EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health Systems and products

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Brussels,
(2015)

Revision 12

NOTICE TO APPLICANTS

Medicinal Products for Human Use

VOLUME 2B
Module 1.2: Administrative information
Application form

September 2015

This application form will be included in:

The Rules governing Medicinal Products in the European Union
The Notice to Applicants - Volume 2B - Common Technical Document - Module1 - Administrative information

To be noted:
Mandatory use of electronic Application Forms for Centralised Procedure that explains parts in light grey. As from 01/01/2016, mandatory use of electronic application forms for all procedures

Revision 12
Update from September 2015 of section 1.4.1; taking into account the review of chapter 1 of July 2015.

[1] OJ L 299 of 27.10.2012, p. 1

TABLE OF CONTENTS

APPLICATION FORM

SUMMARY OF THE DOSSIER

APPLICATION FORM : ADMINISTRATIVE DATA

The application form is to be used for an application for a marketing authorisation of a medicinal product for human use submitted to (a) the European Medicines Agency under the centralised procedure or (b) a Member State (as well as Iceland, Liechtenstein and Norway) under either a national, mutual recognition procedure or decentralised procedure.

Usually a separate application form for each strength and pharmaceutical form is required.
For centralised procedures a combined application form is acceptable (information on each pharmaceutical form and strength should be provided successively, where appropriate).

DECLARATION AND SIGNATURE

Product (invented) name

+ -

Pharmaceutical Form:

+ -

Strength:

Units

+ -

Active Substance(s):

Add Active Substance(s)

Populate data in sections 2.1.2, 2.2.1 and 2.6.1

Applicant

Title

First Name

Surname

Address 1

Address 2

Postcode

Country

Telephone

Telefax

E-mail

Person authorised for communication*, on behalf of the Applicant:

Title

First name

Surname

It is hereby confirmed that all existing data which are relevant to the quality, safety and efficacy of the medicinal product have been supplied in the dossier, as appropriate and that such data are not subject to regulatory data exclusivity in the Union.

It is hereby confirmed that fees will be paid/have been paid according to the national/European Union rules**.

On behalf of the applicant

Copy contact details from previous section

Title

First name*

Surname

Function

Address 1

Address 2

Postcode

Country

Telephone

Telefax

E-mail

Date

Signatory

* ☐ *Note: please attach letter of authorisation for communication/signing on behalf of the applicant in (Annex 5.4)*

** ☐ *Note: if fees have been paid, attach proof of payment in (Annex 5.1) - see information on fee payments on EMA/CMDh website.*

1. TYPE OF APPLICATION

Note: The following sections should be completed where appropriate.

1.1 THIS APPLICATION CONCERNS

◯ 1.1.1 A CENTRALISED PROCEDURE

(according to Regulation (EC) No 726/2004)

◯ 1.1.2 A MUTUAL RECOGNITION PROCEDURE

(according toArticle 28(2) of Directive 2001/83/EC)

◯ 1.1.3 A DECENTRALISED PROCEDURE

(according to Article 28(3) of Directives 2001/83/EC)

◯ 1.1.4 A NATIONAL PROCEDURE

1.2 ORPHAN MEDICINAL PRODUCT DESIGNATION

1.2.1 HAS ORPHAN DESIGNATION BEEN APPLIED FOR THIS MEDICINAL PRODUCT?

◯ Yes ◯ No

+ -

Orphan designation procedure number:

◯ Pending

◯ Orphan Designation Granted

Date:

Based on the criterion of "significant benefit":

◯ Yes ◯ No

Number in the Community Register of Orphan Medicinal Products:

☐ Attach copy of the Designation Decision (Annex 5.18)

◯ Orphan DesignationRefused

Date:

Commission decision reference number:

◯ Orphan DesignationWithdrawn

Date:

1.2.2 INFORMATION RELATING TO ORPHAN MARKET EXCLUSIVITY
Has any medicinal product been designated as an Orphan medicinal product for a condition relating to the indication proposed in this application?

◯ Yes ◯ No

Please specify the EU Orphan Designation Number: + -

Has any of the designated orphan medicinal product(s) been granted a marketing authorisation in the EU?

◯ Yes ◯ No

Please specify:

+ -

Therapeutic indication(s) + -

Product (invented) name

Pharmaceutical form(s) + -

+ -

Strength(s)	Marketing authorisation holder	Marketing authorisation number	Date of authorisation

Is the medicinal product, subject of this application, considered as "similar" to any of the authorised orphan medicinal product(s)?*(as defined in Article 3 of commission regulation (EC) no 847/2000)*

◯ Yes(modules 1.7.1 and 1.7.2 to be completed) ◯ No(module 1.7.1 to be completed)

1.3 APPLICATION FOR A CHANGE TO EXISTING MARKETING AUTHORISATION LEADING TO AN EXTENSION AS REFERRED TO IN ANNEX I OF REGULATIONS (EC) NO 1234/2008, OR ANY NATIONAL LEGISLATION , WHERE APPLICABLE?

◯ Yes*(complete sections belowand also complete 1.4 + 1.6)* ◯ No*(complete section 1.4 + 1.6)*

1.3.1 ◯ Please specify:

☐ Qualitative change in declared active substancenot defined as a new active substance

☐ Change of bioavailability

☐ Change of 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

Note:
- the applicant of the present application must bethe same as the marketing authorisation holder of the existing marketing authorisation
- this section should be completed without prejudice to the provisions of Articles 8(3), 10.1, 10a, 10b, 10c, and Directive 2001/83/EC

1.3.2 ◯ « Article 29 application » (Article 29 of Regulation (EC) No 1901/2006)

For existing marketing authorisation in the European Union/Member State where the application is made:

+	-

Product (invented) name

Pharmaceutical form(s) + -

Strength(s)	Marketing authorisation holder	Marketing authorisation number	Date of authorisation	+ -

1.4 APPLICATION IS SUBMITTED IN ACCORDANCE WITH THE FOLLOWING ARTICLE IN DIRECTIVE 2001/83/EC[2]

Note: Section to be completed for any application, including applications referred to in section 1.3
For further details, refer to Notice of Applicants, Volume 2A, Chapter 1

1.4.1 ◯ Article 8(3) application, (i.e dossier with administrative, quality, pre-clinical and clinical data*)

1.4.2 ☒ Article 10(1) generic application

Note: . application for a generic medicinal product as defined in Article 10(2)(b) referring to a so-called reference medicinal product with a marketing authorisation granted in a Member State or in the Community.
. complete administrative and quality data, appropriate pre-clinical and clinical data when applicable.
. refer to Notice to Applicants, Volume 2A, Chapter 1.

Reference medicinal product:

Note: The chosen reference medicinal product must be a medicinal product authorised in the Union on the basis of a complete dossier in accordance with the provisions of the Article 8 of Directive 2001/83/EC.

■ **Medicinal product which is or has been authorised in accordance with Union provisions in force for not less than 6/10 years in the EEA:**

+	-

Product (invented) name

Pharmaceutical form(s) + -

Strength(s)	Marketing authorisation holder	Marketing authorisation number	Date of authorisation	+ -

Marketing authorisation granted by

☐ Union

☐ Member State(EEA)

Note: This section defines the reference medicinal product chosen for the purposes of establishing the expiry of the data protection period.

- **Medicinal product authorised in the Union / Member State where the application is made or European reference medicinal product:**

+ -

Member State(s) + -

Product (invented) name

Pharmaceutical form(s) + -

Strength(s)	Marketing authorisation holder	Marketing authorisation number	Date of authorisation

+ -

Marketing authorisation granted by

☐ Union

☐ Member State(EEA)

- **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:**

Note: Should be in accordance with the notion of global marketing authorisation, if different from the medicinal product identified above..

+ -

Product (invented) name

Pharmaceutical form(s) + -

Strength(s)	Marketing authorisation holder	Marketing authorisation number	Date of authorisation

+ -

Member State of source

Bioavailabilty study(ies) reference number(s)/EudraCT numbers(s): + -

Marketing authorisation granted by

☐ Union

☐ Member State(EEA)

Note: Section to be duplicated for each product used for the demonstration of bioequivalence.

1.4.3 ☐ Article 10(3) hybrid application

1.4.4 ◯ Article 10(4) similar biological application

1.4.5 ◯ Article 10a well-established use application

Note: For further details, refer to Notice to Applicants, Volume 2A, Chapter 1.
For extensions of bibliographical applications, cross references can only be made to pre-clinical and clinical data

1.4.6 ◯ Article 10b fixed combination application

Note: Complete administrative and complete quality, pre-clinical and clinical data on the combination only; for further details refer to Notice of Applicants, Volume 2A, Chapter 1.
For extensions of fixed combination applications, cross references can only be made to pre-clinical andclinicaldata

1.4.7 ◯ Article 10c informed consent application

Note: - Application for a medicinal product possessing the same qualitative and quantitative composition in terms of active substances and the same pharmaceutical form of an authorised product where consent has been given by the existing marketing authorisation holder to use their data in support of this application
- Complete administrative data should be provided with consent to pharmaceutical, preclinical and clinical data
- The authorised product and the informed consent application can have the same or different MAH

1.4.8 ◯ Article 16a Traditional use registration for herbal medicinal product

Note: Complete application
Refer to Notice to Applicants, Volume 2A, Chapter 1

1.5 CONSIDERATION OF THIS APPLICATION REQUESTED UNDER THE FOLLOWING ARTICLE DIRECTIVE 2001/83/EC OR REGULATION (EC) NO 726/2004[3]

1.5.1 ◯ Conditional Approval

Note: centralised procedure only according to Article 14(7) of Regulation (EC) No 726/2004 and Commission Regulation (EC) No 507/2006

1.5.2 ◯ Exceptional Circumstances

Note: According to Article 22 of Directive 2001/83/EC and Article 14(8) of Regulation (EC) No 726/2004

1.5.3 ☐ Accelerated Review

Note: Centralised procedure only according to Article 14(9) of Regulation (EC) No 726/2004

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)

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

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

1.6 REQUIREMENTS ACCORDING TO REGULATION (EC) No 1901/2006 ('PAEDIATRIC REGULATION')

☐ Sections 1.6.1, 1.6.2 and 1.6.3 not applicable for well-established use, generic, hybrid and bio-similar applications and traditional herbal medicinal products

1.6.1 Does the same[3] applicant hold other marketing authorisation(s) for a medicinal product(s) containing the same active substance(s) in the EEA?

(Note: The notion of 'global marketing authorisation' as stated in Article 6(1) 2nd subparagraph of Directive 2001/83/EC. as amended, should be taken into account for products belonging to the same marketing authorisation holder.
Specific considerations apply if the same active substance is used for the purpose of an orphan and a non-orphan product)

◯ Yes ◯ No (Article 7 of Paediatric Regulation applies) Please complete section 1.6.3

+ -

+ e Substance

- 6

Product (invented) name

Pharmaceutical form(s) + -

+ -

Strength(s) | Marketing authorisation holder | Marketing authorisation number | Date of authorisation

Member State/European Union where product is authorised:

Is the product(s) protected by:

a) a Supplementary Protection Certificate (SPC) -under Regulation (EC) No 469/2009? ◯ Yes ◯ No

b) a patent qualifying for an SPC? ◯ Yes ◯ No

3 "Same" applicant/marketing authorisation holder: as per the Commission Communication (98/C 299/03) (i.e. belonging to the same mother company or group of companies or which are "licensees")

1.6.2 DOES THIS APPLICATION RELATE TO A NEW INDICATION, NEW PHARMACEUTICAL FORM OR NEW ROUTE OF ADMINISTRATION

◯ Yes (Article 8 Paediatric Regulation applies) Please, complete section 1.6.3

◯ No

1.6.3 THIS APPLICATION INCLUDES:

☐ PIP Decision Number[4]		+	-
☐ Product-Specific Waiver Decision Number[5]		+	-
Class Waiver Decision Number		+	-

(Note: a copy of the PIP/Product-Specific Waiver decision, including the Paediatric Committee (PDCO) opinion and the Summary Report, is to be included in Module 1.10)

4 To be ticked when the PIP Opinion includes a waiver

5 To be ticked only if there is a product-specific waiver opinion covering all the subsets of the paediatric population

1.6.4 ☐ ARTICLE 30 (PUMA) OF THE PAEDIATRIC REGULATION APPLIES TO THIS APPLICATION:

(Note: Also applies to Extension applications of PUMA)

1.6.5 HAS THIS APPLICATION BEEN SUBJECT TO PIP COMPLIANCE VERIFICATION?

◯ Yes ◯ No ◯ Not Applicable

If, yes, please specify

The compliance document reference(s)	+	-

(Note: if available a copy of the PDCOcompliance report with, where applicable, the PDCO opinion or the document issued by the national competent authority is to be included in Module 1.10)

Please identify any parallel, ongoing or previous variation(s) or extension(s) containing paediatric data relevant for the full PIP compliance verification, if applicable:

Procedure-number		+	-

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/ Liechtenstein /Norway:

(Value populated from the "Declaration" section.)

☐ If different (invented) names in different Member States are proposed in a mutual recognition or decentralised procedure, these should be listed in (Annex 5.19)

2.1.2 Name of the active substance(s)

Note: Only one name should be given in the following order of priority: INN, Ph.Eur., National Pharmacopeia, common name, scientific name;*
** The active substance should be declared by its recommended INN, accompanied by its salt or hydrate form if relevant (for further details, consult the Guideline on the SPC)*

(The value of the active substances field has been populated from "Declaration" section.)

+ e Substance
- 6

2.1.3 Pharmacotherapeutic group (Please use current ATC code)

ATC code 6 + -

Group

☐ If no ATC code has been assigned, please indicate if an application for ATC code has been made

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 Pharmacopoeia)

(The values of the following fields have been populated from "Declaration" section.)

+ -

Pharmaceutical Form:

+ -

Strength: Units + -

Active Substance(s):

Add Active Substance(s)

2.2.2 Route(s) of administration (use current list of standard terms - European Pharmacopoeia)

+ -

Route of Administration 6

2.2.3 ~~Container, closure and administration device(s), including description of material from which it is constructed.~~ (use current list of standard terms - European Pharmacopoeia)

+ -

For each type of pack give:

2.2.3.1 Package size + -

Note: For mutual recognition and decentralised procedures, all package sizes authorised in the Reference Member State should be listed

Description

For each container give: + -

+ -

Container

Material

Closure

Administration Device

+ -

2.2.3.2 Proposed shelf life

2.2.3.3 Proposed shelf life (after first opening container)

2.2.3.4 Proposed shelf life (after reconstitution or dilution)

2.2.3.5 Proposed storage conditions + -

2.2.3.6 Proposed storage conditions after first opening + -

☐ Attach a list of Mock-ups or Samples/specimens sent with the application, as appropriate (see EMA/CMDh websites) (Annex 5.17)

2.2.4 The medical product incorporates, as an integral part, one or more medical devices within the meaning of Article 1(2)(a) of Directive 93/42/EEC or one or more active implantable medical devices within the meaning of Article 1(2)(c) of Directive 90/385/EEC

☐ Yes

2.3 LEGAL STATUS

2.3.1 Proposed dispensing/classification

(Classification under Article 1(19) of Directive 2001/83/EC)

☐ Subject to medical prescription*(Complete 2.3.2)*

+ -

European Union/Member States(s) + -

☐ Not subject to medical prescription *(Complete 2.3.3 & 2.3.4)*

+ -

European Union/Member States(s) + -

2.3.2 For products subject to medicinal prescription

☐ Product on prescription which may be renewed (if applicable)

Member State(s) + -

☐ Product on prescription which may not be renewed (if applicable)

Member State(s) + -

☐ Product on special prescription*

Member State(s) + -

☐ Product on restricted prescription*

Member State(s) + -

(Not all the listed options are available in each member state. Applicants are invited to indicate which categories they are requesting, however, the Member States reserve the right to apply only those categories provided for in their national legislation)
*Note: *For further information, please refer to Article 71 of Directive 2001/83/EC*

2.3.3 Supply for products not subject to medical prescription

☐ Supply through pharmacies only

Member State(s) + -

☐ Supply through non-pharmacy outlets and pharmacies (if applicable)

Member State(s) + -

2.3.4 Promotion for products not subject to medical prescription

☐ Promotion to health care professionals only

Member State(s) + -

☐ Promotion to general public and health care professionals

Member State(s) + -

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

○ Centralised procedure ○ National procedure including mutual recognition/decentralised procedure

+ -

Copy contact details from Declaration Section

Member State(s) + -

Company name

Address 1

Address 2

Postcode

Country

Telephone

Telefax

E-mail

Contact person at this address

Title

First name

Surname

☐ Attach proof of establishment of the applicant/MAH in the EEA (Annex 5.3)

Has SME status been assigned by the EMA?

○ Yes ○ No

EMA-SME Number

Date of expiry

☐ Attach copy of the "Qualification of SME Status" (Annex 5.7)

Proof of payment (when relevant)

Have all relevant fees been prepaid to competent authorities?

+ -

○ Yes (for fees paid, attach proof of payment in) (Annex 5.1)

○ No

For Member State(s) + -

Copy address from above address details

+ -

For Member State(s) + -

Billing address (when relevant)

Company name

VAT number

Address 1

Address 2

Postcode

Country

Telephone

Telefax

E-mail

Purchase order(PO) number

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

Copy contact details from 2.4.1 Section

Copy contact details from Declaration Section

+ -

Member State(s) + -

The below applicant details relates to all member states selected, if the applicant details are different for each member states then please repeat section.

+ -

Title

First name

Surname

Company name

Address 1

Address 2

Postcode

Country

Telephone

Telefax

E-mail

☐ If different to 2.4.1 above, attach letter of authorisation (Annex 5.4)

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

Copy contact details from 2.4.1 Section

Copy contact details from Declaration Section

+ -

Member State(s) + -

The below applicant details relates to all member states selected, if the applicant details are different for each member states then please repeat section.

+ -

Title

First name

Surname

Company name

Address 1

Address 2

Postcode

Country

Telephone

Telefax

E-mail

☐ If different to 2.4.1 above, attach letter of authorisation (Annex 5.4)

2.4.4 Summary of the applicant pharmacovigilance system

Qualified person in the EEA for Pharmacovigilance

Copy contact details from 2.4.2 Section

+ -

Member State(s) + -

Title

First name

Surname

Company name

Address 1

Address 2

Postcode

Country

Telephone

Telefax

E-mail

☐ The above-mentioned qualified person resides[6] and operates in the EEA

☐ The qualified person is registered with Eudravigilance

Copy contact details from 2.4.2 Section

Pharmacovigilance system master file

Number

Address 1

Address 2

Postcode

Country

Note: For Risk Management Plan, see module 1, 1.8.2

[6]For the purposes of this application form, a Qualified Person Responsible for Pharmacovigilance "resides" in the place where he/she makes his /her home, where he/she lives, can be traced, located, identified for all legal and contractual obligations, whether or not it is owned by him/her or he/she is permanently dwelling there.

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)

+ -

European Union/Member State(s) where application is made + -

Name of the contact person

Title

First name

Surname

Company name

Address 1

Address 2

Postcode

Country

Telephone

Telefax

E-mail

2.5 MANUFACTURERS

Note: ALL manufacturing and control sites mentioned throughout the whole dossier MUST be consistent regarding their names, detailed addresses and activities.

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):

+ -

Do you have aseparate admin and manufacturer address? ○ Yes ○ No

Company name

Admin Office Address 1

Admin Office Address 2

Postcode

Admin Office Country

Admin Office Telephone

Admin Office Telefax

Admin Office E-mail

+ -

Company name

Manufacturer Facility Address 1

Manufacturer Facility Address 2

Postcode

Manufacturer Facility Country

Manufacturer Facility Telephone

Manufacturer Facility Telefax

Manufacturer Facility E-mail

Manufacturing Authorisation number

☐ Attach copy of manufacturing authorisation(s) (Annex 5.6)

Or

☐ Enter EudraGMP manufacturing authorisation reference

If available

☐ Attach latest GMP certificate (Annex 5.9)

Or

☐ Enter EudraGMP certificate reference number

2.5.1 b Official batch releasefor 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)

+

-

Laboratory name

Address 1

Address 2

Postcode

Country

Telephone

Telefax

E-mail

2.5.1.1 Contact person in the EEA for product defects and recalls

+ -

Company name

Title

First name

Surname

Address 1

Address 2

Postcode

Country

Telephone

Telefax

E-mail

2.5.1.2 Batch control Testing arrangements

Site(s) in the EEA or in countries where an MRA or other European Union arrangements apply, where batch control testing takes place as required by Article 51 of Directive 2001/83/EC:

+ -

Company name

Address 1

Address 2

Postcode

Country

Telephone

Telefax

E-mail

Brief description of control tests carried out by the laboratory(ies) concerned
(note: please see the 'Compilation of Union Procedures on Inspections and Exchange of Information' document, (see pages - Interpretation of the Union Format for Manufacturer/Importer Authorisation):http://www.ema.europa.eu/docs/en_GB /document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706.pdf

+ -

☐ Attach copy of manufacturing authorisation(s) or other proof of GMP compliance (Annex 5.6)

Or

☐ Enter EudraGMP manufacturing authorisation reference

2.5.2 Manufacturer(s) of the medicinal product and site(s) of manufacture:
(Note: including manufacturing sites of any diluent/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.)

Copy contact details from 2.5.1.a

+ -

Do you have aseparate admin and manufacturer address? ○ Yes ○ No

Company name

Admin Office Address 1

Admin Office Address 2

Postcode

Admin Office Country

Admin Office Telephone

Admin Office Telefax

Admin Office E-mail

+ -

Company name

Manufacturer Facility Address 1

Manufacturer Facility Address 2

Postcode

Manufacturer Facility Country

Manufacturer Facility Telephone

Manufacturer Facility Telefax

Manufacturer Facility E-mail

Brief description of functions performed:
(note: please see the 'Compilation of Union Procedures on Inspections and Exchange of Information' document, (see pages - Interpretation of the Union Format for Manufacturer/Importer Authorisation):http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706.pdf

+ -

○ Site(s) is in the EEA: ○ Site(s) is outside the EEA:

+ -

Manufacturing authorisation number

☐ Attach copy of manufacturing authorisation(s) (Annex 5.6)

Or

Enter EudraGMP Manufacturing Authorisation reference

Name of qualified person

(if not mentioned in manufacturing authorisation)

☐ Attach flow chart indicating the sequence and activities of the different sites involved in the manufacturing process, including testing sites (Annex 5.8)

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.

Copy contact details from 2.5.1.a

Copy contact details from Declaration Section

\+ -

(The values of the active substances field has been populated from "Declaration" section, hence no search button available. Please click the drop down button to see the list).

\+ e Substance

\-

Do you have aseparate admin and manufacturer address? ○ Yes ○ No

Company name	
Admin Office Address 1	
Admin Office Address 2	
Postcode	
Admin Office Country	
Admin Office Telephone	
Admin Office Telefax	
Admin Office E-mail	

\+ -

Company name	
Manufacturer Facility Address 1	
Manufacturer Facility Address 2	
Postcode	
Manufacturer Facility Country	
Manufacturer Facility Telephone	
Manufacturer Facility Telefax	
Manufacturer Facility E-mail	

Brief description of manufacturing steps performed by manufacturing site:
(note: please see the 'Compilation of Union Procedures on Inspections and Exchange of Information' document, (see pages - Interpretation of the Union Format for Manufacturer/Importer Authorisation):http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706.pdf

\+ -

☐ Attach flow-chart indicating the sequence and activities of the different sites involved in the manufacturing process, including batch control sites (Annex 5.8)

☐ For each active substance, attach a Qualified Person declaration that the active substance is manufactured in compliance with theprinciples and guidelines on good manufacturing practice for starting materials (Annex 5.22)

Has the site 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?

○ Yes ○ No

Please

☐ Attach latest GMP certificate in (Annex 5.9)

Or

EudraGMP certificate reference number

Has the site been inspected for GMP compliance by any other authority (including those of countries where MRA or other European Union arrangements apply but not within their respective territory)?

○ Yes ○ No

☐ If yes, please provide summary information in (Annex 5.9) (and, if available a GMP certificate or a statement from the competent authority which carried out the inspection)

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

○ Yes ○ No

Name of the CEP holder

Name of the manufacturer if different from the above

CEP number

Date of last update

☐ Provide copy in (Annex 5.10)

Is a Active Substance Master File to be used for the active substance(s)

○ Yes ○ No

+ -

Name of the ASMF holder

Name of the manufacturerif different from above

EU ASMF reference number if available

National ASMF reference number: (when applicable and only if EU ASMF reference number is not available)

Applicant part version number

Date of submission

Date of last update

☐ Attach letter of access for European Union/Member State authorities where the application is made (see "European ASMF procedure for active ingredients") (Annex 5.10)

☐ Attach copy of confirmation from the manufacturer of the active substance to inform the applicant in case of modification of the manufacturing process or specifications according to Annex 1 of Directive 2001/82/EC (Annex 5.11)

Is an EMA certificate for a Vaccine Antigen Master File (VAMF) issued or submitted in accordance with Directive 2001/83/EC Annex I, Part III, being used for this MAA?

○ Yes ○ No

+ -

+ e Substance

- 6

Name of the VAMF Certificate Holder / VAMF Applicant

Reference number of Application / Certificate

Date of submission (if pending)

Date of approval or last update (if approved)

☐ Provide copy in (Annex 5.20)

2.5.4 Contract companies used for clinical trial(s) on bioavailability or bioequivalence 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 and give:

Add Study

Delete Study

+ -

Title of study

Protocol code

EudraCT number

Add Company | Delete Company

Company name

Address 1

Address 2

Postcode

Country

Telephone

Telefax

E-mail

Duty performed according to contract

2.6 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

+ -

A note should be given as to which quantity the composition refers (e.g. 1 capsule)

Pharmaceutical Form

(The values of the pharmaceutical form, strength and active substances fields have been populated from "Declaration" section.)

+ -

Strength | Units + -

List the active substance(s) separately from the excipient(s)

+ -

+ Reference / Monograph Standard

- 0

Name of Excipient	Quantity / Unit

*Note: * Only one name of each substance should be given in the following order of priority: INN**, Ph.Eur., National Pharmacopoeia, common name, scientific name*
*** The active substance should be identified by its recommended INN, accompanied by its salt or hydrate form if relevant (for further details, consult the Guideline on the SPC)*

Details of any overages should not be included in the formulation columns but stated below:

	Active Substance Excipient	Overage	Overage

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

☐ NONE

or specify below:

Name

Function* ☐ AS ☐ EX ☐ R

☐ Animal Originsusceptible to TSE**

☐ Other Animal Origin

☐ Human Origin

☐ Certificate of suitability for TSE

TSE number

** AS=active substance, EX=excipient (incl. starting materials used in the manufacture of the active substance/excipient), R=reagent/ culture medium (incl. those used in the preparation of master and working cell banks)*
*** as defined in section 2 (scope) of the CHMP Note for Guidance*

☐ If a Ph. Eur. Certificate of suitability for TSE is available according to the Resolution AP/CSP(99)4 of the Council of Europe attach it in (Annex 5.12)

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?

○ Yes ○ No

☐ Provide copy in (Annex 5.21)

If yes, Enter Substance(s) referring to PMF:

Active substance

Function* ○ AS ○ EX ○ R

Name of the PMF certificate holder/PMF applicant

Reference number of application/certificate

Date of submission (if pending)

Date of approval or last update (if approved)

** AS=active substance, EX=excipient (incl. starting materials used in the manufacture of the active substance /excipient), R=reagent/culture medium (incl. those used in the preparation of master and working cell banks)*

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

○ Yes ○ No

If yes, does the product comply with Directive 2001/18/EC?

○ Yes ○ No

☐ Attach a copy of any written consent(s) of the competent authorities to the deliberate release into the environment of the GMOs for research and development purposes where provided for by Part B of the above-mentioned Directive (Annex 5.13)

3. SCIENTIFIC ADVICE

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

○ Yes ○ No

+ -

Reference(s) of the scientific advice(s)

Date

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

○ Yes ○ No

+ -

Member State

Date

Reference(s) of the scientific advice(s)

☐ Attach copy of scientific advice(s) (Annex 5.14)

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

*Note: * "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 Communications 98/C229/03

☐ Authorised

☐ Submitted (which are not considered as a multiple/duplicate application - see Section 4.3)

+	-
Country	
Date of submission	
Procedure number for MRP/DCP (if applicable)	

☐ Refused

+	-
Country	
Date of refusal	
Procedure number for MRP/DCP (if applicable)	
Reason for refusal	

☐ Withdrawn (by applicant before authorisation)

☐ Withdrawn (by applicant after authorisation)

☐ Suspended/revoked (by competent authority)

4.3 FOR MULTIPLE / DUPLICATE APPLICATIONS OF THE SAME MEDICINAL PRODUCT

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

+	-
Name of other product	
Date of application(s)	
Applicant	
Procedure number for MRP/DCP (if applicable)	

☐ Attach copy of letter from Commission services, for centralised procedures only (Annex 5.16)

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 THE ACTIVE SUBSTANCE(S) AND HAVING THE SAME PHARMACEUTICAL FORM).

☐ Authorised

☐ Pending

☐ Refused

☐ Withdrawn (by applicant before authorisation)

☐ Withdrawn (by applicant after authorisation)

☐ Suspended/revoked (by competent authority)

5. ANNEXED DOCUMENTS (WHERE APPROPRIATE)

☐ 5.1 Proof of payment

☐ 5.2 Informed consent letter of marketing authorisation holder of authorised medicinal product.

☐ 5.3 Proof of establishment of the applicant in the EEA.

☐ 5.4 Letter of authorisation for communication on behalf of the applicant/MAH.

☐ 5.5 (empty)

☐ 5.6 Manufacturing Authorisation required under Article 40 of Directive 2001/83/EC (or equivalent, outside of the EEA where MRA or other European Union arrangements apply); any proof of authorisation in accordance with Article 8.3(k) of Directive 2001/83/EC.

☐ 5.7 Copy of the "Qualification of SME Status".

☐ 5.8 Flow-chart indicating all manufacturing and control sites involved in the manufacturing process of the medicinal product and the active substance.

☐ 5.9 GMP certificate(s) or other GMP statement(s); Where applicable a summary of other GMP inspections performed.

☐ 5.10 Letter(s) of access to Active Substance Master File(s) or copy of ph. Eur. Certificate(s) of Suitability.

☐ 5.11 Copy of written confirmation from the manufacturer of the active substance to inform the applicant in case of modification of the manufacturing process or specifications according to Annex I of Directive 2001/83/EC.

☐ 5.12 Ph. Eur. Certificate(s) of suitability for TSE.

☐ 5.13 Written consent(s) of the competent authorities regarding GMO release in the environment.

☐ 5.14 Scientific Advice given by CHMP and/or by member state(s).

☐ 5.15 Copy of Marketing Authorization(s) required under Article 8(j)-(L) of Directive 2001/83/EC in the EEA and the equivalent in third countries on request (a photocopy of the pages which give the marketing authorization number, the date of authorisation and the page which has been signed by the authorizing competent authority will suffice).

☐ 5.16 Letter by Commission services regarding multiple applications.

☐ 5.17 List of Mock-ups or Samples/specimens sent with the application, as appropriate (see EMA/CMDh websites).

☐ 5.18 Copy of the Orphan Designation Decision.

☐ 5.19 List of proposed (invented) names and marketing authorisation holders in the concerned member states.

☐ 5.20 Copy of EMA certificate for a Vaccine Antigen Master File(VAMF).

☐ 5.21 Copy of EMA certificate for a Plasma Master File (PMF).

☐ 5.22 For each active substance, attach a declaration(s) from the Qualified Person of the manufacturing authorisation holder in Section 2.5.1 and from the Qualified Person of the manufacturing authorisation holders (i.e located in EEA) listed in Section 2.5.2 where the active substance is used as a starting material that the active substance is manufactured in compliance with the principles and guidelines of good manufacturing practice for starting materials. Alternatively, such declaration may be signed by one Qualified Person on behalf of all QPs involved (provided this is clearly indicated). The declaration should refer to an audit and the date of the audit.

☐ 5.23 Evidence and justification to support the claim of new active substance status in the Union for applications based on Article 8(3) of Directive 2001/83/EC.

Note: To include attachments with this form, do not use the paper clip function. Attachments and annexes should be included in the same (eCTD) folder as the application form. For more detailed guidance see the eAF user guidance.

FORM VALIDATION

Validation Errors

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