Appendix 2

Example of information included in the list of participating reference stringent regulatory authority(ies)

Details of reference stringent regulatory authority (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 reference SRA**	**Agreement to authenticate the reference SRA-issued assessment and inspection reports on request of participating NRAs, which have received an application for registration according to the Procedure**	**Provision of additional explanation with scientific justification of granting authorization to NRAs, which have received an application for registration according to the Procedure**	**Reference SRA position on post-registration management of medicines registered by participating NRA using the Procedure**
Name and address of reference SRA Focal point for communication in matters related to the Procedure	**Example 1 (EMA – current situation)** **EMA does not object to MAHs of centrally authorized medicines and holders of scientific opinions according to European Union Article 58 using final assessment and inspection reports in support of national registrations.**	**Example 1 (EMA – current position)** **It is expected that requests for authentication of documents will be exceptional.** Subject to previous agreement with MAH (see Appendix 3 of the Procedure) the EMA can provide to the requesting NRA the full assessment reports or other relevant assessment documents.	Possible, on the understanding that these situations are exceptional and that such a request is channelled by WHO or the respective NRA, not by the manufacturer.	For example, the EMA supports the obligation of MAHs to keep national regulators informed of due major variations or line extensions; however, for the Procedure the EMA would suggest to focus on initial applications.

Table *continued*

Details of reference stringent regulatory authority (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 reference SRA	Agreement to authenticate the reference SRA-issued assessment and inspection reports on request of participating NRAs, which have received an application for registration according to the Procedure	Provision of additional explanation with scientific justification of granting authorization to NRAs, which have received an application for registration according to the Procedure	Reference SRA position on post-registration management of medicines registered by participating NRA using the Procedure
	However, when documents are provided to authorities in third countries by the MAH or holder of scientific opinion, personal information needs to be redacted. **The "no objection statement" is provided by the EMA on request of individual MAHs. The request has to specify each NRA with which the assessment and inspection reports will be shared.** **The "no objection statement" is normally issued within 10 days.**	As regards inspection reports, it is expected that the applicant will forward the latest inspection report(s) for the manufacturing site(s) to the participating NRA. Communication with the relevant Member State authority might be necessary to confirm authenticity of the inspection reports.		

Table *continued*

Details of reference stringent regulatory authority (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 reference SRA	Agreement to authenticate the reference SRA-issued assessment and inspection reports on request of participating NRAs, which have received an application for registration according to the Procedure	Provision of additional explanation with scientific justification of granting authorization to NRAs, which have received an application for registration according to the Procedure	Reference SRA position on post-registration management of medicines registered by participating NRA using the Procedure
	Example 2 (hypothetical reference SRA) Reference SRA does not object to MAHs of centrally authorized medicines 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 needs to be redacted.			

Table *continued*

Details of reference stringent regulatory authority (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 reference SRA	Agreement to authenticate the reference SRA-issued assessment and inspection reports on request of participating NRAs, which have received an application for registration according to the Procedure	Provision of additional explanation with scientific justification of granting authorization to NRAs, which have received an application for registration according to the Procedure	Reference SRA position on post-registration management of medicines registered by participating NRA using the Procedure
	The general statement confirming reference SRA position and conditions for sharing of the final assessment and inspection reports are made publicly available at www			

EMA: European Medicines Agency; MAH: marketing authorization holder; NRA: national regulatory authority; SRA: stringent regulatory authority as stipulated by WHO.