Ministry of Health
ORDER No. 1540
of 13 August 2021

on approval of the Rules for implementation of provisions of Article 883 of Law 95/2006 on healthcare reform regarding the authorisation for marketing of some medicinal products needed on grounds of public health

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On seeing Approval report no. IM 7211 of 13.08.2021 of the Pharmaceutical and Medical Devices Directorate and notification no. 56973 of 5.07.2021 of the National Agency for Medicines and Medical Devices of Romania, registered at the Ministry of Health with no. P 948 of 06.07.2021,

taking into account the provisions of Article 883 of Law 95/2006 on healthcare reform, republished, as further amended and supplemented,

taking into account the provisions of Article 4 (3) point 1 of Law no. 134/2019 on reorganisation of the National Agency for Medicines and Medical Devices and amendment of further ruling provisions;

pursuant to Article 7 (4) of Government Decision no. 144/2010 on the organisation and operation of the Ministry of Health, as further amended and supplemented,

the minister of health hereby issues the following order:

Article 1 – The Norms for implementation of provisions of Article 883 of Law 95/2006 on healthcare reform regarding the authorisation for marketing of some medicinal products needed on grounds of public health, mentioned in the Annex which is integral part of this Order, are approved.

Article 2 - The Ministry of Health and the National Agency for Medicines and Medical Devices of Romania, hereinafter the ***NAMMDR***, shall carry out the provisions of this Order.

Article 3 - This Order shall be published in the Official Gazette of Romania, Part I.

Minister of health,
Ioana Mihăilă

ANNEX

RULES
for implementation of provisions of Article 883 of Law 95/2006 on healthcare reform regarding the authorisation for marketing of some medicinal products needed on grounds of public health

Article 1 - (1) These Rules establish the procedure regarding the marketing authorisation of certain medicinal products needed on grounds of public health, to solve unmet medical needs, hereinafter referred to as ***medicinal products needed on grounds of public health***.

(2) The marketing authorisation of the medicinal product needed on grounds of public health is granted if the following conditions are cumulatively met:

a) the medicinal product, characterised by a trade name, strength and pharmaceutical form, is authorised for marketing in at least one member state of the European Union (***EU***);

b) the medicinal product, characterised by a trade name, strength and pharmaceutical form, does not have a valid marketing authorisation in Romania or an application for authorisation submitted in this regard;

c) the medicinal product, characterised by a trade name, strength and pharmaceutical form, does not have a pharmaceutical equivalent within the meaning of provisions of Order of the Minister of Health no. 85/07.02.2013 on approval of the Rules for implementation of provisions of Article 699 (1) and (2) of Law No. 95/2006 on healthcare reform concerning medicinal products for special needs, as further amended and supplemented, for which there is a valid marketing authorisation on the date of the request for release of the marketing authorisation of the medicinal product needed on grounds of public health, except for the situation in which such an authorisation exists, but the medicinal product has not actually been placed on the market in the last 6 months prior to the request for release of the marketing authorisation of the medicinal product needed on grounds of public health;

d) there is a medical justification report for the medicinal product characterised by an international non-proprietary name, strength and pharmaceutical form, issued by the specialised commissions within the Ministry of Health on their own initiative or upon request of the specialised directorate.

(3) The following do not fall within the regulatory scope of these rules:

a) medicinal products with valid marketing authorisations in Romania at the time of request of issuance of a marketing authorisation of the medicinal product needed on grounds of public health;

b) the authorisation of a medicinal product for off-label use in the country of origin;

c) medicinal products subject to a clinical trial carried out in Romania.

Article 2 - (1) Prior to issuance of the marketing authorisations for the medicinal products mentioned in Article 1 (1), in line with the provisions of Article 883 (2) and (3) of Law 95/2006 on healthcare reform, republished, as further amended and supplemented, the

NAMMDR, on its own initiative or within 10 working days from the notification in this respect from the specialised structure within the Ministry of Health, takes the following measures:

a) notifies the Marketing Authorisation Holders (***MAHs***) in the Member State(s) of origin where the medicinal product in question is authorised of the proposal to grant a marketing authorisation for the medicinal product needed on grounds of public health;

b) may request the competent authority in the Member State where the medicinal product is authorised for grant of a marketing authorisation of the medicinal product needed on grounds of public health to send copies of the assessment report provided by Article 21 (4) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use and of the marketing authorisation in force for the respective medicinal product, with all its Annexes.

(2) Notifications are sent to all MAHs provided for in paragraph (1) a). The NAMMDR grants the marketing authorisation of the medicinal product needed on grounds of public health to the first MAH who has submitted the complete documentation provided for in Article 4.

(3) The NAMMDR may request the necessary documents from the competent authority of the member state in which the medicinal product is authorised for grant of an authorisation, according to the provisions of paragraph (1) b), including the situation where a MAH accepts the grant of a marketing authorisation of the medicinal product needed on grounds of public health in Romania.

Article 3 - (1) In the situation provided for in Article 2 paragraph (1) a), the notification sent by the NAMMDR to the MAH in the member state where the medicinal product in question is authorised must contain at least the following:

a) an estimation of the annual consumption of the respective medicinal product;

b) the manufacturer's approved price for the respective medicinal product, if it has been authorised for marketing in Romania and if its price was approved by the Ministry of Health;

c) a brief summary of the regulations in force regarding the marketing authorisation, the wholesale distribution of medicinal products and the rules for establishing and approving the price of medicinal products in Romania, stating the applicable normative acts.

(2) The NAMMDR can request the specialised department within the Ministry of Health for the information provided in paragraph (1) a) and b). The specialised department within the Ministry of Health requests the necessary information from the specialised commissions/National Health Insurance House within 5 working days and communicates them to the NAMMDR within 3 working days after receiving them.

Article 4 - In order to obtain the marketing authorisation for a medicinal product needed on grounds of public health, the applicant submits to the NAMMDR a documentation which includes:

a) the standard form for the application for grant of a marketing authorisation for a medicinal product needed on grounds of public health, according to Annex 1, and the related documents mentioned therein;

b) the marketing authorisation of the medicinal product from the country of origin, with all amendments, as well as the Romanian translation of it and of the Summary of Product Characteristics, the leaflet and the labeling information, except for the case provided for in Article 2 paragraph (1) b);

c) a statutory declaration stating that the authorisation granted according to Article 1 will not be the basis for obtaining an authorisation for distribution of the medicinal product outside the Romanian territory;

d) a summary of the pharmacovigilance system which includes the elements provided for in Article 706 paragraph (4) l) of Law 95/2006 on healthcare reform, republished, as further amended and supplemented.

Article 5 - (1) The NAMMDR issues the marketing authorisation of the medicinal product needed on grounds of public health in line with the provisions of Article 883 (2) and (3) of Law 95/2006, republished, as further amended and supplemented, if the translations into Romanian of the marketing authorisation, the summary of product characteristics (SmPC), the leaflet and the labeling information from the EU member state are made by an authorised translator, from the original version of the respective member state, if it is authorised through national procedure, or from the original English version, if authorised through decentralised or mutual recognition procedure.

(2) The NAMMDR may decide that the provisions of Article 785 (1) and (2) of Law 95/2006, republished, as further amended and supplemented, are not applicable to medicinal products authorised in line with these Rules.

(3) The NAMMDR issues the marketing authorisation of the medicinal product needed on grounds of public health within a maximum of 15 working days from the date on which the applicant submits all the documents provided for in Article 4.

Article 6 - The holder of the marketing authorisation in Romania, granted in accordance with these Rules, has the following obligations:

a) to make sure that the medicinal product is compliant with the marketing authorisation granted by the EU Member State and includes all variations, especially those impacting the summary of product characteristics, labeling information and leaflet, transfer of the marketing authorisation, if applicable, other changes to the design and imprinting, as approved in the EU member state;

b) to notify the NAMMDR about any change that occurred after the release of the marketing authorisation granted by the EU member state and to forward the updated documentation referred to in Article 4 b), accompanied by the standard application/notification form according to Annex 2;

c) in order to fulfill the duties related to pharmacovigilance, to comply with the obligations mentioned in Chapter X of Title XVIII of Law 95/2006, republished, as further amended and supplemented;

d) to place the authorised medicinal product on the market, in adequate and continuous stocks, according to Article 804 paragraph (2) of Law 95/2006, republished, as further amended and supplemented, and in accordance with the requirements established according to Article 3 paragraph (2), as soon as possible, but no later than 90 days after being granted the authorisation;

e) to not request a change of classification for release of the medicinal product during the entire period of validity of the authorisation, unless this change has been approved in the EU member state in which the medicinal product is authorised;

f) to submit to the NAMMDR the proof that he/she owns wholesale distribution units of medicinal products for human use authorised by the NAMMDR or a document certifying the contractual relationship with a wholesale distributor authorised by the NAMMDR, as soon as possible, but no later than 60 days after being granted the authorisation.

Article 7 - (1) If the MAH of the medicinal product needed on grounds of public health is not the product's wholesale distributor, he/she will forward to the NAMMDR an authenticated copy of the marketing authorisation, together with the access declaration of the Marketing Authorisation Holder by which the holder grants the wholesale distributor(s) of the medicinal product the right to use the authorisation.

(2) The MAH/MAH representative does not have the obligation provided by Article 799 paragraph (6) of Law 95/2006, republished, as further amended and supplemented.

Article 8 - (1) If the MAH of the medicinal product needed on grounds of public health is also the product's wholesale distributor, he/she has the following obligations:

a) to hold a wholesale distribution authorisation issued in Romania by the NAMMDR;

b) to immediately inform the NAMMDR about safety or quality issues, including those caused by a potential falsification, about which he/she was informed;

c) to keep specific records regarding its distribution, in line with the provisions of Article 803 lit. f) of Law 95/2006, republished, as further amended and supplemented, and with Article 20 of the Guideline on the Good Distribution Practice of wholesale medicinal products, approved through Order of the Minister of Health no. 761/2015;

d) to notify the NAMMDR about the effective intra-community purchased/commercialised quantity of the medicinal product needed on grounds of public health at each entry/exit and about any other issues arising in its supply chain, according to the provisions of Order of the Minister of Health no. 502/2013 on approval of mandatory monthly reporting of placement on the market in Romania and of sales of medicinal products for human use, respectively, by authorised wholesale distributors/importers/manufacturers;

e) to notify the NAMMDR if the medicinal product ceases to be placed on the market in Romania, temporarily or permanently, in compliance with the provisions of Article 737 paragraph (2) of Law 95/2006, republished, as further amended and supplemented.

(2) The MAH/MAH representative does not have the obligation provided by Article 799 paragraph (6) of Law 95/2006, republished, as further amended and supplemented.

Article 9 - (1) A marketing authorisation of a medicinal product needed on grounds of public health is valid for 3 years.

(2) The marketing authorisation of the medicinal product needed on grounds of public health can be extended for a 3-year period, based on an application whose model is provided in Annex 3, which is submitted to the NAMMDR at least 6 months before the expiration of the 3-year term mentioned in paragraph (1).

(3) Medicinal products for which requests for extension of authorisation have been submitted according to paragraph (2) can be maintained in the therapeutic circuit until the request for extension of authorisation is resolved.

(4) In the event that until the expiration of the 3-year validity term mentioned in paragraph (1), a medicinal product with the same trade name, strength and pharmaceutical form is authorised in line with provisions of Article 704 paragraph (1) of Law 95/2006, republished, as further amended and supplemented, and actually placed on the market, the marketing authorisation of the medicinal product needed on grounds of public health can no longer be extended.

Article 10 - The marketing authorisation of the medicinal product needed on grounds of public health is suspended by the NAMMDR if it is found that the conditions under which it was granted are no longer met; similarly, any of the MAH obligations related to the medicinal product needed on grounds of public health shall be suspended, except for the obligation provided for in Article 6 d), whose non-compliance determines the NAMMDR to withdraw the authorisation. Suspension is maintained until the identified deficiencies are remedied, without extension of the authorisation term.

Article 11 - The NAMMDR may, at any time, request the wholesale distributor the status of the records provided for in Article 8 paragraph (1) c) and may order any measure related to the medicinal product authorised on grounds of public health, in order to reduce a potential risk to the patient's health or to public health related to the product’s quality, safety or effectiveness.

Article 12 - The NAMMDR notifies the European Commission about the fact that a medicinal product is authorised or ceases to be authorised, according to Article 126a of Directive 2001/83/EC of the European Parliament and of the Council.

Article 13 - Annexes 1 - 3 are integral part of these Rules.

ANNEX 1
to the Rules

Form for application for marketing authorisation

Marketing authorisation for a medicinal product needed on grounds of public health in line with the provisions of Article 883 of Law 95/2006 on healthcare reform, republished, as further amended and supplemented, transposing the provisions of Article 126a of Directive 2001/83/EC

FORM FOR APPLICATION FOR MARKETING AUTHORISATION

Annexes 1 - 5 of this Form are an integral part of it, as the case may be.

A separate application form is submitted for each medicinal product (for each strength and each pharmaceutical form).

The forms can be submitted via the Common European Submission Portal (CESP) or by submitting documents in electronic format, regardless of the storage type (e.g. CD/DVD).

1. Information about the medicinal product

1.1. a) Trade name (invented name) of the medicinal product

b) Pharmaceutical form[1])

c) Strength(s) of the active substance(s)

d) Route(s) of administration[2])

1.2. Active substances and excipients[3])

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[1]) The current list of Standard Terms (EDQM/European Pharmacopoeia) is employed

[2]) The current list of Standard Terms (EDQM/European Pharmacopoeia) is employed

[3]) For each active substance and excipient, a single name is specified, in the following order of priority: (INN, Ph. Eur., British Pharmacopoeia, any other national pharmacopoeias of the Member State [EEA], common name, scientific name). The active substance must be declared according to the recommended INN, accompanied by the salt or hydrated form, if applicable [for more details, see the Guideline for Applicants (***Notice to Applicants***) regarding the summary of product characteristics].

Active substance(s)	Quantity of active substance/active substances per unit dose	Reference/Monograph/Standard

Excipient(s)	Quantity per unit dose	Reference/Monograph/Standard

1.3. Pharmacotherapeutic group (according to the current ATC code)

ATC code:

Pharmacotherapeutic group:

1.4. Container, closure system and administration device(s)[4]) of the medicinal product proposed for being placed on the Romanian market (including the description of manufacturing materials)

1.5. Please specify the size(s) proposed for being placed on the market in Romania for each type of packaging.

1.6. Legal status: (Classification in line with Article 699 point 21 of Law 95/2006, republished, as further amended and supplemented)

Subject to medical prescription

Not subject to medical prescription

2. Marketing Authorisation Holder/Contact persons/Manufacturers

2.1. Marketing Authorisation Holder of the medicinal product authorised in the EU member state

Company name .....

Address .....

Telephone .....

Telefax .....

E-mail .....

2.2. Proposed Marketing Authorisation Holder[5]) responsible for placing the medicinal product on the Romanian market

Name .....

Address .....
Telephone .....
Telefax .....
E-mail .....
Please attach the poof of the existence of the applicant's headquarters in Romania/EU.

2.3. Person/Company authorised for communication with the National Agency for Medicines and Medical Devices of Romania during the authorisation procedure/for signing, on behalf of the Marketing Authorisation Holder (Annex 1 to this form) (if required)

Company name .....
Address .....
Telephone .....
Telefax .....
E-mail .....
If different from point 2.2, please attach the letter of authorisation.

2.4. Person from the EU (name, address and contact data) responsible for adverse reaction reporting and implementation of risk minimization measures for the medicinal product authorised in Romania (must reside in the EU and work there as well)[6]).

Name .....
Address .....
Telephone .....
Telefax .....
E-mail .....

2.5. Official batch release for blood products and vaccines: identification data of an OMCL (Official Medicines Control Laboratories) or of a laboratory designated for the purpose of official batch release [in line with Article 857 (1), Articles 861, 862 and 863 of Law 95/2006, republished, as further amended and supplemented].

Name .....
Address .....
Telephone .....

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[4]) The current list of Standard Terms (EDQM/European Pharmacopoeia) is employed.

[5]) The Marketing Authorisation Holder should reside in an EU member state.

[6]) For the purpose of this application, the person in the EU responsible for adverse reaction reporting and enforcement of risk minimisation measures "is established" at the place of residence, at the site where he/she can be tracked, located, authenticated in association with all his/her legal and contractual obligations, regardless of whether the respective site is the person's property or whether the person resides there permanently or temporarily.

Address .....
Telephone .....
Telefax .....
E-mail .....

2.7. EU contact person (name, address and permanent contact data) responsible for complaints concerning the product and recalls

Name .....
Address .....
Telephone .....
Telefax .....
E-mail .....

2.8. Local representative of the Marketing Authorisation Holder

Name .....
Address .....
Telephone .....
Telefax .....
E-mail .....

3. Medicinal product information in line with the authorisation in the EU member state of origin

3.1. EU member state of origin of the medicinal product. Please specify only one country as member state of origin

3.2. Number of the marketing authorisation of the medicinal product authorised in the EU member state of origin[8])

3.3. The medicinal product's marketing authorisation procedure in the EU member state of origin

Number of the mutual recognition procedure[9])/decentralised procedure[10])

Number of the national procedure[11])

DECLARATION

I, the undersigned, Marketing Authorisation Holder, hereby declare that, in line with the data I own, all the information provided in this application, as well as the Annexes and all the attached documents are correct and complete.

Name of the proposed marketing authorisation holder (capital letters)

Signature(s)

.....

Job

.....

Date and place

.....

[7]) The batch release site should be within the EEA. Several batches may be specified, as required.

[8]) This number can be obtained from a valid marketing authorisation issued by the national competent authority in the EU/EEA member state of origin.

[9]) Mutual recognition procedure [in line with the provisions of Article 28 (2) of Directive 2001/83/EC].

[10]) Decentralised procedure [in line with the provisions of Article 28 (3) of Directive 2001/83/EC].

[11]) Please specify the date of the first authorisation, the date of MA renewal, variation history, the legal grounds for authorisation

Annex 1
to the Form for marketing authorisation application

Address for authorisation for the purpose of communication/signing on behalf of the Marketing Authorisation Holder.....

(Please fill in only if required.)

Name of the medicinal product, pharmaceutical form and strength:

I, the undersigned, ..., hereby authorize, until further notice,
(name and address of the marketing authorisation holder)

....., residing in ....., as representative
(name of the contact person) (office address of the contact person)

of ..... and for the purpose of the following actions (please check, if required):
(name of the Marketing Authorisation Holder)

Communication regarding requests for additional information/clarification of the information provided in the application forms and submitted documents ☐

Signing documents during the authorisation process, if necessary ☐

Receipt of authorisation ☐

.....
Name (capital letters) of the proposed Marketing Authorisation Holder

....
Date Signature of the proposed Marketing Authorisation Holder

.....
Name (capital letters) of the person authorised for the purpose of communication/signing
(as required) on behalf of the Marketing Authorisation Holder

....

Date

Signature of the person authorised for the purpose of communication/signing (as required) on
Behalf of the Marketing Authorisation Holder

Annex 2
to the Form for marketing authorisation application

DECLARATION on placing a medicinal product on the Romanian market according to the mentioned authorisation

Name of the medicinal product, pharmaceutical form and strength:

I, the undersigned, Marketing Authorisation Holder, hereby declare that:

- the medicinal product to be placed on the Romanian market based on the respective authorisation, at any time during the validity period of the authorisation in question, is identical to the one authorised in order to be placed on the market in

.....

(EU member state) (EU member state of origin)

based on the marketing authorisation in the respective member state;

- the medicinal product which shall be placed on the Romanian market according to the respective marketing authorisation is not authorised through centralised procedure granted in line with provisions of Regulation (EC) no. 726/2004 and does not come from the parallel import of a medicinal product authorised through centralised procedure;

- the medicinal product which shall be placed on the Romanian market according to the respective marketing authorisation is not authorised as an herbal medicinal product in the EU member state of origin;

- the medicinal product which shall be placed on the Romanian market according to the respective marketing authorisation does not come from parallel import from the EU member state of origin;

- the medicinal product which shall be placed on the Romanian market according to the respective marketing authorisation is not authorised in the EU member state of origin, in line with the provisions of Article 126a of Directive 2001/83/EC;

- I am fully aware of my obligations in line with the provisions of Law 95/2006, republished, as further amended and supplemented, and I assume their fulfillment and compliance with the terms and conditions of this authorisation;

- The leaflet and labeling of the medicinal product which shall be placed on the Romanian market according to the respective marketing authorisation shall be developed in Romanian, with the exception of the situations provided for in Article 5 (2) of the Rules for the implementation of the provisions of Article 883 of Law 95/2006 on healthcare reform, for marketing authorisation of medicinal products needed on grounds of public health, approved through Order of the Minister of Health no. 1.540/2021.

.....	.....
Date	Name (capital letters) of the proposed marketing authorisation holder
	.....
	Signature of the proposed marketing authorisation holder

Annex 3
to the Form for marketing authorisation application

A. Declaration of the proposed Marketing Authorisation Holder regarding the submitted documentation

Name of the medicinal product, pharmaceutical form and strength:

I, the undersigned, proposed Marketing Authorisation Holder, hereby declare that all presented documents, including the Summary of Product Characteristics (RCP), the labeling information and the leaflet of the medicinal product subject to this application are the latest versions approved in

..... .

(EU member state) (EU member state of origin).

.....	.....
Date	Name (capital letters) of the proposed Marketing Authorisation Holder
	.....
	Signature of the proposed Marketing Authorisation Holder

B. As regards relabeling and/or repackaging of medicinal products imprinted in Romanian:

Correct translation of the medicinal product information

I, the undersigned, hereby declare that the Summary of Product Characteristics (RCP), Leaflet (PL) and labeling of the medicinal product which shall be placed on the Romanian market are a correct translation into English and Romanian of the Summary of Product Characteristics (SmPC), Leaflet and labeling information authorised for this

medicinal product in

..... .

(EU member state) (EU member state of origin).

Please attach the original version in the language of the EU member state of origin, as well as the certified/legalised versions of the translations of the SmPC, leaflet and labeling information.

.....
Name (capital letters) of the proposed marketing authorisation holder

....
Date Signature of the proposed marketing authorisation holder

Annex 4
to the Form for marketing authorisation application

DECLARATION of the proposed Marketing Authorisation Holder regarding the fulfillment of post-authorisation obligations

Name of the medicinal product, pharmaceutical form and strength:

I, the undersigned, proposed Marketing Authorisation Holder, hereby declare that I will fulfill all my post-authorisation obligations, including notification of the NAMMDR and subsequent implementation of all variations related to quality and to medicinal product information approved in.....,
(EU member state of origin)
as well as reporting adverse reactions and the implementation in Romania of the measures for minimisation of the risks related to this medicinal product. I also declare that I undertake to simultaneously implement all urgent safety measures in Romania and in
.....
(EU member state of origin)
and that I shall immediately notify the NAMMDR about all quality defects and batch/medicinal product withdrawals.

.....
Name (capital letters) of the proposed marketing authorisation holder

....
Date Signature of the proposed marketing authorisation holder

Annex 5
to the Form for marketing authorisation application

Documents attached to the application form

1. Proof of establishment of the proposed Marketing Authorisation Holder in the EU member state of origin	☐
2. Copy of the valid marketing authorisation (MA)*) for the concerned medicinal product, released by the competent authority in the EU member state of origin, which should include all amendments approved through variation, valid upon submission of the application. If the authorisation is written in a language other than English, a legalised/certified translation of the MA in English and/or Romanian must be submitted	☐
3. The latest approved version of the medicinal product's SmPC authorised in the EU member state of origin (electronic copy) The legalised/certified translation of the SmPC into English and Romanian (electronic copy)	☐
4. The latest approved version of the Leaflet of the medicinal product authorised in the EU member state of origin (electronic copy) The legalised/certified translation of the leaflet into English and Romanian (electronic copy)	☐
5. The latest approved version of the (primary and secondary) labeling information of the medicinal product authorised in the (EU) member state of origin (electronic copy) The legalised/certified translation of the (primary and secondary) labeling information into English and Romanian (electronic copy)	☐

Name of the medicinal product, pharmaceutical form and strength:

I, the undersigned, ..., hereby confirm the authenticity of the copy

(proposed Marketing Authorisation Holder)

of the marketing authorisation submitted for the specified medicinal product, in line with the original marketing authorisation for the same medicinal product, issued by the EU member state of origin.

Name of the proposed Marketing Authorisation Holder (capital letters) .....

Signature of the proposed Marketing Authorisation Holder .....

Date

.....

_____

*) The declaration of authenticity regarding the copy of the marketing authorisation in force in the EU member state of origin.

Annex 2
to the Rules

Application/notification form received on (date): .../.../...

Form for notification of variations and other amendments related to design and imprinting of marketing authorisations for a medicinal product needed on grounds of public health, in line with Article 883 of Law 95/2006 on healthcare reform, republished, as further amended and supplemented, transposing the provisions of Article 126a of Directive 2001/83/EC

Annexes 1 - 4 of this Form are integral part of it, as required.

Forms may be submitted via the Common European Submission Portal (CESP) or submission of electronic documents, regardless of type (CD/DVD)

This form is submitted only in relation to the variation of the terms of the marketing authorisation, of the medicinal product information (Summary of Product Characteristics, leaflet and labeling information) and the information presented for the initial authorisation or extension of the authorisation (according to the details presented in the notification form), as well as in relation to the amendments related to the design and imprinting of these medicinal products.

Notice of variation(s)/amendment(s) approved in the EU member state[1]) as a result of the granting in Romania of an authorisation for a medicinal product for special needs on grounds of public health, in line with Article 883 of Law 95/2006, republished, as further amended and supplemented

Name(s) of the medicinal product(s)*), Pharmaceutical form and strength:

I, the undersigned, ..., following release of the marketing authorisation(s), hereby

(Marketing Authorisation Holder)

notify the National Agency for Medicines and Medical Devices on the following amendment(s) to the aforementioned medicinal product, authorised in Romania based on the respective authorisation.

I hereby declare that this amendment was approved/these amendments were already approved in ..... .

(member state)

[1]) "(EU) member state of origin" refers to the member state where the concerned medicinal product is authorised. In Romania, a marketing authorisation in line with provisions of Article 883 of Law 95/2006, republished, can be granted exclusively for medicinal products with a marketing authorisation valid in the (EU) member state of origin. The medicinal product placed on the Romanian market must be the same as the one authorised in order to be placed on the market in the respective member state.

*) In the event that the variation/variations/amendment/amendments notified to the competent authority concern(s) several medicinal products, the list of medicinal products and the corresponding authorisation numbers shall be attached.

Only the types of variations/amendments referred to in this notification are sent to the NAMMDR.

A. The variation/amendment targets medicinal product information (Please fill in as appropriate.)

YES |¯| NO |¯|

If YES, please specify the targeted field (the following shall be checked, as required; please attach the appropriate supporting documents, updated, as required).

Summary of Product Characteristics |_|

Leaflet |_|

Information on (primary and/or secondary) labeling |_|

(Variation approval/notification approval/confirmation of approval or a copy of the renewed APP issued by the competent national authority of the Member State of origin shall be attached, as required.)

(The revised version of the medicinal product information shall be attached, as required.)

B. The variation/amendment targets details of the authorisation in Romania (please fill in as appropriate)

YES |¯| NO |¯|

If YES, please specify the aspect concerned (the following shall be checked, as required; please attach the appropriate supporting documents, updated, as required)

1. Number of the marketing authorisation(s)[2]) in the (EU) member state of origin |_|

Current	Proposed

(The approval of the change of the marketing authorisation number from the competent national authority in the Member State of origin is submitted. PLEASE NOTE: The medicinal product must be the same as the previously approved one, and the change in the marketing authorisation number is a consequence of another change approved in the member state of origin.)

(The revised version of the medicinal product information shall be attached, as required.)

2. Identification data of the Marketing Authorisation Holder (name, address, contact information) for the medicinal product from the EU country of origin |_|

[2]) This number can be obtained from a valid marketing authorisation issued by the national competent authority of the EU member state of origin.

Current	Proposed

a) Change of the identification data of the Marketing Authorisation Holder for the respective medicinal product in the member state of origin, following a variation in the member state of origin (for example, a change of name and/or address, if the change does not constitute a change of the legal entity, i.e. it is not a transfer), if the holder of the respective marketing authorisation in Romania may or may not be the holder of the marketing authorisation for the medicinal product authorised in its country of origin.

YES |¯| NO |¯|

(The approval of the change of the marketing authorisation number from the competent national authority in the Member State of origin is submitted, as required.)

[An official document issued by a competent official body is submitted, specifying the new name/address (proof of operation).]

(The revised version of the medicinal product information shall be attached, as required.)

b) Change of the identification data of the Marketing Authorisation Holder for the respective medicinal product in the member state of origin, following a marketing authorisation transfer (change of the legal person) in the member state of origin, if the holder of the respective marketing authorisation in Romania can or cannot be the Marketing Authorisation Holder of the medicinal product authorised in the country of origin.

YES |¯| NO |¯|

(The approval of the change of the legal person from the competent national authority in the member state of origin shall be submitted, as required.)

[An official document concerning the appointment of the new legal person (proof for appointment) shall be submitted as well].

(The revised version of the medicinal product information shall be attached, as required.)

3. Identification data of the Marketing Authorisation Holder[3]) [the person responsible for placing the medicinal product on the Romanian market, holding a marketing authorisation in line with Article 883 of Law 95/2006, republished, as further amended and supplemented (name, address and contact data)] |¯|

[3]) The Marketing Authorisation Holder should reside in an EU member state.

Current	Proposed

PLEASE NOTE: The change of the Marketing Authorisation Holder, following the changes targeting the Marketing Authorisation Holder (regardless whether it is a transfer, involving the change of the legal person, or if it is a change of name and/or address of the same legal person) is accepted for the medicinal product in the state of origin. In such cases, the relevant documentation mentioned above shall be presented, in line with points 2 a) and b).

PLEASE NOTE: Change of the Marketing Authorisation Holder, if different from the Marketing Authorisation Holder of the medicinal product authorised in the member state of origin, can only be accepted in case of the change of the name and/or address of the Marketing Authorisation Holder, without changing the legal person who holds the authorisation. [An official document issued by a competent official body shall be submitted, specifying the new name/address (proof of operation).]

4. Amendments (addition, deletion, replacement) of the manufacturing site(s) of batch release*) (name, address and contact data) |_|

*) Authorised manufacturer(s) responsible for batch release[4]) in the EU, in line with provisions of Articles 755 and 769 of Law 95/2006, republished, as further amended and supplemented, for the medicinal product which is to be marketed in Romania [should already be authorised as the EU site for batch release in the member state (country of origin)].

[4]) Batch release sites should be within the EU/EEA. Several batch release sites may be specified, as required

Current	Proposed

(The approval of the variation/notification/ confirmation of approval or a copy of the renewed MA issued by the national competent authority in the member state of origin shall be sent, as required.)

(The revised version of the medicinal product information shall be attached, as required.)

5. Change of the medicinal product's name in the member state of origin |_|

(The approval of the change of the name of the medicinal product by the competent national authority in the Member State of origin shall be sent.)

(The revised version of the medicinal product information shall be attached.)

Current	Proposed

C. The amendment targets packaging sizes and/or the container's closure system

YES |¯| NO |¯|

If YES, please specify the aspect concerned (please check and fill in the following, as required).

Packaging sizes |_|

The recipient's closure system |_|

a) In case of amendments related to packaging sizes and container's closure systems, already approved in the member state of origin following a variation, the following documents shall be mentioned and forwarded:

Current	Proposed

(The approval of the amendment(s) of packaging sizes and/or container closure system is submitted, issued by the national competent authority in the member state of origin.)

(The revised version of the product information approved in the member state of origin shall be submitted)

b) In case of introduction of new packaging sizes and container closure systems, already approved in the member state of origin, but which have not been previously submitted/notified in Romania, please specify below.

Current	Proposed

(The information on primary and secondary labeling for added packaging types, which have not been previously sent to the NAMMDR, shall be forwarded; the respective labeling information must have the prior approval of the member state of origin.)

D. The amendment targets other aspects of those presented in the original authorisation application form (please fill in as appropriate)

YES |¯| NO |¯|

If YES, please specify the targeted aspect (please check and fill in the following, as required).

Person from the EU (name, address and contact data) responsible for adverse reaction reporting and implementation of risk minimisation measures for the medicinal product authorised in Romania (must reside in the EU and work there as well)[5]).

Current	Proposed

Official batch release for blood products and vaccines: identification data of an OMCL (Official Medicines Control Laboratories) or of a laboratory designated for the purpose of official batch release [in line with Articles 857 (1), 861, 862 and 863 of Law 95/2006, republished, as further amended and supplemented].

Current	Proposed

EU contact person (name, address and permanent contact data) for quality complaints and medicinal product withdrawal

Current	Proposed

Local representative of the Marketing Authorisation Holder (name, address and contact data)

Current	Proposed

[5]) For the purpose of this application, the person in the EU/EEA responsible for adverse reaction reporting and enforcement of risk minimisation measures "is established" at the place of residence, at the site where he/she can be tracked, located, authenticated in association with all his/her legal and contractual obligations, regardless of whether the respective site is the person's property or whether the person resides there permanently or temporarily.

DECLARATION

I, the undersigned, hereby declare that, in line with the data I own, all the information provided in this application, as well as the Annexes and all the attached documents are correct and complete.

Name of the Marketing Authorisation Holder (capital letters)

.....

Signature(s)

.....

Job

.....

Date and place

.....

If required, the person/company authorised for communication with the NAMMDR/signing, on behalf of the Marketing Authorisation Holder and/or for receipt of the authorisation document(s) according to this application and during the application evaluation process

[If needed, this section shall be filled in and a corresponding letter for authorisation of communication with the NAMMDR/signing shall be provided, on behalf of the Marketing Authorisation Holder/receipt of the document(s) for authorisation (this shall be included, if required).]

Name .....

Address .....

Telephone .....

Telefax .....

E-mail .....

Annex 1
to the form for application/notification

DECLARATION for placing a medicinal product on the Romanian market based on the mentioned authorisation

Name(s) of the medicinal product(s), Pharmaceutical form and strength:

I, the undersigned, Marketing Authorisation Holder, hereby declare that the:

- The medicinal product which shall be placed on the Romanian market according to the respective marketing authorisation, at any time during the validity period of the authorisation in question, is the same medicinal product as the one authorised for marketing in
....., based on a marketing authorisation in the respective
(EU member state) (EU member state of origin)
member state.

- The medicinal product which shall be placed on the Romanian market according to the respective marketing authorisation does not come from parallel import from the EU member state of origin.

I, the undersigned, I am fully aware of my obligations in line with the provisions of Law 95/2006, republished, as further amended and supplemented, and I assume their fulfillment and compliance with the terms and conditions of this authorisation.

The product's leaflet and labeling information which shall be placed on the Romanian market according to the respective marketing authorisation shall be developed in Romanian (except for closed-circuit medicinal products).

All the documents submitted, including the Summary of Product Characteristics (RCP), the labeling information and the leaflet of the medicinal product subject to this application are the latest versions approved in the EU member state of origin
..... .
(EU member state of origin)

.....
Name of the Marketing Authorisation Holder (capital letters)

....
Date Signature of the Marketing Authorisation Holder

Annex 2

to the form for application/notification

(As regards relabeling and/or repackaging of medicinal products imprinted in Romanian)

Name(s) of the medicinal product(s), Pharmaceutical form and strength:
Correct translation of the medicinal product information

I, the undersigned, Marketing Authorisation Holder, hereby declare that the Summary of Product Characteristics (RCP), the product's leaflet and labeling information which shall be placed on the Romanian market are a correct translation into Romanian of the Summary of Product Characteristics (SmPC), Leaflet (PL) and labeling authorised for this medicinal product in EU member state of origin .....
.

(EU member state of origin)

Please attach the original version in the language of the EU member state of origin, as well as the certified/legalised versions of the translations of the SmPC, leaflet and labeling information.

.....
Name of the Marketing Authorisation Holder (capital letters)

....
Date Signature of the Marketing Authorisation Holder

Annex 3

to the form for application/notification

The Marketing Authorisation Holder's commitment regarding the fulfillment of post-authorisation obligations

Name(s) of the medicinal product(s), Pharmaceutical form and strength:

I, the undersigned, Marketing Authorisation Holder, hereby declare that I will fulfill all my post-authorisation obligations, including notification of the NAMMDR and subsequent implementation of all variations related to the information about the medicinal product approved in ....., as well as adverse reaction reporting adverse

(EU member state)

and the implementation in Romania of the measures for minimisation of the risks related to this medicinal product. Moreover, I commit to simultaneously implement all emergency safety measures in Romania and in ..... and that I shall immediately notify the NAMMDR about all quality defects and

(EU member state)

batch/medicinal product withdrawals.

.....
Name of the Marketing Authorisation Holder (capital letters)

....
Date Signature of the Marketing Authorisation Holder

Annex 4

to the form for application/notification

Documents attached to the application form (if required, according to the variation/variations/change/changes in question)

PLEASE NOTE: A legalised/certified translation into English and/or Romanian of relevant documents shall be submitted.

1. Approval of the variation/Approval of the notification/Approval confirmation or a copy of the renewed marketing authorisation (MA) issued by the national competent authority in the member state of origin, as required.	☐
2. For variations associated with the name and/or address of the Marketing Authorisation Holder of the medicinal product in the (EU) member state of origin, together with the approval of the variation from the national competent authority in the country of origin, an official document issued by an official competent body is required, stating the new name or address.	☐
3. In case of a change of the Marketing Authorisation Holder of the medicinal product in the (EU) member state of origin, as a legal person, proof of establishment of the new legal person (the new MAH) in an (EU) member state	☐
4. In case of a change of the legal person of the Marketing Authorisation Holder of the medicinal product in the EU member state of origin, a copy of the valid marketing authorisation*) for the concerned medicinal product or approval of the change of the legal person holding a MA by the competent authority in the (EU) member state of origin	☐
5. In case of amendment of the product information: the latest approved version of the Summary of Product Characteristics (SmPC) of the medicinal product authorised in the EU member state of origin (electronic copy)	☐
6. The latest approved version of the Leaflet of the medicinal product authorised in the EU member state of origin (electronic copy)	☐
7. The latest approved version of the (primary and secondary) labeling information of the medicinal product authorised in the EU member state of origin (electronic copy)	☐
8. Address for authorisation (if needed) of the communication with the NAMMDR/signing on behalf of the Marketing Authorisation Holder and/or receipt of authorisation document(s) (with details depending on relevance and case)	☐

9. In case of change of the name and/or address of the Marketing Authorisation Holder of the medicinal product which is to be marketed in Romania, in line with provisions of Article 883 of Law 95/2006, republished, as further amended and supplemented, when this person is not the Marketing Authorisation Holder for the medicinal product in the member state of origin, an official document from a relevant official body shall be presented, stating the new name or the new address.	☐

Name(s) of the medicinal product(s), Pharmaceutical form and strength:

I, the undersigned, ..., hereby confirm the authenticity of the copy of the marketing authorisation

(Marketing Authorisation Holder)

Submitted for the specified medicinal product, in line with the original marketing authorisation for the same medicinal product, issued by the EU member state of origin.

Name of the Marketing Authorisation Holder (capital letters) .....

Signature of the Marketing Authorisation Holder .....

Data .....

---

*) Declaration of authenticity regarding the copy of the marketing authorisation in force in the EU member state of origin

Annex 3
to the Rules

Form for application for extension, received on (date): ...../...../

Extension of the marketing authorisation for a medicinal product needed on grounds of public health in line with the provisions of Article 883 of Law 95/2006 on healthcare reform, republished, as further amended and supplemented, transposing the provisions of Article 126a of Directive 2001/83/EC

FORM FOR APPLICATION FOR EXTENSION OF THE MARKETING AUTHORISATION

Annexes 1 - 5 of this Form are integral part of it, as required.

For extension of the marketing authorisation: please specify its number: ...../...../

An individual form for application shall be submitted for each medicinal product, strength and pharmaceutical form.

Forms may be submitted via the Common European Submission Portal or by submission of electronic documents, regardless of type (CD/DVD).

1. Medicinal product information

1.1.a) Trade name (invented name) of the medicinal product

b) Pharmaceutical form[1])

c) Strength(s) of the active substance(s)

d) Route(s) of administration[2])

[1]) The current list of Standard Terms (EDQM/European Pharmacopoeia) is employed.

[2]) The current list of Standard Terms (EDQM/European Pharmacopoeia) is employed.

Active substance(s)	Amount of active substance(s) per unit dose	Reference/Monograph/Standard

Excipient(s)	Amount per unit dose	Reference/Monograph/Standard

[3]) Please specify a single name for each active substance and excipient, in the next order of priority: INN, Ph. Eur., British Pharmacopoeia, any other pharmacopoeia of the (EU/EEA) member state, trade name, scientific name. The active substance should be declared in accordance with the recommended INN, accompanied by its salt or hydrated form, if applicable [for more details, see the Guideline for Applicants (***Notice to Applicants***) - Summary of Product Characteristics].

1.3. Pharmacotherapeutic group (in accordance with the current ATC code)

Cod ATC:

Pharmacotherapeutic group:

1.4. Container, closure system and administration device(s)[4]) of the medicinal product proposed for marketing in Romania (including the description of manufacturing materials)

1.5. Please indicate the size(s) proposed for marketing in Romania for each type of packaging.

1.6. Legal status: (Classification in line with Article 699 point 21 of Law 95/2006, republished, as further amended and supplemented)

Subject to medical prescription

Not subject to medical prescription

Additional information related to extension:

Authorisation number: ...../...../.....

Marketing Authorisation Holder:

Company name .....

Address .....

Telephone .....
Telefax .....
E-mail .....

2. Marketing authorisation holder/Contact persons/Manufacturers

2.1. Marketing Authorisation Holder of the medicinal product authorised in the EU member state of origin[5])

Company name .....
Address .....
Telephone .....
Telefax .....
E-mail .....

2.2. Proposed marketing authorisation holder[6]) responsible for placing the medicinal product on the Romanian market

Name .....
Address .....
Telephone .....
Telefax .....
E-mail .....

Please attach the poof of the existence of the applicant's headquarters in Romania/EU.

2.3. Person/Company authorised for communication with the National Agency for Medicines and Medical Devices of Romania during the procedure for extension/signing, on behalf of the Marketing Authorisation Holder (Annex 1) (if required)

Company name .....
Address .....
Telephone .....
Telefax .....
E-mail .....

If different from point 2.2, please attach the letter of authorisation.

2.4. Person from the EU (name, address and contact data) responsible for adverse reaction reporting and enforcement of risk minimisation measures of the medicinal product authorised in Romania (must reside in the EU and work there as well)[7])

Name .....
Address .....
Telephone .....

Telefax .....
E-mail .....

2.5. Official batch release for blood products and vaccines: identification data of an OMCL (Official Medicines Control Laboratories) or of a laboratory designated for the purpose of official batch release [in line with Articles 857 (1), 861, 862 and 863 of Law 95/2006, republished, as further amended and supplemented]

Name .....
Address .....
Telephone .....
Telefax .....
E-mail .....

2.6. Authorised manufacturer(s) responsible for batch release[a]) in the EU, in line with provisions of Articles 755 and 769 of Law 95/2006, republished, as further amended and supplemented, for the medicinal product which is to be marketed in Romania [should already be authorised as the EU site for batch release in the member state (country of origin)]

Name .....
Address .....
Telephone .....
Telefax .....
E-mail .....

2.7. EU contact person (name, address and permanent contact data) responsible for complaints concerning the product and recalls

Name .....
Address .....
Telephone .....
Telefax .....
E-mail .....

2.8. Local representative of the Marketing Authorisation Holder

Name .....
Address .....
Telephone .....
Telefax .....
E-mail .....

3. Medicinal product information in line with the authorisation in the EU member state of origin

3.1. EU member state of origin of the medicinal product. Please specify only one country as member state of origin

3.2. Number of the marketing authorisation of the medicinal product authorised in EU member state of origin[9])

3.3. The medicinal product's marketing authorisation procedure in the EU member state of origin

Number of the mutual recognition procedure[10])/decentralised procedure[11])

Number of the national procedure[12])

DECLARATION

I, the undersigned, Marketing Authorisation Holder, hereby declare that, in line with the data I own, all the information provided in this application, as well as the Annexes and all the attached documents are correct and complete.

Name of the proposed marketing authorisation holder (capital letters)

.....

Signature(s)

.....

Job

.....

Date and place

.....

---

[4]) The current list of Standard Terms (EDQM/European Pharmacopoeia) is employed.

[5]) "Valid in the EU/EEA member state of origin" refers to the member state where the concerned medicinal product is authorised. In Romania, a marketing authorisation in line with provisions of Article 126 (a) of Directive 2001/83/EC can be granted exclusively for medicinal products benefitting from a marketing authorisation valid in the valid in the EU/EEA member state of origin. The medicinal product placed on the market in Romania must be identical to the one authorised to be placed on the market in the respective member state.

[6]) The Marketing Authorisation Holder should reside in an EU/EEA member state.

[7]) For the purpose of this application, the person in the EU/EEA responsible for adverse reaction reporting and enforcement of risk minimisation measures "is established" at the place of residence, at the site where he/she can be tracked, located, authenticated in association with all his/her legal and contractual obligations, regardless of whether the respective site is the person's property or whether the person resides there permanently or temporarily.

[8]) The batch release site should be established in the EU/EEA. Several batches may be specified, as required.

[9]) This number can be obtained from a valid marketing authorisation issued by the national competent authority in the EU/EEA member state of origin.

[10]) Mutual recognition procedure [in line with the provisions of Article 28(2) of Directive 2001/83/EC].

[11]) Decentralised procedure [in line with the provisions of Article 28(3) of Directive 2001/83/EC].

[12]) Please specify the date of the first authorisation, the date of MA extension, the variation history, the legal grounds for authorisation

Annex 1
to the form for extension of the marketing authorisation

Address for authorisation for the purpose of communication/signing on behalf of the Marketing Authorisation Holder.....

(Please fill in only if necessary)

Name of the medicinal product, pharmaceutical form and strength:

I, the undersigned, ..., hereby authorize, until further notice,
(name and address of the marketing authorisation holder)
....., residing in ....., as representative
(name of the contact person) (office address of the contact person)
of ..... and for the purpose of the following actions (please check, if required):
(name of the Marketing Authorisation Holder)

Communication regarding requests for additional information/clarification of the information provided in the application forms and submitted documents ☐

Signing documents during the authorisation process, if necessary ☐

Receipt of authorisation ☐

.....
Name (capital letters) of the proposed marketing authorisation holder

.....
Signature of the proposed marketing authorisation holder

.....
Date

.....
Name (capital letters) of the person authorised for the purpose of communication/signing (as required) on behalf of the Marketing Authorisation Holder

.....
Signature of the person authorised for the purpose of communication/signing (as required) on behalf of the Marketing Authorisation Holder

.....
Date

Annex 2
to the form for extension of the marketing authorisation

DECLARATION on placing a medicinal product on the Romanian market according to the mentioned authorisation

Name of the medicinal product, pharmaceutical form and strength:

I, the undersigned, proposed holder of the extension of the marketing authorisation, hereby declare that the:

- the medicinal product which shall be placed on the Romanian market according to the respective marketing authorisation, at any time during the validity period of the extension of the authorisation in question, is identical to the one authorised for marketing

in ..... based on the marketing authorisation in the respective member state;

(member state) (member state of origin)

- I am fully aware of my obligations in line with provisions of Law 95/2006, republished, as further amended and supplemented, and I assume their fulfillment and compliance with the terms and conditions of this authorisation.

.....

Name (capital letters) of the proposed marketing authorisation holder

....

Date Signature of the proposed marketing authorisation holder

Annex 3
to the form for extension of the marketing authorisation

A. Declaration of the proposed holder of the extension of the marketing authorisation regarding the submitted documentation

Name of the medicinal product, pharmaceutical form and strength:

I, the undersigned, proposed holder of the extension of the marketing authorisation, hereby declare that all presented documents, including the Summary of Product Characteristics (RCP), the labeling information and the leaflet of the medicinal product subject to this application are the latest approved versions in ..... .

(EU member state) (EU member state of origin)

.....

Name (capital letters) of the proposed marketing authorisation holder

....

Date Signature of the proposed marketing authorisation holder

B. As regards relabeling and/or repackaging of medicinal products imprinted in Romanian:

I, the undersigned, hereby declare that the Summary of Product Characteristics (RCP), Leaflet (PL) and labeling of the medicinal product which shall be placed on the Romanian market are a correct translation into English and Romanian of the Summary of Product Characteristics (SmPC), Leaflet and labeling information authorised for this medicinal product in ..... .

(EU member state) (EU member state of origin)

Please attach the original version in the language of the EU member state of origin, as well as the certified/legalised versions of the translations of the SmPC, leaflet and labeling information.

.....

Name (capital letters) of the proposed marketing authorisation holder

....

Date Signature of the proposed marketing authorisation holder

Annex 4

to the form for extension of the marketing authorisation

DECLARATION of the proposed holder of the extended marketing authorisation regarding the fulfillment of post-authorization obligations

Name of the medicinal product, pharmaceutical form and strength:

I, the undersigned, proposed holder of the extension of the marketing authorisation, hereby declare that I will fulfill all my post-authorisation obligations, including notification of the NAMMDR and subsequent implementation of all variations related to quality and to medicinal product information approved in.....,

(EU member state of origin)

as well as reporting adverse reactions and the implementation in Romania of the measures for minimisation of the risks related to this medicinal product. I also declare that I shall implement all urgent safety measures simultaneously in Romania and in ..... and that I shall immediately inform the

(EU member state of origin)

NAMMDR about quality defects and batch/medicinal product withdrawals.

.....

Name (capital letters) of the proposed marketing authorisation holder

....

Date Signature of the proposed marketing authorisation holder

Annex 5

to the form for extension of the marketing authorisation

Documents attached to the application form

1. The proposed Marketing Authorisation Holder's proof of establishment in the EU member state of origin	☐
2. Copy of the valid marketing authorisation (MA)*) for the concerned medicinal product, released by the competent authority in the EU member state of origin, which should include all amendments approved through variation, valid upon submission of the application. If the authorisation is written in a language other than English, a legalised/certified translation of the MA in English and/or Romanian must be submitted	☐
3. The latest approved version of the medicinal product's SmPC authorised in the EU member state of origin (electronic copy) a) The legalised/certified translation of the SmPC into English and Romanian (electronic copy)	☐
4. The latest approved version of the Leaflet of the medicinal product authorised in the EU member state of origin (electronic copy) a) The legalised/certified translation of the leaflet into English and Romanian (electronic copy)	☐
5. The latest approved version of the (primary and secondary) labeling information of the medicinal product authorised in the (EU) member state of origin (electronic copy) a) The legalised/certified translation of the (primary and secondary) labeling information into English and Romanian (electronic copy)	☐

*) The declaration of authenticity regarding the copy of the marketing authorisation in force in the EU member state of origin.

Name of the medicinal product, pharmaceutical form and strength:

I, the undersigned, ..., hereby confirm the authenticity copy
(proposed holder of the extension of the marketing authorisation)
of the marketing authorisation submitted for the specified medicinal product, in line with the original marketing authorisation for the same medicinal product, issued by the EU member state of origin.

Name of the proposed holder of the extension of the marketing authorisation (capital letters) .....
Signature of the proposed holder of the extension of the marketing authorisation .....

Date .....

_____