PAYMENT FORM FOR THE TARIFF FOR MARKETING AUTHORISATION ACCORDING TO ARTICLE 893 OF LAW NO. 95/2006 AND THE TARIFF FOR THE ASSESSMENT OF DOCUMENTATION IN VIEW OF MARKETING AUTHORISATION ACCORDING TO MINISTER OF HEALTH ORDER NO. 888/2014 FOR MEDICINAL PRODUCTS PROPOSED FOR AUTHORISATION THROUGH MUTUAL RECOGNITION OR DECENTRALISED PROCEDURE WITH ROMANIA AS CONCERNED MEMBER STATE

Name of the medicinal product:

Pharmaceutical form, strength, administration route	
Pharmaceutical form:	
Strength:	
Administration route:	

Marketing Authorisation Holder	
Name :	
Address :	

City:	
Country:	
Telephone no.:	
Fax no.:	
E-mail address:	

Status of the medicinal product

Authorisation	□

Type of authorisation procedure

Mutual recognition procedure	□
Decentralised procedure	□

Paying company

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

Proposed form of payment

Lei :	□
Euro :	□

Tariff for marketing authorisation according to Article 893 of Law no. 95/2006 on healthcare reform, as republished, with the further amendments

For all types of medicinal products mentioned by Law no. 95/2006 on healthcare reform = 5000 €	□

Tariff for assessment of documentation in view of marketing authorisation through European procedures

Activity		**The fee in euro currency according to the MHO no. 888/2014*)**
Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State – full dossier [Art. 8(3) of Directive 2001/83/EC or Article 702 (4) of Law 95/2006, as amended] according to Order No. 888/2014, Annex III, letter. B, point. 20. *Note: Article 702 (4) of Law 95/2006, as amended, corresponds to Article 706 (4) of Law 95/2006, as republished and amended*	□	
Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State - full dossier – different pharmaceutical form, submitted at the same time as the initial application [Article 8(3) of Directive 2001/83/EC or Article 702 (4) of Law 95/2006, as amended] according to Order No. 888/2014, Annex III, letter. B, point. 20.a)	□	

Note: Article 702 (4) of Law 95/2006, as amended, corresponds to Article 706 (4) of Law 95/2006, as republished and amended		
Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State - full dossier - the second and following strengths, submitted at the same time as the initial application [Article 8(3) of Directive 2001/83/EC or Article 702 (4) of Law 95/2006, as amended] according to Order No. 888/2014, Annex III, letter. B, point. 20.b) *Note: Article 702 (4) of Law 95/2006, as amended corresponds to Article 706 (4) of Law 95/2006, as republished and amended*	□	
Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State– generic medicinal products [Article 10(1) of Directive 2001/83/EC or Article 704 (1) and (2) of Law 95/2006, as amended] according to Order No. 888/2014, Annex III, letter. B, point. 21. *Note: Article 704 (1) and (2) of Law 95/2006, as amended corresponds to Article 708 (1) and (2) of Law 95/2006, as republished and amended*	□	
Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State– generic medicinal products – different pharmaceutical form, submitted at the same time as the initial application [Article 10(1) of Directive 2001/83/EC or Article 704 (1) and (2) of Law 95/2006, as amended] according to Order No. 888/2014, Annex III, letter. B, point. 21.a) *Note: Article 704 (1) and (2) of Law 95/2006, as amended corresponds to*	□	

Article 708 (1) and (2) of Law 95/2006, as republished and amended		
Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State- generic medicinal products - the second and following strengths, submitted at the same time as the initial application [Article 10(1) of Directive 2001/83/EC or Article 704 (1) and (2) of Law 95/2006, as amended] according to Order No. 888/2014, Annex III, letter. B, point. 21.b) *Note: Article 704 (1) and (2) of Law 95/2006, as amended corresponds to Article 708 (1) and (2) of Law 95/2006, as republished and amended*	□	
Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State - "hybrid" (mixed) application [Article 10(3) of Directive 2001/83/EC or Article 704 (3) of Law 95/2006, as amended] according to Order No. 888/2014, Annex III, letter. B, point. 22. *Note: Article 704 (3)* of Law 95/2006, *as amended corresponds to Article 708 (3) of Law 95/2006, as republished and amended*	□	
Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State – "hybrid" (mixed) application - different pharmaceutical form, submitted at the same time as the initial application [Article 10(3) of Directive 2001/83/EC or Article 704 (3) of Law 95/2006, as amended] according to Order No. 888/2014, Annex III, letter. B, point. 22.a) *Note: Article 704 (3)* of Law 95/2006, *as amended corresponds to Article 708 (3) of Law 95/2006, as republished and amended*	□	

Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State - "hybrid" (mixed) application – the second and following strengths, submitted at the same time as the initial application [Article 10(3) of Directive 2001/83/EC or Article 704 (3) of Law 95/2006, as amended] according to Order No. 888/2014, Annex III, letter. B, point. 22.b) *Note: Article 704 (3) of Law 95/2006*, *as amended corresponds to Article 708 (3 of Law 95/2006, as republished and amended*	□	
Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State - "biosimilar medicinal product" [Article 10(4) of Directive 2001/83/EC or Article 704 (4) of Law 95/2006, as amended] according to Order No. 888/2014, Annex III, letter. B, point. 23. *Note: Article 704 (4) of Law 95/2006*, *as amended corresponds to Article 708 (4) of Law 95/2006, as republished and amended*	□	
Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State - "biosimilar medicinal product" - different pharmaceutical form, submitted at the same time as the initial application [Article 10(4) of Directive 2001/83/EC or Article 704 (4) of Law 95/2006, as amended] according to Order No. 888/2014, Annex III, letter. B, point. 23.a) *Note: Article 704 (4)* of Law 95/2006, *as amended corresponds to Article 708 (4) of Law 95/2006, as republished and amended*	□	
Marketing authorisation of medicinal products through mutual recognition	□	

procedure or decentralised procedure with Romania as Concerned Member State - "biosimilar medicinal product" - the second and following strengths, submitted at the same time as the initial application [Article 10(4) of Directive 2001/83/EC or Article 704 (4) of Law 95/2006, as amended] according to Order No. 888/2014, Annex III, letter. B, point. 23.b) *Note: Article 704 (4) of Law 95/2006, as amended corresponds to Article 708 (4) of Law 95/2006, as republished and amended*		
Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State - "bibliographic" application [Article 10(a) of Directive 2001/83/EC or Art. 705 of Law 95/2006, as amended] according to Order No. 888/2014, Annex III, letter. B, point. 24. *Note: Article 705 of Law 95/2006, as amended corresponds to Article 709 of Law 95/2006, as republished and amended*	□	
Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State - "bibliographic" application - different pharmaceutical form, submitted at the same time as the initial application [Article 10(a) of Directive 2001/83/EC or Article 705 of Law 95/2006, as amended] according to Order No. 888/2014, Annex III, letter. B, point. 24.a) *Note: Article 705 of Law 95/2006, as amended corresponds to Article 709 of Law 95/2006, as republished and amended*	□	
Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with	□	

Romania as Concerned Member State - "bibliographic" application – the second and following strengths, submitted at the same time as the initial application [Article 10(a) of Directive 2001/83/EC or Article 705 of Law 95/2006, as amended] according to Order No. 888/2014, Annex III, letter. B, point. 24.b) *Note: Article 705 of Law 95/2006, as amended corresponds to Article 709 of Law 95/2006, as republished and amended*		
Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State – fixed combination [Article 10(b) of Directive 2001/83/EC or Article 706 of Law 95/2006, as amended] according to Order No. 888/2014, Annex III, letter. B, point. 25. *Note: Article 706 of Law 95/2006, as amended corresponds to Article 710 of Law 95/2006, as republished and amended*	□	
Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State – fixed combination - different pharmaceutical form, submitted at the same time as the initial application [Article 10(b) of Directive 2001/83/EC or Article 706 of Law 95/2006, as amended] according to Order No. 888/2014, Annex III, letter. B, point. 25.a) *Note: Article 706 of Law 95/2006, as amended corresponds to Article 710 of Law 95/2006, as republished and amended*	□	
Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State – fixed combination - the second and following strengths, submitted at the same	□	

time as the initial application [Article 10(b) of Directive 2001/83/EC or Article 706 of Law 95/2006, as amended] according to Order No. 888/2014, Annex III, letter. B, point. 25.b) *Note: Article 706 of Law 95/2006, as amended corresponds to Article 710 of Law 95/2006, as republished and amended*		
Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State - "informed consent" [Article 10(c) of Directive 2001/83/EC or Article 707 of Law 95/2006, as amended] according to Order No. 888/2014, Annex III, letter. B, point. 26. *Note: Article 707 of Law 95/2006, as amended corresponds to Article 711 of Law 95/2006, as republished and amended*	□	
Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State - "informed consent" - different pharmaceutical form, submitted at the same time as the initial application [Article 10(c) of Directive 2001/83/EC or Article 707 of Law 95/2006, as amended] according to Order No. 888/2014, Annex III, letter. B, point. 26.a) *Note: Article 707 of Law 95/2006, as amended corresponds to Article 711 of Law 95/2006, as republished and amended*	□	
Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State - "informed consent" – the second and following strengths, submitted at the same time as the initial application [Article 10(c) of Directive 2001/83/EC or Article 707 of	□	

Law 95/2006, as amended] according to Order No. 888/2014, Annex III, letter. B, point. 26.b) *Note: Article 707 of Law 95/2006, as amended corresponds to Article 711 of Law 95/2006, as republished and amended*		
Marketing authorisation of traditional herbal medicinal products [Article 16 lit. (a) of Directive 2001/83/EC or Article 714 of Law 95/2006, as amended] authorisation by simplified procedure - European procedures according to Order No. 888/2014, Annex III, letter. B, point. 26[1]. *Note: Article 714 of Law 95/2006, as amended corresponds to Article 718 of Law 95/2006, as republished and amended*		

*) The applicant will fill in the fee in euro currency

Date of application submission (Applicant, NAMMDR)

Representative to Romania/Contact person

Name:	
Address:	
City:	
Country:	
Telephone no.:	
Fax no.:	
E-mail address:	

Signatories assume responsability for accuracy of data in the present form.

Date…….

Marketing Authorisation Holder/Representative to Romania
Name, signature, stamp