APPLICATION FOR RENEWAL OF A MARKETING AUTHORISATION FOR MEDICINAL PRODUCTS FOR HUMAN USE

Invented name: Active substance (s): Pharmacotherapeutic classification (Group + ATC code): Pharmaceutical form and strength[1]: Route of administration[1:] Target species [1]: MA number[1]:	Name and address of MA holder: Name and address of Contact Person[2]: Telephone: Fax: E-mail: Applicant's reference:

1- For centrally authorised products, the above information, including container and pack size(s), should be provided as a table in a separate appendix (according to CPMP opinion)

2- As specified in Section 2.4.3 din part 1A of the dossier. If different, attach letter of authorisation.

Signature _____Date _____

Member State/EMEA _____Contact _____

Date of first authorisation in Reference Member State/Community: Date of expiry of current authorisation in Reference Member State/Community:	Date of first authorisation in Romania: Date of expiry of current authorisation in Romania:

APPROVED MANUFACTURERS

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

Name:
Address:
Country:
Telephone: *Telefax:* *E-mail:*

Further manufacturers responsible for batch release can be detailed in the text field below, in the same format as shown above

***For blood products and vaccines**:*

State laboratory or laboratory designated for official batch release, as accordance with Articles

823 (1), 825, 826 (1) and (2) and 827 of Law no. 95/2006 on healthcare reform, Title XVII, The Medicinal Product
Name:
Address:
Country:

Telephone: *Telefax:* *E-mail:*

Further manufacturers responsible for batch release can be detailed in the text field below, in the same format as shown above.

Site(s) in Romania or the EEA, where batch control/testing takes place, as required by Article 760 of Law no. 95/2006 on healthcare reform, Title XVII, The Medicinal Product, if different from above:

Name:
Address:
Country:
Telephone: *Telefax:* *E-mail:*

Further sites can be detailed in the text field below, in the same format as shown above.

Manufacturer(s) of ***the medicinal product*** *and site(s) of manufacture (including diluent and solvent manufacturing sites):*

Name:
Address:
Country:
Telephone: *Telefax:* *E-mail:*

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

Further manufacturers can be detailed in the text field below, in the same format as shown above

Manufacturer(s) of ***the active substance(s)***
Note: All manufacturing sites involved in the manufacturing process of each source of active substance should be listed. Broker or supplier details alone are not sufficient.

Name:
Address:
Country:
Telephone: *Telefax:* *E-mail:*

Further active substance manufacturers can be detailed in the text field below, in the same format as shown above.

QUALITATIVE AND QUANTITATIVE COMPOSITION IN TERMS OF THE ACTIVE SUBSTANCE(S) AND THE EXCIPIENT(S)

(For centrally authorised products the composition should be provided separately in tabular format as part of the Quality Expert Statement).
A note should be given as to which quantity the composition refers (e.g. 1 capsule).
List the active substance(s) separately from the excipients.

*Name of the active substance (s)**	*Quantity*	*Unit*	*Monograph standard*
*Name of excipient (s) **	*Quantity*	*Unit*	*Monograph standard*

**Only one name for each substance should be given in the following order of priority: 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*

Details of any overages should not be included in the formulation but stated below:
- active substance (s)
- excipient(s)

(*If revised product information (SPC, Labelling and/or Package Leaflet) is proposed to take account of issues raised by the expert, specify the precise present and proposed wording, underlining or highlighting the changed words. Alternatively, such listing may be provided as a separate document attached to the application form.*)

PRESENT PRODUCT INFORMATION TEXT	**PROPOSED PRODUCT INFORMATION TEXT**

DOCUMENTS APPENDED TO THIS APPLICATION

For applications under NATIONAL procedure:

Module 1:

1.0 Cover letter

1.1 Comprehensive table of content

1.2 Renewal Application Form with the following annexes:

• A list of all authorised product presentations for which renewal is sought in tabular format

• Details on contact persons

• Qualified person in Romania and the EEA for Pharmacovigilance

• Contact person in Romania and the EEA with overall responsibility for product defects and recalls

• Contact person for scientific service in Romania and the EEA in charge of information about the medicinal product

• List of EU Member States / Norway / Iceland where the product is on the market and indicating for each country which presentations are marketed and the launch date

• Chronological list of all post-authorisation submissions since grant of the Marketing authorisation or last renewal: a list of all approved or pending Type IA/IB and Type II variations, Extensions, Notifications under Article 771 (3) of Law no. 95/2006 on healthcare reform, Title XVII, The Medicinal Product; USR, giving the procedure number (where applicable), date of submission, date of approval (if approved) and brief description of the change

• Chronological list of letters related to Follow-up measures

• A statement, or when available, a certificate of GMP compliance, not more than three years old, for the manufacturer(s) of the medicinal product listed in the application issued by an EEA competent authority or MRA partner authority. A reference to the Community EudraGMP database will suffice, once this is available.

• For manufacturing sites of the medicinal product not located in the EEA or in the territory of an MRA partner, a list of the most recent GMP inspections carried out by other authorities indicating the date, inspection team and outcomes

• In accord with Article 754, (f) of Law no. 95/2006 on healthcare reform, Title XVII, The Medicinal Product, the manufacturing authorisation holder must use as raw materials only such active substance(s) as manufactured in accordance with the guidelines on good manufacturing practice for starting materials as adopted by the Community.

The following declarations are required:

i. A declaration by the Qualified Person (QP) of each of the manufacturing authorisation holders (i.e. located in the EEA), listed in the application form where the active substance(s) is used as a starting material

ii. Where different, a declaration by the Qualified Person of the manufacturing authorisation holder(s) listed in the application form as responsible for batch release.

1.3 Product information:

1.3.1 SPC, Labelling and Package Leaflet

Current SPC in English, either accompanied by a translation or not or, in case a new SPE is proposed with highlighted proposed changes, in English and the appropriate translation.

1.3.3 Specimen/sample

1.4 Information about the expert's qualification and experience
1.4.1 For quality documents (signature + CV)
1.4.3 For clinical documents(signature + CV)

Module 2:

2.3 Quality Overall Summary (Quality Expert Statement)
2.5 Clinical Overview (Clinical Expert Statement)

Module 5:

5.3.6 Reports of Post-marketing experience (Periodic Safety Update Report and Summary Bridging Report if applicable)

For medicinal products for human use authorized in Romania under <u>CADREAC</u> simplified procedure for medicinal products authorised in the EU under centralised procedure or mutual recognition procedure:

Module 1:

1.0 Cover letter
1.1 Comprehensive table of content
1.2 Renewal Application Form with the following annexes

• A list of all authorised product presentations for which renewal is sought in tabular format (according to Annex structure of CHMP Opinion)

• Details on contact persons

• Qualified person in Romania and the EEA for Pharmacovigilance

• Contact person in Romania and the EEA with overall responsibility for product defects and recalls

• Contact person for scientific service in Romania and the EEA in charge of information about the medicinal product

• List of EU Member States / Norway / Iceland where the product is on the market and indicating for each country which presentations are marketed and the launch date

• Chronological list of all post-authorisation submissions since grant of the Marketing authorisation or last renewal: a list of all approved or pending Type IA/IB and Type II variations, Extensions, Notifications under Article 771 (3) of Law no. 95/2006 on healthcare reform, Title XVII, The Medicinal Product; USR, giving the procedure number (where applicable), date of submission, date of approval (if approved) and brief description of the change

• Chronological list of Follow-up measures and any Specific Obligations submitted since grant of marketing authorisation or last renewal indicating scope, status, date of submission and date when issue has been resolved

• Revised list of all remaining Follow-up measures/post-authorisation commitments, and for Community Authorisations only any Specific Obligations and signed letter of commitment (where applicable)

• A statement, or when available, a certificate of GMP compliance, not more than three years old, for the manufacturer(s) of the medicinal product listed in the application issued by an EEA competent authority or MRA partner authority. A reference to the Community EudraGMP database will suffice, once this is available.

• in addition, For manufacturing sites of the medicinal product not located in the EEA or in the territory of an MRA partner, a list of the most recent GMP inspections carried out by other authorities indicating the date, inspection team and outcome

• in accord with Article 754 lit. (f) of Law no. 95/2006 on healthcare reform, Title XVII,

The Medicinal Product, the manufacturing authorisation holder must use as raw materials only such active substance(s) as manufactured in accordance with the guidelines on good manufacturing practice for starting materials as adopted by the Community.

The following declarations are required:

i. A declaration by the Qualified Person of each of the manufacturing authorisation holders (i.e. located in the EEA), listed in the application form where the active substance(s) is used as a starting material

ii. Where different, a declaration by the Qualified Person of the manufacturing authorisation holder(s) listed in the application form as responsible for batch release.

1.3 Product information:
1.3.1 SPC, Labelling and Package Leaflet
1.3.3 Specimen
1.4 Information about the expert's qualification and experience
1.4.1 For quality documents (signature + CV)
1.4.2 For nonclinical documents (signature + CV) – if applicable
1.4.3 For clinical documents(signature + CV)

Module 2:

2.3 Quality Overall Summary (Quality Expert Statement)
2.4 Nonclinical Overview (Nonclinical Expert Statement), if applicable
2.5 Clinical Overview (Clinical Expert Statement)

Module 5:

5.3.6 Reports of Post-marketing experience (Periodic Safety Update Report and Summary Bridging Report, if applicable)

I hereby make application for the above Marketing Authorisation to be renewed. I declare that the quality of the product, in respect of the methods of preparation and control, has been regularly updated by variation procedure to take account of technical and scientific progress in accordance with Article 728 of Law no. 95/2006 on healthcare reform, Title XVII, The Medicinal Product. The product conforms with current CHMP quality guidelines where relevant. I confirm that no changes have been made to the product particulars other than those approved by the Competent Authorities.

Fees will be paid according to NMA payment rules ☐ Amount/Currency:

Main Signatory _____ Function_____

Print name _____ Date

Second Signatory _____ Function_____
(where appropriate)
Print name _____ Date