature of person who completes this form:**

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| --- | --- |
| 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 supply requirements**

**Note:** See GPEI SOPs on “Responding to a poliovirus event and outbreak” to determine the type of vaccine, size of target population and number of SIAs recommended for each situation.

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| Total quantity of nOPV2 requested by this form = doses |

**Note:** Please complete the tables below for each round.

### SIA round \_\_ (starting date \_\_/\_\_/ \_\_)

Table A: Immunization plan for SIA round \_\_

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Province | District | City/town/locality | Target age group | Target population (number) | Total doses (including waste factor of 1.25\*) |
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| Grand Totals | | | |  |  |

### SIA round \_\_ (starting date \_\_/\_\_/ \_\_)

Table B: Immunization plan for SIA round \_\_

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Province | District | City/town/locality | Target age group | Target population (number) | Total doses (including waste factor of 1.25\*) |
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### SIA round \_\_ (starting date \_\_/\_\_/ \_\_)

Table C: Immunization plan for SIA round \_\_

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| --- | --- | --- | --- | --- | --- |
| Province | District | City/town/locality | Target age group | Target population (number) | Total doses (including waste factor of 1.25\*) |
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\* If a different wastage factor is used please provide supportive document e.g. vaccine wastage studies or monitoring exercise conducted in selected provinces/districts. Up to 15% buffer stock can be added to the Round One request, if approved by the ORPG and the WHO Director-General has authorized the release.

**By signing this Request Form, the Government accepts and agrees that the supply by WHO of the nOPV2 will be subject to the terms and conditions contained herein.**

**SIGNATURE**

**On behalf of the Government of ………………... :**

1. **I, Minister of Health, or designated official with the delegated authority to sign this document on behalf of the Minister of Health, request supplies of the nOPV2, as described in this Request Form, and confirm that this vaccine has been authorized by the Government of …………… for importation and use in the control of a WHO confirmed outbreak of ………..….. in ………..…….; and**
2. **I irrevocably and unconditionally accept and agree to the above terms and conditions.**

**Signature:**

**Name:**

**Acceptance letter (template)**

[*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 nOPV2

On behalf of the government of [*country*], I hereby confirm the government’s acceptance of and agreement with the terms and conditions of the nOPV2 vaccine request form for response to a type 2 vaccine-derived poliovirus (VDPV2) and wild poliovirus (WPV2).

I confirm that the nOPV2 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 nOPV2 vaccine 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:

a

**Annex 1: Terms and conditions**

The government accepts and agrees that the supply of vaccine from the WHO nOPV2 stockpile will be subject to the following terms and conditions:

1. Your government represents and warrants that nOPV2 (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.
2. 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 (including possible serious adverse reactions), as described in the relevant and most recent literature (it being understood that the Government shall be responsible for identifying such literature).
3. The vaccine has been approved by a functional regulatory authority with jurisdiction over the facility where the vaccine has been or will be manufactured, and has been prequalified by WHO. Notwithstanding the preceding sentence, the vaccine quantity provided hereunder is being supplied by WHO, and delivered to the Country by UNICEF, “as is”, without any warranties or representations whatsoever, whether express or implied, including, but expressly not limited to, any implied warranties as to the vaccine’s fitness for a particular purpose or use, or as to its safety, efficacy, or quality in any respect.
4. Without prejudice to the foregoing, 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 or will be 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 or will be manufactured; and is of even quality, free from faults and defects in design, material, manufacture and workmanship.
5. 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.
6. It is understood and agreed that neither WHO, nor 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. In the event the vaccine is delivered to and used in your Country without such authorization, your Government agrees to indemnify and hold harmless WHO, UNICEF and the manufacturer against and from any and all liability, including, but not limited to, costs and expenses, which may be made, filed or assessed against, or suffered or incurred by WHO, UNICEF and the manufacturer as a result of such delivery and use without appropriate authorization, except that your Government shall not be held to indemnify and hold harmless the manufacturer to the extent such liabilities, costs and expenses arise from the breach of the manufacturer’s warranties and representations referred to above.
7. 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).
8. Ownership of, and risk of damage to and loss of, the vaccine will transfer to the government upon availability of the vaccine FCA nearest international airport to the production site in the producing country 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 port of entry of 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)[[3]](#footnote-3) accompanying the shipment, within 24 hours after delivery in the country, adhering to section 5 of Annex 3 of the request form: “Notice of recipient countries of nOPV2”. 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)[[4]](#footnote-4) and ensure its rapid delivery and administration to patients.
9. 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, including 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.[[5]](#footnote-5)

1. 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.
2. 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 that go beyond the standard packaging and insert leaflets.
3. The government explicitly accepts and agrees with the use of standard packaging, labelling and leaflets as described above. The government will distribute the leaflets to health-care professionals who administer the vaccine, together with literature on the risks of using the vaccine and the possible adverse events.
4. 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”;[[6]](#footnote-6)
* will have put into place a recall procedure as described in “Annex 5: good distribution practices for pharmaceutical products”;[[7]](#footnote-7)
* 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.

1. 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](mailto:vaccsalert@who.int).
2. 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
3. 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 general principles of international commercial law, to the exclusion of any single national system of law.
4. The parties will use their best efforts to settle amicably any dispute, controversy or claim arising out of, or relating to the present request form.  Where the parties wish to seek such an amicable settlement through conciliation, the conciliation will take place in accordance with the UNCITRAL Conciliation Rules then in force, or according to such other procedure as may be agreed between the parties.  Any dispute, controversy or claim between the parties arising out of the present request form which is not resolved within sixty (60) days after one party receives a request from the other party for amicable settlement can be referred by either party to arbitration. The arbitration will take place in accordance with the UNCITRAL Arbitration Rules then in force. The arbitral tribunal will have no authority to award punitive damages. In addition, the arbitral tribunal will have no authority to award interest in excess of four per cent (4%) per annum and any such interest will be simple interest only. The parties will be bound by any arbitration award rendered as a result of such arbitration as the final adjudication of any such controversy, claim or dispute.
5. 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.

1. 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.

**By signing this Request Form, the Government accepts and agrees that the supply by WHO of the nOPV2 will be subject to the terms and conditions contained herein.**

**SIGNATURE**

**On behalf of the Government of ………………... :**

1. **I, Minister of Health, or designated official with the delegated authority to sign this document on behalf of the Minister of Health, request supplies of the nOPV2, as described in this Request Form, and confirm that this vaccine has been authorized by the Government of …………… for importation and use in the control of a WHO confirmed outbreak of ………..….. in ………..…….; and**
2. **I irrevocably and unconditionally accept and agree to the above terms and conditions.**

**Signature:**

**Name:**

**Title:**

**Date:**

text

**Annex 2: Guiding notes to fill the request form**

1. **General information**

Once GPLN ITD and sequencing results are available, a rapid response must be initiated using type 2 OPV 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 can be ordered 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).

1. **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 to avoid delays in clearing the vaccine.

By signing Annex 1: Terms and Conditions, the government confirms its understanding and acceptance of the need to expedite nOPV2 importation and use during an outbreak response. This includes ensuring either the vaccine has an authorization for importation and use issued by the country's regulatory bodies or that appropriate waivers are in place to allow swift importation. Endorsing the Terms and Conditions signals the government's responsibility to complete these processes and is essential for initiating the vaccine release process. It is important to note that the recipient government solely bears the responsibility for these actions; WHO, UNICEF, and the vaccine manufacturer hold no liability in this regard.

1. **Vaccine requirements**

Enter the nOPV2 requirements for each of the SIAs as appropriate. The wastage factor for nOPV2 is 1.25. If you want to use another wastage factor, please provide justification, such as vaccine wastage studies or monitoring exercise in selected areas.

Additional droppers can be provided up to a maximum of 5% of the total requested nOPV2 vials. If additional droppers are needed this should be included along with the VRF specifying the requirement.

1. **Signatory Authority for the nOPV2 Vaccine Request Form**

The signatory to the nOPV2 Vaccine Request Form (VRF) must be the Minister of Health or another official formally designated with delegated authority to act on behalf of the recipient country's government. This signature legally authorizes the importation and use of nOPV2 within the country and binds the government to the terms and conditions outlined in the document.

Recipient countries are strongly encouraged to make all necessary arrangements to ensure prompt signing of the VRF by the appropriate official. Swift completion of this document is critical to expedite the release of nOPV2 from the global stockpile. Delays in signatory confirmation may hinder timely outbreak response efforts, potentially impacting public health outcomes.

**Annex 3: Notice for recipient countries of nOPV2**

1. **Release and use of nOPV2**

WHO will prioritize the requests for vaccines from the global nOPV2 stockpile based on the recommendations of the GPEI ORPG. The decision and the ORPG 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 nOPV2 stockpile, and the prioritization of the requests received by WHO based on countries’ needs to receive nOPV2 from WHO. 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 quantities 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 ORPG 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, or designated official with the delegated authority 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 nOPV2 (see above).

1. **Country acceptance to authorize importation and use of nOPV2**

nOPV2 has been prequalified by WHO based on approval by a functional national regulatory authority with jurisdiction over the facility where the vaccine has been manufactured. nOPV2 is intended for emergency use as a response to a type 2 outbreak or event, and must be duly authorized for importation and use in the country. Countries that are experiencing a type 2 outbreak or event, and that are requesting the release of nOPV2 doses from the global nOPV2 stockpile, should authorize the importation based on WHO pre-qualification and the approval of the vaccine by a functional national regulatory authority with jurisdiction over the facility where the vaccine has been manufactured, 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 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. This vaccine request form contains the mandatory template letter which should be copied on Ministry of Health letterhead and completed and signed by the Minister of Health or designated official with delegated authority to sign for the Minister of Health.

1. **Recipient Country Responsibilities for nOPV2 Importation and Use**

The requesting country bears the sole responsibility for facilitating the uninterrupted importation and use of nOPV2 for outbreak response. This includes, but is not limited to, ensuring that the country's relevant authorities have authorized the vaccine's importation and use, or issuing appropriate waivers to expedite the process.

It is important to note that WHO, UNICEF, and the vaccine manufacturer are not responsible for the authorization of nOPV2 within the recipient country. These actions fall under the purview of the government requesting the vaccine. Delays in these processes may directly impact the timely access to and deployment of nOPV2.

1. **Releases from the nOPV2 global stockpile with regard to product expiry dates**

The vaccine is safe, and potency is maintained throughout the approved shelf life provided the vaccine is maintained under the appropriate conditions up until the end of the month indicated on the label as valid shelf life. Requesting countries will be expected to take delivery of nOPV2 with the shortest shelf life at all times to make best use of this limited resource, to store and transport at proper conditions, and to use nOPV2 until the expiry date of each vial.

1. **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 legalization and stamps in specific colors), as well as pre-inspection requirements. Should a country continue to require additional, non-standard documentation and/or make pre-inspection requirements, WHO cannot guarantee that the manufacturers will be able and willing to supply the nOPV2 quantity in question. In addition, if the manufacturer is able and willing to provide such additional documents, and/or pre-inspection, then the country should accept the responsibility for any delays in delivery of the vaccine.

1. **Physical inspection of consignment after delivery**

Physical inspection and verification of the nOPV2 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.

WHO/POLIO/20.05

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1. Standard Operating Procedures Responding to a poliovirus event or outbreak, version 4.0. <http://polioeradication.org/tools-and-library/field-resources-for-polio-eradicators/gpei-tools-protocols-and-guidelines/> [↑](#footnote-ref-1)
2. [↑](#footnote-ref-2)
3. See <http://www.unicef.org/supply/files/VAR_English-with_VaxAlert_and_Qtag_instr.pdf.> [↑](#footnote-ref-3)
4. 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>). [↑](#footnote-ref-4)
5. Guidance for implementing the switch. Geneva: World Health Organization; 2015 (<http://www.who.int/immunization/diseases/poliomyelitis/endgame_objective2/oral_polio_vaccine/implementation/en/>). [↑](#footnote-ref-5)
6. 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>) [↑](#footnote-ref-6)
7. Annex 5: good distribution practices for pharmaceutical products. WHO Technical Report Series 957. Geneva: World Health Organization; 2010 (https://www.who.int/docs/default-source/medicines/norms-and-standards/guidelines/distribution/trs957-annex5-who-good-distribution-practices-for-pharmaceutical-products.pdf). [↑](#footnote-ref-7)