Appendix 3

Expression of interest to national regulatory authority (NRA) in the assessment and accelerated national registration, acceptance by NRA and notification of Procedure outcomes

Appendix 3, Part A

Expression of interest to the national regulatory authorities (NRAs) in the assessment and accelerated national registration of a World Health Organization (WHO)-prequalified pharmaceutical product or vaccine

In line with the Procedure, the undersigned Applicant[1] expresses its interest in the application of the above-mentioned Procedure by the NRA of _____ [country] ("the NRA") in respect of the following submission for national registration:

☐ pharmaceutical product

☐ vaccine

Application details:

Name of entity: _____ ("the Applicant")

Street: _____

City and country: _____

Email: _____

Telephone: _____

Date of application (dd/mm/yyyy): _____

Product name in national system (if known): _____

National reference number (if known): _____

[1] If the applicant for national registration is not the same as the WHO prequalification (PQ) holder, the WHO PQ holder must confirm to the NRA and to WHO/Prequalification Team (PQT) by an authorization letter (as per the template annexed to Appendix 3, Part A) that the applicant is acting for, or pursuant to rights derived from, the WHO PQ holder, and that the PQ holder agrees with the application of the Procedure in the country concerned.

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: _____

The Applicant confirms that the information and documentation provided in support of the above-mentioned submission for national registration is true and correct, that the product submitted for national registration is the same[2] as the WHO-prequalified product and that the technical information in the registration dossier is the same[3] as that approved by WHO/PQT during the initial prequalification procedure, and consecutive variation procedures and

[2] Within the context of this Procedure, the same pharmaceutical product/same vaccine is characterized by the same product dossier; the same manufacturing chain, processes and control of materials and finished product, and in the case of vaccines also by the same batch release scheme; the same active ingredient and finished product specifications; as well as the same essential elements of product information for pharmaceutical products, and, in the case of vaccines, by the same product information, packaging presentation and labelling.

[3] Only the technical data included in the dossier must be the same. There may be country-specific differences in administrative data, or if required by NRAs under exceptional circumstances, additional technical data can be provided (e.g. bioequivalence with a country-specific comparator).

requalification (where applicable). Minor differences[4] from the information submitted to WHO/PQT are the following:

Subject to the NRA agreeing to conduct the assessment and consider the accelerated registration of the Product under the Procedure, the Applicant:

1. undertakes to adhere to, and collaborate with the NRA and WHO/PQT in accordance with the terms of the Procedure; and
2. will authorize WHO/PQT[5] to provide the NRA confidential access to the following information and documentation and to freely discuss the same with the aforesaid NRA for the above-mentioned Purpose:
   - the full WHO/PQT assessment and inspection outcomes (reports), results of laboratory testing and if relevant, also assessment and inspections reports of other regulatory bodies, provided that these bodies gave their written consent to the use of such reports for the purpose of the Procedure,
   - information and documentation on subsequent variations (as defined in WHO guidelines[6]), as well as information and documentation on any actions taken by WHO/PQT post-prequalification of the Product.

As regards sharing the outcomes of assessments and inspections, only data owned by the WHO PQ holder and WHO are shared. Sharing of any other data is subject to additional agreement of the data owners concerned.

[4] As defined in section 3.2 of the Procedure, in the case of pharmaceutical products, examples of minor differences which are not considered essential may include differences in administrative information, brand name, name of applicant (provided that the applicant is acting for, and has the authority to represent the WHO PQ holder), format of product information, level of detail of product information, labelling of internal and external packaging and language of product information.

[5] If the applicant for national registration is not the same as the WHO PQ holder, then the authorization to WHO/PQT must be provided by the WHO PQ holder or their legal representative.

[6] *For pharmaceutical products*: WHO guidelines on variations to a prequalified product. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: forty-seventh report. Geneva: World Health Organization; 2013: Annex 3 (WHO Technical Report Series, No. 981), (and any updates thereto).
For vaccines: http://www.who.int/immunization_standards/vaccine_quality/variations_pq_vaccine/en/ (and any updates thereto).

3. authorizes the NRA to freely share and discuss all registration-related and Product-related information provided by the Applicant to the NRA, with WHO/PQT, subject to the obligations of confidentiality and restrictions on use as contained in the NRA's participation agreement and focal points' undertakings.

☐ The application for national registration was submitted before the Applicant decided to apply the Procedure to the Product and therefore at the time of submission the registration dossier did not respect conditions of the Procedure. Steps taken to update the submission to the NRA to make the dossier "the same" as required by the Procedure are listed and referenced in the attached letter.

☐ The Applicant is not the WHO PQ holder. An authorization letter from the WHO PQ holder is attached.

For the Applicant

Signature: _____

Name: _____

Title: _____

Place: _____

Date (dd/mm/yyyy): _____

Template for authorization letter

[To be provided if the applicant is not the WHO PQ holder. Please provide a separate letter for each NRA concerned, with a copy to WHO/PQT.]

This is to confirm that _____ (*name of applicant*) seeking registration for prequalified product number _____ (*WHO PQ number*) in _____ (*name of country*) under the WHO collaborative procedure for accelerated registration of WHO-prequalified products, is acting for, or pursuant to rights derived from _____ (*name of WHO PQ holder*) and that _____ (*name of WHO PQ holder*) agrees with the application of the Procedure in the country concerned.

For _____ (*name of WHO PQ holder*):

Signature: _____

Name: _____

Title: _____

Date: _____