EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Consumer goods
Pharmaceuticals

Brussels,
F2/ (2008)

Revision 9

NOTICE TO APPLICANTS

Medicinal Products for Human Use

VOLUME 2B
Module 1: Administrative information
Application form

May 2008

This application form will be included in:

The Rules governing Medicinal Products in the European Community
The Notice to Applicants - Volume 2B - Common Technical Document-Module 1-Administrative information

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) 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:

Strength(s):

Pharmaceutical form:

Active Substance(s):

Applicant:

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

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.
It is hereby confirmed that fees will be paid/have been paid according to the national/Community rules**.
On behalf of the applicant

_____
Signature(s)

_____
NAME*

_____
Function

_____
Place date (yyyy-mm-dd)

* ☐ *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 in the Notice to Applicants, Volume 2A, chapter 7.*

Table of contents

[1] OJ L 159 27/06/2003, p. 1 – 23 and OJ L 159 27/06/2003, p.24 - 45
[2] Amended by Directive 2004/27/EC OJ L - 136, 30/04/2004, p. 34 – 57 and Directive 2004/24/EC OJ L – 136, 30/04/2004, p. 85 - 90
[3] OJ L 136 30/04/2004, p.1 - 33

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)

❍ « Mandatory scope » (Article 3(1))
- ❍ Annex (1) (Biotech medicinal product)
- ❍ Annex (3) (New active substance for mandatory indications)
- ❍ Annex (4) (Orphan designated medicinal product)

❍ « Optional scope » (Article 3(2))
- ❍ Article 3(2)(a) (New active substance)
- ❍ Article 3(2)(b) (Significant innovation or interest of patients at Community level)

❍ « Generic of a Centrally Authorised Medicinal Product » (Article 3(3))

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

❍ « Article 29 application » (Article 29 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)

☐ Rapporteur: (Name of CHMP Member)

☐ Co-rapporteur: (Name of CHMP Member)

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

- 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:

❍**First use**

- Concerned Member State(s) (specify):

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

Proposed Common Renewal Date:

If a waiver or amendment of PSUR-cycle is applied for, to harmonise with a substance birthdate, please specify:

❍ **Repeat Use 1st Wave** (please also complete section 4.2)
- ❍ After initial decentralised procedure
- ❍ After initial mutual recognition procedure

▪ Concerned Member State(s) (specify):

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

For subsequent procedures copy the boxes above

Agreed Common Renewal Date:

❍ **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	☐	HU	☐	IE	☐	IS	☐	IT	☐
LI	☐	LT	☐	LU	☐	LV	☐	MT	☐	NL	☐	NO	☐	PL	☐
PT	☐	RO	☐	SE	☐	SI	☐	SK	☐	UK	☐				

▪ If a waiver or amendment of PSUR-cycle is applied for, to harmonise with a substance birthdate, please specify:

In case of a repeat-use procedure after an initial decentralised procedure, please complete section 1.1.2 – Repeat Use 1st wave

❍ **1.1.4. A NATIONAL PROCEDURE**

▪ Member State:
▪ If available, application number:
▪ If a waiver or amendment of PSUR-cycle is applied for, to harmonise with a substance birthdate, please specify:

1.2. ORPHAN MEDICINAL PRODUCT INFORMATION

1.2.1. HAS ORPHAN DESIGNATION BEEN APPLIED FOR 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, 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)

1.3. IS THIS AN APPLICATION FOR A CHANGE TO YOUR EXISTING MARKETING AUTHORISATION LEADING TO AN EXTENSION AS REFERRED TO IN ANNEX II OF REGULATIONS (EC) NO 1084/2003 OR 1085/2003, 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:

☐ 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

●**For existing marketing authorisation in the Community / 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. THIS APPLICATION IS 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*)

❍ New active substance
Note: constituent of a product not yet authorised by a competent authority or by the Community (for centralised procedure)

❍ Known active substance
Note: . constituent of a product already authorised by a competent authority or the Community
. same or different marketing authorisation holder
. for extensions of complete applications, cross references can only be made to pre-clinical and clinical data*

1.4.2 ❍ **Article 10(1) <u>generic application</u>**

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

<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 Community 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:
    - Community
    - 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 Community/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:
    - Community
    - Member State (EEA):

■ ***Medicinal product which is or has been authorised in accordance with Community 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:
    - Community
    - 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.

[4] 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")

1.4.3 ❍ Article 10(3) hybrid application

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 Community (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

Reference medicinal product:

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 Community provisions in forcefor 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:
  - Community
  - 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 Community/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:
  - Community
  - Member State (EEA) :
- Marketing authorisation number(s):

■ Difference(s) compared to this reference medicinal product:

☐ 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 Community 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:
  - Community
  - 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 ❍ Article 10(4) 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

Reference medicinal product:

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 Community 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:
  - Community
  - 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 Community/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:
  - Community
  - Member State (EEA):

■ Difference(s) compared to this reference medicinal product:

- ☐ 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 Community 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:
  - Community
  - 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 Community / 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 IS ALSO 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)

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 exclusivity 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'):

(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)

1.6.1. DOES THE SAME[5] APPLICANT HOLD OTHER MARKETING AUTHORISATION(S) FOR A MEDICINAL PRODUCT(S) CONTAINING THE SAME ACTIVE SUBTANCE(S) IN THE EEA?

❍ **No** *(complete section 1.6.1.1)*

❍ **Yes** *(complete section 1.6.1.2)*
- Product name, strength, pharmaceutical form:
- Marketing authorisation holder:
- Member State/Community where product is authorised:
- Marketing authorisation number(s):
- Indication(s):

1.6.1.1 ❍ **ARTICLE 7 OF THE PAEDIATRIC REGULATION APPLIES TO THIS APPLICATION, SINCE:**
(Note: Does not apply to well-established use, generic, hybrid and bio-similar applications and traditional herbal medicinal products)

☐ The medicinal product is not authorised in the Community on 26 July 2008

THIS APPLICATION INCLUDES:

❍	PIP	PIP Decision Number(s):
❍	Product-Specific Waiver	Waiver Decision Number:
❍	Class waiver	Waiver Decision Number:

(Note: a copy of the PIP/Waiver decision is to be included in Module 1.10)

1.6.1.2 ❍ ARTICLE 8 OF THE PAEDIATRIC REGULATION APPLIES TO THIS APPLICATION, SINCE:
(Note: Does not apply to well-established use, generic, hybrid and bio-similar applications and traditional herbal medicinal products)

❍ The application relates to a new indication, new pharmaceutical form or new route of administration of an authorised medicinal product, which:
- ❍ is protected by a supplementary protection certificate under Regulation (EEC) No 1768/92
- ❍ is protected by a patent which qualifies for the granting of the supplementary protection certificate

[5] "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")

THIS APPLICATION INCLUDES:

- ❍ PIP — PIP Decision Number(s):
- ❍ Product-Specific Waiver — Waiver Decision Number:
- ❍ Class waiver — Waiver Decision Number:

(Note: a copy of the PIP/Waiver decision is to be included in Module 1.10)

❍ **THIS APPLICATION DOES NOT FALL WITHIN THE SCOPE OF ARTICLE 8 OF THE PAEDIATRIC REGULATION.**

1.6.2 ❍ **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 (EEC) No 1768/92, 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 is to be included in Module 1.10)

1.6.3 HAS THIS APPLICATION BEEN SUBJECT TO PIP COMPLIANCE VERIFICATION?

❍ No

❍ Yes
If, yes, please specify:
❍ PDCO compliance Opinion Number:
❍ National competent authority/EMEA document reference:

(Note: If available, a copy of the PDCO opinion + report, document issued by the national competent authority/EMEA, or applicant's compliance report 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):

2. MARKETING AUTHORISATION APPLICATION PARTICULARS

2.1. Name(s) and ATC code

2.1.1 Proposed (invented) name of the medicinal product in the Community/ 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)

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 Notice to Applicants, volume 2A, chapter 7) (Annex 5.17).

2.3 Legal status

2.3.1 Proposed dispensing/classification

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

❍ subject to medical prescription

❍ not subject to medical prescription

2.3.2 For products subject to medical prescription:

☐ product on prescription which **may** be renewed (if applicable)
☐ product on prescription which **may not** be renewed (if applicable)
☐ product on **special** prescription*
☐ product on **restricted** prescription*

(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

❍ supply through non-pharmacy outlets and pharmacies (if applicable)

2.3.4 Promotion for products not subject to medical prescription

❍ promotion to health care professionals only

❍ promotion to the general public and health care professionals

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 Community / each MS:

(Company) Name:
Address:
Country:
Telephone:
Telefax:
E-Mail:
Contact person at this address (for centralised procedure only):
☐ Attach proof of establishment of the applicant in the EEA (Annex 5.3)

Has SME status been assigned by the EMEA?

❍ No
❍ Yes
EMEA-SME Number:
Date of expiry: (yyyy-mm-dd)
☐ Attach copy of the 'Qualification of SME Status' (Annex 5.7)

2.4.2 Person/company authorised for communication on behalf of the applicant during the procedure in the Community/each MS:

Name:
Company name:
Address:
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 the Community/each MS:

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

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

2.4.4 Qualified person in the EEA for Pharmacovigilance

Name:
Company name:
Address:
Country:
24 H Telephone:
Telefax:
E-Mail:

☐ Attach C.V. of qualified person (Annex 5.5)
☐ The above-mentioned qualified person resides[6] in the EEA

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)

Name of contact person:
Company name:
Address:
Country:
Telephone:
Telefax:
E-Mail:

[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.

2.5 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:
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:
Country:
Telephone:
Telefax:
E-Mail:

2.5.1.1 Contact person in the EEA for product defects and recalls

Name:
Address:
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 Community arrangements apply, where batch control testing takes place as required by Article 51 of Directive 2001/83/EC:

Company name:
Address:
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, and importer(s))

Company name:
Address:
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 is in the EEA:
  - Manufacturing authorisation number

    ☐ Attach 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:

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

- Site is outside the EEA:
  ☐ Attach document equivalent of manufacturing authorisation in accordance with Article 8(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 Community arrangements apply within the terms of the agreement?

❍ no ❍ yes

If yes, please provide in Annex 5.9:
☐ a statement less than 3 years old from the competent authority which carried out the inspection,
or,
If available:
☐ Attach latest GMP certificate
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 Community 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.

Active Substance:
Company name:
Address:
Country:
Telephone:
Telefax:
E-Mail:
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 detailed 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 Community arrangements apply within the terms of the agreement?
❍ no ❍ yes

If yes, please provide in Annex 5.9:

☐ a statement from the competent authority which carried out the inspection,

or,
If available:
☐ Attach latest GMP certificate
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 Community 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,
- substance:
- name of the manufacturer:
- reference number:
- date of last update (*yyyy-mm-dd*):

• Is a Active Substance Master File (European Drug Master File) to be used for the active substance(s) reference/original?
❍ no ❍ yes
If yes,
- substance:
- name of the manufacturer:
- reference number for EMEA / competent authority:
- date of submission (*yyyy-mm-dd*):
- date of last update (*yyyy-mm-dd*):
- ☐ attach letter of access for Community/Member State authorities where the application is made (see "European ASMF procedure for active ingredients") (Annex 5.10)
- ☐ attach 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 (Annex 5.11)

• Is an EMEA 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:
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*			Animal origin	Other	Human	Certificate of
	AS	EX	R	susceptible to TSE**	animal origin	origin	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 EMEA 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 the CHMP 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:
authorisation number:

☐ Attach marketing authorisation (Annex 5.15)

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

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

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

☐ 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:
invented name:

4.3 For multiple/duplicate applications of the same medicinal product:

Multiple/duplicate applications for:
Name of the other product(s):
Date of application(s) (*yyyy-mm-dd*):
Applicant(s):

☐ Attach copy of correspondence with the European Commission, 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*):

☐ 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**	Curriculum Vitae of the Qualified Person for Pharmacovigilance.
☐ **5.6**	Manufacturing Authorisation required under Article 40 of Directive 2001/83/EC (or equivalent, outside of the EEA where MRA or other Community arrangements apply); any proof of authorisation in accordance with Article 8(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**	Correspondence with European Commission regarding multiple applications.
☐ **5.17**	List of Mock-ups or Samples/specimens sent with the application, as appropriate (see Notice to Applicants, volume 2A, chapter 7).
☐ **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 EMEA certificate for a Vaccine Antigen Master File (VAMF).
☐ **5.21**	Copy of EMEA 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 detailed guidelines on 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).