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)