Date:

To

**RE:** **<Stringent Regulatory Authority> Sharing of Non-Public Information concerning <Product>** **with the <National Regulatory Authority> and the World Health Organization (WHO)[[1]](#footnote-1)**

Dear [<Stringent Regulatory Authority>],

On behalf of <Company>, the <Marketing Authorization Holder> in <Stringent Regulatory Authority country / region> of the above-referenced regulated product, I authorize the <Stringent Regulatory Authority> to share the information described below (“Information”) only with <National Regulatory Authority focal point - contact person/function>and the World Health Organization (WHO) <contact person/function>solely for the purpose of the “*Pilot of Collaborative Procedure in Assessment and Accelerated National Registration of Pharmaceutical Products Approved by Stringent Regulatory”*<date;version>. Confidentiality agreements are in place between <Company> and the 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 <Stringent Regulatory Authority> harmless for any injury caused by <Stringent Regulatory Authority>'s sharing of the Information with the <National Regulatory Authority>and the WHO under the terms set out herein.

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Information authorized to be shared with the <National Regulatory Authority and/or the WHO:

* All available quality data on <Product>,
* All available non-clinical data on <Product>
* All available clinical data on <Product>,
* Any other document reasonably requested by the <National Regulatory Authority or the WHO> during the evaluation procedure.
* All other information regarding GxP inspections and <Product> assessment

Authorization is given to <Stringent Regulatory Authority> 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 <Company> and my full name, title, address, telephone number, and email address is set out below for verification.

Sincerely,

Name

Title

Address

Company

E-mail:

Phone number:

Fax number:

Cc:

1. \* During the pilot phase of the *Facilitated Process in National Registration of Pharmaceutical Products approved by stringent Regulatory Authorities <date; version>,* WHO plays a facilitating role in process testing [↑](#footnote-ref-1)