Template for declaration of dossier conformity of the cross-referred product in support to 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 the dossier of the veterinary medicinal product <*Name*>, <*MA number*> is up to date and the appropriate variations were submitted, as described in Regulation (EU) 2019/6 as amended.

A flow-chart indicating all approved sites involved in the manufacturing process of the veterinary medicinal product or active substance (including sites involved in sampling and testing for batch release of products manufactured in third countries), the approved qualitative/quantitative composition and an overview of the approved finished product specifications at release and at the end of shelf-life are attached as an annex to this declaration.

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

Date and place

Signature

Name, Job Title

Annex I: Flow-chart indicating all registered sites involved in the manufacturing process of the veterinary medicinal product or active substance (including sites involved in sampling and testing for batch release of products manufactured in third countries).

Annex II: Qualitative and quantitative composition

Annex III: Finished product specifications at release and at the end of shelf-life.