EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation

Brussels,
Revision 1

NOTICE TO APPLICANTS

Medicinal Products for Human Use

VOLUME 2B
Presentation and content of the dossier

Module 1.2: Administrative information
Application form

HOMEOPATHIC MEDICINAL PRODUCT FOR HUMAN USE

2016

This application form will be included in:

The Rules governing Medicinal Products in the European Union
The Notice to Applicants - Volume 2B - Presentation and content of the dossier

Revision 1, December 2016.

APPLICATION FORM

SUMMARY OF THE DOSSIER

●●●●●

APPLICATION FORM : ADMINISTRATIVE DATA

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

A separate application form is required for each pharmaceutical form. Depending on national legislation, a separate application form may be required for each potency.

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 name:

Pharmaceutical form(s):

Homeopathic stock(s) and potency(ies):

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 its the use 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 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 4.4*
** ☐*Note: if fees have been paid, attach proof of payment in Annex 4.1 - see information on fee payments on the EMA/CMDhwebsite*

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Declaration and signature

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[1] OJ L –334, 12/12/2008, p. 7 – 24.
[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.

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)

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

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

- Reference Member State:
- Date of authorisation/registration: (yyyy-mm-dd):
- Marketing authorisation/registration number:
  (a copy of the authorisation/registration should be provided - see section 3.2)
- Procedure number:

❍**First use**

- 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	☐				

Proposed Common Renewal Date[3]:

If a waiver or amendment of PSUR-cycle is applied for, to harmonise with a substance birthdate, please specify[3]:

❍**Repeat Use 1st Wave** (please also complete section 3.2)

- Concerned Member State(s) (specify):

For subsequent procedures copy the boxes above

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	☐				

Agreed Common Renewal Date :

[3] Not applicable for registration of homeopathic medicinal product.

❍ **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	☐				

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

❍ **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. APPLICATION FOR A CHANGE TO EXISTING MARKETING AUTHORISATION/REGISTRATION LEADING TO AN EXTENSION AS REFERRED TO IN ANNEX I OF REGULATION (EC) NO 1234/2008, OR ANY NATIONAL LEGISLATION , WHERE APPLICABLE

❍ **No** *(complete section 1.3. only)*

❍ **Yes** *(complete sections below and also complete section 1.3.)*
Please specify:

☐ qualitative change in declared active substance[4] 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

- ❍ change to the extraction solvent or the ratio of herbal substance to herbal 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

[4] Active substance can be either homeopathic stock or its dilution.

Note:
. the applicant of the present application must be <u>the same</u> as the marketing authorisation/registration holder of the existing marketing authorisation/registration
. 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

●**<u>For existing marketing authorisation/registration in the European Union / Member State where the application is made</u>:**
- Name of the marketing authorisation/ registration holder/:
- Name, potency, pharmaceutical form of the existing product:
- Marketing authorisation/registration number(s):

1.3. <u>APPLICATION SUBMITTED IN ACCORDANCE WITH THE FOLLOWING ARTICLE IN DIRECTIVE 2001/83/EC</u>

Note: . section to be completed for any application, including applications referred to in section 1.2
. for further details, refer to Notice to Applicants, Volume 2A, Chapter 1

❍**1**.3.1 Article 14 of Directive 2001/83/EC (simplified registration procedure)

❍**1**.3.2 Article 16(1) of Directive 2001/83/EC (marketing authorisation procedure)[5]

❍**1**.3.2.1 Article 8(3) of Directive 2001/83/EC (i.e dossier with administrative, quality, preclinical and clinical data)

❍**1**.3.2.2 Article 10 of Directive 2001/83/EC

❍**1**.3.2.3 Article 10a of Directive 2001/83/EC (well-established use application)

❍**1**.3.2.4 Article 10b of Directive 2001/83/EC (fixed combination application)

❍**1**.3.2.5 Article 10c of Directive 2001/83/EC (informed consent application~~)~~

1.4 <u>ADMINISTRATIVE DATA/DOSSIER REQUIREMENTS</u>

Article 14 simplified registration procedure

Part of the dossier	Submitted in the Application dossier or in the Master dossier
Module 1	❍
Manufacturing license	❍
Mock ups of outer and immediate packaging and of package leaflet	❍
Module 2	❍
Module 3	❍
Module 4	❍
Module 5 = Justification of the homeopathic use	❍

[5] A Member State may introduce or retain in its territory specific rules for the preclinical tests and clinical trials of homeopathic medicinal products other than those referred to in Article 14(1) in accordance with the principles and characteristics of homeopathy as practised in that Member State (Article 16(2) of Directive 2001/83)).

Article 16 marketing authorisation procedure

Part of the dossier	Presence required Submitted in the Application dossier or in the Master dossier
Module 1	❍
Manufacturing license	❍
SmPC in National language	❍
Package leaflet in National language	❍
Mock ups of outer and immediate packaging and of package leaflet	❍
Module 2	❍
Module 3	❍
Module 4**)	❍
Module 5 including the justification of homeopathic use *) **)	❍

*) Justification of the homeopathic use should be given in module 5
**) National legislation may be available for the requirements on Module 4 and Module 5 for article 16(2) procedures (national application). Justification of the homeopathic use (indication) should be given in accordance with national legislation.

2. MARKETING AUTHORISATION/REGISTRATION APPLICATION PARTICULARS

2.1. Name(s) and potency

2.1.1 Proposed (invented) name of the homeopathic medicinal product

☐ If different (invented) names in different Member States are proposed in a mutual recognition procedure or decentralised procedure, these should be listed in Annex **4.19**

2.1.2 Name of the Homeopathic stock(s) and potencies[1]

[1] *For botanicals the following order of priority should be used: Scientific name of the Ph. Eur. or National Pharmacopoeia or in absence of a monography,a Scientific Latin name (botanical scientific name..) followed by the Homeopathic(s) name(s)*

2.2. Pharmaceutical form, route of administration, container and pack sizes

2.2.1 Pharmaceutical form (use current list of standard terms - European Pharmacopoeia)

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 procedures, all package sizes authorised/registered 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 EMA/CMDh websites) (Annex 4.17).

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
Member State(s):

☐ not subject to medical prescription
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*
Member State(s):
☐ product on **restricted** prescription*
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 Directive. 2001/83/EC, Article 71*

2.3.3 Supply for products <u>not</u> 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 <u>not</u> 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/registration holder / Contact persons / Company

2.4.1 Proposed marketing authorisation/registration holder/person legally responsible for placing the product on the market:

❍ **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/registration holder's affiliates in the Member States)

☐Attach proof of establishment of the applicant/MAH/RH in the EEA (Annex 4.3)

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 4.7)

Proof of payment (when relevant)

Have all relevant fees been prepaid to competent authorities?

❍ Yes (for fees paid, attach proof of payment in Annex 4.1)
❍ 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:

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 4.4)

2.4.3 Person/Company authorised for communication between the marketing authorisation/registration holder and the competent authorities after authorisation if different from 2.4.2:

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 4.4)

2.4.4 Qualified person in the EEA for Pharmacovigilance

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

24 H contact telephone number:
Telefax:
E-Mail:

☐ Attach C.V. of qualified person (Annex 4.5)
☐ The above-mentioned qualified person resides[6] and operates in the EEA
☐ The qualified person is registered with Eudravigilance

2.4.5 Scientific service of the MAH/RH 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:
Title: First name: Surname:
Company name:
Address:
Postcode:
Country:
Telephone:
Telefax:
E-Mail:

2.5 Manufacturers

2.5.1 Authorised manufacturer(s) (or importer) 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):

Name of Company:
Address:
Postcode:
Country:
Telephone:
Telefax:
E-Mail:

Manufacturing Authorisation number:
☐ Attach copy of manufacturing authorisation(s) (Annex 4.6)
or
☐ Enter EudraGMP Manufacturing Authorisation reference:

If available:

[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.

☐ Attach latest GMP certificate (Annex 4.9)
or
☐ Enter EudraGMP certificate reference number:

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 EEA or in countries with MRAor other EU arrangements in operation, where batch control/testing takes place (if different from 2.5.1):

Name of the Company:
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 4.6)
or
☐ Enter EudraGMP Manufacturing Authorisation reference:

2.5.2 Manufacturer(s) of the homeopathic 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 homeopathic medicinal product quality control / in-process testing sites, immediate and outer packaging and importer(s). For each site provide the relevant information.) :

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

Brief description of functions performed by manufacturer of dosage form/assembler, etc.:

☐Attach flow-chart indicating the sequence of the different sites involved in the manufacturing process (Annex 4.8)

- If the manufacturing site is in the EEA,
  - Manufacturing authorisation number (under Article 40 of Directive 2001/83/EC):

☐ Attach manufacturing authorisations required under Article 40 of Directive 2001/83/EC (Annex 4.6) or
☐ Enter EudraGMP Manufacturing Authorisation reference:

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

- If the manufacturing site is outside the EEA,

D-U-N-S number[7], if available:

- ☐ Where MRA or other EU arrangements are in operation, attach equivalent of manufacturing authorisation (Annex 4.6)

- Has the site been inspected for GMP Compliance by an EEA authority or by an authority of countries where MRA or other EU arrangements apply within the terms of the agreement?

❍ no ❍yes

If yes, please
☐ Attach latest GMP certificate in Annex 4.9
or

[7] 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

☐ 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 EU arrangements apply but not within their respective territory)?

❍ no ❍ yes

☐ If yes, please provide summary information in Annex 4.9 (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 dilutions and site(s) of manufacture: (Note: If different from the manufacturer of the finished homeopathic medicinal product.):

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

Brief description of functions performed by manufacturer of dosage form/assembler, etc.:

☐Attach flow-chart indicating the sequence of the different sites involved in the manufacturing process (Annex 4.8)

- <u>If the manufacturing site is in the EEA</u>,
  - Manufacturing authorisation number (under Article 40 of Directive 2001/83/EC):
    ☐ Attach manufacturing authorisations required under Article 40 of Directive 2001/83/EC (Annex 4.6)
  - Name of qualified person: (if not mentioned in manufacturing authorisation)

- <u>If the manufacturing site is outside the EEA</u>,

☐ Where MRA or other EU arrangements are in operation, attach equivalent of manufacturing authorisation (Annex 4.6)

- Has the site been inspected for GMP Compliance by an EEA authority or by an authority of countries where MRA or other EU arrangements are in operation

❍ no ❍yes

☐If yes, please provide in Annex 4.9 for each site a statement from the competent authority which carried out the inspection, including:

- last GMP inspection date
- name of competent authority which carried out the inspection
- type of inspection (pre/post-authorisation/special/re-inspection)
- category of products and activities inspected
- outcome: GMP compliant: ❍ no ❍ yes

2.5.4 Manufacturer(s) of the Homeopathic stock(s):

Note: only the final manufacturer(s) to be mentioned

Substance:
Name:
Address:
Country:
Telephone:
Telefax:
E-Mail:

☐ 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 4.22).

- Has a Ph.Eur. Certificate of suitability been issued for the homeopathic stock(s) :

❍ no ❍yes

If yes,please provide the following information:
- homeopathic stock:
- name of the manufacturer:
- reference number:
- date of last update (*yyyy-mm-dd*):

☐ Provide copy in Annex 4.10

- Is an Active Substance Master File to be used for the homeopathic stock(s)?

❍no ❍yes

If yes, please provide the following information:

- name of the ASMF holder
- name of the manufacturer if different from above:
- EU ASMF reference number if available:
- National ASMF reference number: (when applicable and only if EU ASMF reference number is not available):
- applicant part version number:
- date of submission (*yyyy-mm-dd*):
- date of last update (*yyyy-mm-dd*):
- ☐ attach letter of access for EU/Member State authorities where the application is made (see "European ASMF procedure for active substance) (Annex 4.10)

- ☐ 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 4.11)

Where an active substance manufacturer has been inspected by an EEA Country:

☐ *The following information should be provided in Annex 4.9 for each site*

- *last inspection date by an EEA country* (*yyyy-mm-dd*)
- *name of competent authority which carried out the inspection*
- *type of inspection (pre/post-authorisation/special/re-inspection)*
- *categories of substance and activities inspected*
- *outcome:* ❍ *positive* ❍*negative*

2.5.5 Source/manufacturer(s) of the raw material(s):

Raw material:
Name:
Address:Postcode:
Country:
Telephone:
Telefax:
E-Mail:

• Has a Ph.Eur. Certificate of suitability been issued for the raw material(s):

❍ no ❍yes

If yes,
- Raw material:
- name of the manufacturer/supplier:
- reference number:
- date of last update (*yyyy-mm-dd*):

☐ Provide copy in Annex 4.10

Where an active substance manufacturer has been inspected by an EEA Country:

☐ *The following information should be provided in Annex 4.9 for each site*

- *last inspection date by an EEA country* (*yyyy-mm-dd*)
- *name of competent authority which carried out the inspection*
- *type of inspection (pre/post-authorisation/special/re-inspection)*
- *categories of substance and activities inspected*
- *outcome:* ❍ *positive* ❍*negative*

2.6 Qualitative and quantitative composition

2.6.1 Qualitative and Quantitative composition in terms of the homeopathic 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 homeopathic active substance(s) separately from the excipient(s):

Name of homeopathic active substance(s)*	Quantity	Unit	Reference/Monograph standard
1.			
2.			
3.			
etc.			

Name of excipient(s)**	Quantity	Unit	Reference/Monograph standard
1.			
2.			
3.			
etc.			

*Note: * the following order of priority should be used: Scientific Latin name of the Ph. Eur. Or of National Pharmacopoeia, or , in absence of a monograph, a scientifica Latin name (botanical scientific name...) followed by the homeopathic name*
*** Only one name of each subsance should be given in the following order of priority: INN, Ph. Eur., National Pharmacopoeia, Common name, Scientific name.*

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

NONE ☐

Name	Function* HAS	EX	R	Animal origin susceptible to TSE**	Other animal origin	Human origin	Certificate of suitability for TSE (state no)
1.	☐	☐	☐	☐	☐	☐	❍
2.	☐	☐	☐	☐	☐	☐	❍
3.	☐	☐	☐	☐	☐	☐	❍
4.	☐	☐	☐	☐	☐	☐	❍
etc.							

* HAS=homeopathic active substance, EX=excipient (incl. starting materials used in the manufacture of the active substance/excipient), R=reagent/culture medium (incl. those used in the preparation of master and working cell banks)
** as defined in section 2 (scope) of the CPMP 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 4.12

3 OTHER MARKETING AUTHORISATION /REGISTRATION APPLICATIONS

3.1 FOR NATIONAL/MRP/DCP APPLICATIONS, PLEASE COMPLETE THE FOLLOWING IN ACCORDANCE WITH ARTICLE 8(j)-(l) OF DIRECTIVE 2001/83/EC

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

❍yes ❍no
If yes, section 3.2. must be completed

3.1.2 Is there another Member State(s) where an authorisation/registration is granted for the same* product?

❍yes ❍ no
If yes, section 3.2 must be completed and copy of authorisation/registration 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, Art. 17 or 18 of Directive 2001/83/EC may apply).

❍yes ❍no
If yes, please elaborate:

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

❍yes ❍no

If yes, section 3.2 must be completed

** Note: 'same product' means same qualitative and quantitiative composition in active substance(s) and having the same pharmaceutical form from applications belonging to the same mother company or group of companies OR which are 'licensees'.*

3.2. Marketing authorisation/registration applications for the same homeopathic medicinal product in the EEA (*'same product' means same qualitative and quantitiative composition in active substance(s)and having the same pharmaceutical form from applications belonging to the same mother company or group of companies OR which are 'licensees'.*
Note: refer to Commission Communication 98/C229/03

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

☐ Attach marketing authorisation/registration (Annex 4.15)

☐ Pending
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/registration)
country:
date of withdrawal (*yyyy-mm-dd*):
name:
reason for withdrawal:
procedure number for MRP/DCP (if applicable):

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

3.3 <u>For multiple applications of the same homeopathic medicinal product:</u>

Multiple application (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):

3.4. Marketing authorisation/registration applications for the <u>same</u> homeopathic medicinal product outside the EEA ('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: refer to Commission Communication 98/C229/03*

☐ <u>Authorised/registered</u>
country:
date of authorisation/registration (*yyyy-mm-dd*):
name:

☐ <u>Pending</u>
country:
date of submission (*yyyy-mm-dd*):

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

☐ <u>Withdrawn (by applicant before authorisation/registration)</u>
country:
date of withdrawal:
name:
reason for withdrawal (*yyyy-mm-dd*):

☐ <u>Withdrawn (by applicant after authorisation/registration)</u>
country:
date of withdrawal (*yyyy-mm-dd*):
authorisation/registration number:
reason for withdrawal:
name:

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

4. ANNEXED DOCUMENTS (WHERE APPROPRIATE)

☐ **4.1** Proof of payment

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

☐ **4.3** Proof of establishment of the applicant in the EEA.

☐ **4.4** Letter of authorisation for communication on behalf of the applicant/MAH/RH.

☐ **4.5** Curriculum Vitae of the Qualified Person for Pharmacovigilance.

☐ **4.6** Manufacturing Authorisation required under Article 40 of Directive 2001/83/EC (or equivalent, outside of the EEA where MRA or other EU arrangements apply). A reference to EudraGMP will suffice when available.

☐ **4.7** Copy of the 'Qualification of SME Status'.

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

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

☐ **4.10** Letter(s) of access to Active Substance Master File(s) or copy of Ph. Eur. Certificate(s) of Suitability.

☐ **4.11** 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.

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

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

☐ **4.14** Scientific Advice given by CHMP and/or by Member State(s).

☐ **4.15** Copy of Marketing Authorization(s) required under Article 8(3)(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).

☐ **4.16** Letter by Commission services regarding multiple applications.

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

☐ **4.18** Copy of the Orphan Designation Decision.

☐ **4.19** List of proposed (invented) names and marketing authorisation/registration holders in the concerned member states.

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

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

☐ **4.22** For each active substance, attach a declaration 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 manufacturered 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.This does not apply to Blood or blood components.

☐ **4.23** 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.