

# Procedure for Fast Track Registration of Imported Pre-qualified Vaccines for Use in National Immunization Programme

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## Abbreviations and acronyms

AEFI	Adverse event following immunization
BCG	Bacille Calmette-Guérin (vaccine)
BOI	Board of Investment
CMC	Chemistry, manufacturing, control
CTD	Common Technical Document, as Defined by the International Conference on Harmonization
DCC	Drug Control Committee
DTP	Diphtheria-Tetanus-Pertussis (vaccine)
GCP	Good Clinical Practice
GMP	Good Manufacturing Practice
Hib	Haemophilus Influenza Type B (Conjugate Vaccine)
ICH	International Conference on Harmonization
MA	Marketing Authorization
NCL	National Control Laboratory
NRA	National Regulatory Authority
OPV	Oral Polio Vaccine
PSF	Product Summary File
TRS	Technical Report Series (WHO)
TT	Tetanus Toxoid (vaccine)
UN	United Nations
UNICEF	United Nations Children's Fund
VVM	Vaccine Vial Monitor
WHO	World Health Organization

# 1. Introduction

The national immunization programme in Bangladesh source its vaccines through UNICEF that supply vaccines from the list of WHO pre-qualified products. Expanded Programme on Immunization (EPI) thus using vaccines that meet international standards of quality, safety and efficacy. However, while the WHO prequalification procedure ensures that these vaccines meet WHO recommended standards, it does not replace the oversight role of the NRA of the country. WHO recommends that each NRA must have an independent and functional system that covers at least two functions<sup>1</sup>, even if most or all of the vaccines are sourced through UN agencies. Furthermore, WHO recommends that a priority for countries in this situation should be to strengthen their ability to detect and resolve adverse events following immunization (AEFI).

Countries that source their vaccines using the WHO pre-qualified list could expedite the regulatory process for these products by using a fast track procedure because in executing the prequalification process WHO assures that the necessary regulatory functions are in place.

WHO has published a guideline for expedited review of imported pre-qualified vaccines for use in national immunization programmes. The aim of the expedited procedure is two-fold: a) to propose a methodology that will be in accord with national regulations and international standards of regulatory approval of products; b) to continue to provide timely access to vaccines used in national immunization programmes that meet standards of assured quality.

This guideline for fast track registration of imported pre-qualified vaccines for use in national immunization programme has been adapted from WHO guideline for expedited review of imported pre-qualified vaccines for use in national immunization programmes

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<sup>1</sup> Marketing authorization (MA) and licensing activities to give regulatory approval, and post marketing surveillance, including monitoring of adverse events following immunization (AEFIs)

## 2. Definitions

***Fast track (Expedited) procedure.*** An abbreviated regulatory process building on the WHO prequalification procedure, which allows an NRA to provide regulatory approval for imported vaccine products that are included on the WHO list of pre-qualified products, intended for use in national immunization programme.

***Applicability of the expedited procedure.*** This procedure is applicable to all imported pre-qualified vaccines that are supplied through a UN agency or are bought using a direct procurement mechanism for use in national immunization programme. If such a product is directly procured, this procedure is applicable only if the specifications it is required to meet are identical to those outlined in the UN agency tender. The currently used vaccines<sup>2</sup> in EPI and the vaccines which will be used in future will be eligible for expedited procedure.

***Pre-qualified product.*** A vaccine product that appears on the list of products on the WHO website<sup>3</sup> that have been through a published prequalification process to be eligible for purchase by UN agencies for use in national immunization programme.

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<sup>2</sup> Currently used EPI vaccines are BCG, OPV, DPT, Hepatitis B, Measles and TT. Hib vaccine will be introduced in the country from 2009.

<sup>3</sup> [http://www.who.int/vaccines-access/quality/un\\_prequalified/un\\_prequalified\\_procedures.htm](http://www.who.int/vaccines-access/quality/un_prequalified/un_prequalified_procedures.htm)

### 3. The prequalification process

The purpose of the prequalification assessment is to verify that the vaccines meet the specifications of the relevant UN agency, and are produced and overseen in accordance with the principles and specifications recommended by WHO<sup>4</sup> for good manufacturing practice (GMP), and for good clinical practice (GCP). This is to ensure that vaccines used in national immunization services in different countries are safe and effective for the target population at the recommended schedules, and that they meet particular operational specifications for packaging and presentation.

The vaccine assessment (prequalification) procedure established by WHO is based on the following principles:

- reliance on the NRA of the country of manufacture which meets the WHO published NRA indicators;
- general understanding of the product and presentations offered, the production process, quality-control methods and relevance for the target population of available clinical data;
- assurance of production consistency through application of GMP specifications;
- random check-testing of vaccines by independent WHO-contracted laboratories to monitor compliance with tender specifications on a continuing basis;
- monitoring complaints from the field and assisting in the investigation of AEFI.

For the evaluation of vaccines, WHO requires information related to the manufacturing company and also to the product itself. The manufacturer provides this information in the Product Summary File (PSF) and during the site visit.

Once the process is complete, and if WHO considers that the outcome is satisfactory, WHO sends a letter to UNICEF and other UN agencies advising on (a) compliance of the vaccine with both the WHO requirements and the specifications of the relevant UN agency, and (b) the role of the NRA in certifying this fact. This letter will be copied to the manufacturer, the NRA, the National Control Laboratory (NCL) or other entity responsible for lot release, and the relevant WHO regional and country offices. The vaccine will then be included in the WHO list of pre-qualified vaccines<sup>5</sup> the following month. The pre-qualified status of a vaccine is normally valid for a period of two years; however, under certain circumstances this status can be extended for up to five years.

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<sup>4</sup> WHO Expert Committee on Biological Standardization. Good manufacturing practices for biological products. Geneva, World Health Organization, adopted 1991. (WHO Technical Report Series, No. 822, Annex 1) available at <http://www.who.int/biologicals/publications/trs/areas/vaccines/gmp/en/index.html>, and WHO Expert Committee on Biological Standardization. Guidelines on clinical evaluation of vaccines: regulatory expectations. Geneva, World Health Organization, adopted 2001. (WHO Technical Report Series, No. 924, Annex 1) available at [http://www.who.int/biologicals/publications/trs/entity\\_biologicals\\_publications\\_trs\\_52\\_en/en/index.html](http://www.who.int/biologicals/publications/trs/entity_biologicals_publications_trs_52_en/en/index.html).

<sup>5</sup> The current list may be consulted at [http://www.who.int/vaccines-access/quality/un\\_prequalified/un\\_prequalified\\_producers.htm](http://www.who.int/vaccines-access/quality/un_prequalified/un_prequalified_producers.htm)

#### **4. Activities to be in place for registration/marketing approval of a product by an NRA (WHO definition of functions)**

According to the WHO definitions of NRA functions, for marketing approval of a product and continuing regulatory oversight, the following activities should be in place for an NRA overseeing production: review of the CMC file (chemistry, manufacturing, control), corresponding to Module 3 of the Common Technical Document (CTD); assessment of GMP compliance of the facility and of the production procedure, ongoing after marketing; continuing review of variations and changes submitted to the product registration file; review of appropriate clinical data; continuing review of product safety - first through clinical trials and after marketing through a functional AEFI system; lot release; and development, validation, standardization and use of tests that correlate with efficacy (laboratory correlates of efficacy), such as the measles potency test, or if none, with consistency (e.g. immunogenicity test for acellular pertussis potency)<sup>6</sup>.

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<sup>6</sup> It should be noted that the procedure covers general pre-approval activities by the NRAs using it. Post-approval activities will derive from the updates received from WHO and the UN procuring agency (Annex 1c), and will include also those activities already in place in the countries for products undergoing the full regulatory approval process.

## **5. Activities that are assured for WHO pre-qualified products**

The WHO prequalification process ensures that the functions listed in the preceding paragraph are executed by the producer's NRA. In addition, WHO reviews clinical data to make sure that they are applicable to the immunization schedule recommended for general use on a global basis, and for the epidemiological situations in different WHO regions. If not, WHO may choose to pre-qualify the product and provide detailed information on the scope of applicability of the vaccine, as well as providing a disclaimer stating that prequalification of a vaccine does not imply a recommendation for use in all countries and referring to WHO position papers reflecting use recommendations. These products are referred to in the procedure that follows as "pre-qualified products not recommended for global use". To date there are no such products.

The producer's NRA is responsible for continuing communication with WHO regarding GMP compliance, variations, failures in the lot-release process, and AEFI, all of which should be communicated by the manufacturer. However, assurance of continued compliance with specifications is done only through random laboratory testing, not on a lot-by-lot basis, unless this is done by the producer's NRA as part of the lot-release process. Manufacturers may produce several products of a certain type, complying with different specifications of packaging, presentation and potency. If the product is procured directly, in the application of the fast track process it should be ensured that the product in question has specifications identical to those specified in the UN agency tender.

## **6. Responsibilities of the importing country's NRA under the expedited review procedure**

NRA using the expedited procedure have a responsibility to follow the review time frames and conditions as outlined in the procedure. In the event that the manufacturer's application is disapproved, the NRA will provide WHO (with a copy to the procuring agency if applicable), with a detailed justification. Should WHO find such disapproval justified, this may trigger an investigation into the product, and a review of its prequalification status. However, if the disapproval is not justified, this could jeopardize future supply of the indicated product through the given UN agency route. For this expedited review procedure NRA will not require more information from manufacturers or relevant distributors than that defined in section 8.

The implementation process for such a fast track procedure will take time. All products cannot be reviewed at the same time, even using an expedited review procedure. Thus Bangladesh adopting this procedure, need to have a transition period of two years or more (if needed) to ensure that all necessary products can eventually be reviewed without threatening the national vaccine supply. Moreover, the review process should not be construed as a means to block import of any pre-qualified vaccine sourced through a UN agency for use in national immunization programmes.

As new vaccines are pre-qualified on a regular basis, NRAs Bangladesh would monitor the WHO list of pre-qualified vaccines on a monthly basis.

## **7. Responsibilities of WHO under the expedited review procedure**

WHO agrees to inform all countries that have indicated their intent to use this process, of any changes in the prequalification status of the products, together with a brief explanatory statement. This information can be provided on the supplementary form included in Annex 1c. Such statements will be based on ongoing communication with the manufacturer and the NRA, as well as the reassessment process for prequalification by WHO.

WHO will also distribute to all countries using this process for fast track approval of vaccines, information relating to decisions not to purchase the product, that are based on product quality, product packaging, or any other conditions which may impact its suitability for use in a national immunization programme, which have been reported to WHO by UN procurement agencies. This information will be provided to NRAs by WHO on the supplementary form provided in Annex 1c.

## **8. Procedure for fast track (expedited) registration of imported pre-qualified vaccines for use in national immunization programme**

This procedure is applicable to all imported pre-qualified vaccines that are used in national immunization programme either supplied through UNICEF or directly procured by the government.

To trigger the process, manufacturer through their local agent or office will submit an application for registration of a given vaccine, along with samples of products, lot release certificates, and the corresponding summary lot protocols of three final lots of product derived from three consecutive bulk lots. A complete description is given in Annex 1a, along with the application form, and the complementary information to be provided by WHO (Annex 1b).

### **8.1. NRA responsibilities for the expedited process**

The process described below differs significantly from a normal review process because of the recognition of the work already done by the manufacturer's NRA and by WHO, the review of the file will not require review by experts in different subjects. Therefore, the file for an expedited review should go to designated person/persons within the NRA. Because the process rests on visual inspection and review of summary lot protocols, opinion of NCL will be taken.

The following steps will be followed for fast track registration of vaccines which are procured through UNICEF from WHO prequalified list to be used in national immunization programme-EPI.

**Step 1.** Check the prequalification status of the product. This should be provided in the application by the manufacturer using the form provided in Annex 1b (information to be provided by WHO).

**Step 2.** Ensure that the necessary documents are provided. This should be limited to product samples, product inserts, NRA lot release certificates from the country of origin, a list of countries where the product is licensed and marketed, and summary lot protocols of three final lots derived from three consecutive bulk lots for consistency determination. A sample manufacturer's application form is provided in Annex 1a.

**Step 3.** Conduct a visual inspection of the samples supplied for consistency determination with respect to colour, freedom from particulates, vial size, vial filling, stoppers, labels, etc.

**Step 4.** Check that the specifications met by the product provided in the summary lot protocol match those in the appropriate WHO Technical Report Series (referred to in the UN agency tender document, and referenced in the form provided in Annex 1b).

**Step 5.** Review the product leaflet against the model insert (obtainable from WHO; provided with the application form by the manufacturer in Annex 1b).

**Step 6.** Review the product label and inner box against the appropriate WHO Technical Report Series publication (referred to in the UN agency tender document, and referenced in the form provided in Annex 1b).

**Step 7.** Review the samples, label, and inner box for consistency, and also that they match the description supplied in the summary lot protocols.

**Step 8.** Assure the presence of the Vaccine Vial Monitor (VVM) and of other items as specified in the *WHO Guidelines on the international packaging and shipping of vaccines*<sup>7</sup>.

**Step 9.** Prepare a report based on the review indicating compliance or non-compliance with national norms and the tender specifications. The checklist provided in Annex 1d will be used for this purpose.

**Step 10.** If compliant, issue the Certificate of Approval and add the product to the list of authorized products.

**Step 11.** Notify WHO and the manufacturer of the outcome, and copy to the UN procurement agency. In the event of disapproval of the application, provide a detailed justification to WHO, with a copy to the UN procurement agency<sup>8</sup>.

**Step 12.** Upon receipt of updated information from WHO, including information from the UN procurement agency (information in form provided in Annex 1c), add this information to the product file. No further action will be necessary unless WHO recommends that the prequalification status be withdrawn.

## **8.2 Documentation needs**

The form in Annex 1a is the application for regulatory review using the expedited procedure for imported vaccines used in national immunization programmes, to be provided by the manufacturer to the NRA of Bangladesh. The form in Annex 1b is the initial information provided by WHO to the NRA of Bangladesh through the manufacturer, verifying the prequalification process and duration and conditions, if any, for prequalification, and providing specifications. The form in Annex 1c is for use by WHO to regularly update the NRA of Bangladesh if there are any changes in the prequalification status, based on assessments by WHO and/or the UN procurement agency. The form in Annex 1d is a sample checklist that will be used for reporting the results of the product assessment in the fast-track process, and for reporting to WHO.

## **8.3 Conditions and review time frames**

The guiding principle is to build on the WHO prequalification process and conserve NRA time and resources. Note that notification to WHO (with a copy to the UN procurement agency, if relevant, and justification if the decision is negative), should follow the same time frames for the review process as indicated below.

**8.3.1** Bangladesh NRA will provide the information of the disposition of the expedited procedure to the manufacturer and to WHO (with a copy to the UN procurement agency). This notification would be dated and sent at least 30 working days after receipt from the manufacturer of a complete information package, as defined in Annex 1a. Information to be provided by WHO on the form in Annex 1b as outlined in section 8.2 of this procedure, should be provided by the manufacturer as part of the application. The form in Annex 1d will be used for reporting.

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<sup>7</sup> WHO/IVB/05.23.

<sup>8</sup> Notifications should be made through the WHO representative who will forward through the respective WHO Regional Office to the Prequalification Officer, World Health Organization Quality, Safety and Standards, IVB, Avenue Appia, 1211 Geneva 27, Switzerland, email vaccines@who.int.

- 8.3.2** In the event that the information provided by the manufacturer is not complete, the process will be halted pending supply of the necessary documentation.
- 8.3.3** WHO should be notified of the results of the expedited regulatory process, in addition to the applicant manufacturer. In the event that the application is disapproved, NRA will provide WHO with detailed justification for the disapproval within the timelines for the review process as outlined in Section 8.3.1 (with a copy to UN procurement agency).
- 8.3.4** The period of validity of the regulatory approval is for 2 years, so long as the pre-qualified status remains valid. If for any reason the prequalification status is withdrawn, the regulatory approval would be automatically terminated pending a full investigation.
- 8.3.5** Registration fees will be decided by appropriate authority.
- 8.3.6** This procedure does not apply to vaccines being imported for private sector use.

## List of documents

### 1a. Fast Track Registration Application Form

#### Part 1. General information

##### 1.1 Information about the manufacturer

- a. Name of the manufacturer : \_\_\_\_\_
- b. Address of the manufacturer : \_\_\_\_\_  
\_\_\_\_\_
- c. Telephone number : \_\_\_\_\_
- d. Facsimile number : \_\_\_\_\_
- e. e-mail address of principal contact : \_\_\_\_\_

##### 1.2 Information about the local agent: (If the application is being submitted by a local agent within the importing country, this information should also be provided for the local agent.)

- a. Name of the local agent : \_\_\_\_\_
- b. Address of the local agent : \_\_\_\_\_  
\_\_\_\_\_
- c. Telephone number : \_\_\_\_\_
- d. Facsimile number : \_\_\_\_\_
- e. e-mail address of principal contact : \_\_\_\_\_

##### 1.3 Information about the NRA of the manufacturing country :

- a. Name of the principal contact of this particular product : \_\_\_\_\_
- b. Name of the Institutional Chief/Head : \_\_\_\_\_
- c. Address of NRA : \_\_\_\_\_  
\_\_\_\_\_
- d. Telephone number : \_\_\_\_\_
- e. Facsimile number : \_\_\_\_\_
- f. e-mail address of principal contact of this particular product : \_\_\_\_\_

##### 1.4 Information about the NCL of the manufacturing country:

- a. Name of the principal contact of this particular product : \_\_\_\_\_
- b. Name of the Institutional Chief/Head : \_\_\_\_\_
- c. Address of NCL : \_\_\_\_\_  
\_\_\_\_\_
- d. Telephone number : \_\_\_\_\_
- e. Facsimile number : \_\_\_\_\_
- f. e-mail address of principal contact of this particular product : \_\_\_\_\_

##### 1.5 Information about the designated contract laboratory (if applicable):

- a. Name of the principal contact of this particular product : \_\_\_\_\_
- b. Name of the Institutional Chief/Head : \_\_\_\_\_
- c. Address of designated contract laboratory : \_\_\_\_\_  
\_\_\_\_\_
- d. Telephone number : \_\_\_\_\_
- e. Facsimile number : \_\_\_\_\_
- f. e-mail address of principal contacts of this particular product : \_\_\_\_\_

## Part 2. Vaccine composition, presentation, and schedules

### 2.1 Name of the product :

Generic name : \_\_\_\_\_

Brand name (if applicable) : \_\_\_\_\_

### 2.2 Composition of the product : \_\_\_\_\_

\_\_\_\_\_

### 2.3 Description of presentation of the vaccine

a. Form : \_\_\_\_\_

b. Dose size : \_\_\_\_\_

c. Type of container : \_\_\_\_\_

d. Vaccine Vial Monitor (VVM) type used : \_\_\_\_\_

e. Description of application devices (e.g. syringes, droppers) to be delivered with the vaccine, if applicable : \_\_\_\_\_

### 2.4 Description of presentation of the diluent (if applicable)

a. Dose size : \_\_\_\_\_

b. Type of container : \_\_\_\_\_

### 2.5 Recommended schedule : \_\_\_\_\_

### 2.6 Administration route : \_\_\_\_\_

## Part 3. Following to be provided with this application

a. Samples of vials /ampoules \_\_\_\_\_ (mention the number)

(Samples of vials/ampoules should be submitted from three final lots produced from three consecutive bulk lots of the product including relevant packaging. All labeling should be provided in English)

a. Samples of diluents (if applicable) \_\_\_\_\_ (mention the number)

b. Samples of secondary package \_\_\_\_\_ (mention the number)

c. Package inserts \_\_\_\_\_ (mention the number).

d. Lot Release Certificate of NRA of the manufacturing country

e. Summary lot protocols for the three final lots listed above

f. Prequalification status form filled in & signed by WHO (see Annex1b)

g. Registration fee in the form of Bangladesh Bank Treasury Chalan

If local office of the manufacturer applies the following to be provided with the application:

- i. Permission of BOI (board of investment) for local office establishment
- ii. Valid whole sale drug license
- iii. Trade License

If local agent of the manufacturer applies the following to be provided with the application:

- i. Copy of agreement between the local agent and the manufacturer duly attested by the appropriate authority.
- ii. Valid whole sale drug license
- iii. Trade License

Signature : \_\_\_\_\_

\_\_\_\_\_  
Name and title of the person submitting application (typed)

Office Seal

\_\_\_\_\_  
Date submitted

**1b. Form for provision of prequalification status and specifications requested from WHO** (This form will be filled in and signed by WHO)

Information provided to: \_\_\_\_\_  
(Name and country of NRA using expedited review procedure for this product)

The product: \_\_\_\_\_

Manufactured by: \_\_\_\_\_

Located at: \_\_\_\_\_  
(Include any additional clarification needed for the manufacturing site)

Distributed by: \_\_\_\_\_ (if relevant)

Under the ongoing regulatory oversight of: \_\_\_\_\_  
(Insert name of National Regulatory Authority and National Control Laboratory as applicable)

Provided in: \_\_\_\_\_ dose (vials/ampoules) supplied:

- with diluent in (vials/ampoules);
- with syringes (description);
- with droppers.

WHO\_pre-qualified as of: \_\_\_\_\_ (date)

The following conditions (if any), are attached to the prequalification status:

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The prequalification status will be reassessed in: \_\_\_\_\_ (month, year) unless a decision based on history, is made to waive the reassessment process. WHO will advise the recipient of this form if, as a result of the reassessment, or for any other reason the prequalification status is withdrawn.

The vaccine listed above meets the following specifications: (insert packaging specifications, relevant TRS documents, and product specifications if different from those stated in the TRS, and VVM type).

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A copy of the sample product insert for the product is attached.

As part of the granting of prequalification status, the manufacturer and the NRA agree to keep WHO updated on an ongoing basis relative to verification of ongoing GMP compliance, AEFI monitoring, and control of variations. In the event that prequalification and/or national regulatory approval are withdrawn, WHO will provide the addressee named above with a notification to that effect, along with a brief summary statement explaining the reason for withdrawal.

Signed below by the WHO designated officer responsible for prequalification of vaccines:

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name and title (typed)

cc: UN procurement agency

**1c. Form for updating information on regulatory status, packaging and other information that may impact the product's continuing suitability for use in national immunization programmes, for use by WHO**  
(This form will be filled in by WHO)

Information provided to: \_\_\_\_\_  
(Name and country of NRA using expedited review procedure for this product)

The product: \_\_\_\_\_

Manufactured by: \_\_\_\_\_

Located at: \_\_\_\_\_  
(Include any additional clarification needed for the manufacturing site)

Distributed by: \_\_\_\_\_ (if relevant)

Under the ongoing regulatory oversight of: \_\_\_\_\_  
(Insert name of National Regulatory Authority and National Control Laboratory as applicable)

Provided in: \_\_\_\_\_ dose (vials/ampoules) supplied:

- with diluent in (vials/ampoules);
- with syringes (description);
- with droppers.

WHO prequalified as of: \_\_\_\_\_ (date)

The following conditions (if any), are attached to the prequalification status:

\_\_\_\_\_  
\_\_\_\_\_

On the basis of information provided to WHO and the UN procurement agency by the manufacturer and the NRA, or as a result of reassessment activities by WHO, the product has undergone a suspension of prequalification status due to:

- withdrawal from the market;
- withdrawal of national regulatory approval;
- unsatisfactory reassessment;
- unsatisfactory field performance.

Additional comments: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name and title of WHO Prequalification Officer

## 1d. Checklist for reporting product compliance

(Form to be filled by National Regulatory Authority of Bangladesh and sent to WHO within 30 working days of receipt of information via WHO Country Representative and respective Regional Office, to Prequalification Officer ivb@who.int).

Name of product: \_\_\_\_\_

Manufacturer: \_\_\_\_\_

Presentation: \_\_\_\_\_

Prequalification Status: \_\_\_\_\_  
(Date) (Conditions)

Product received in (Country): Bangladesh

through UN procurement;

through direct procurement : \_\_\_\_\_  
(Name of distributor if applicable)

Lot numbers assessed for consistency and conformity : \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

- Application form complete including WHO documentation of prequalification status :  
Yes No
- Summary Lot Protocols reviewed and indicated compliance with specifications in :
  - TRS number \_\_\_\_\_: Yes No
  - UN Tender (specify) \_\_\_\_\_: Yes No
- Product leaflet consistent with sample product insert : Yes No
- Product label and inner box match TRS number : Yes No
- Product label, samples, and inner box consistent with each other : Yes No
- Product label, samples & inner box match Summary Lot Protocols : Yes No
- VVM and relevant temperature monitoring devices present (as per WHO/IVB/05.23) :  
Yes No

Other observations : \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

Decision: Product is approved for distribution in (country name): \_\_\_\_\_  
until (month/year): \_\_\_\_\_/\_\_\_\_ or WHO prequalification status lapses, whichever  
comes first.

Product is NOT approved for distribution (attach detailed justification).

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\_\_\_\_\_  
Date

\_\_\_\_\_  
Name and title of NRA Officer responsible

Send via WHO country representative and respective Regional Office to Prequalification Officer, vaccines@who.int, with a copy to UN procurement agency, unless product received through direct procurement.