February 2023

CMDh/364/2017, Rev.5

<Applicant>

<Address>

<Address>

<Post code> <Town>

<Country>

<Date>

<Reference>

<National Agency>

<Address>

<Address>

<Post code> <Town>

<Country>

**Subject: Submission of Application for Renewal of <Product Name(s) in the MS where the application is submitted> <Full Renewal Procedure Number(s)>**

Dear Sirs,

We are pleased to submit our Application for Renewal, details of which are as follows:

**Name of the medicinal product(s) (in the RMS):**

**Pharmaceutical form(s) and strength(s):**

**INN/active substance(s):**

**ATC Code(s):**

**Renewal type:**

[ ]  Standard renewal

[ ]  Renewal following a mutual recognition or repeat use procedure where unlimited validity has been granted in the RMS

[ ]  Renewal following an Article 30 or 31(1) Referral Procedure

[ ]  Expanded renewal with full documentation according to Annex 3 in the CMDh Best Practice Guide on the Processing of Renewals in the Mutual Recognition and Decentralised Procedures *(Only applicable if an additional renewal has been requested on pharmacovigilance grounds or if requested by the RMS)*

**Statements regarding the application:**

[ ]  We declare that full documentation is available for submission upon request. *(This declaration is required for standard renewals)*

[ ]  We confirm that the product information is up to date in accordance with Article 23(3) of Directive 2001/83/EC. The latest update of the product information was done with <variation procedure number> *(This declaration is required for all renewals)*

[ ]  No new data are available that change, or would result in a re‑evaluation of, the benefit/risk balance. We are not aware of any notable grounds for this marketing authorisation not to be renewed cf. Article 116 of the Directive 2001/83/EC *(This declaration is required for all renewals)*

[ ]  We confirm that there are no changes to the dossier included in this renewal application *(This declaration is required for standard renewals. For expanded renewals it should be ticked, if relevant)*

[ ]  Valid GMP certificate(s) for all manufacturers as relevant is enclosed or reference to the EudraGMP database is given *(This declaration is only required for expanded renewals)*

[ ]  Valid QP declaration(s) for all manufacturers responsible for batch release and/or manufacturers where the active substance is used as starting material is enclosed. <The QP declaration template has been used.> *(This declaration is only required for expanded renewals)*

[ ]  The product information is enclosed *(This declaration is only required for expanded renewals)*

[ ]  The approved SmPC, package leaflet and labelling are enclosed or reference is made to eCTD sequence

[ ]  The proposed SmPC, package leaflet and labelling are enclosed with any proposed changes highlighted

[ ]  Additional data requested cf. publishedtable “Data requested for Variations and/or Renewal Applications in the MRP/DCP which are not stated in the current EU legislation and/or in Volume 2B, Presentation and format of the dossier Common Technical Document (CTD) and/or in the EEA approved Guidelines/ Recommendation papers” is enclosed. *(This declaration is required for all renewals, as relevant)*

**You will find enclosed the submission dossier as specified hereafter:**

[ ]  eCTD Sequence number: <Four-digit number>

[ ]  We confirm that the electronic submission has been checked with an up-to-date and state-of-the-art virus checker.

<- Multiple/duplicate renewal applications are submitted.>[[1]](#footnote-1)

<Free text field – when appropriate and if important for the validation of the application(s) additional information can be provided e.g. location of Notes to Reviewers, National file number if provided before submission etc.>

Yours sincerely,

<Signature>

<Name>

<Title>

<Phone number>

<Email address>

<Email address for technical validation issues>

1. *When duplicates are not submitted simultaneously, a reference to the first application should be given.* [↑](#footnote-ref-1)