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## Module 1: Administrative information Application form

User guide for the electronic application form for a Marketing Authorisation

### **Purpose and general rules**

This User guide has been prepared in order to facilitate the work of applicants when completing the Electronic Application Forms (eAF) as part of an application for a marketing authorisation of a medicinal product for human use / registration of a traditional herbal medicinal products.

For traditional herbal medicinal products, “marketing authorisation” should be understood as “registration of traditional herbal medicinal products” and as “registration holder” for “marketing authorisation holder”.

In addition, a document called Practical user guide for electronic Application Forms (eAF) for human and veterinary products in the EU has been prepared to provide practical and technical support to use the eAF. For practical reason, the content of the regulatory guidance should be read in the context with the technical document referenced (<http://esubmission.ema.europa.eu/eaf/index.html>).

### ***How to fill in the electronic application form?***

The electronic application form has been prepared to be filled in by the applicant in case of an application made either by national route or by mutual recognition, decentralised or centralised procedures.

In the case of a mutual recognition or decentralised procedure an application form should be filled in for all competent authorities where the application is made.

The same applicant should apply in all concerned member states. Since some information may differ between member states (e.g. marketing authorisation holder/registration holder, legal status, contact persons etc.), the appropriate sections should be replicated where necessary.

For relevant sections, the applicant is requested to specify to which Member State the information relates.

Where EEA is indicated in the application form, the applicant should understand that EEA includes EU countries.

For national, mutual recognition and decentralised procedures, a completed separate application form is required for each strength and pharmaceutical form. For centralised procedures a combined application

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form for all strengths and pharmaceutical forms should be used and the relevant sections should be replicated as necessary.

Fields relevant for certain types of applications or related to legal basis do only appear after ticking the concerned box.

Square boxes indicate that multiple choices are possible while round boxes indicate that one choice excludes the other possibilities.

Some fields should be filled in by choosing a value from a dropdown list that is based on a controlled dictionary. Further information on the dictionaries used is provided in this document and on the e-submissions website (including instructions on requesting additions to some of the lists).

Where necessary, the fields can be duplicated by clicking on a boxed "+" symbol.

Further guidance on technical aspects of the electronic application form can be found on the e-submissions website (<http://esubmission.ema.europa.eu/eaf/index.html>), in particular the Questions and answers relating to practical and technical aspects of the Electronic Application Forms and the Harmonised Technical Guidance (see above).

### ***Which language should be used in the application form?***

- English should be used for a centralised procedure.
- English should be used for a mutual recognition or decentralised procedure.
- For national procedures, please refer to the document *Languages to be used for Marketing Authorisation Application (MAA), Variations and Renewals* at the CMDh website.).

Language requirements apply also to the annexes to the Application form and therefore, as applicable, translations may need to be provided.

## **Administrative data**

### ***Declaration and signature***

In this declaration, data must be identical to the information provided in other sections, as well as the supportive documents provided (e.g. annexes to the application form, proposed product information, other Modules of the dossier).

When this section is completed the data should be populated to corresponding fields in other sections of the application form by clicking on the respective push-button "Populate data".

### ***Product (Invented) name***

In case of an application under the mutual recognition (MRP) or decentralised (DCP) procedure, the product name used in the reference Member State (RMS) should be listed.

Here should be quoted only the product or invented name and not the full name of the product (i.e. without strength and pharmaceutical form).

A list of the different proposed invented names and marketing authorisation holders in the concerned member states should be appended to the application form in annex 5.19.

For centralised procedure, the invented name should be agreed by Name Review Group prior submission. Please refer to the EMA website for further information (<http://www.ema.europa.eu/ema/>).

## **Pharmaceutical form**

The pharmaceutical form should be chosen from the list, which includes the pharmaceutical forms described in the Standard terms published in the European Pharmacopoeia that provides standardised nomenclatures and quality standards for medicinal substances and products (<https://www.edqm.eu/en/standard-terms-590.html>). Only the full term should be mentioned (not the short term).

If the application for several pharmaceutical forms is made with a combined application form, the pharmaceutical form field should be duplicated and all pharmaceutical forms included.

## **Strength (s) and active Substance(s)**

The two fields "Strength" and "Active substance" should be considered as linked and corresponding values listed in the same order for both fields. Strength is to be entered as a free text, Unit is to be chosen from a drop-down list and active substance selected from the dropdown list (based on a controlled dictionary).

The full name of the active substance(s) should be stated, including salt or hydrate (if applicable). The expression of strength for active substances presented in the form of salt or hydrate should be based on base/active moiety.

To see the drop-down list click on "Add Active Substance(s)". If more than one "Active Substance" is contained, duplicate the field by clicking on +.

If the concerned pharmaceutical form has several strengths that are applied for in the same application form, the field should be duplicated and all strengths included (only applicable to centralised procedures).

If the product contains more than one active substance, each active substance should be added.

## **Applicant**

For MRP and DCP applications, the applicant should be the same as the MAH/Applicant in the RMS.

The name of the applicant should be included in the field 'Applicant', and its address in the field 'Address'.

Person signing the application form should have a letter of authorisation for communication/signing on behalf of the applicant (to be attached in annex 5.4).

# **1. Type of application**

## **1.1. This application concerns**

### **1.1.1. A Centralised Procedure**

Article 3 of Regulation (EC) No 726/2004 defines the eligibility of applications for evaluation under the centralised procedure through which medicinal products must or may be authorised by the Union. The eligibility to centralised procedure should be confirmed by the CHMP in advance of the submission of the application for the marketing authorisation.

The basis for eligibility should be indicated in line with the CHMP acceptance/confirmation of the eligibility to centralised procedure, indicating also the date of acceptance/confirmation of eligibility. Only one eligibility basis should be indicated (additional information must be indicated for Advanced Therapy

Medicinal Products, as applicable). If the product falls under 'mandatory' eligibility scope, this scope should be indicated, even if the product falls also under an 'optional' scope.

The EMA product number and appointed Rapporteurs from the concerned Committees should also be indicated in this section.

For applications for a change to an existing marketing authorisation leading to an extension as referred to in Annex I of Regulation (EC) No 1234/2008, it is not necessary to request (re)confirmation of eligibility and the same basis for eligibility to the centralised procedure as for the original application should be indicated, whenever possible. If the corresponding original eligibility basis of the product is obsolete (no longer exists), only 'Centralised Procedure' should be indicated, leaving the eligibility basis tick boxes blank.

Please refer to the website of European Medicines Agency (<http://www.ema.europa.eu/ema/>) for further guidance on process for confirmation of eligibility to centralised procedure and Rapporteur appointment.

### **1.1.2. A Mutual Recognition Procedure**

The applicant should indicate the reference Member State, details of the marketing authorisation (date and number), procedure number, and for each "wave" of mutual recognition procedure concerned Member State(s) and the proposed (or agreed) common renewal date.

The procedure number is the Mutual Recognition Procedure number allocated by the RMS.

"First Use" means the first Mutual Recognition Procedure.

All the concerned Member states should be indicated.

"Repeat use" means a new use ("wave") of the same mutual recognition or decentralised procedure made to include new concerned member state(s).

When applying for a repeat use, the applicant only complete information regarding the new CMS included in this specific wave.

Further information on previous applications should be provided in section 4 of the application.

### **1.1.3. A Decentralised Procedure**

The applicant should indicate reference Member State, procedure number concerned Member State(s) and proposed common renewal date.

For repeat-use of decentralised procedure, please complete section 1.1.2.

### **1.1.4. A National Procedure**

In the case of a national application, the application number is allocated by some member states prior to the official application and therefore should be indicated.

No specific format can be given for this application number.

## **1.2. Orphan Medicinal Product Information**

### **1.2.1. Has Orphan designation been applied for this medicinal product?**

Regulation (EC) No 141/2000 and Commission Regulation (EC) No 847/2000 foresee incentives for development of medicinal products for rare diseases (orphan medicinal products) including market

exclusivity, protocol assistance, eligibility for initiatives which support research and development, access to the centralised procedure and the possibility to request fee reductions from the EMA. Medicinal products eligible for these incentives are clearly identified through a procedure for orphan designation.

The applicant should note whether an application for orphan designation, for the medicinal product concerned, has ever been submitted to the EMA for the condition that is the subject of the application for marketing authorisation, and if 'yes', the EMA procedure number (EMA/OD/XXX/year or EMA/OD/XXX/year) should be provided together with details of the status as follows:

- if a designation application is pending, tick this option;
- if orphan designation has been granted, note details of the date of designation (i.e. date Commission Decision on designation was adopted), whether or not the designation was based on the 'significant benefit' criterion in accordance with Article 3(1)(b), Regulation (EC) No 141/2000, and the Number in the Community Register of Orphan Medicinal Products (EU/X/year/XXX). A copy of the Commission Decision on orphan designation should be attached as Annex 5.18;
- if orphan designation has been refused, provide the date of the Commission Decision refusing the designation and its reference;
- if an application for designation has at any time been submitted and subsequently withdrawn, note the date of withdrawal by the sponsor.

### **1.2.2. Information relating to orphan market exclusivity**

**This section is to be completed for all applications, whether the applicant is the holder of an orphan designation or not, and regardless of the legal basis of the application being submitted** (e.g. including applications under Art 10(1)).

In accordance with Article 8 of Regulation (EC) No 141/2000, when an orphan medicinal product is authorised throughout the EU, a 10-year period of market exclusivity commences from the date of the granting of the marketing authorisation and protects orphan medicinal product for the authorised 'orphan' therapeutic indication. In certain cases, this market exclusivity period can be extended to 12 years or reduced to 6 years. During the market exclusivity period similar medicinal products will not be granted a marketing authorisation for the same therapeutic indication unless the marketing authorisation holder for the orphan product gives consent, is unable to supply sufficient quantity of the medicinal product, or the second applicant demonstrates that although 'similar', the medicinal product is 'clinically superior' to the already authorised orphan medicinal product.

The definition of 'similar' and 'clinically superior' in this context is defined in Article 3 of Commission Regulation (EC) No 847/2000.

All applicants are requested to indicate whether or not any other medicinal product has been granted orphan designation in the EU for the condition relating to the indication proposed in the application for marketing authorisation.

To complete this section of the application form the applicant should check the "Active" part of "Community Register of orphan medicinal products for human use" that is available on the Website of the European Commission ([http://ec.europa.eu/health/documents/community-register/index\\_en.htm](http://ec.europa.eu/health/documents/community-register/index_en.htm)).

If the condition relating to the proposed therapeutic indication proposed in the application has been the subject of an orphan designation:

- all corresponding EU orphan designation number(s) (EU/X/year/XXX) should be provided;

- the applicant should indicate whether or not any designated orphan medicinal product(s) has been granted a marketing authorisation in the EU;

If any of the designated orphan medicinal products have been granted a marketing authorisation:

- for each of the authorised orphan medicinal product(s) the applicant should specify, repeating the fields as necessary:
  - The therapeutic indication(s) of the authorised product for a condition which is related to the indication proposed in the application that is being submitted;
  - Name, pharmaceutical form(s) and strength(s) of the authorised product;
  - Name of the marketing authorisation holder;
  - Marketing authorisation number(s);
  - Date of authorisation.
- the applicant should indicate whether or not the medicinal product which is the subject of the application for marketing authorisation is considered 'similar' to any of the authorised orphan medicinal products.
- a critical report should be submitted in module 1.7.1 of the application for marketing authorisation addressing the possible similarity with the authorised orphan medicinal product(s) and concluding on "similarity" or "non-similarity".

Article 3 of Commission Regulation (EC) No 847/2000 defines similar medicinal product as a medicinal product containing a similar active substance or substances as contained in a currently authorised orphan medicinal product, and which is intended for the same therapeutic indication. It also defines **similar active substance** as an identical active substance, or an active substance with the **same principal molecular structural features** (but not necessarily all of the same molecular features) and which acts via the **same mechanism**. Based on the above-mentioned definitions, the assessment of similarity between two medicinal products takes into consideration the following criteria:

- Principal molecular structural features;
- Mechanism of action and
- Therapeutic indication.

If significant differences exist within one or more of these criteria, the two products will not be considered as similar.

If the medicinal product, which is the subject of the application for marketing authorisation is deemed to be "similar" to one or more orphan medicinal product(s) covered by orphan market exclusivity provisions:

- the applicant should submit in module 1.7.2 of the application for marketing authorisation a justification for each of the "similar" orphan medicinal product(s) that one of the **derogations** laid down in Article 8.3, paragraphs (a) to (c) of the Regulation (EC) No 141/2000 applies, that is:
  - (a) the holder of the marketing authorisation for the orphan medicinal product has given his **consent** to the applicant of this application, or
  - (b) the holder of the marketing authorisation for the orphan medicinal product is **unable to supply sufficient quantities** of the medicinal product, or

(c) the applicant can establish in the application that their medicinal product, although similar to the orphan medicinal product already authorised, is safer, more effective or otherwise **clinically superior**.

Further guidance can be found in the Guideline on aspects of the application of Article 8(1) and (3) of Regulation (EC) No 141/2000: Assessing similarity of medicinal products versus authorised orphan medicinal products benefiting from market exclusivity and applying derogations from that market exclusivity ([http://ec.europa.eu/health/sites/health/files/files/orphanmp/doc/c\\_2008\\_4077\\_en.pdf](http://ec.europa.eu/health/sites/health/files/files/orphanmp/doc/c_2008_4077_en.pdf))

### **1.3. Application for a change to existing marketing authorisation leading to an extension as referred to in Annex I of Regulation (EC) no 1234/2008**

Certain changes to a marketing authorisation are considered to fundamentally alter the terms of a marketing authorisation and therefore cannot be considered as a variation. For these changes, set out in Annex I of Regulation (EC) 1234/2008, a new application must be made that shall be evaluated in accordance with the same procedure as for the initial marketing authorisation to which it relates.

If the applicant of the present application ticks "Yes," he must be **the same** as the marketing authorisation holder of the existing marketing authorisation. Applications for changes or additions falling under the scope of Annex I can only be submitted for the existing marketing authorisation by the marketing authorisation holder.

An application for an extension is made under the same legal basis as the original MA (see section 1.4 of the Application Form).

#### **1.3.1. Changes applied for**

For extension applications the applicant should specify which of the changes set out in Annex I of Regulation (EC) 1234/2008 this application concerns:

- a qualitative change in declared active substance not defined as a new active substance (indicating the type of change);
- change in bioavailability;
- change in pharmacokinetics;
- change or addition of a new strength/potency;
- change or addition of a new pharmaceutical form;
- change or addition of a new route of administration.

Several of the changes above are possible to be included in a single application form if applied for at the same time. All of the changes applied for should be indicated therefore all relevant boxes should be ticked (e.g. change of pharmaceutical form and change of strength).

The European Commission has published a guideline to clarify the terms 'pharmaceutical form' and 'strength' and to include relevant examples for this classification:

([http://ec.europa.eu/health/files/eudralex/vol-2/c/v2c\\_ea\\_v\\_10\\_2003\\_en.pdf](http://ec.europa.eu/health/files/eudralex/vol-2/c/v2c_ea_v_10_2003_en.pdf)).

This guideline on categorisation should be read in conjunction with the European Directorate for the Quality of Medicines and Healthcare (EDQM) guidance: Standard terms: Introduction and guidance for use (<https://standardterms.edqm.eu/>), Regulation (EC) No 1234/2008 and Regulation (EC) N° 1901/2006.

In case of doubt, the MAH is advised to contact the concerned Competent Authority in advance of the submission.

For changes relating to the active substance where the active substance is viewed as a “new active substance” as defined in Chapter I – Volume 2A of the Notice to Applicants, application for an independent marketing authorisation should be made (not an extension application).

### **1.3.2. Article 29 application**

This subsection should be filled in for applications submitted to the EMA according to Article 29 of Regulation (EC) No 1901/2006, where an extension application is made for use in the paediatric population for a new pharmaceutical form or a new route of administration.

In such case the applicant should indicate whether the application concerns new pharmaceutical form and/or new route of administration.

#### **Existing marketing authorisation**

For applications that are a change to existing marketing authorisation, the applicant should provide information regarding existing marketing authorisation in the European Union / Member State where the application is made:

- (Invented) name of the product;
- Pharmaceutical forms(s);
- Strength(s);
- Name of the marketing authorisation holder;
- Marketing authorisation number (all marketing authorisation numbers of each presentation should be given, when applicable) and date of marketing authorisation.

### ***1.4. This application is submitted in accordance with the following article in Directive 2001/83/EC as amended***

This Section should be completed for each application and **only one** round box should be ticked.

The applicant should indicate the “legal basis” of their application – the corresponding Article of Directive 2001/83/EC, according to which the application is made. Please refer to Notice to Applicants, Volume 2A, Chapter 1 for further guidance.

For applications for a change to an existing marketing authorisation leading to an extension as referred to in Annex I of Regulation (EC) No 1234/2008, the legal basis of the extension should be the same as the one used previously for the existing marketing authorisation. For extensions, cross references to pre-clinical and clinical data of the existing marketing authorisation could be made.

#### **1.4.1. Article 8(3) application**

For applications made according to Article 8(3) of Directive 2001/83/EC, i.e. full or full-mixed dossier, please refer to Notice to Applicants, Volume 2A, Chapter 1 for further guidance.

#### **1.4.2. Article 10(1) generic application**

For applications made according to Article 10(1) of Directive 2001/83/EC the applicant should indicate under:



- *"Medicinal product which is or has been authorised in accordance with Union provisions in force (acquis communautaire) for not less than 6/8/10 years in the EEA"* – a reference medicinal product for which regulatory data protection and, if applicable, orphan market protection periods have expired;
- *"Medicinal product authorised in the Union/Member State where the application is made or European reference medicinal product"* – a reference medicinal product with the same pharmaceutical form(s) (please see Article 10(2) of Directive 2001/83/EC regarding immediate release oral forms), strength(s) and route of administration, on which the product information of the generic product is based;
- *"Medicinal product which is or has been authorised in accordance with Union provisions in force and to which bioequivalence has been demonstrated by appropriate bioavailability studies"* – a reference medicinal product used as the reference product in bioequivalence studies.

**All 3 subsections must be filled out, otherwise the Applicant should justify.**

The reference medicinal products listed above must belong to the same Global Marketing Authorisation, contain the same active substance(s) as the generic product and be authorised on the basis of a complete dossier. When there are any differences between products indicated under the second and third indent of this section, the applicant should justify in Module 2 the relevance of the bioequivalence data.

In centralised procedure, European reference medicinal product(s) should be chosen for first and second indent of this section (not separate reference products for each Member State).

Please refer to Notice to Applicants, Volume 2A, Chapter 1 for further guidance.

For each of the reference medicinal products in this section the applicant should indicate all the particulars listed in the application form:

- (Invented) name of the product;
- Pharmaceutical form(s);
- Strength(s);
- Name of the marketing authorisation holder;
- Marketing authorisation number;
- Procedure number for MRP/DCP (if applicable);
- Date of authorisation;
- The EEA (including EU) Member State or EU that has granted the marketing authorisation;

For the product to which the bioequivalence has been demonstrated the applicant should also indicate the Member State in which the product has been sourced for the bioequivalence studies and the references numbers/ EudraCT numbers of those studies.

Further details and justification for the type of application should be provided in section 1.5.2 of CTD Module 1.

### **1.4.3. Article 10(3) hybrid application**

For applications made according to Article 10(3) of Directive 2001/83/EC the applicant should indicate:

- *"Medicinal product which is or has been authorised in accordance with Union provisions in force (acquis communautaire) for not less than 6/8/10 years in the EEA"* – medicinal product for which regulatory data protection and, if applicable, orphan market protection periods have expired;
- *"Medicinal product authorised in the Union/Member State where the application is made or European reference medicinal product"* – medicinal product, on which the product information of the hybrid product is based;
- Differences (several possible) to the reference medicinal product on which the product information of the hybrid product is based:
  - change in the active substance(s);
  - change in therapeutic indications;
  - change in pharmaceutical form;
  - change in strength (quantitative change to the active substance(s));
  - change in route of administration;
  - bioequivalence cannot be demonstrated through bioavailability studies;
- If applicable, *"medicinal product which is or has been authorised in accordance with Union provisions in force and to which bioequivalence has been demonstrated by appropriate bioavailability studies"* – medicinal product used as the reference product in bioequivalence studies.

**All subsections must be filled out, otherwise the Applicant should justify.**

For each of the products in this section the applicant should indicate all the particulars listed in the application form:

- (Invented) name of the product;
- Pharmaceutical form(s);
- Strength(s);
- Name of the marketing authorisation holder;
- Marketing authorisation number;
- Procedure number for MRP/DCP (if applicable);
- Date of authorisation;
- The EEA (including EU) Member State or EU that has granted the marketing authorisation;

The products referred to must belong to the same Global Marketing Authorisation, contain the same active substance(s) and be authorised on the basis of a complete dossier. When there are any differences between products indicated under second and third indent of this section, the applicant should justify in Module 2 the relevance of the bioequivalence data.

In centralised procedure European reference medicinal product(s) should be chosen for first and second indent of this section (not separate reference products for each Member State).

Please refer to Notice to Applicants, Volume 2A, Chapter 1 for further guidance.

Further details and justification for the type of application should be provided in section 1.5.2 of CTD Module 1.

#### **1.4.4. Article 10(4) similar biological application**

For applications made according to Article 10(4) of Directive 2001/83/EC the applicant should indicate:

- *"Medicinal product which is or has been authorised in accordance with Union provisions in force (acquis communautaire) for not less than 6/8/10 years in the EEA"* – medicinal product for which regulatory data protection and, if applicable, orphan market protection periods have expired;
- *"Medicinal product authorised in the Union/Member State where the application is made or European reference medicinal product"* – medicinal product on which the product information of the biosimilar product is based;
- Differences (several possible) to the reference medicinal product on which the product information of the biosimilar product is based:
  - change(s) in the raw material(s),
  - change(s) in the manufacturing process(es),
  - change in therapeutic indication(s),
  - change in pharmaceutical form(s),
  - change in strength (quantitative change to the active substance(s)),
  - change in route(s) of administration,
  - other changes
- *"Medicinal product which is or has been authorised in accordance with Union provisions in force and to which comparability tests and studies have been conducted"* – medicinal product used as the reference product in comparability tests and studies.

For each of the products in this section the applicant should indicate all the particulars listed in the application form.

The reference medicinal product to which comparability tests and studies have been conducted must be authorised in the EEA. When a non-EEA authorised comparator has been used for certain clinical or in vivo non-clinical studies in the comparability programme, it must be clearly identified in Module 1.5.2 but should not be additionally listed under third indent of this section of the application form. The "Guideline on similar biological medicinal products" should be consulted on the acceptability of a Non-EU comparator.

In centralised procedure European reference medicinal product(s) should be chosen for first and second indent of this section (not separate reference products for each Member State).

The products referred to must belong to the same Global Marketing Authorisation and be authorised on the basis of a complete dossier. When there are any differences between products indicated under the second and third indent of this section, the applicant should justify in Module 2 the relevance of the comparability data. Please refer to Notice to Applicants, Volume 2A, Chapter 1 for further guidance.

Further details and justification for the type of application should be provided in section 1.5.2 of CTD Module 1.

#### **1.4.5. Article 10a well-established use application**

Further details and justification for the type of application should be provided in section 1.5.1 of CTD Module 1. Please refer to Notice to Applicants, Volume 2A, Chapter 1 for further guidance.

#### **1.4.6. Article 10b fixed combination application**

Please refer to Notice to Applicants, Volume 2A, Chapter 1 for further guidance.

#### **1.4.7. Article 10c informed consent application**

The applicant should indicate the medicinal product for which the marketing authorisation holder has provided the consent and from which all pharmaceutical, preclinical and clinical data form the basis of the informed consent application. Letter of consent from the marketing authorisation holder of the authorised product, should be provided in Annex 5.2 to the application form.

#### **1.4.8. Article 16a traditional use registration for herbal medicinal product**

Please refer to Notice to Applicants, Volume 2A, Chapter 1 for further guidance.

### ***1.5. Consideration of this application requested under the following article of Directive 2001/83/EC or Regulation (EC) No 726/2004***

#### **1.5.1. Conditional Approval**

Article 14(7) of Regulation (EC) No 726/2004 and Commission Regulation (EC) No 507/2006 are applicable to the centralised procedure only. The applicant should indicate if conditional marketing authorisation is requested. Further details and justification for the request should be provided in section 1.5.5 of CTD Module 1.

#### **1.5.2. Exceptional Circumstances**

Provision foreseen according to Article 22 of Directive 2001/83/EC and Article 14(8) of Regulation (EC) No 726/2004. The applicant should indicate if marketing authorisation under exceptional circumstances is requested. Further details and justification for the request should be provided in section 1.5.4 of CTD Module 1.

#### **1.5.3. Accelerated Review**

Article 14(9) of Regulation (EC) No 726/2004 is applicable to the centralised procedure only. The CHMP agreement on accelerated procedure should be obtained in advance of the submission of the application for marketing authorisation. The applicant should indicate if accelerated assessment has been requested and agreed, together with the date of acceptance by the CHMP.

#### **1.5.4. Article 10(1) of Directive 2001/83/EC / Article 14(11) of Regulation (EC) No 726/2004 (one year of market protection for a new indication)**

The applicant should indicate if this request is made. Further details and justification for the request should be provided in section 1.5.3 of CTD Module 1. Please refer to Notice to Applicants, Volume 2A, Chapter 1 for further guidance.

### **1.5.5. Article 10(5) of Directive 2001/83/EC (one year of data exclusivity for a new indication)**

The applicant should indicate if this request is made. Further details and justification for the request should be provided in section 1.5.3 of CTD Module 1. Please refer to Notice to Applicants, Volume 2A, Chapter 1 for further guidance.

### **1.5.6. Article 74(a) of Directive 2001/83/EC (one year of data exclusivity for a change in classification)**

The applicant should indicate if this request is made. Further details and justification for the request should be provided in section 1.5.3 of CTD Module 1. Please refer to Notice to Applicants, Volume 2A, Chapter 1 for further guidance.

## **1.6. Requirements according to Regulation (EC) N° 1901/2006 ('Paediatric Regulation')**

For well-established use, generic, hybrid and bio-similar applications and traditional herbal medicinal products the applicant should indicate that sections 1.6.1, 1.6.2 and 1.6.3 are not applicable. In such case further parts of section 1.6 do not need to be filled in.

### **1.6.1. Does the same applicant hold other marketing authorisation(s) for a medicinal product(s) containing the same active substance(s) in the EEA.**

The applicant should indicate whether the applicant (including other companies belonging to the same mother company or group of companies or which are "licensees") holds in the EEA (including EU) at least one marketing authorisation(s) for a medicinal product(s) containing the same active substance(s) (falling in the same Global Marketing Authorisation) as the product for which this application is made. For applications for a change to existing marketing authorisation leading to an extension the existing authorised medicinal product should be included here.

Specific considerations apply if the same active substance is used for the purpose of an orphan and a non-orphan product, and the applicants are advised to consult with EMA in advance of the submission.

If the applicant does not hold existing marketing authorisation(s), section 1.6.3 should be completed.

If the applicant holds existing marketing authorisation(s), the details of all such products should be provided in the application form by providing the particulars listed:

- active substance(s);
- (invented) name of the product;
- pharmaceutical form(s);
- strength(s);
- name of the marketing authorisation holder;
- member State or EU that has granted the marketing authorisation;
- marketing authorisation number (s);
- date(s) of marketing authorisation.

The applicant should indicate whether any of the authorised product(s) is protected by a Supplementary Protection Certificate (SPC) under Regulation (EC) No 469/2009, or a patent qualifying for an SPC. If 'yes', section 1.6.2. should be completed.

### **1.6.2. Does the application relate to a new indication, new pharmaceutical form or new route of administration?**

If this section needs to be completed (please see above), the applicant should indicate whether this application introduces a new indication, new pharmaceutical form or new route of administration, as compared to already authorised (in EEA) medicinal products within same Global Marketing Authorisation. If 'yes', section 1.6.3. should be completed.

### **1.6.3. PIP and/or waiver**

If this section needs to be completed (please see above), the applicant should indicate which of the following applies to this application:

- Paediatric Investigation Plan (PIP) agreed by the Paediatric Committee (PDCO), indicating also the PIP Decision number(s) (format P/XXXX/year). This option covers also situation when PIP includes a waiver for a subset of the paediatric population.
- Product-specific waiver agreed by the PDCO, also indicating the Waiver Decision number (format P/XXXX/year). This option applies only if the waiver covers all subsets of the paediatric population.
- Class waiver agreed by the PDCO, also indicating the Waiver Decision number (format CW/XXXX/year).

These elements should cover all subsets of the paediatric population and all indication(s), pharmaceutical form(s) and route(s) of administration applied for.

For PIP and Product-specific waiver the respective PDCO Opinion and Summary report should be included in section 1.10 of CTD Module 1.

### **1.6.4. Article 30 (PUMA) of the Paediatric Regulation**

If the application is made according to Art. 30 of the Paediatric Regulation (EC) No 1901/2006 (Paediatric Use Marketing Authorisation – PUMA), it should be indicated in this section. The applicant should confirm that the product is not protected by either a SPC under Regulation (EC) No 469/2009, or by a patent which qualifies for the granting of the SPC and include the PIP decision number(s). PDCO Opinion and Summary report should be included in section 1.10 of CTD Module 1.

### **1.6.5. Has this application been subject to PIP compliance verification?**

The applicant should indicate if this application has been subject to a PIP compliance verification. If 'yes', a reference number of the document on the compliance should be included, and PDCO compliance report with (where applicable) PDCO opinion or documents to be included in section 1.10 of CTD Module 1.

The applicant should also indicate any parallel, ongoing or previous applications containing paediatric data relevant for the full PIP compliance verification (if applicable). As stated in Volume 2B of Notice to Applicants, an overview table of the PIP results, indicating in which application(s) they were/are going to be submitted, status of the application(s), as well as their location in the present application must be included in the Module 1.10.

## **2. Marketing Authorisation Application particulars**

### **2.1. Name(s) and ATC code**

#### **2.1.1. Proposed (invented) name of the medicinal product in the European Union / Member State/Iceland/Lichtenstein/ Norway**

The information is identical to the one in section "Declaration and signature" (populated automatically).

If different (invented) names in Member States are proposed in the MRP or DCP, the box should be ticked and these should be listed in Annex 5.19.

#### **2.1.2. Active substance(s)**

The information on full active substance is identical to the one in section "Declaration and signature" (populated automatically).

The active substance should be indicated as a full substance; if the substance is included in the product as salt or hydrate, the corresponding base/active moiety should be indicated in the additional field.

Name of the active substance should be based on the following order of priority: INN, European Pharmacopoeia, National Pharmacopoeia, common name or scientific name.

Where no INN is available from EDQM, the name of a national pharmacopoeia, a common name or scientific name should be provided. If the INN has not yet been published by the WHO, the applicant should confirm that the approval of the INN is pending.

Herbal substances / herbal preparations being the active substance of a (traditional) herbal medicinal product should be declared according to the "[Guideline on declaration of herbal substances and herbal preparations in herbal medicinal products / traditional herbal medicinal products \(EMA/HMPC/CHMP/CVM/287539/2005 Rev.1\)](#)".

If there is more than one active substance, this field should be duplicated.

For applications made according to Article 8(3) or Article 10a of Directive 2001/83/EC, the applicant should indicate whether it concerns a new active substance (as of the time of submission) or a known active substance. In case the claim of a new active substance is made, the corresponding justification should be provided as Annex 5.23 to the Application Form and the corresponding box in section 2.1.2 ticked.

#### **2.1.3. Pharmacotherapeutic group (Please use current ATC code)**

The applicant should include ATC code agreed by the WHO.

When a WHO agreed ATC code is not available, the most complete code corresponding to the claimed therapeutic use of the product should be given. This section should be duplicated where needed.

The two fields "ATC Code" and "Group" are linked and should be both completed.

When the agreed ATC code is not yet available, but the application for it has been submitted to the WHO, this should be indicated on the application form by ticking the box "If no ATC code has been assigned, please indicate if an application for the ATC code has been made".

If an ATC code is agreed and published by the WHO, but it is not used in the application, a justification should be provided.

**In the case of a traditional herbal medicinal product:** the ATC code should be mentioned if available.

## **2.2. Strength, pharmaceutical form, route of administration, container and pack sizes**

### **2.2.1. Strength and pharmaceutical form (use current list of standard terms – European Pharmacopeia)**

The values for “Pharmaceutical form”, “Strength” fields are populated from “Declaration and signature” section (please refer to the administrative data section in the user guide).

The value for “Active Substance” should be selected from the dropdown list (based on values entered in “Declaration and signature” section and section 2.1.2). For active substance presented in the form of salt or hydrate, the expression of strength should be based on base/active moiety.

### **2.2.2. Route(s) of administration:**

The route of administration should be chosen from the List of Standard Terms published by the European Directorate for the Quality of Medicines and Healthcare (EDQM) (<https://www.edqm.eu/en/standard-terms-590.html>)

### **2.2.3. Container, closure and administration device(s), including description of material from which it is constructed:**

The container should be chosen from the List of Standard Terms published by the European Directorate for the Quality of Medicines and Healthcare (EDQM).

This subsection should be repeated for each type of pack, also where two similar types of packages (e.g. two different types of blister material) are applied for.

- For each type of pack give package materials and different package sizes.

*Note. For mutual recognition and decentralised procedures, all package sizes authorised in the Reference Member State and in the Concerned Members States should be listed.*

For each container the proposed container, closure and administration device should be indicated.

The subsections should be repeated, if necessary.

Both, container and closure system have a dropdown field to select the correct option (The dropdown lists are based on a controlled dictionary).

Indicate if a list of Mock-ups or Samples/specimens sent with the application is attached, as appropriate (see EMA/CMDh websites). The list should contain short description (names) of mock-ups or samples/specimens sent and be provided as Annex 5.17 to the application form.

- Proposed shelf life Sections: For each container indicate (if applicable):
  - Proposed shelf life (before first opening of the container);
  - Proposed shelf life (after first opening of the container);
  - Proposed shelf life (after reconstitution or dilution);

Two sub-sections (rows) have been implemented:



- The row on the left side includes Free text field to enter numbers;
- The row on the right side includes dropdown fields with standard units list (seconds, minutes, hours,);

**The information should be identical to Module 3 and section 6.3.**

**Proposed storage conditions section and Proposed storage conditions after first opening Section.**

Dropdown field to select the correct option (The dropdown lists are based on a controlled dictionary)

**Proposed storage conditions after opening Section:**

Dropdown field to select the storage conditions after first opening ("Click arrow button").

The information related to Shelf life / storage conditions will be linked to one container and type of pack.

Consequently, those sections need to be replicated for different containers and types of pack.

*Indicate if a list of Mock-ups or samples/specimens sent with the application is attached as appropriate (see EMA/CMDh websites). The list should contain short description (names) of mock-ups or samples / specimens sent and be provided (ANNEX 5.17) to the application form.*

Additional rows for "Proposed storage conditions/Proposed storage conditions after opening and "Proposed storage conditions after reconstitution or dilution" are allowed, where needed.

**2.2.4. Medical devices**

This section should identify, where applicable, all the medical devices or accessories to be used with the applied medicinal product, whether they form an integral drug-device combination, or are co-packaged or obtained separately but referenced in the product information of the medicinal product.

This section should systematically be completed; if no device is related to the application, "No" should be completed for all sections (a, b, c, d, e).

If this section is applicable, information on each device or accessory to be used with the medicinal product should be provided and the section can be duplicated as needed. Several devices can be listed for each category (a, b, c, d, e).

All fields of sections 2.2.4.1. requested should be completed.

**2.2.4.1. Device(s) identification and classification**

Name, brief description and information on the intended use of the device should be indicated in this section.

Classification of the device should be indicated in accordance with the classification rules included in Annex VIII of Regulation (EU) n°2017/745. For class I medical devices, it should be specified whether there are sterile, with a measuring function or reusable surgical instrument in order to clarify whether an involvement from the Notified Body is required in the certification.

If applicable, serial number / unique device identifier (UDI) or other indications necessary to delimit precisely the device incorporated should also be specified.

#### **2.2.4.2. Manufacturer of the device**

The contact details of the EU medical device manufacturer should be provided.

For manufacturers located outside the EEA, information on the authorised representative in the EEA should be included instead.

#### **2.2.4.3. Documentation to confirm compliance to the Medical Device Regulation (EU n°2017/745)**

If applicable, it should be indicated if the application includes a Manufacturer's EU declaration of conformity, an EU certificate issued by a Notified Body or a Notified body opinion. Such document should be included in module 3.2.R of the EU-CTD.

The documentation is expected to be provided at the time of application submission. If not yet available, it should be indicated when the relevant document is expected to be available. Time point for its submission during the procedure should be agreed with the concerned competent authority.

Of note, this documentation should be provided as early as possible in the procedure to avoid possible delays in the assessment.

#### **2.2.4.4. Notified Body**

For all medical devices concerned by the application, and that require a Notified Body involvement to demonstrate compliance with the Medical Device Regulation\*, the name, the number, the address of the Notified body should be included as well as the contact details. This is also applicable to combined Advanced Therapy Medicinal Products (ATMPs) in accordance with article 9 of Regulation (EC) No. 1394/2007.

The NANDO database provides the list of Notified Bodies designated under the Regulation (EU) n°2017/745 on medical devices, as well as their Notified Body Number (with the form nnnn, where n is a number from 0-9) is available at the next link: <http://ec.europa.eu/growth/tools-databases/nando/>.

\* Class I (sterile and/or with a measuring function and/or reusable surgical instrument), Class IIa, Class IIb, Class III medical devices.

### **2.2.5. Companion diagnostic**

#### **2.2.5.1. Is the medicinal product to be used with a companion diagnostic within the meaning of Article 2(7) of Regulation (EU) n°2017/746?**

This section aims to identify whether the medicinal product is intended to be used with a companion diagnostic (*in-vitro* diagnostic medical device). This should systematically be completed.

#### **2.2.5.2. Name, description and intended purpose of the device**

The name, brief description and information on the intended use of the companion diagnostic should be indicated in this section.

#### **2.2.5.3. When is the Notified Body consultation on the suitability of the companion diagnostic with the medicinal product planned with the Competent Authority?**

This section should be completed with the anticipated date for the EMA consultation by the Notified Body, if this information is already known at time of submission. If not, the applicant should indicate in the free text when the CE-marking application was submitted to the Notified Body.

#### **2.2.5.4. Notified Body contact details**

The name, the number, the address of the Notified body should be included as well as the contact details.

The NANDO database provides the list of Notified Bodies designated under the Regulation (EU) n°2017/746 on *in-vitro* diagnostic medical devices, as well as their Notified Body number (with the format nnnn, where n is a number from 0-9) <http://ec.europa.eu/growth/tools-databases/nando/>.

### **2.3. Legal status**

Differences in proposed prescription status are acceptable among Member States, in line with national rules in force.

The legal status may differ from one presentation to another but not all Member States accept more than one legal status at one marketing authorisation.

Consequently, in mutual recognition and decentralized procedure this section may need to be replicated where needed and appropriate Member State filled in.

In centralised procedure only some of the categories are agreed at the European level (please see further details in CHMP Guideline on Legal Status for the Supply to the Patient of Centrally Authorised Medicinal Products, published on the EMA website). Further sub-categories can be applied at the national level, based on the main category agreed at the European level and product information of the concerned product.

#### **2.3.1. Proposed dispensing/classification**

#### **2.3.2. For products subject to medical prescriptions**

A CHMP Opinion is not given on the first two categories listed in this section, therefore in centralised procedure applicants should indicate only third and/or fourth category, if applicable.

#### **2.3.3. Supply for products not subject to medical prescription**

A CHMP Opinion is not given on these sub-categories, therefore applicants should not fill in this section for applications in centralised procedure.

#### **2.3.4. Promotion for products not subject to medicinal prescription**

A CHMP Opinion is not given on these sub-categories, therefore applicants should not fill in this section for applications in centralised procedure.

### **2.4. Marketing authorisation holder / Contact persons / Company**

#### **2.4.1. Proposed marketing authorisation holder/person legally responsible for placing the product on the market in the European Union/each MS**

For MRP/DCP applications if the proposed marketing authorisation holder differs among Member State the fields can be duplicated in order to indicate more than one proposed marketing authorisation holder.

Proof of establishment of the applicant in EEA must be provided as Annex 5.3 and must have the same name and address (if mentioned) as in the application form.

In centralised procedure, if the applicant has SME status confirmed by the EMA, the copy of "Qualification of SME Status" should be included as Annex 5.7 and the EMA SME number should be indicated on the application form.

#### **2.4.2. Person/company authorised for communication on behalf of the applicant during the procedure in the European Union/each MS**

In mutual recognition and decentralized procedures, if more than one person/company is authorized for communication the related fields can be duplicated in order to indicate more than one person/company.

It is recommended to Applicants to have a contact person located in EEA/EFTA.

National competent authorities' business hours need to be preferably considered for contacts and exchanges.

In centralised procedure, only one contact person can be indicated. For MRP, DCP and national procedures all authorised contact persons should be included.

#### **2.4.3. Person/company authorised for communication between the marketing authorisation holder and the competent authorities after authorisation if different from 2.4.2 in European Union/each MS**

In mutual recognition and decentralised procedures, if more than one person/company is authorized for communication the related fields can be duplicated in order to indicate more than one person/company.

In centralised procedure, only one contact person can be indicated.

#### **2.4.4. Summary of the applicant pharmacovigilance system**

In mutual recognition and decentralised procedures, if more than one Qualified person in the EEA for Pharmacovigilance is assigned and/or for different Member States, related fields can be duplicated in order to indicate more than one Qualified person and/or different Member States.

In centralised procedure, only one qualified person can be indicated.

For the Pharmacovigilance system master file, it should be indicated if its location has been registered in Article 57 data base (box to be ticked).

#### **2.4.5. Scientific service of the MAH in the EEA as referred to in Article 98 of Directive 2001/83/EC (for DCP, MRP and national applications, the contact person in the country where the application is made)**

According to Article 98 of Directive 2001/83/EC the marketing authorisation holder shall establish, within his undertaking, a scientific service in charge of information about the medicinal products which he places on the market. Differences in establishing within MAH undertaking, a scientific service are acceptable among Member States, in line with national rules in force.

In centralised procedure a single contact person should be indicated for the scientific service.

### **2.5. Manufacturers**

For each company two "addresses" are described: Address 1 field to enter building name/number or street and Address 2 field to enter city/town.

For manufactures there are two options:

- Option # 1:- The administrative address and manufacture address are the same;
- Option # 2:- The administrative address and manufacture address are different: In this case administrative and manufacturing facility address fields are separate.

*Note: ALL manufacturing and control sites mentioned throughout the whole dossier (~~ANNEX 5.8~~, in Module 3.2S, Module 3.2.P, Module 1.2 (section 2.5 of the Application form ~~section 2.5~~ and annex 5.8) and in the Product Information) MUST be consistent regarding their names, detailed addresses and activities. Sites should not be included in one part of the dossier and left out in another for the reason of their activity. Data synchronisation has to be kept throughout the whole procedure.*

For manufacturing sites in section 2.5 of the application form, it is recommended to enter the EUDRA GMDP document reference number, if it exists, instead of attaching the GMP certificate in Annex 5.9. Similarly, it is recommended to enter the EUDRA GMDP document reference number, if it exists, instead of attaching a copy of the manufacturing authorisation(s) or other proof of GMP compliance in ANNEX 5.6.

**2.5.1. a. Authorised manufacturer(s) (or importer(s)) responsible for batch release in the EEA in accordance with Article 40 and Article 51 of Directive 2001/83/EC (as shown in the package leaflet and where applicable in the labelling or Annex II of the Commission Decision):**

Several Authorised Manufacturers can be included, if necessary. The manufacturer country field has a dropdown to select each one, based on a controlled list of countries.

**2.5.1. b. Official batch release for Blood products and Vaccines**

Details of the Official Medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official batch release (in accordance with Articles 111(1), 113, 114(1)-(2) and 115 of Directive 2001/83/EC as amended).

The laboratory country field has a dropdown based on a controlled list of countries (only site(s) in the EEA).

The address, phone number and e-mail of the relevant functional office including the international area codes should be included.

**2.5.1.1. Contact person in the EEA for product defects and recalls**

For 24 H Telephone field, the phone number of the relevant functional office including the international area codes should be included.

Only one contact person per marketing authorisation should be indicated.

**2.5.1.2. Batch control/Testing arrangements**

Unless a MRA or other Community arrangement is in operation with the third country concerned, applicants are reminded that each production batch has to undergo all the controls required by Article 51 of Directive 2001/83/EC as amended, in the EEA.

A brief description of control tests carried out by the laboratory(ies) concerned should be selected from the dropdown field based on a controlled dictionary (e.g., Quality control testing - Biological, Quality control testing Chemical/Physical, ...).

The functions must be selected from the check boxes. The free text field should only be used for additional explanations in exceptional case.

Search Criteria for Manufacturing Activity.

### **2.5.2. Manufacturer(s) of the medicinal product and site(s) of manufacture:**

*(Note: including manufacturing sites of any diluents / solvent presented in a separate container but forming part of the medicinal product, quality control/ in-process testing sites, immediate and outer packaging and importer(s). For each site provide the relevant information.)*

Sites mentioned in sections 2.5.1 and 2.5.1.2 should only be repeated here when they have an additional function in the manufacturing of the medicinal product.

A brief description of functions performed for each manufacturer(s) concerned is available in the dropdown field based on a controlled dictionary (e.g., Primary packaging, quality control testing, Processing of medicinal product, etc.). In case a manufacturer already present in 2.5.1.2 is repeated here, do not repeat the functions for this manufacturer in this section.

The functions must be selected from the check boxes. The free text field should only be used for additional explanations in exceptional case.

The term "Processing of medicinal product" covers the manufacture of the finished product. "This terminology is based on the agreed terms used in the EU format for MIAs and GMP certificates included in the Compilation of Community Procedures on Inspections and Exchange of Information.

*Note. More information about the functions performed is available at <http://spor.ema.europa.eu/rmswi/#/>*

### **2.5.3. Manufacturer(s) of the active substance(s) and site(s) of manufacture**

*Note: All manufacturing sites involved the manufacturing process of each source of active substance, including quality control/ in-process testing sites, should be listed. Broker or supplier details alone are not acceptable. For biotech products include all sites of storage of master and working cell bank and preparation of working cell banks when relevant.*

For each site provide the relevant information.

The selection for Active Substance are populated from previous sections (please refer to the administrative data in the user guide). The full name of the active substance(s) has (have) to be indicated in line with section 2.6.1.

A brief description of **manufacturing steps performed by manufacturing site** for each manufacturer(s) concerned is available in the dropdown field based on a controlled dictionary (e.g., Manufacture of active substance, Manufacture of active substance intermediate, Packaging of active substance, etc.)

The functions must be selected from the check boxes. The free text field should only be used for additional explanations in exceptional case.

Note: More information about the manufacturing steps performed is available on <http://spor.ema.europa.eu/rmswi/#/>

Note: When other procedures selected in Section 1 – both free text field and dropdown field will be visible and either one is mandatory.

Several items are included on the e-Application Form and should be selected based on the following criteria:

**Item # 1: GMP inspection evidence from EEA or state with MRA etc.**

Indicate if the site has been inspected for GMP compliance by an EEA authority or by an authority of countries where MRA or other European Union arrangements apply within the terms of agreement.

In case of YES attach latest GMP certificate or other proof of GMP compliance in annex 5.9 or enter the Eudra GMDP document reference number.

**Item # 2: other GMP inspection evidence**

In case of YES provide summary information in Annex 5.9.

**Item # 3: CEP**

Indicate if a Ph. Eur. Certificate of suitability has been issued for the active substance(s):

In case of YES, provide the Name of the CEP holder, the Name of all manufacturers if different from the above, the CEP number and the date of the last update. Provide copy of certificate in Annex 5.10.

**Item # 4: ASMF**

Indicate if an Active Substance Master File has been used for the active substance(s).

In case of YES, complete the information required and attach letter of access for European Union/Member State authorities where the application is submitted (see "European ASMF procedure for active ingredients") (Annex 5.10).

In case of modification of the manufacturing process or specifications according to Annex 1 of Directive 2001/83/EC attach copy of confirmation from the manufacturer of the active substance to inform the applicant.

**Item # 5 VAMF**

Indicate if an EMA certificate for a Vaccine Antigen Master File (VAMF) has been issued or submitted in accordance with Directive 2001/83/EC Annex I, Part III. In case of YES, complete the information required and provide a copy of the certificate in Annex 5.9.

**2.5.4. Contract companies used for all clinical trial(s) (including bioavailability and bioequivalence trials) included in the application or used for the validation of blood product manufacturing processes. For each contract company state where analytical tests are performed and where clinical data are collected**

This section should specify all clinical trials and is not restricted only to clinical trials on bioavailability.

**Duty performed according to contract:** a brief description of the duty performed according to the contract should be given.

For each contract company, clearly indicate where analytical tests are performed and where clinical data are collected. The subsections should be duplicated, if necessary.

## **2.6. Qualitative and quantitative composition**

### **2.6.1. Qualitative and Quantitative composition in terms of the active substance(s) and the excipient(s)**

The Qualitative and quantitative composition in terms of the active substance(s) and the excipient(s) should be consistent with the composition presented in Module 3.2.P.1

The presentation of the composition should take account of the recommendations of the QRD Recommendations on the expression of strength in the name of centrally authorised human medicinal products (as stated in section 1 of SmPC, and in the name section of labelling and PL) [EMA/707229/2009],

[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Regulatory\\_and\\_procedural\\_guideline/2010/01/WC500056428.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2010/01/WC500056428.pdf)

In some cases an interval of values could be indicated in "Quantity/Unit" fields, for example, in the case of radiopharmaceutical products, or for some excipients used "q.s.p." for a pH. Under "reference/monograph standard" the current Ph.Eur reference should be indicated. Where no Ph Eur monograph exists, reference to a monograph of a national pharmacopeia, an in-house monograph, or monograph of a third country pharmacopeia can be included.

For liquid formulations with strength expression as total content (e.g. 12 mg), the liquid volume and the concentration of active substance(s) per 1 ml should also be given in the free text comment box (e.g. 5 ml, 2.5 mg/ml).

The active substance should be indicated as a full substance; if the substance is included in the product as salt or hydrate, the corresponding base/active moiety should be indicated in the additional field.

Name of the active substance should be based on the following order priority: INN, European Pharmacopoeia, National Pharmacopoeia, common name or scientific name.

### **2.6.2. List of materials of animal and/or human origin contained or used in the manufacturing process of the medicinal product?**

If a substance is listed, it should be clear that if no Certificate of suitability for TSE is available, appropriate data should be included in relevant sections of the dossier (3.2.A.2, 3.2.S.2.3 or 3.2.P.4.5).

### **2.6.3. Is an EMA certificate for a Plasma Master File (PMF) issued or submitted in accordance with Directive 2001/83/EC Annex I, Part III, being used for this MAA?**

### **2.6.4. Does the medicinal product contain or consist of Genetically Modified Organisms (GMOs) within the meaning of Directive 2001/18/EC?**

## **3. Scientific Advice**

### **3.1. Was there formal scientific advice(s) given by EMA for this medicinal product?**

***Was there scientific advice(s) given by Member State(s) for this medicinal product?***



These sections may be replicated when needed.

## **4. Other Marketing Authorisation Applications**

**4.1. For National / MRP / DCP applications, please complete the following in accordance with Article 8(j)-(l) of Directive 2001/83/EC**

**4.1.1. Is there another Member State(s) where an application for the same\* product is pending\*\*?**

If yes, section 4.2 must be completed.

**4.1.2. Is there another Member State(s) where an authorisation is granted for the same product?**

Where differences are identified by the applicant concerning authorisations granted in other Member States through a national procedure /MRP/ DCP, the applicant should explain clearly if different therapeutic indications have been granted in those Member States and on which grounds.

**4.1.3. Is there another Member State(s) where an authorisation was refused/suspended/ revoked by competent authorities for the same product?**

If yes, section 4.2 must be completed.

\* "same product" means same qualitative and quantitative composition in active substance(s) and having the same pharmaceutical form from applicants belonging to the same mother company or group of companies OR which are "licensees".

\*\* This is covering applications submitted at an earlier time or in parallel to this application if not already listed under 1.1.2 or 1.1.3.

### **4.2. Marketing authorisation applications for the same product in the EEA**

(Same qualitative and quantitative composition in active substance(s) and having the same pharmaceutical form from Applicants belonging to the same mother company or group of companies or which are "Licensees").

*Note: refer to Commission Communication 98/C229/03.*

For each case (authorised, pending, refused, withdrawn, suspended or revoked), all the information should be linked to one country and the whole section could be duplicated. This whole section 4.2 should be updated by the applicant as soon as a change occurs during the procedure.

In case of refusal, withdrawal by the Applicant, suspension or revocation by a Competent Authority, the reason for refusal, withdrawal, suspension or revocation should be clearly specified.

### **4.3. For multiple / duplicate applications of the same medicinal product**

Multiple / duplicate applications (submitted simultaneously or subsequently to the original product) for:

All the information should be linked to one duplicate and the whole section should be replicated for each duplicate application.

A copy of letter from Commission services is required for validation in the centralised procedure.

*Moreover, in case of parallel multiple applications, the applicant is requested to use the same legal basis as for the original authorisation application.*

#### **4.4. Marketing authorisation applications for the same product outside the EEA**

(i.e. from applicants belonging to the same mother company or group of companies or which are "licensees". Same qualitative and quantitative composition in active substance(s) and having the same pharmaceutical form).

*Note: refer to Commission Communication 98/C229/03.*

For each case (authorised, pending, refused, withdrawn, suspended or revoked) all the information should be linked to one country and the whole section could be duplicated. In case of refusal, withdrawal, suspension or revocation, the reason for each case should be clearly specified.

### **5. Annexed documents (where appropriate)**

All annexes provided should be identified by the correct identification number.