

**WHO TRS 996 Annex 8, Appendix 3 Part B**

Decision on acceptance by the NRA to apply the Procedure to a specified WHO-prequalified product and request for access to product-specific information and documentation

Annex 8

**Appendix 3, Part B**

*Decision on acceptance by the NRA to apply the Procedure to a specified WHO-prequalified product and request for access to product-specific information and documentation*

Please complete all fields marked \*. For other fields, if there have been changes to the details as completed in Part A, please complete the relevant fields below. Where fields below are left blank, the data in Part A are considered to be valid.

**Application details:**

Name of entity: \_\_\_\_\_ (“the Applicant”)

Street: \_\_\_\_\_

City and country: \_\_\_\_\_

Email: \_\_\_\_\_

Telephone: \_\_\_\_\_

\*Date of receipt of submission (dd/mm/yyyy): \_\_\_\_\_

Product name in national system (if known): \_\_\_\_\_

\*National reference number: \_\_\_\_\_

**Product details for pharmaceutical products:**

Active pharmaceutical ingredient(s) (API(s)) (international nonproprietary name (INN)): \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Dosage form and strength: \_\_\_\_\_

Packaging: \_\_\_\_\_

Manufacturing site(s), including block(s)/unit(s) if appropriate: \_\_\_\_\_

\_\_\_\_\_

**Product details for vaccines:**

Name of vaccine: \_\_\_\_\_

Composition: \_\_\_\_\_

\_\_\_\_\_

Packaging: \_\_\_\_\_

Manufacturing site(s), including block(s)/unit(s), if appropriate: \_\_\_\_\_

\_\_\_\_\_

**WHO prequalification details:**

\*WHO PQ reference number: \_\_\_\_\_

Date of prequalification (dd/mm/yyyy): \_\_\_\_\_

WHO PQ holder: \_\_\_\_\_

**Please complete either section A or section B below:**

**Section A**

The NRA agrees to conduct the assessment and the accelerated registration of the above-mentioned product (“the Product”) under the Procedure and requests access to product-specific information, in accordance with and subject to the terms of the Procedure and the Agreement between WHO/PQT and the NRA dated \_\_\_\_ / \_\_\_\_ / \_\_\_\_ (dd/mm/yyyy).

**Section B**

The NRA has decided not to apply the Procedure to the above-mentioned Product for the following reasons: \_\_\_\_\_  
\_\_\_\_\_

\*For the NRA of \_\_\_\_\_ (indicate country)

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

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Place: \_\_\_\_\_

\*Date (dd/mm/yyyy): \_\_\_\_\_

