EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Consumer goods
Pharmaceuticals

Brussels,
F2/BL D(2005)

NOTICE TO APPLICANTS

Medicinal Products for Human Use

VOLUME 2B
Presentation and content of the dossier-Part 1
Summary of the dossier Part 1A
or
Module 1: Administrative information
Application form

HOMEOPATHIC MEDCINAL PRODUCT FOR HUMAN USE

December 2005

This application form will be included in:

The Rules governing Medicinal Products in the European Community
The Notice to Applicants - Volume 2B - Presentation and content of the dossier-1998 edition
or
The Notice to Applicants - Volume 2B - Common Technical Document-Module 1- Administrative information-2001 edition

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APPLICATION FORM

SUMMARY OF THE DOSSIER

●●●●●

APPLICATION FORM : ADMINISTRATIVE DATA

The application form is to be used for an application for a marketing authorisation of a medicinal product for human use submitted to (a) the European 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.

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 name:

Pharmaceutical form(s):

Homeopathic stock(s) and potency(ies):

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 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)

_____
NAME*

_____
Function

_____
Place date (yyyy-mm-dd)

* ☐*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 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

1. TYPE OF APPLICATION

Note: The following sections should be completed where appropriate.

1.1. THIS APPLICATION CONCERNS:

1.1.1. 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 5.2)
- Procedure number:

❍ **First use**

- Concerned Member State(s) (specify):

AT	☐	BE	☐	CY	☐	CZ	☐	DE	☐	DK	☐	EE	☐	EL	☐
ES	☐	FI	☐	FR	☐	HU	☐	IE	☐	IS	☐	IT	☐	LI	☐
LT	☐	LU	☐	LV	☐	MT	☐	NL	☐	NO	☐	PL	☐	PT	☐
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 5.2)

- Concerned Member State(s) (specify):

For subsequent procedures copy the boxes above

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

Agreed Common Renewal Date :

❍ **1.1.2. 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	☐	CY	☐	CZ	☐	DE	☐	DK	☐	EE	☐	EL	☐
ES	☐	FI	☐	FR	☐	HU	☐	IE	☐	IS	☐	IT	☐	LI	☐

LT	☐	LU	☐	LV	☐	MT	☐	NL	☐	NO	☐	PL	☐	PT	☐
SE	☐	SI	☐	SK	☐	UK	☐								

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

❍ **1.1.3. 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:

1.3. 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 1.3. only)*

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

1.3. 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**.3.1 Article 14 of Directive 2001/83/EC (simplified registration procedure)

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

1.4 Administrative data/dossier requirements

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	❍	
Justification of the homeopathic nature	❍	

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	❍	
SPC 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	❍	
Justification of the homeopathic nature	❍	

2. MARKETING AUTHORISATION/REGISTRATION APPLICATION PARTICULARS

2.1. Name(s)

2.1.1 Name of the homeopathic medicinal product

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

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

[1]*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)

For each type of pack give

2.2.3.1 Package size(s):

Note: for mutual recognition 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) (4.17).

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 Directive. 2001/83/EC, Article 71*

2.3.3 Supply for products <u>not</u> subject to medical prescription:

❍ supply through pharmacies only

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

2.3.4 Promotion for products <u>not</u> subject to medical prescription:

❍ promotion to health care professionals only

❍ promotion to the general public and health care professionals

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:

(Company) Name:
Address:
Country :
Telephone:
Telefax:
E-Mail:
Contact person at this address
☐Attach proof of establishment of the applicant in the EEA (Annex 4.3)

2.4.2 Person/company authorised for communication on behalf of the applicant during the procedure:

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

☐ If different to 2.4.1 above,
Attach 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:

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

☐ If different to 2.4.1 above,
Attach letter of authorisation (Annex 4.4)

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 4.5)

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:
Country:
Telephone:
Telefax:
E-Mail:

- Manufacturing Authorisation number:
- ☐ Attach copy of manufacturing authorisation(s) (Annex 4.6)
- ☐ Attach justification if more than one manufacturer responsible for batch release is proposed (Annex 4.7)

2.5.1.1 <u>Batch control/Testing arrangements</u>
Site(s) in EEA or in countries with MRA/PECA in operation, where batch control/testing takes place (if different from 2.5.1):

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

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):

Name:
Company name:
Address:
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)

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

- If the manufacturing site is outside the EEA,
  - ☐ Where MRA/PECA is 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/PECA is 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

2.5.3 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:
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)

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

• If the manufacturing site is outside the EEA,
- ☐ Where MRA/PECA is 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/PECA is 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:

• Has a Ph.Eur. Certificate of suitability been issued for the active substance(s):
❍ no ❍yes

If yes,
- substance:
- name of the manufacturer:
- reference number:
- date of last update (*yyyy-mm-dd*):
☐ Provide copy in Annex 4.10

• Is a 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 DMF procedure for active substance) (Annex 4.10)
- ☐ 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 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:
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*
*** Onley 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 APPLICATIONS ONLY, 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
country:
date of authorisation/registration (*yyyy-mm-dd*):
invented name:
authorisation number:

☐ Attach marketing authorisation/registration (Annex 4.13)

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

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

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

☐ Withdrawn (by applicant after authorisation/registration)
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:

3.3 For multiple applications of the same homeopathic medicinal product:

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

3.4. Marketing authorisation/registration applications for the same homeopathic medicinal product outside the EEA (i.e. from applicants belonging to the same mother company or group of companies OR which are "licensees". (Same qualitative and quantitative composition in active substance(s) and having the same pharmaceutical form.) *Note: refer to Commission Communication 98/C229/03*

☐ 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:

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

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

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

☐ **4.7** Justification for more than one manufacturer responsible for batch release in the EEA

☐ **4.8** Flow-chart indicating all sites involved in the manufacturing process of the medicinal product or active substance (including sites involved in sampling and testing for batch release of products manufactured in third countries). *Note: ALL manufacturing and control sites mentioned throughout the whole dossier MUST be consistent regarding their names, detailed addresses and activities.*

☐ **4.9** Statement (or GMP Certificate issued by an EEA inspectorate, when available) from the competent authority which carried out the inspection of the manufacturing site(s)
(not older than 3 years). References to EudraGMP will suffice when available. Where applicable a summary of other GMP inspections performed in the last 2 years

☐ **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

☐ **4.15** 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).

☐ **4.16** Correspondence with European Commission regarding multiple applications.

☐ **4.17** List of Mock-ups or Samples/specimens sent with the application, as appropriate (see Notice to Applicants, volume 2A, chapter 7)

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

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

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

☐ **4.21** Copy of EMEA 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 manufacturer(s) referred to in Section 2.5.3 operate in compliance with the detailed guidelines on good manufacturing practice for starting materials. This does not apply to Blood or blood components.