Annex 11

**Appendix 3A**

**Manufacturer’s consent for information sharing with participating national regulatory authority(ies) and the World Health Organization**

Date: *dd/mm/yyyy*

To:

# RE: <SRA> sharing of non-public information concerning <Product> with the

**<NRA(s)> and the World Health Organization (WHO)1**

Dear [<SRA>],

On behalf of <manufacturer>, the <MAH> in <SRA country/region> of the above-referenced regulated product, I authorize the <SRA> to share the information described below (“Information”) only with <NRA focal point – contact person/function> and WHO <contact person/function> solely for the purpose of the *Collaborative procedure in assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities* <date; version>. Confidentiality agreements are in place between <manufacturer> and WHO.

I understand that the Information may contain confidential commercial or financial information or trade secrets that are exempt from public disclosure. I agree to hold <SRA> harmless for any injury caused by <SRA>’s sharing of the Information with the <NRA> and WHO under the terms set out herein.

Information authorized to be shared with the <NRA> and/or WHO:

* all available quality data on <Product>;
* all available nonclinical data on <Product>;
* all available clinical data on <Product>;
* any other document reasonably requested by the <NRA or WHO> during the evaluation procedure;

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.

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* all other information regarding GxP inspections and <Product> assessment.

Authorization is given to <SRA> to provide the Information without deleting confidential, commercial or financial, or trade secret information.

As indicated by my signature, I am authorized to provide this consent on behalf of <manufacturer> and my full name, title, address, telephone number and email address are set out below for verification.

Yours sincerely,

Name: Title: Address:

Manufacturer: Email: Telephone number: Fax number:

cc:

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