Marketing Authorisation Pre-submission checklist

We aim to keep validation timelines to a minimum. Please help us to achieve this by using this pre-submission checklist when preparing your dossier for submission to avoid the most frequent issues

If you have any questions or concerns about your application please do not hesitate to contact us:

RIS.NA@mhra.gov.uk (National applications and general regulatory advice)

MRDCprocedures@mhra.gov.uk (European procedures)

Application Requirements	Confirm
Format Only submit your dossier in an eCTD format. 'Special Mail' and NeeS formats are no longer acceptable. We recommend that eCTD submissions are technically validated using a suitable proprietary validation tool prior to submission. You can send your application to the MHRA by - **MHRA Submissions** - **CESP (NI)** - **MHRA Portal**	

SmPC and label and leaflet

- Please send a copy of the SmPC and the clean individual SmPC fragments in a word format
- A consolidated label and leaflet

These documents should be included in the working documents folder

NOTE*:* For abridged applications:

Please ensure the therapeutic indications in the SmPC support the Reference Product (If you wish to include additional indications please contact RIS prior to submission). RIS.NA@mhra.gov.uk

Application form section 1 – Type of Application	Confirm
Orphan Designation Please remember to provide an answer for this question. **If it is left blank your application will be invalidated.**	
Article of Submission Please check that you have selected the correct legal basis for your submission. More information can be found **here :-** **http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Marketingauthorisations/Typesofapplication/index.htm**	
Data Protection period For applications under Articles 10(1) and 10(3) and 10c (generics) you must ensure that the data protection period for the Reference Medicinal Product has expired **before** submission. Details on "Data exclusivity and market protection periods for reference medicinal products" may be found here **Reference Medicinal Product** The reference medicinal product must have been granted a marketing authorisation by a Member State or by the EMA on the basis of a complete dossier (i.e. with pharmaceutical, pre-clinical and clinical data) in accordance with the provisions of Article 8 of Directive 2001/83/EC. Have you included the product name, strength, pharmaceutical form, MAH, date of authorisation, Union or Member State (EEA) of authorisation for the following : • The reference medicinal product used to demonstrate the data protection period has expired (see here for more information) • The reference medicinal product authorised in the UK or the European Reference Product • The reference medicinal product used in the bioequivalence study(ies)	

Application form section 2 - Marketing Authorisation Application Particulars	Confirm
Invented names (Annex 5.19) Please remember to include a list of proposed invented names and Marketing Authorisation Holders in the Concerned Member States. This may be given in the application form or in Annex 5.19. If it is included in the Annex please add a note to the form. **Your application will be invalidated if this information is not provided.** General guidance about invented names can be found here. http://www.mhra.gov.uk/Howweregulate/Medicines/Namingofmedicines/	
Pharmacovigilance System Summary (M1.8.1) Please remember to include: • Signed statement that applicant/MAH has the necessary means to fulfil the tasks and responsibilities listed • The location of the PSMF (physical (postal) address and must be UK/EU/EEA) • Name and address of the QPPV (including telephone and email address) • The Member States in which the QPPV resides and operates (must be UK/EU/EEA) The QPPV has to be the same person named in section 2.4.4 of the application form and Annex 5.5 **Your application will be invalidated if you do not provide the PSS.** The Detailed Description of the Pharmacovigilance System (DDPS) is no longer accepted for new applications.	
Risk Management Plan (M1.8.2) • Please ensure that the RMP includes details of the active substance Your application will be invalidated if this document is not included. More information can be found here http://www.mhra.gov.uk/Howweregulate/Medicines/Pharmacovigilancelegislation/2012pharmainfoformahs/index.htm	

ASMF

- Has the ASMF been submitted by the manufacturer prior to submission of the licence application, and
- Have all MSs received the correct version?

The following documents should be provided by the ASMF holder for a new ASMF submission (please refer to the notes at the end of this section):

- Submission letter and administrative details form [1]
- Letter of access [1]
- Applicant's part [2]
- Restricted part [2]
- Separate or combined quality overall summary (QOS) for the applicant's and restricted parts [2]
- Copy of the expert's curriculum vitae
- A copy of the proposed ASMF holder's drug substance specification (3.2.S.4.1)

The applicant's part, restricted part and quality overall summary(ies) should be submitted as individual PDF documents for the relevant sub-sections of the CTD. All documents should be submitted and named according to eCTD or NeeS conventions

The following documents are needed for updates to previously submitted ASMF :

- Submission letter and administrative details form [1]
- A table of changes between the present and proposed (updated) versions of the applicant's part and/or restricted part [2]
- Updated CTD sections of the applicant's part (where applicable) [2, 3]
- Updated CTD sections of the restricted part (where applicable) [2, 3]
- Updated quality overall summary(ies) (QOS) [2]
- Copy of the expert's curriculum vitae
- A copy of the proposed ASMF holder's drug substance specification (3.2.S.4.1)

Please ensure the relevant PL numbers and/or European Procedure numbers are included in the Letter of Access (Annex 5.10). Information in the ASMF Holder's Submission letter and Letter of Access should agree with each other.

Notes: [1] The templates for the submission letter and administrative details form (Annex 3) and the letter of access (Annex 2) are published on the EMA website in guidance CPMP/QWP/227/02 Rev. 3 Active Substance Master File Procedure. Guidance on completing the annexes is published on the CMD website. The submission letter and administrative details form should be provided by the ASMF holder for each marketing authorisation or variation application. [2] The ASMF holder should provide the most recent version only once. [3] A complete applicant's or restricted part(s) will also be accepted. [4] Updated CTD sections should be version controlled to differentiate them from the previously submitted versions	

Application form section 4 – Other Marketing Authorisation Applications	Confirm
Pending applications in other Member States If duplicate procedures have been granted, or duplicate applications are pending in other member states, you should also specify this in the cover letter, stating that the granted/pending procedures are duplicates of the proposed DC procedure. You are strongly advised to refer to CMDh guidance particularly Q and As 1, 4 and 7 for further information on the submission of duplicates of already authorised medicinal products.	

Application form section 5 – Annexed Documents	Confirm
Annex 5.5 - Curriculum vitae of QPPV • If using version 10 of the application form please check that the CV has been included and refers to the person named in section 2.4.4 of the form. • If using version 10.1 please tick 'The above-mentioned qualified person resides and operates in the EEA' and The qualified person is registered with Eudravigilance'. **Annex 5.6 – Manufacturing Authorisation** • The relevant Manufacturing Authorisations should be included • Where appropriate translated copies of the Manufacturing Authorisations should be submitted. **Annex 5.9 – GMP certificate(s)** • Please provide relevant GMP certificates • Check that GMP certificates are in date or within the 6 months grace period. **NOTE:** Certificates for all manufacturing functions must be provided. A frequent issue is that only certificates for the manufacturer of the medicinal product and active substance are included. **Annex 5.19 – Invented names** Please see notes in Section 2 above.	
National requirements in CMSs For Mutual Recognition and Decentralised Procedures applicants are strongly advised to check CMDh guidance for CMS National requirements when preparing your submission.	

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