APPLICATION FOR MARKETING AUTHORISATION OF MEDICINAL PRODUCTS FOR HUMAN USE

SUMMARY OF THE DOSSIER

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APPLICATION FOR MARKETING AUTHORISATION:

ADMINISTRATIVE DATA

The application form is to be used for an application for a marketing authorisation of a medicinal product submitted to the National Medicines Agency under national procedure or nCADREAC simplified procedure.

Separate application is submitted for each strength and pharmaceutical form of the medicinal product for human use.

DECLARATION and SIGNATURE

Name of the medicinal product:

Strength:

Pharmaceutical form:

Active substance(s):

Applicant:

Person authorised on behalf of the Applicant for communication* with the National Medicines Agency, during authorisation procedure:

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 and tariffs will be paid according to the National Medicines Agency payment rules.

On behalf of the Applicant:

_____

Signature

_____

NAME*

_____

Function

_____

Place Date (yyyy-mm-dd)

* ☐ *Note: Please attach letter of authorisation for communication with NMA/ signing on behalf of the applicant.*

This form is intended for use before Accession. After Accession, the form provided in Notice to Applicants shall be used.

1. TYPE OF APPLICATION

Note: The following sections should be completed where appropriate.

1.1. THIS APPLICATION CONCERNS:

❍ **1.1.1. AUTHORISATION UNDER nCADREAC SIMPLIFIED PROCEDURE FOR MEDICINAL PRODUCTS FOR HUMAN USE AUTHORISED IN THE EU UNDER CENTRALISED PROCEDURE**

❍ YES ❍ NO

❍ Part A ❍ Part B
Date of acceptance by CHMP:
(yyyy-mm-dd)

λ Rapporteur: (Name of CHMP Member) λ Co-Rapporteur: (Name of CHMP Member)

❍ **1.1.2. AUTHORISATION UNDER nCADREAC SIMPLIFIED PROCEDURE FOR MEDICINAL PRODUCTS FOR HUMAN USE AUTHORISED IN THE EU UNDER MUTUAL RECOGNITION PROCEDURE**

❍ YES ❍ NO

- Reference Member State:
- Date of authorisation: (yyyy-mm-dd):
- Marketing authorisation number:
(a copy of the marketing authorisation shall be provided - see Section 5.2)

- Concerned Member State(s):

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

❍ **1.1.3. UNDER NATIONAL PROCEDURE FOR MEDICINAL PRODUCTS FOR HUMAN USE**

❍ YES ❍ NO

- Please specify if a waiver or amendment of PSUR-cycle is applied for, to harmonise with a substance birthdate.

1.2. **THIS IS AN APPLICATION FOR A CHANGE TO A MARKETING AUTHORISATION IN PLACE WITH REFERENCE TO ANNEX III OF ORDER OF THE MINISTER OF HEALTH NO. 89/02.02.2004, WHERE APPLICABLE**

❍ **YES (***please complete the section below and also complete Section 1.3.)*

❍ **NO (***please complete Section 1.3 only)*

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.

- This section should be completed without prejudice to the provisions of Articles 702 (3), 704 (1), 705, 706, 707 and 726 of Law no. 95/2006 on healthcare reform, Title XVII, The Medicinal Product.

● **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 ARTICLES OF LAW NO. 95/2006 ON HEALTHCARE REFORM, TITLE XVII, THE MEDICINAL PRODUCT**

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

1.3.1. ❍ Article 702 (4) application of Law no. 95/2006 on healthcare reform, Title XVII, The Medicinal Product, (i.e. Complete dossier with administrative, quality, preclinical and clinical data*)

❍ New active substance
Note: Constituent of a product not yet authorised in Romania

❍ Known active substance

Note: - Constituent of a product already authorised in Romania

- Same or different marketing authorisation holder

*- * For extensions of complete applications, cross references can only be made to preclinical and clinical data.*

1.3.2. ❍ Article 704 (1) and (2) of Law no. 95/2006 on healthcare reform, Title XVII, The Medicinal Product – "generic application"

Note: - Application for a generic medicinal product as defined in Article 704 (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.

■ Reference medicinal product which is or has been authorised for not less than 6/10 years in the European Economic Area (EEA):

▪ Name of the medicinal product, strength, pharmaceutical form:
▪ Marketing authorisation holder:
▪ First authorisation: Date (yyyy-mm-dd) Member State (EEA)/Community:

■ Reference medicinal product authorised in the Community/Member State where the application is made:

▪ Name of the medicinal product, strength, pharmaceutical form:
▪ Marketing authorisation holder:
▪ Marketing authorisation number(s):

■ Medicinal Product used for bioequivalence study, where applicable:

▪ Name of the medicinal product, strength, pharmaceutical form:
▪ Marketing authorisation holder:
▪ Member State of source:

1.3.3. ❍ Article 704 (3) of Law no. 95/2006 on healthcare reform, Title XVII, The Medicinal Product – "hybrid application"

Note: - Application for marketing authorisation for a medicinal product referring to a so-called reference medicinal product with a marketing authorisation in a Member State or in the Community (i.e. different pharmaceutical form, different therapeutic use …).

- Complete administrative and quality data, preclinical and clinical data in accord with regulations (Notice to Applicants, Volume 2A, Chapter 1).

■ Reference medicinal product which is or has been authorised for not less than 6/10 years in EEA:

▪ Name of the medicinal product, strength, pharmaceutical form:
▪ Marketing authorisation holder:
▪ First authorisation: Date (yyyy-mm-dd) Member State (EEA)/Community:

■ Reference medicinal product authorised in the Community/Member State where the application is made:

▪ Name of the medicinal product, strength, pharmaceutical form:
▪ Marketing authorisation holder:
▪ Marketing authorisation number(s):

■ Medicinal product used in bioequivalence studies, where applicable
- Name of the medicinal product, strength, pharmaceutical form:
- Marketing authorisation holder:
- Member State of source:

■ Difference(s) compared to the reference medicinal product:
- ☐ changes in active substance(s)
- ☐ changes in therapeutic use
- ☐ changes in pharmaceutical form
- ☐ changes in strength (quantitative change to active substance(s))
- ☐ changes in route of administration
- ☐ bioequivalence cannot be demonstrated through bioavailability studies

1.3.4. ❍ Article 704 (4) of Law no. 95/2006 on healthcare reform, Title XVII, The Medicinal Product – „similar biological application"

Note: - Application for a product referring to a reference biological product
- Complete administrative and quality data, appropriate pre-clinical and clinical data in accord with regulations (Notice to Applicants, Volume 2A, Chapter 1)

■ Reference medicinal product which is or has been authorised for not less than 6/10 years in the EEA:
- Name of the medicinal product, strength, pharmaceutical form:
- Marketing authorisation holder:
- First authorisation: Date (yyyy-mm-dd) Member State (EEA)/Community:

■ Reference medicinal product authorised in the Community/Member State where the application is made:
- Name of the medicinal product, strength, pharmaceutical form:
- Marketing authorisation holder:
- Marketing authorisation(s) number(s):

■ Medicinal Product used for bioequivalence study, where applicable
- Name of the medicinal product, strength, pharmaceutical form:
- Marketing authorisation holder:
- Member State of source:

1.3.5. ❍ Article 705 of Law no. 95/2006 on healthcare reform, Title XVII, The Medicinal Product – "well-established use application"

Note: - For further details, please refer to Notice to Applicants, Volume 2A, Chapter1
- For extensions of bibliographical applications, cross references can only be made to preclinical and clinical data

1.3.6 ❍ Article 706 of Law no. 95/2006 on healthcare reform, Title XVII, The Medicinal Product – „fixed combination application"

Note: - Complete administrative and quality data, pre-clinical and clinical data on the combination only.
- For extensions of fixed combination applications, cross references can only be made la preclinical and clinical data.

1.3.7. ❍ Article 707 of Law no. 95/2006 on healthcare reform, Title XVII, The Medicinal Product – so-called "informed consent application"

Note: - Application for a medicinal product with the same qualitative and quantitative composition in terms of active substances and the same pharmaceutical form of an authorised product where consent has been given by the existing marketing authorisation holder to use their data in support of this application.

- Complete administrative data should be provided with consent to pharmaceutical, preclinical and clinical data.

- The authorised product and the informed consent application can have the same marketing authorisation holder.

Authorised product in the Community / Member State where the application is made:

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

☐ Attach letter of consent from the marketing authorisation holder of the authorised product (Annex 6.2)

1.3.8 ❍ Article 714 of Law no. 95/2006 on healthcare reform, Title XVII, The Medicinal Product – „ application for marketing authorisation for Traditional herbal medicinal product"

Note: - Complete application (see Notice to Applicants, Volume 2A, Chapter 1)

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 procedure, these are to be listed in Annex 6.18.

2.1.2 Name of the active substance(s):

Note: - Only one name should be given in the following order of priority: International Nonproprietary Name (INN), European Pharmacopoeia, the Romanian 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: **Pharmacotherapeutic group:**

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

2.2. Pharmaceutical form, strength, route of administration, container and pack size(s)

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

***Pharmaceutical form*:**
Active substance(s) ***Strength(s):***

2.2.2 Route of administration (please use current list of standard terms according to European Pharmacopoeia)

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

For each type of pack, please give:

2.2.3.1 Package size(s):
Note: - For mutual recognition and decentralised procedures, all package sizes authorised in the Reference Member 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.

2.3 Legal status

2.3.1 Proposed dispensing/classification

(Classification under Article 695 (19) of Law no. 95/2006 on healthcare reform, Title XVII, The Medicinal Product)

❍ Subject to medical prescription

❍ Not subject to medical prescription

2.3.2 For medicinal products subject to medical prescription:

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

Applicants are required to indicate which categories they are requesting, however, the NMA reserves the right to apply only those categories provided for in Law no. 95/ 2006 on healthcare reform, Title XVII, The Medicinal Product.

**Note: - For further information, please refer to Article 781 of Law no. 95/2006 on healthcare reform, Title XVII, The Medicinal Product.*

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 person/Company

2.4.1 Proposed marketing authorisation holder/person legally responsible for placing the product on the market in Romania

(Company) Name:
Address:
Country:
Telephone:
Telefax:
E-Mail:
Contact person at this address:

☐ Attach proof of establishment of the applicant in Romania or the European Economic Area (Annex 6.3)

2.4.2 Person/Company authorised for communication with the National Medicines Agency during authorisation procedure in Romania:

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

☐ If different from pct. 2.4.1 above, attach letter of authorisation (Annex 6.4)

2.4.3 Person/Company authorised for communication between the marketing authorisation holder and the National Medicines Agency, after authorisation, in Romania, If different from Person/Company under 2.4.2

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

☐ If different from 2.4.1 above, please attach letter of authorisation (Annex 6.4)

2.4.4 Qualified person in Romania for Pharmacovigilance

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

☐ Attach C.V. of qualified person (Annex 6.5)

2.4.5 Person in charge of scientific service of the marketing authorisation holder in Romania as referred to in Article 809 of Law no. 95/2006 on healthcare reform, Title XVII, The Medicinal Product

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

2.5 Manufacturers

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

2.5.1 Authorised manufacturer(s) (or importer) responsible for batch release in Romania in accord with Articles 748 and 760 of Law no. 95/2006 on healthcare reform, Title XVII, The Medicinal Product:

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

- Manufacturing Authorisation number:

- ☐ Attach copy of manufacturing authorisation(s) (Annex 6.6)
- ☐ Attach justification if more than one manufacturer responsible for batch release are proposed (Annex 6.7)

For Blood Products and Vaccines:

Details of the state laboratory or laboratory designated for that purpose where the official batch release takes place (in accordance with Articles 823 (1), 825, 826 (1) and (2) and Article 827 of Law no. 95/2006 on healthcare reform, Title XVII, The Medicinal Product, for products authorised in the EEA)

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

2.5.1.1 Contact person in the EEA for product defects and recalls, as defined in Article 790 of Law no. 95/2006 on healthcare reform, Title XVII, The Medicinal Product (for decentralised procedure only)

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

2.5.1.2 Batch control/Testing arrangements

Site(s) in EEA or in countries where an mutual recognition agreement or other Community arrangements apply where batch control/testing takes place (if different from 2.5.1., as required by Article 760 of Law no. 95/2006 on healthcare reform, Title XVII, The Medicinal Product):

Company name:
Address:
Country:
Telephone:
Telefax:
E-mail:

Please provide brief description of control test carried out by the laboratory(ies) concerned.

2.5.2 Manufacturer(s) of the medicinal product and site(s) of manufacture (including manufacturing sites of any diluent/solvent presented in a separate container but forming part of the medicinal product)

Name:
Company name:
Address:
Country:
Telephone:
Telefax:

E-Mail:

Please provide brief description of functions performed by manufacturer of dosage form/assembler etc.:

☐ Attach flow-chart indicating the sequence and activities of the different sites involved in the manufacturing process, including testing sites (Annex 6.8)

- If the manufacturing site is in the EEA:
  - Manufacturing Authorisation number

  ☐ Attach manufacturing authorisations required under Article 748 of Law no. 95/2006 on healthcare reform, Title XVII, The Medicinal Product (Annex 6.6)

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

- If the manufacturing site is outside the EEA:
  - ☐ Where MRA or other Community arrangements apply, attach equivalent of manufacturing authorisation (Annex 6.6)
  - The site has 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.

❍ YES ❍ NO

☐ If yes, please provide in Annex 6.9, 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
- Category of products and activities inspected
- Outcome: GMP compliant: ❍ YES ❍ NO

- The site has been inspected for GMP Compliance by any other authority including those of countries where MRA or other Community arrangements apply but not within the respective territory?

❍ YES ❍ NO

☐ If YES, please provide summary information in Annex 6.9

Including: - Last GMP inspection date (yyyy-mm-dd)
- Name of competent authority which carried out the inspection
- Category of products and activities inspected
- Outcome: ❍ Positive ❍ Negative

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

Note: - All manufacturing sites involved in the manufacturing process of each source of active substance should be listed. For biotech products, include all sites of storage of master and working cell bank and preparation of working cell banks.

Substance:

Name:

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

Please provide brief description of manufacturing steps performed by manufacturing site:

• The European Pharmacopoeia has issued a Certificate of suitability for the active substance(s)

❍ YES ❍ NO

If YES, please specify:
- Substance:
- name of the manufacturer:
- reference number:
- Date of last update (*yyyy-mm-dd*):

☐ Please provide copy in Annex 6.10

• An Active Substance Master File (Drug Master File - DMF) is to be used for the active substance

❍ YES ❍ NO

If YES, please specify
- Substance:
- Name of the manufacturer:
- Reference number for EMEA/competent authority:
- Date of submission (*yyyy-mm-dd*):
- Date of last update (*yyyy-mm-dd*):

☐ Please attach letter of access for Community/Member State authorities where the application is made (please refer to European DMF procedure) (Annex 6.10)

☐ Please 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 Law no. 95/2006 on healthcare reform, Title XVII, The Medicinal Product (Annex 6.11)

• There 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 application for marketing authorisation

❍ YES ❍NO

If YES, please specify:
- 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*):

☐ Please attach copy in Annex 6.19

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

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

☐ *The following information is provided in Annex 6.9 for each manufacturing 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 ingredients and activities inspected*
- *Outcome:* ❍ *Positive* ❍*Negative*

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, specify the state where analytical tests have been performed and where clinical data are collected and given:

Title of the study:
Protocol code:
EudraCT-Number:
Company name:
Address:
Country:
Telephone:
Telefax:
Email:
Duty performed according to contract:

2.6 Qualitative and quantitative composition

2.6.1 Qualitative and quantitative composition – Active substance(s) and excipient(s):
A note is to be given as to which quantity the composition refers (e.g. 1 capsule)
Please 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**, European Pharmacopoeia, Romanian Pharmacopoeia, Common name, Scientific name*
***The active substance should be declared by its recommended INN accompanied by its salt or hydrate form if relevant*

Details of any overages are stated below:

- Active substance:
- excipient(s):

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

NONE ☐

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

etc.

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

** EST = transmissible spongiform encephalopathy

☐ If a European Pharmacopoeia Certificate of Suitability for TSE is available according to Resolution AP/CSP (99)4 of the Council of Europe, please attach in Annex 6.12

2.6.3 There 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 application for marketing authorisation

❍ YES ❍ NO

If YES, please give:

- Substance referring to PMF:

function* AS	EX	R
❍	❍	❍

- Name of the PMF Certificate Holder/ PMF applicant:
- Number of Application/ Certificate:
- Date of submission (if pending) (*yyyy-mm-dd*):
- Date of approval or last update (if approved) (*yyyy-mm-dd*):

☐ Please provide copy in Annex 6.20

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

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

2.6.4 The medicinal product contains or consists of genetically modified organisms within the meaning of Directive 2001/18/EC

❍ YES ❍ NO

If YES, the product complies with Directive 2001/18/EC:

❍ YES ❍ NO

☐ Please a*ttach a copy of any written consent(s) of the competent authorities to the deliberate release into the environment of the Genetically Modified Organisms for research and development purposes where provided for by Part B of the above-mentioned Directive (Annex 6.13)*

3. SCIENTIFIC ADVICE

3.1. Formal scientific advice has been given by the CHMP for this medicinal product:

❍ YES ❍ NO

If YES, please give:

Date (*yyyy-mm-dd*):
References:
☐ Please attach copy of the scientific letter (Annex 6.14)

3.2. Scientific advice has been given by Member State(s) for this medicinal product:

❍ YES ❍ NO

If YES,

Member State(s): Date (*yyyy-mm-dd*):

4. PAEDIATRIC DEVELOPMENT PROGRAMME

4.1. There is a paediatric development programme for this medicinal product:

❍ YES

❍ NO

Please indicate the relevant section(s) in the dossier if included:

5 OTHER MARKETING AUTHORISATION APPLICATIONS

5.1 FOR NATIONAL APPLICATIONS ONLY, PLEASE COMPLETE THE SECTION BELOW, IN ACCORDANCE WITH ARTICLE 702 LIT. m)-o) OF LAW NO. 95/2006 ON HEALTHCARE REFORM, TITLE XVII, THE MEDICINAL PRODUCT:

5.1.1 There is another/are other Member State(s) where an application for the same medicinal product is pending*.

❍ YES ❍ NO

If YES, please complete Section 5.2.

5.1.2 There is/are other Member State(s) where an authorisation is granted for the same medicinal product.**

❍ YES ❍ NO

If YES, Section 5.2 must be completed and copy of authorisation provided.

There are differences which have therapeutic implications between this application and the applications/authorisations for the same product in other Member States (for national applications, in accord with Article 722 or Article 723 of Law no. 95/2006 on healthcare reform, Title XVII, The Medicinal Product).

❍ YES ❍ NO

If YES, please elaborate:

5.1.3 There is/are other Member State(s) where an authorisation has been refused/ suspended/ revoked by competent authorities for the same* medicinal product.

❍ YES ❍ NO

If YES, please complete Section 5.2

**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"*.

5.2. Marketing authorisation applications for the same product in the EEA (e.g. *medicinal products with 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: Please refer to Commission Communication 98/C229/03

☐ Countries which have authorised the medicinal product:

Country:

Date of authorisation (*yyyy-mm-dd*):

Invented name:

Authorisation number:

☐ Please provide copy of the marketing authorisation (Annex 6.15)

☐ Countries in which authorisation of the medicinal product is pending

Country:

Date of submission (*yyyy-mm-dd*):

☐ Countries in which authorisation of the medicinal product has been refused

Country:

Date of refusal (*yyyy-mm-dd*):

☐ Countries in which authorisation of the medicinal product has been withdrawn (by the Applicant, before authorisation)

Country:

Date of withdrawal (*yyyy-mm-dd*):

Invented name:

Reason for withdrawal:

☐ Countries in which authorisation of the medicinal product has been withdrawn (by the Applicant, after authorisation)

Country:

Date of withdrawal (*yyyy-mm-dd*):

Authorisation number:

Invented name:

Reason for withdrawal:

☐ Countries whose competent authorities have suspended /revoked authorisation of the medicinal product

Country:

Date of suspension/revocation (*yyyy-mm-dd*):

Reason for suspension/revocation:

Invented name:

5.3 For multiple applications of the same medicinal product:

Multiple applications for:

Name of the other product(s):

Date of application(s) (*yyyy-mm-dd*):

Applicant(s):

☐ Please attach copy of correspondence with the European Commission, for centralised procedures only (Annex 6.16)

5.4 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")*

Note: Please refer to Commission Communication 98/C229/03

☐ Countries which have authorised the medicinal product

Country:

Date of authorisation (*yyyy-mm-dd*):
Invented name:

☐ Countries in which authorisation of the medicinal product is pending

Country:
Date of submission (*yyyy-mm-dd*):

☐ Countries in which authorisation of the medicinal product has been refused

Country:
Date of refusal (*yyyy-mm-dd*):

☐ Countries in which authorisation of the medicinal product has been withdrawn (by the Applicant before authorisation)

Country:
Date of withdrawal (*yyyy-mm-dd*):
Invented name:
Reason for withdrawal:

☐ Countries in which authorisation of the medicinal product has been withdrawn (by the Applicant after authorisation)

Country:
Date of withdrawal (*yyyy-mm-dd*):
Authorisation number:
Invented name:
Reason for withdrawal:

☐ Countries whose competent authorities have suspended /revoked authorisation of the medicinal product

Country:
Data date of suspension/revocation (*yyyy-mm-dd*):
Reason for suspension/revocation:
Invented name:

6. ANNEXED DOCUMENTS (WHERE APPROPRIATE)

☐ **6.1** Proof of payment

☐ **6.2** Consent of the Marketing Authorisation Holder for the reference medicinal product who allows an applicant to make use of the pharmaceutical, preclinical and clinical documentation contained in the file on the medicinal product, with a view to examining subsequent applications (for informed consent marketing authorisation applications)

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

☐ **6.4** Letter of authorisation for communication on behalf of the applicant/marketing authorisation holder.

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

☐ **6.6** Manufacturing Authorisation required under Article 748 of Law no. 95/2006 on healthcare reform, Title XVII, The Medicinal Product (or equivalent, outside of the EEA where MRA or other Community arrangements apply). A reference to EudraGMP will suffice when available**.**

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

☐ **6.8** 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). ALL manufacturing and control sites mentioned throughout the whole dossier MUST be consistent regarding their names, detailed addresses and activities.

☐ **6.9** 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.

☐ **6.10** Letter(s) of access to Active Substance Master File(s) or copy of European Pharmacopoeia Certificate(s) of suitability.

☐ **6.11** 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 to order of the ministry of health on approval of ”Analytical, pharmacotoxicological and clinical norms and protocols in respect of the testing of medicinal products” (transposing Annex I of Directive 2001/83)

☐ **6.12** European Pharmacopoeia Certificate(s) of suitability for TSE.

☐ **6.13** Written consent(s) of the competent authorities regarding genetically modified organisms release in the environment.

☐ **6.14** Scientific advice given by CHMP.

☐ **6.15** Copy(ies) of Marketing Authorisation(s) granted in an EEA country or third country under Article 702, m)-o) of Law no. 95/2006 on healthcare reform, Title XVII, The Medicinal Product and the equivalent in third countries on request (photocopies of the pages which give the Marketing authorisation number, Date of authorisation and pages which have been signed by the competent authorities).

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

☐ **6.17** List of Mock-ups or Samples/specimens sent with the application, as appropriate.

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

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

☐ **6.20** Copy of EMEA certificate for Plasma Master File (PMF)

☐ **6.21** For each active substance, attach a declaration from the Qualified Person of the manufacturing authorisation holder authorisation holder 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.