Date:

<Company>

RE: **Request to <Stringent Regulatory Authority> for a Permission to <Company>** **To Share <Stringent Regulatory Authority>’s Non-Public Information concerning <Product> with the <National Regulatory Authority/ies> and the World Health Organization1**

Dear <SRA>,

<Company> as a <Marketing Authorization Holder> of the <Stringent Regulatory Authority> authorized <Product> (product for which has been given an opinion according to Art 58 …), hereby requests the <SRA> permission to share <Stringent Regulatory Authority> owned Non-Public Information concerning <Product> for the purpose of the “Pilot of *Collaborative Procedure in Assessment and Accelerated National Registration of Pharmaceutical Products Approved by Stringent Regulatory Authorities Assisted the by the WHO Prequalification Team”*

The information to be shared consists of

<Stringent Regulatory Authority> final GxP inspection reports for Product <date; version>;

<Stringent Regulatory Authority> Product assessment reports< and

. <Stringent Regulatory Authority> Product owned documents/reports that may be needed in the context of this Procedure.

The information will be shared with the <National Regulatory Authority/ies> and the World Health Organization (“WHO”).

Sincerely,

Name

Title

<Stringent Regulatory Authority>

Address

 E-mail:

 Phone number:

Cc:

 \* 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