WHO TRS 996 Annex 8, Appendix 2
Consent of WHO prequalification holder for WHO to share information with the national regulatory authority confidentially under the Procedure

Appendix 2

Consent of WHO prequalification holder for WHO to share information with the national regulatory authority confidentially under the Procedure

Reference is made to the attached expression of interest in the assessment and accelerated national registration under the Procedure of the following World Health Organization (WHO) prequalified pharmaceutical product or vaccine (hereafter referred to as "the Product") in _____ [country].[1]

☐ pharmaceutical product
☐ vaccine

WHO prequalification details:

WHO prequalification (PQ) reference number: _____
Date of prequalification (dd/mm/yyyy): _____
Date of requalification (if applicable): _____
WHO PQ holder:[2] _____

Application details:

Name of entity: _____ ("the Applicant")
Street: _____
City and country: _____
Email: _____
Telephone: _____

The WHO PQ holder hereby consents to the WHO Prequalification Team (WHO/PQT) providing the following information and documentation to the national regulatory authority (NRA) of _____ [country]

[1] Please complete a separate copy of this Annex for each country.

[2] If the applicant for national registration is not the same as the WHO PQ holder, the WHO PQ holder must confirm to the NRA and to WHO/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.

("the NRA") for the assessment and accelerated registration of the Product in the country under the Procedure and to freely discuss the same with the aforesaid NRA for this 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[3]), as well as information and documentation on any actions taken by WHO/PQT post-prequalification of the Product;
- all such data, reports, information and documentation being hereinafter referred to as "the Information".

As regards sharing the outcomes of assessments and inspections, only data owned by the WHO PQ holder and WHO/PQT are shared. Sharing of any other data is subject to additional agreement of the data owners concerned.[4]

Such consent is subject to the NRA having entered into an agreement with WHO/PQT as per Part A of Appendix 1 to the Procedure and having agreed to conduct the assessment and consider the accelerated registration of the Product under the Procedure, by having submitted the form reproduced in Part B of Appendix 3 to the Procedure to WHO/PQT.

The WHO PQ holder/Applicant commits to submit post-prequalification variations to WHO/PQT and any relevant participating authorities respecting national regulatory requirements. Variations should be submitted to participating authorities at the latest 30 calendar days after acceptance of the variation by WHO/PQT. Participating authorities should be informed about the fact that the same application for a variation is being processed by WHO/PQT. If a national variation procedure results in the nationally-registered product being no longer

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[3] *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).

[4] In the case that certain data submitted to WHO/PQT by the WHO PQ holder in relation to PQ of the Product are not in his/her ownership, the WHO PQ holder specifies such data in an annex to this declaration of consent.

the same[5] as the WHO-prequalified product, or if a variation of the WHO-prequalified product is not followed by a variation of the nationally-registered product and, as a consequence, the nationally-registered product is no longer the same, the WHO PQ holder/Applicant will inform WHO/PQT of the differences and their reasons.

For the WHO PQ holder

Signature: _____

Name: _____

Title: _____

Place: _____

Date (dd/mm/yyyy): _____

[5] 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.