EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health Systems and products

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-Module 1-Administrative information

To be noted:
As from 01/01/2016, mandatory use of electronic application forms for all procedures. This document is for information purposes only. Not to be used for submissions.

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

APPLICATION FORM

SUMMARY OF THE DOSSIER

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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 Member State (as well as Iceland, Liechtenstein and Norway) under either a national, mutual recognition procedure or decentralised procedure.
For the European Medicines Agency under the centralised procedure use the electronic Application form available from: http://esubmission.ema.europa.eu/eaf/index.html

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

DECLARATION and SIGNATURE

Product (invented) name:

Strength(s):

Pharmaceutical form:

Active Substance(s):

Applicant: **Title:** **First name:** **Surname:**
Address:

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

Signature(s)

Title: First name: * Surname:

Function

Address: date (yyyy-mm-dd)

Email:

* ☐ *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 CMDh website.*

Table of contents

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)

The use of the eAF is mandatory for Centralised Procedure.

http://esubmission.ema.europa.eu/eaf/index.html

« Mandatory scope » (Article 3(1) of Regulation (EC) No 726/2004)
Annex (1) (Biotech medicinal product)
Annex (1a) (Advanced Therapy Medicinal Product)
Gene therapy medicinal product
Somatic cell therapy medicinal product
Tissue engineered product

The product is also a
Combined Advanced Therapy Medicinal Product

Annex (3) (New active substance for mandatory indications)
Annex (4) (Orphan designated medicinal product)

« Optional scope » (Article 3(2) of Regulation (EC) No 726/2004)
Article 3(2)(a) (New active substance)
Article 3(2)(b) (Significant innovation or interest of patients at EU level)

« Generic of a Centrally Authorised Medicinal Product »

« Marketing Authorisation including paediatric indication » (Article 28 of Regulation (EC) No 1901/2006)

« Paediatric Use Marketing Authorisation (PUMA) » (Article 31 of Regulation (EC) No 1901/2006)

Date of acceptance/confirmation by CHMP:
(yyyy-mm-dd)

☐ CHMP Rapporteur:
Title:
First name:
Surname:

☐ CHMP Co-rapporteur:
Title:
First name:
Surname:

☐ PRAC Rapporteur:
Title:
First name:
Surname:

☐ If applicable, PRAC Co-rapporteur:
Title:
First name:
Surname:

In case of Advanced Therapy Medicinal Products:

☐ CAT Rapporteur:
Title:
First Name:
Surname:

☐ CAT Co-rapporteur:
Title:
First name:
Surname:

☐ CHMP Co-ordinator:
Title:
First name:
Surname:

☐ CHMP Co-coordinator:
Title:
First name:
Surname:

☐ PRAC Rapporteur:
Title:
First name:
Surname:

☐ If applicable, PRAC Co-rapporteur:
Title:
First name:
Surname:

❍ **1.1.2. A MUTUAL RECOGNITION PROCEDURE** (according to Article 28(2) of Directive 2001/83/EC)

Procedure type: (from the first procedure or wave to the last one)

❍ First use ❍ Repeat Use (please also complete section 4.2)

- Reference Member State:
- Date of authorisation: (yyyy-mm-dd):
- Marketing authorisation number:
  (a copy of the authorisation should be provided - see section 4.2)
- Procedure number:
- Concerned Member State(s) (specify):

AT	☐	BE	☐	BG	☐	CY	☐	CZ	☐	DE	☐	DK	☐	EE	☐
EL	☐	ES	☐	FI	☐	FR	☐	HR	☐	HU	☐	IE	☐	IS	☐
IT	☐	LI	☐	LT	☐	LU	☐	LV	☐	MT	☐	NL	☐	NO	☐
PL	☐	PT	☐	RO	☐	SE	☐	SI	☐	SK	☐	UK	☐		

Proposed (or agreed) Common Renewal Date:

(For subsequent procedures or waves, copy the procedure section above)

❍ **1.1.3. A DECENTRALISED PROCEDURE** (according to Article 28(3) of Directive 2001/83/EC)

- Reference Member State:
- Procedure number:

- Concerned Member State(s) (specify):

AT	☐	BE	☐	BG	☐	CY	☐	CZ	☐	DE	☐	DK	☐	EE	☐
EL	☐	ES	☐	FI	☐	FR	☐	HR	☐	HU	☐	IE	☐	IS	☐
IT	☐	LI	☐	LT	☐	LU	☐	LV	☐	MT	☐	NL	☐	NO	☐
PL	☐	PT	☐	RO	☐	SE	☐	SI	☐	SK	☐	UK	☐		

Proposed Common Renewal Date:

❍ **1.1.4. A NATIONAL PROCEDURE**

- Member State:
- If available, application number:

1.2. ORPHAN MEDICINAL PRODUCT INFORMATION

1.2.1. HAS ORPHAN DESIGNATION BEEN APPLIED FOR THIS MEDICINAL PRODUCT?

❍ No

❍ Yes Orphan Designation Procedure Number:

❍ Pending

❍ Orphan Designation Granted
Date (yyyy-mm-dd):
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 Designation Refused
Date (yyyy-mm-dd):
Commission Decision Reference Number:

❍ Orphan Designation Withdrawn
Date (yyyy-mm-dd):

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?

❍ No
❍ Yes
Please specify the EU Orphan Designation Number(s):

If yes, has any of the designated Orphan medicinal product(s) been granted a marketing authorisation in the EU?

❍ No
❍ Yes
Please specify:
- Name, therapeutic indications, strength, pharmaceutical form of the authorised product:
- Name of the marketing authorisation holder:
- Marketing authorisation number(s):
- Date of authorisation:

If yes, 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)*

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

Note: Repeat as necessary

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 ?

❍ **No** *(complete section 1.4. + 1.6)*

❍ **Yes** *(complete sections below and also complete section 1.4. + 1.6)*

Please specify:

1.3.1 ❍

☐ qualitative change in declared active substance not defined as a new active substance
- ❍ replacement by a different salt/ester, complex/derivative (same therapeutic moiety)
- ❍ replacement by a different isomer, mixture of isomers, of a mixture by an isolated isomer
- ❍ replacement of a biological substance or product of biotechnology
- ❍ new ligand or coupling mechanism for a radiopharmaceutical
- ❍ change to the extraction solvent or the radio of herbal drug to herbal drug preparation

☐ 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 be the 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 21 of Directive 2001/83/EC

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

☐ authorisation of a new pharmaceutical form
☐ authorisation of a new route of administration

Note:
the applicant of the present application must be the same as the marketing authorisation holder of the existing marketing authorisation

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

- Name of the marketing authorisation holder:
- Name, strength, pharmaceutical form of the existing product:
- Marketing authorisation number(s):

1.4. APPLICATION SUBMITTED IN ACCORDANCE WITH THE FOLLOWING ARTICLE IN DIRECTIVE 2001/83/EC

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

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

** for extensions of complete applications, cross references can only be made to pre-clinical and clinical data*

❍ Claim for new active substance
Note: active substance not yet authorised in a medicinal product by a competent authority or by the European Union (for centralised procedure)
Please provide evidence and justification to support the claim of new active substance status in annex 5.2.

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 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 name, strength(s), pharmaceutical form(s):
- Marketing authorisation holder:
- Date of authorisation (yyyy-mm-dd):
- Marketing authorisation granted by:
  - Union
  - Member State (EEA):
- Marketing authorisation number(s):

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:***
- Product name, strength(s), pharmaceutical form(s):
- Marketing authorisation holder[1]:
- Marketing authorisation number(s):
- Marketing authorisation(s) granted by:
  - Union

[1] Should be considered the "same" as the one identified above, as per the Commission Communication (98/C 299/03) (i.e. belonging to the same mother company or group of companies or which are "licencees")

- 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 name, strength(s), pharmaceutical form(s):
- Marketing authorisation holder[4]:
- Date of authorisation (dd-mm-yyyy):
- Marketing authorisation(s) granted by:
  - Union
  - Member State (EEA):
- Marketing authorisation number(s):
- Member State of source:
- Bioavailability study(ies) reference number(s)/EudraCT number(s):

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

1.4.3 ❍ <u>Article 10(3) hybrid application</u>

Note: . application for a medicinal product referring to a so-called reference medicinal product with a Marketing Authorisation in a Member State or in the Union (e.g. different pharmaceutical form, different therapeutic use ….)
. complete administrative and quality data, appropriate preclinical and clinical data
. refer to Notice to Applicants, Volume 2A, Chapter 1

<u>Reference medicinal product:</u>

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 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 name, strength(s), pharmaceutical form(s):
- Marketing authorisation holder:
- Date of authorisation (yyy-mm-dd):
- Marketing authorisation(s) granted by:
  - Union
  - Member State (EEA):
- Marketing authorisation number(s):

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:***

- Product name, strength(s), pharmaceutical form(s):
- Marketing authorisation holder[4]:
- Marketing authorisation(s) granted by:
  - Union
  - Member State (EEA) :
- Marketing authorisation number(s):

■ <u>Difference(s) compared to this reference medicinal product</u>:

☐ changes 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

■ ***Medicinal Product which is or has been authorised in accordance with Union provisions in force used for the demonstration of bioequivalence (if applicable) and/or in other studies.***

- Study reference number/EudraCT number:
- Product name, strength(s), pharmaceutical form(s):
- Marketing authorisation holder[4]:
- Marketing authorisation(s) granted by:
  - Union
  - Member State (EEA):
- Marketing authorisation number(s):
- Member State of source:

Note: Section to be duplicated for each product used for the demonstration of bioequivalence and/or in other studies.

1.4.4 ❍ <u>Article 10(4)</u> similar biological application

Note: . application for a product referring to a reference biological product
. complete administrative and quality data , appropriate preclinical and clinical data
. refer to Notice to Applicants, Volume 2A, Chapter 1

<u>Reference medicinal product:</u>

Note: The chosen reference medicinal product must be a medicinal product authorised in the Community on the basis of a complete dossier in accordance with the provisions of 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 name, strength(s), pharmaceutical form(s):
- Marketing authorisation holder:
- Date of authorisation (yyyy-mm-dd):
- Marketing authorisation(s) granted by:
  - Union
  - Member State (EEA) :
- Marketing authorisation number(s):

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:***

- Product name, strength(s), pharmaceutical form(s):
- Marketing authorisation holder[4] :
- Marketing authorisation number(s):
- Marketing authorisation(s) granted by:
  - Union
  - Member State (EEA):

■ <u>Difference(s) compared to this reference medicinal product</u>:

☐ 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 of administration(s)
☐ other

■ ***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:***
Note: The chosen reference medicinal product must be a medicinal product authorised in the Community and should be used throughout the comparability programme for quality, safety and efficacy studies.

- Product name, strength(s), pharmaceutical form(s):
- Marketing authorisation holder[4]:
- Date of authorisation (yyyy-mm-dd):
- Marketing authorisation(s) granted by:
  - Union
  - Member State (EEA):
- Marketing authorisation number(s):

(*Note: An overview of the chosen reference medicinal product used throughout the comparability programme for quality, safety and efficacy studies during the development of the similar biological medicinal product, is to be included in Module 1.5.2.*)

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 to Applicants, Volume 2A, Chapter 1
. for extensions of fixed combination applications, cross references can only be made to pre-clinical and clinical data

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, pre-clinical and clinical data
. the authorised product and the informed consent application can have the same or different MAH

Authorised product in the Union / Member State where the application is made:
- Product name, strength, pharmaceutical form
- Marketing authorisation holder:

▪ Marketing authorisation number(s):

☐ Attach letter of consent from the marketing authorisation holder of the authorised product (Annex 5.2)

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 IN DIRECTIVE 2001/83/EC OR REGULATION (EC) N° 726/2004

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)

Date of acceptance by CHMP:
(yyyy-mm-dd)

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) N° 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[2] APPLICANT HOLD OTHER MARKETING AUTHORISATION(S) FOR A MEDICINAL PRODUCT(S) CONTAINING THE SAME ACTIVE SUBTANCE(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[5] 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**
- Product name(s), strength(s), pharmaceutical form(s):
- Marketing authorisation holder(s):
- Member State/European Union where product is authorised:
- Marketing authorisation number(s):
- Date(s) of marketing authorisation(s):

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

If the answer to a) or b) above is "Yes", please complete section 1.6.2

❍ **No** (Article 7 of Paediatric Regulation applies) Please complete section 1.6.3

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

❍ Yes (Article 8 of Paediatric Regulation applies) Please, complete section 1.6.3
❍ No

1.6.3 THIS APPLICATION INCLUDES:

☐ PIP[3] PIP Decision Number(s):

[2] "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 "licencees")

[3] To be ticked when the PIP Opinion includes a waiver.

☐ Product-Specific Waiver[4] Waiver Decision Number(s):

☐ Class waiver Waiver Decision Number(s):

(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)

1.6.4 ❍ ARTICLE 30 (PUMA) OF THE PAEDIATRIC REGULATION APPLIES TO THIS APPLICATION:
(Note: Also applies to Extension applications of PUMA)

☐ The application relates to a medicinal product, which is not protected by either a Supplementary Protection Certificate under Regulation (EC) No 469/2009, or by a patent which qualifies for the granting of the Supplementary Protection Certificate

☐ PIP PIP Decision Number(s):

(Note: a copy of the PIP decision, including the PDCO opinion and the Summary Report, is to be included in Module 1.10)

1.6.5 HAS THIS APPLICATION BEEN SUBJECT TO PIP COMPLIANCE VERIFICATION?

❍ No

❍ Yes
If, yes, please specify the compliance document reference(s):

(Note: If available, a copy of the PDCO compliance 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(s):

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

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:

☐ 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 Pharmacopoeia, 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)*

2.1.3 Pharmacotherapeutic group (Please use current ATC code):

ATC Code: **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)

Pharmaceutical form:

Active substance(s) ***Strength(s)***

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

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)

(Duplicate section 2.2.3 as needed)

For each container give:

Description:

Container	**Material**	**Closure**

Administration device:

For each type of pack give:

2.2.3.1 Package size(s):
Note: for mutual recognition and decentralised procedures, all package sizes authorised in the Reference Member State should be listed

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

2.2.4 The medicinal 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

2.2.4.1.: Manufacturer of the device (for manufacturers outside the EEA, please add the authorised representative):

Name of contact person:

Title: First name: Surname:

Address:

Postcode:

Country:

Telephone:

Fax:

E-mail:

2.2.4.2.: Device(s) identification

Name of the device(s):

Serial numbers or other indications necessary to delimit precisely the device(s) incorporated:

2.2.4.3.: CE mark

Does the device(s) have a CE mark?

❍ No ❍ Yes

If yes, please add the Manufacturers declaration of conformity in module 3.2.R of the EU-CTD.

2.2.4.4.: Notified Body

Is the device(s) covered by certificates issued by a Notified Body?

❍ No ❍ Yes

If yes, please add the certificate(s) in module 3.2.R of the EU-CTD.

Please indicate for each Notified Body involved:
(For combined ATMPs, identify a Notified Body in any case)

Name of the Notified Body:

Notified Body Number:

Name of contact person:

Title: First name: Surname:

Address:

Postcode:

Country:

Telephone:

Fax:

E-Mail:

2.3 Legal status

2.3.1 Proposed dispensing/classification

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

☐ subject to medical prescription
European Union/Member State(s):

☐ not subject to medical prescription
European Union/Member State(s):

2.3.2 For products subject to medical 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*
European Union/Member State(s):
☐ product on **restricted** prescription*
European Union/Member State(s):

(not all the listed options are applicable 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 the 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
(Company) Name:
Address:
Postcode:
Country:
Telephone:
Telefax:
E-Mail:
Contact person at this address:
Title: First name: Surname:

❍ **National procedure including mutual recognition/decentralised procedure**
Member State(s):
(Company) Name:
Address:
Postcode:
Country:
Telephone:
Telefax:
E-Mail:
(Repeat section for different proposed marketing authorisation holder' affiliates in the Member States)

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

Has SME status been assigned by the EMA?

❍ No
❍ Yes
EMA-SME Number:
Date of expiry: (yyyy-mm-dd)
☐ 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):

Billing address (when relevant)
Company name:
VAT number:
Address:
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:

Title: First name: Surname:
Company name:
Address:
Postcode:
Country:
Telephone:

Telefax:
E-Mail:
☐ If different to 2.4.1 above, attach a 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 the European Union/each MS:

Title: First name: Surname:

Company name: Address:
Postcode:
Country:
Telephone:
Telefax:
E-Mail:
☐ If different to 2.4.1 above, attach a letter of authorisation (Annex 5.4)

2.4.4 Summary of the applicant pharmacovigilance system

Qualified person in the EEA for Pharmacovigilance

Title: First name: Surname:
Company name:
Address:
Postcode:
Country:
24 H Telephone:
Telefax:
E-Mail:

☐ The above-mentioned qualified person resides[5] and operates in the EEA
☐ The qualified person is registered with Eudravigilance

Pharmacovigilance system master file
Number:
Address:
Postcode:
Country:

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

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 contact person:

[5] 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.

Title: First name: Surname:
Company name:
Address:
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):

Company name:
Address:
Postcode:
Country:
Telephone:
Telefax:
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 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)

Laboratory name:
Address:
Postcode:
Country:
Telephone:
Telefax:
E-Mail:

2.5.1.1 Contact person in the EEA for product defects and recalls

Title: First name: Surname:
Address:
Postcode:
Country:
24H contact telephone number:
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:
Postcode:
Country:
Telephone:
Telefax:
E-Mail:

Brief description of control tests carried out by the laboratory (ies) concerned:

☐ 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.)

Company name:
Address:
Postcode:
Country:
Telephone:
Telefax:
E-Mail:

Brief description of functions performed:

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

- Site(s) is in the EEA:
  - Manufacturing authorisation number

☐ Attach manufacturing authorisation(s) (Annex 5.6)
or
☐ Enter EudraGMP Manufacturing Authorisation reference:

- Name of qualified person:
(if not mentioned in manufacturing authorisation)

• Site(s) is outside the EEA:

If available, D-U-N-S number[6]:

☐ Attach document equivalent of manufacturing authorisation in accordance with Article 8.3 (k) of Directive 2001/83/EC (Annex 5.6)

- 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 the agreement?

❍ no ❍ yes

If yes, please
☐ Attach latest GMP certificate in Annex 5.9
or
☐ Enter 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)?

❍ no ❍ yes

☐ 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),

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

Note: All manufacturing sites involved in the manufacturing process of each source of active substance, including quality control / in-process testing sites, should be listed. Brokers 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).

Active Substance:
Company name:
Address:
Postcode:
Country:
Telephone:
Telefax:
E-Mail:

[6] The Data Universal Numbering System (D-U-N-S) is a system developed by Dun & Bradstreet (D&B) which assigns a unique digit numeric identifier to a single business entity. It is used in this case to facilitate the identification of manufacturing sites outside of EEA

Brief description of manufacturing steps performed by manufacturing site:

☐ 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 the principles 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 the agreement?
  ❍ no ❍ yes

  If yes, please
  ☐ Attach latest GMP certificate in Annex 5.9
  or
  ☐ Enter 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)?
  ❍ no ❍ yes

  ☐ 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):
  ❍ no ❍ yes ☐ Provide copy in Annex 5.10
  If yes, please provide the following information:
  - name of the CEP holder:
  - name of the manufacturer if different from the above:
  - CEP number:
  - date of last update (*yyyy-mm-dd*):

• Is an Active Substance Master File to be used for the active substance(s)?
  ❍ no ❍ yes

  ☐ If yes, please provide the following information:
  - name of the ASMF holder:
  - name of the manufacturer if different from the 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 (*yyyy-mm-dd*):
  - date of last update (*yyyy-mm-dd*):

- ☐ 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 I of Directive 2001/83/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?

❍ no ❍ yes ☐ Provide copy in Annex 5.20

If yes,
- substance name:
- name of the VAMF Certificate Holder/ VAMF Applicant:
- reference number of Application/ Certificate:
- date of submission (if pending) (*yyyy-mm-dd*):
- date of approval or last update (if approved) (*yyyy-mm-dd*):

(Section to be copied as per however many VAMFs may be cross-referenced)

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:

Title of the study:
Protocol code:
EudraCT-Number:
Name of the company:
Address:
Postcode:
Country:
Telephone:
Telefax:
Email:
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)

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

Name of active substance(s)*	Quantity	Unit	Reference/Monograph standard

etc.

Name of excipient(s)*	Quantity	Unit	Reference/Monograph standard

etc.

*Note: * only one name for 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 declared 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(s):
- excipient(s):

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

NONE ☐

Name	Function* AS	EX	R	Animal origin susceptible to TSE**	Other animal origin	Human origin	Certificate of suitability for TSE (state number)
1.	☐	☐	☐	☐	☐	☐	☐
2.	☐	☐	☐	☐	☐	☐	☐
3.	☐	☐	☐	☐	☐	☐	☐
4. etc.	☐	☐	☐	☐	☐	☐	☐

* AS=active substance, EX=excipient (incl. starting materials used in the manufacture of the active substance/exipient), 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 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?

❍ no ❍ yes ☐ Provide copy in Annex 5.21

If yes,
- Substance referring to PMF:

function* AS	EX	R
❍	❍	❍

- name of the PMF Certificate Holder/ PMF Applicant:
- reference number of Application/ Certificate:
- date of submission (if pending) (*yyyy-mm-dd*):
- date of approval or last update (if approved) (*yyyy-mm-dd*):

* 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)

(Section to be copied as per however many PMFs may be cross-referenced)

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

❍ No ❍ Yes

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

❍ No ❍ Yes

☐ 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?

❍ No ❍ Yes

If yes,

Date (*yyyy-mm-dd*):
Reference(s) of the scientific advice(s):

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

❍ No ❍ Yes

If yes,

Member State(s): Date(s) (*yyyy-mm-dd*):
Reference(s) of the scientific advice(s):

☐ Attach copy of the 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:

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

❍ yes ❍ no
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?

❍ yes ❍ no
If yes, section 4.2 must be completed and copy of authorisation provided

Are there any differences which have therapeutic implications between this application and the applications/authorisations for the same product in other Member States (for national applications, Article 17 or 18 of Directive 2001/83/EC shall apply).

❍ yes ❍ no
If yes, please elaborate:

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

❍ yes ❍ no

If yes, section 4.2 must be completed

**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".*
*** Note: 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*

☐ Authorised
country:
date of authorisation (*yyyy-mm-dd*):
invented name:
marketing authorisation number:
procedure number for MRP/DCP (if applicable)

☐ Attach marketing authorisation (Annex 5.15)

☐ Submitted (which are not considered as a multiple/duplicate application – see Section 4.3)
country:
date of submission (*yyyy-mm-dd*):
procedure number for MRP/DCP (if applicable):

☐ Refused
country:
date of refusal (*yyyy-mm-dd*):
procedure number for MRP/DCP (if applicable):
reason for refusal

☐ Withdrawn (by applicant before authorisation)
country:
date of withdrawal (*yyyy-mm-dd*):
invented name:
reason for withdrawal:
procedure number for MRP/DCP (if applicable):

☐ Withdrawn (by applicant after authorisation)
country:
date of withdrawal (*yyyy-mm-dd*):
authorisation number:
reason for withdrawal:
invented name:
procedure number for MRP/DCP (if applicable):

☐ Suspended/revoked (by competent authority)
country:
date of suspension/revocation (*yyyy-mm-dd*):
reason for suspension/revocation:
invented name:
procedure number for MRP/DCP (if applicable):

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 the other product(s):
Date of application(s) (*yyyy-mm-dd*):
Applicant(s):
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 active substance(s) and having the same pharmaceutical form.)

☐ Authorised
country:
date of authorisation (*yyyy-mm-dd*):
invented name:

☐ Pending
country:
date of submission (*yyyy-mm-dd*):

☐ Refused
country:
date of refusal (*yyyy-mm-dd*):
reason for refusal

☐ Withdrawn (by applicant before authorisation)
country:
date of withdrawal:
invented name:
reason for withdrawal (*yyyy-mm-dd*):

☐ Withdrawn (by applicant after authorisation)
country:
date of withdrawal (*yyyy-mm-dd*):
authorisation number:
reason for withdrawal:
invented name:

☐ Suspended/revoked (by competent authority)
country:
date of suspension/revocation (*yyyy-mm-dd*):
reason for suspension/revocation:
trade name:

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 EMACMDh 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 each 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.