Template for letter of access for an application under Article 21 of Regulation (EU) 2019/6 ('Informed consent' application)

Section to be completed by the MAH of the cross-referred product

I, the undersigned acting in my capacity as *<Job title>* of *<name of the MAH for the cross-referred product>* whose registered office is located at *<address of the MAH for the cross-referred product>* hereby confirm that permanent and full access has been granted to *<name of the MAH for the proposed informed consent MA>*, whose registered office is located at *<address of the MAH for the proposed informed consent MA>* to Part IC, II, III and IV of the MA dossier for the following medicinal product:

<name and MA number of the cross-referred product>

This access has been granted for the purposes of the submission of a marketing authorisation application under Article 21 of Regulation (EU) 2019/6 as amended to *<name of competent authority(ies) to which the application has been submitted>* for the following product:

<name of the proposed informed consent MA and procedure number if available >.

In the event that the Marketing Authorisation is granted to *<name of the MAH for the proposed informed consent MA>*, access to the data will be available to *<name of the MAH for the proposed informed consent MA>* and *<name of the competent authority(ies) to which the application has been submitted>* for as long as the product is authorised. The data in the dossier may be used in the assessment of any variation or renewal of the Marketing Authorisation or for any other purposes whatsoever relating to the Marketing Authorisation and we can confirm that *<name of the MAH for the proposed informed consent MA>* will have full access to the dossier to enable them to fulfil their obligations as MAH as described in Regulation (EU) 2019/6 as amended.

For and on behalf of *<name of the MAH for the cross referred product>*

Date and place

Signature

Name, Job Title

Section to be completed by the MAH for the proposed informed consent MA

I, the undersigned acting in my capacity as *<Job title>* of *<name of the MAH for the proposed informed consent MA>* whose registered office is located at *<address of the MAH for the proposed informed consent MA>* hereby confirm that we have received full access to Part IC, II, II and IV of the MA dossier for *<name and MA number of the cross-referred MA>* by *<name of the MAH for the cross-referred product>*, whose registered office is located at *<address of the MAH for the cross-referred product>*.

This access has been granted for the purposes of the submission of a marketing authorisation application under Article 21 of Regulation (EU) 2019/6 as amended to *<name of the competent authority(ies) to which the application has been submitted>* for the following product:

<name of the proposed informed consent MA and procedure number if available >.

Submitted by the applicant:

<name and address of the MAH for the proposed informed consent MA>

We can confirm that *<name of the MAH for the proposed inform consent MA>* has full access to the dossier and that we are in a position to fulfil our obligations as MAH as described in Regulation (EU) 2019/6 as amended, in the event that the Marketing Authorisation is granted.

For and on behalf of *<name of the MAH for the proposed informed consent MA>*

Date and place

Signature

Name

Job Title