<Applicant>
<Address>
<Address>
<Post code> <Town>
<Country>

<Date>
<Reference>

<National Agency>
<Address>
<Address>
<Post code> <Town>
<Country>

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

Dear Sirs,

We are pleased to submit our Application Dossier(s) for a <Mutual Recognition><Decentralised> Procedure which details 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):

Legal Basis of the Application(s):

When appropriate, please indicate:

- Use of European Reference Medicinal Product	☐ Yes	☐ No
- If the strength(s) of the Reference MP differs between RMS/CMS	☐ Yes	☐ No
- If the pharmaceutical form(s) of the Reference MP differs between RMS/CMS	☐ Yes	☐ No
- If the indication(s) of the Reference MP differs between RMS/CMS	☐ Yes	☐ No

You will find enclosed the submission dossier as specified hereafter:

☐ eCTD format, Sequence number: <Four digit number>

<Number> media units per application and <number> copies are provided.

☐ We confirm that all future submissions for this specific product will be submitted in this same format.

☐ The eCTD has passed the applicant's internal technical validation (all P/F criteria passed and all BP criteria have been fulfilled up to our best knowledge) using <name and version number of the validation software>

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

☐ The dossier is submitted in paper format *(Note: Full paper dossiers can only be submitted to NCAs still accepting paper submissions and should only be used exceptionally when a valid electronic format dossier really could not be provided.)*

☐ An identical electronic copy of the paper dossier is also provided
Number of paper binders provided:
- Module 1: <xx> enclosures
- Module 2: <xx> enclosures
- Module 3: <xx> enclosures
- Module 4: <xx> enclosures
- Module 5: <xx> enclosures

☐ Different formats (eCTD or paper) are submitted to different RMS/CMS (specify differences to different NCAs in text below): (*This is not recommended and do require an explanation if needed.)*
<Text field>

<- Multiple/duplicate applications are submitted.>[1]
<- A transfer of ownership (MAH) for the medicinal product is to take place in the national step after finalisation of the procedure.>[2]
<- The relevant fees have been paid.>
<- The Risk Management Plan in module 1.8.2 is similar to the one <submitted><approved> in the procedure(s) <Full procedure number(s).>

<- The MAA/MAH confirms that the RMP is fully in line with the current "Guideline on good pharmacovigilance practices (GVP) Module V – Risk Management systems" and the "Guidance on format of the risk management plan (RMP) in the EU <please indicate the applicable revision no.>.>

<- The MAA/MAH confirms that the summary of safety concerns and all corresponding sections of the RMP, including all risk minimisation measures and pharmacovigilance measures are fully in line with the RMP from the originator or a similar medicinal product as recently adopted by CHMP (EPAR), and/or CMD(h), and/or NCAs published on the respective websites.>

<Weblink to the relevant RMP Summary of the reference RMP is as follows: <include URL>". (If published, the weblink to the referenced RMP summary of the chosen reference medicinal product or similar medicinal product shall also be mentioned.) >

<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.>

☐ We, <Applicant>, hereby certify that the dossier submitted to the RMS and CMS(s) are fully identical.

☐ There are, however, some different **national** documents (<cover letter><application form><specific national requirements>) that are submitted to the relevant RMS/CMS only, **outside** the eCTD dossier
☐ There are, however, some different **national** documents (<cover letter><application form><specific national requirements>) that are submitted to the relevant RMS/CMS only, **within** the eCTD dossier

Yours sincerely,

[1] *When duplicates are not submitted simultaneously, a reference to the first application should be given.*
[2] *Confirmation that transfer during that step is possible, to be obtained from MSs concerned.*

<Signature>
<Name>
<Title>
<Phone number>
<Email address>
<Email address for technical validation issues>