**WHO Expert Committee on Specifications for Pharmaceutical Preparations** Fifty-second report

**Appendix 7**

**Expression of interest to national regulatory authority**

Date:

To:

**RE: declaration to the <national regulatory authority (NRA)> to initiate and proceed with registration of <Product> in line with the Procedure**

Dear <NRA>,

On behalf of <manufacturer>, the <marketing authorization holder (MAH)> in <stringent regulatory authority (reference SRA) country/region> of the

<Product> that is registered with the <reference SRA> under the <reference number>, and solely for the purpose of the “*Collaborative procedure in the assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities*” (The Procedure – <date; version>) organized by WHO.

I, <manufacturer representative name> certify that:

1. The product submitted for registration is identical in all aspects of manufacturing and quality to that currently approved by the

<reference SRA> under the <reference number>, including formulation, method and site(s) of manufacture, sources of active and excipient starting materials, quality specifications and control methods of the product and starting material, packaging, shelf life and product information.

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If applicable:

The only exception(s) to the conditions approved by the <reference SRA> are:

<Deviations from current reference SRA approval, explanations and related commitments>.

1. Submitted assessment and inspection reports are complete reports as issued by the <reference SRA>. The <reference SRA> has been authorized by the <manufacturer> to share with <NRA focal point> all < Product> related regulatory information, including information

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of a confidential nature. A copy of the authorization letter to the

<reference SRA> is attached as <Appendix No. 1>.

If applicable:

The only data hidden in the assessment and/or inspection report of the <reference SRA> concern <nature and scope of missing data> and are hidden because of <reason>.

1. Information included in the registration dossier is identical with data currently approved by the <reference SRA>. As for the purpose of the Procedure, Module IV of the registration dossier in CTD format containing nonclinical data and Module V containing clinical data are replaced by respective summaries included in Module II, the <manufacturer> commits to submit without delay the non-submitted data on request of the <NRA>.
2. On behalf of <manufacturer>, the <MAH> in <SRA country/ region> of the above-mentioned SRA regulated product, I hereby commit to
   1. Supplying any additional information in accordance with local regulations or upon request from the <NRA> as soon as possible during the process.
   2. Should the registration be granted, submitting in accordance with local regulations without delay all relevant variations as approved by the <SRA country/region>.
   3. Supplying in accordance with local regulations any information about <SRA> regulatory actions relevant to the <Product>, including suspension or termination of registration, should it happen for whichever reason.

Signature

<Appendix No. 1>: Copy of the authorization letter to the <SRA (reference SRA)>

If appropriate:

* Current storage conditions approved by the <SRA country/region> are <storage conditions approved by reference SRA>. On behalf

of <manufacturer>, the <MAH> in <SRA country/region> of the above-referenced regulated product, I hereby commit to supplying within <time period> results of stability data applicable to Zones III–IVa or IVb should any of these stability zones be applicable to your country.

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In addition, <NRA> will be informed of any out-of-specification (OOS) results during the study and protocol for the relevant applicable zones.

* The WHO focal person (s) <name/s> has/have been provided with the <Product> dossier to facilitate the Procedure and is/are

authorized by the <manufacturer> to communicate on the Product- related issues with <NRA representatives >. By this letter the <NRA> is authorized to share with WHO all <Product> related regulatory information and communicate for the purpose of the Procedure

on the <Product> related regulatory issues, including exchange of confidential information.

* Should the local applicant be a different legal entity from a holder of reference SRA marketing authorization or from a holder of scientific opinion in the case of European Union Article 58 procedures,

the relationship should be clarified and agreements assuring information flow should be adjusted to this situation.

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