Annex 3: Confirmation of data sharing

Manufacturer's request for reference institution's (RI) permission for sharing RI-owned non- public information with MCA

Date:_____
dd/mmm/yyyy

<manufacturer>

RE: Request to <RI> for a permission to <manufacturer> to share <RI>'s non-public information concerning <Product> with MCA.

Dear <reference institution>,

<Manufacturer> as a <Marketing Authorisation Holder> of the <RI> authorised <Product>, hereby requests the <RI's> permission to share <RI>-owned non-public information concerning <Product> for the purpose of the procedures of verification or abridged/abbreviated review and accelerated national registration of medicines based on reliance on recognised reference institutions.[1]

The information to be shared consists of

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

<RI> Product assessment reports; and

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

The information will be shared with the MCA The Gambia.

Yours sincerely,

Name: _____

Title: _____

RI: _____

Address: _____

Email: _____

Phone no: _____

cc: _____

_____

[1] Reference to Guideline and Annex 1