Appendix 1

Agreement of the national regulatory authority to participate in the collaborative procedure in assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities

Coordinated by the World Health Organization (WHO)

Details of national medicines regulatory authority (NRA)

Name of NRA: _____ ("the NRA")

Postal address: _____

Country: _____

Telephone number (please include codes): _____

Email: _____

Scope of agreement

Applicants for national registration of a pharmaceutical product or vaccine approved by a stringent regulatory authority (reference SRA) (hereafter referred to as "Applicants") may express their interest to the NRA for the assessment and accelerated registration of this product ("the Product") in the country under the "*Collaborative procedure in assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities*" (hereafter referred to as "the Collaborative procedure of reference SRA approved products" or "the Procedure").[1]

Subject to the NRA agreeing to participate in the Procedure and conduct such assessment and consider such accelerated registration of the product under the Procedure, the NRA hereby confirms for each such product that it will adhere to, and collaborate with, the Applicant for marketing authorization of the product and if relevant with the respective reference SRA and WHO in accordance with the terms of the Procedure.

[1] If the applicant for national registration is not the same as the reference SRA registration/marketing authorization holder, the reference SRA registration holder must confirm to the NRA with an authorization letter that the applicant is acting for, or pursuant to rights derived from, the reference SRA registration holder, and that the reference SRA registration holder agrees with the application of the Procedure in the country concerned.

Confidentiality of information

Any information and documentation relating to the product and provided by the Applicant or reference SRA to the NRA under the Procedure may include but shall not necessarily be limited to:

- the registration dossier as defined by the Procedure
- the full reference SRA assessment and inspection outcomes (reports);
- information and documentation on variations, as well as information and documentation on any actions taken by the reference SRA after national registration 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, full reference SRA assessment and inspection reports are shared by Applicants with participating NRAs with the agreement of the respective reference SRA. Should any data in the assessment and inspection report be hidden for whatever reason, the nature and scope of missing data will be clearly indicated. Sharing of any data by the reference SRAs is subject to consent of the data owner.

The Applicant and reference SRA agree to make the Information available to the NRA exclusively for the purpose of the assessment and accelerated registration of the Product in the Country and any post-registration processes that may be required, in accordance with and subject to the terms of the Procedure ("the Purpose"). The NRA agrees to treat any Information provided by the Applicant and reference SRA as aforesaid as strictly confidential and proprietary to the Applicant, parties collaborating with the Applicant and/or reference SRA as relevant. In this regard, the NRA agrees to use such Information only for the Purpose and to make no other use thereof. Thus, the NRA undertakes to maintain the Information received from the Applicant and reference SRA in strict confidence, and to take all reasonable measures to ensure that:

- the Information received from the Applicant or reference SRA shall not be used for any purpose other than the Purpose;
- the Information shall only be disclosed to persons who have a need to know for the aforesaid Purpose and are bound by confidentiality undertakings in respect of such information and documentation, which are no less stringent than those contained herein.

The NRA warrants and represents that it has adequate procedures in place to ensure compliance with its aforesaid obligations.

The obligations of confidentiality and restrictions on use contained herein shall not cease on completion of the Purpose.

The obligations of confidentiality and restrictions on use contained herein shall not apply to any part of the Information which the NRA is clearly able to demonstrate:

- was in the public domain or the subject of public knowledge at the time of disclosure by the Applicant or reference SRA to the NRA under the Procedure; or
- becomes part of the public domain or the subject of public knowledge through no fault of the NRA; or
- is required to be disclosed by law, provided that the NRA shall in such event immediately notify the reference SRA and the Applicant in writing of such obligation and shall provide adequate opportunity to the reference SRA and/or the Applicant to object to such disclosure or request confidential treatment thereof.

Upon completion of the Purpose, the NRA shall cease all use and make no further use of the Information disclosed to it under the Procedure, and shall promptly destroy the Information received from the Applicant and the reference SRA, which is in tangible or other form and is not archived in accordance with archival procedures established by the NRA. The Purpose for each product shall be deemed completed as soon as:

- the reference SRA authorization holder/Applicant discontinues participation in the Procedure for the particular product;
- the Product is deregistered by the NRA and/or ceases to be authorized by reference SRA.

The NRA agrees that it has no right in or to the Information and that nothing contained herein shall be construed, by implication or otherwise, as the grant of a licence to the NRA to use the Information other than for the Purpose.

Should WHO staff or external experts independent on the Applicant or NRA be provided with an access to the Information in order to coordinate the Collaborative reference SRA procedure or provide an expert opinion, an access to the Information shall be subject to a confidentiality undertaking.

Timelines

In respect of each Product which the NRA accepts to assess and consider under the Procedure, the NRA undertakes to abide by the terms of the Procedure, including but not limited to the following timelines for processing each application:

- within 90 calendar days of regulatory time[2] after obtaining the assessment and inspection outcomes (reports) and validated QIS-SRA as well as receipt of validated submission, the participating NRA undertakes to take a final decision on the national registration of the Product;
- within 30 calendar days of regulatory time after obtaining the assessment outcomes (reports) and evidence of approval for variations and validated QIS-SRA (where applicable) as well as receipt of data submitted to the reference SRA for the variations, the participating NRA undertakes to take a final decision on the variation of the Product.

Miscellaneous

The NRA agrees that WHO may list its name on the WHO-PQT website as a participant in the reference SRA Procedure. Except as provided hereinbefore, neither party shall, without the prior written consent of the other party, refer to the relationship of the parties under this Agreement and/or to the relationship of the other party to the Product, the Information and/or the Purpose, in any statement or material of an advertising or promotional nature.

This Agreement shall not be modified except by mutual agreement of WHO and the NRA in writing. The NRA furthermore undertakes to promptly inform WHO/PQT of any circumstances or change in circumstances that may affect the implementation of this Agreement and its participation in the Procedure. This Agreement can be invalidated by a written note from the NRA to WHO. Validity of this Agreement expires at termination of the Procedure, which will be publicly announced.

Focal point(s) for communication

The NRA has designated the person(s) listed below to act as a focal point(s) for communication concerning the Procedure.

Title: _____

Name: _____

Position: _____

[2] Regulatory time starts after a valid application for the registration according to the Procedure has been received and access to the confidential information has been granted (whichever is the later) and continues until the date of decision on registration. The regulatory time does not include the time granted to the applicant to complete missing parts of the documentation, provide additional data or respond to queries raised by NRAs.

Email: _____
Telephone: _____

Title: _____
Name: _____
Position: _____
Email: _____
Telephone: _____

Agreed and accepted
For the NRA

Signature: . _____
Name: . _____
Title: . _____
Place and date: . _____