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): _____