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.