Annex 2

Collaborative Procedure in Assessment and Accelerated National Registration of Pharmaceutical Products Approved by Stringent Regulatory Authorities – Pilot Assisted the by the WHO Prequalification Team.

Example of information included in the list of participating SRAs

Acronyms:

SRA – Stringent regulatory authority as stipulated in WHO

MAH – Marketing Authorization Holder

NMRA – National Medicines Regulatory Authority

The Procedure - Collaborative Procedure in Assessment and Accelerated National Registration of Pharmaceutical Products Approved by Stringent Regulatory Authorities (pilot phase)

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Details of SRA agreeing to proceed, in principle, in line with conditions of the Procedure	**Provision of consent or 'no objection statement' to share the assessment and inspection reports issued by the SRA**	**Agreement to authenticate the SRA issued assessment and inspection reports on request of NMRAs, which have received an application for registration according to the Procedure**	**Provision of additional explanation with scientific justification of granted authorization to NMRAs, which have received an application for registration according to the Procedure**	**SRA position to post-registration management of medicinal product registered by NMRA using the Procedure**
Name and address of SRA Focal point for communication in matters related to the Procedure	Example 1: (EMA - current situation) EMA does not object to MAHs of centrally authorised medicinal products and holders of scientific opinions according to Article 58 using final assessment and inspection reports in support of national registrations. However, when documents are provided to authorities in third countries by the MAH or holder of scientific opinion, personal information need to be redacted. The 'no objection statement' is provided by EMA on request of individual MAHs. The request has to specify each NMRA with which the assessment and inspection reports will be shared. The 'no objection statement' is normally issued within 10 days.	Example 1: (EMA - current position) It is expected that requests for authentication of documents will be exceptional. Subject to previous agreement with MAH (See Annex 3 of the Procedure) the EMA can provide to requesting NMRA the full assessment reports or other relevant assessment documents. As regards inspection reports, it is expected that the applicant in the third country to the EU will forward the latest inspection report(s) for the manufacturing site(s) to the concerned authority. Communication with the relevant Member State authority might be necessary to confirm authenticity.	Possible, on the understanding that these situations are exceptional and that request is channeled by WHO or the respective NMRA, not by the company.	E.g.: EMA supports the obligation of MAHs to keep national regulators informed of due major variations or line extensions, however for the pilot EMA would suggest to focus on initial applications.
	Example 2: (hypothetical SRA) SRA does not object to MAHs of centrally authorised medicinal products and holders of scientific opinions according to Article 58 using final assessment and inspection reports in support of national registrations. However, when documents are provided to authorities in third countries by the MAH or holder of scientific opinion, personal information need to be redacted. The general statement confirming SRA position and conditions for sharing of the final assessment and inspection reports are made publicly available at www……..			