Annex 11

**Appendix 3B**

**Manufacturer’s request for stringent regulatory authority’s (SRA’s) permission for sharing SRA-owned non- public information with participating national regulatory authority(ies) and the World Health Organization**

Date: *dd/mm/yyyy*

<manufacturer>

**RE: Request to <SRA> for a permission to <manufacturer> to share <SRA>’s non-public information concerning <Product> with the <NRA(s)> and the World Health Organization (WHO)1**

Dear <reference SRA>,

<Manufacturer> as a <MAH> of the <SRA> authorized <Product>, hereby requests the <reference SRA’s> permission to share <SRA>-owned non-public information concerning <Product> for the purpose of the *Collaborative procedure in assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities* assisted by WHO.

The information to be shared consists of

<SRA> final GxP inspection reports for Product <date; version>;

<SRA> Product assessment reports; and

<SRA> <other, please specify> documents/reports that may be needed in the context of this Procedure.

The information will be shared with the <NRA(s)> and WHO. Yours sincerely,

Name: Title: SRA:

1 During the *Collaborative procedure in national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities (WHO Technical Report Series No. 1010, 2018)*, WHO plays a facilitating role.

381

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

Address:

Email: Telephone number:

cc:

382

*WHO Technical Report Series, No. 1010, 2018*