PAYMENT FORM
TARIFF FOR TYPE IA, TYPE IB, TYPE II VARIATIONS OF A MARKETING AUTHORISATION, TRANSFER OF A MARKETING AUTHORISATION AND OTHER CHANGES TO MARKETING AUTHORISATION FOR MEDICINAL PRODUCTS AUTHORISED THROUGH MUTUAL RECOGNITION PROCEDURE OR DECENTRALISED PROCEDURE[1,2]

Name of the medicinal product[2]

Pharmaceutical form/s, strength/s	
Pharmaceutical form:	
Strength:	

Marketing Authorization Holder	
Name:	
Address :	
City:	
Country:	
Phone:	

[1]Two originally signed copies should be submitted for EACH medicinal product. The same requirement applies for grouped notification affecting more than one marketing authorisation and worksharing procedure.

[2]For the purpose of handling the present document, the following definition applies for a medicinal product: all strengths and pharmaceutical forms of a certain product belonging to the same MRP/DCP procedure e.g. RO/H/1234/001-001N

Fax:	
E-mail :	

Procedure number*

Variation procedure number	
Product specific variation sequence number /s*	
MRP/DCP procedure number**	

* To be indicated in case of grouped notification affecting more than one MA and worksharing procedure.
** To be indicated in case of transfer of the marketing authorisation or notification according to Minister of Health Order number 1205/2006 or type P notification (Art. 61(3)).

Medicinal product status

MA no. ……../ Date of issue	□

Paying Company

Name:	
Address :	
City:	
Country:	
Phone:	
Fax :	
E-mail :	
Fiscal Code:	
Trade Registry no:	
IBAN Account no.:	
Bank :	

Proposals for payment

Lei :	□
Euro :	□

Tariffed service*

Romania as Reference Member State (RMS)		**Amount of tariff in Euro according to MHO no. 888/2014*** **
Approval of Type IA variations for medicinal products authorised through mutual recognition procedure and decentralised procedure with Romania as Reference Member State in conformity with MOH Order No. 888/2014, Annex III, letter D, point 41. *Note: **the principal variation**, that defines the type of the variations group*	□ {number of variations**}	
Approval of Type IA **variation included in the group**, other than the group defining variation, for medicinal products authorised through mutual recognition procedure and decentralised procedure with Romania as Reference Member State in conformity with MOH Order No. 888/2014, Annex III, letter D, point 47.	□ {number of variations**}	
Approval of Type IB variations for medicinal products authorised through mutual recognition procedure and decentralised procedure with Romania as Reference Member State in conformity with MOH Order No. 888/2014, Annex III, letter D, point 42. *Note: **the principal variation**, that defines the type of the variations group*	□ {number of variations**}	
Approval of Type IB **variation included in the group**, other than the group defining variation, for medicinal products authorised	□ {number of variations**}	

through mutual recognition procedure and decentralised procedure with Romania as Reference Member State in conformity with MOH Order No. 888/2014, Annex III, letter D, point 47.a)		
Approval of Type II variations for medicinal products authorised through mutual recognition procedure and decentralised procedure with Romania as Reference Member State in conformity with MOH Order No. 888/2014, Annex III, letter D, point 43. *Note: **the principal variation**, that defines the type of the variations group*	□ {number of variations**}	
Approval of Type II **variation included in the group**, other than the group defining variation, for medicinal products authorised through mutual recognition procedure and decentralised procedure with Romania as Reference Member State in conformity with MOH Order No. 888/2014, Annex III, letter D, point 47.b)	□ {number of variations**}	

*theservice will be tariffed per strength of the medicinal product/pharmaceutical form of the medicinal product.
**number of variations = total number of proposed classified changes (type IA, type IB or type II) x number of marketing authorisations to be varied. A Marketing Authorisation corresponds to a strength/a pharmaceutical form of the medicinal product.
***amount of tariff in Euro to be completed by the Applicant, according to MHO no. 888/2014.

Tariffed service*

Romania as Concerned Member State (CMS)	**Amount of tariff in Euro according to MHO no. 888/2014***

Approval of Type IA variations for medicinal products authorised through mutual recognition procedure and decentralised procedure with Romania as Concerned Member State in conformity with MOH Order No. 888/2014, Annex III, letter D, point 44. *Note: **the principal variation**, that defines the type of the variations group*	□ {number of variations**}	
Approval of Type IA variation **included in the group**, other than the group defining variation, for medicinal products authorised through mutual recognition procedure and decentralised procedure with Romania as Concerned Member State in conformity with MOH Order No. 888/2014, Annex III, letter D, point 48.	□ {number of variations**}	
Approval of Type IB variations for medicinal products authorised through mutual recognition procedure and decentralised procedure with Romania as Concerned Member State in conformity with MOH Order No. 888/2014, Annex III, letter D, point 45. *Note: **the principal variation**, that defines the type of the variations group*	□ {number of variations**}	
Approval of Type IB variation **included in the group**, other than the group defining variation, for medicinal products authorised through mutual recognition procedure and decentralised procedure with Romania as Concerned Member State in conformity with MOH Order No. 888/2014, Annex III, letter D, point 48.a)	□ {number of variations**}	

Approval of Type II variations for medicinal products authorised through mutual recognition procedure and decentralised procedure with Romania as Concerned Member State in conformity with MOH Order No. 888/2014, Annex III, letter D, point 46. *Note: **the principal variation**, that defines the type of the variations group*	□ {number of variations**}	
Approval of Type II variation **included in the group**, other than the group defining variation, for medicinal products authorised through mutual recognition procedure and decentralised procedure with Romania as Concerned Member State in conformity with MOH Order No. 888/2014, Annex III, letter D, point 48.b)	□ {number of variations**}	

*the service will be tariffed per strength of the medicinal product/pharmaceutical form of the medicinal product.
**number of variations = total number of proposed classified changes (type IA, type IB or type II) x number of marketing authorisations to be varied. A Marketing Authorisation corresponds to a strength/a pharmaceutical form of the medicinal product.
***amount of tariff in euro to be completed by the Applicant, according to MHO no. 888/2014.

Note: In case of grouped variations, the final tariff is obtained by summing the corresponding tariff applied to the principal variation (that defines the group) and the corresponding tariff applied for each type of the variation included in that group, calculated for total number of proposed classified changes (number of variations from column II).

Tariffed service*		
Romania as Reference Member State (RMS) or Romania as Concerned Member State (CMS)		**Amount of tariff in euro according to MHO No. 888/2014*** **
Approval of marketing authorisation transfer in conformity with MOH Order No. 888/2014, Annex III, letter E, point 49.	□ {number of Applications**}	

Note: Approval of Transfer of Marketing Authorisation Application, according with MOH No. 1206/2006, for a medicinal product authorised through mutual recognition procedure or decentralized procedure with Romania as concerned member state/reference member state		
Approval of changes in primary and secondary packaging design and labelling, regarding changes to Leaflet and SmPC, other than resulting from Type IA, IB and II variations in conformity with MOH Order No. 888/2014, Annex III, letter E, point 50. *Note:* ***according to MOH. No. 1205/2006****, for a medicinal product authorised through mutual recognition procedure or decentralized procedure with Romania as concerned member state/reference member state*	□ {number of Applications**}	
Approval of changes in primary and secondary packaging design and labelling, regarding changes to Leaflet and SmPC, other than resulting from Type IA, IB and II variations in conformity with MOH Order No. 888/2014, Annex III, letter E, point 50. *Note:* ***according to Article 61(3) of Directive 2001/83/EC*** *–* ***named as type P Notifications****, for a medicinal product authorised through mutual recognition procedure or decentralized procedure with Romania as concerned member state/reference member state*	□ {number of Applications**}	

*the service will be tariffed per strength of the medicinal product/pharmaceutical form of the medicinal product.

**number of Applications = total number of strengths of the medicinal product/pharmaceutical forms of the medicinal product.

***amount of tariff in euro to be completed by the Applicant, according to MHO no. 888/2014.

Representative to Romania/ Contact Person

Name:	
Address:	
City:	
Country:	
Phone:	
Fax:	
E-mail:	
Fiscal Code:	

Signatories assume responsibility for accuracy of data in the present form.
Date.....…….

Applicant:
Marketing Authorization Holder / Representative to Romania
Name, signature, stamp

Note: Following the submission of Payment Form by Applicant, NAMMDR (RO-Agency) will issue the corresponding invoice, in accordance with the tariff of the service ticked.