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 NATIONAL PROCEDURE

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

National 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 €	□

Activity		The fee in euro currency according to the MHO no. 888/2014*)
1. Marketing authorisation of medicinal products submitted - full dossier according to Article 706(4), of Law 95/2006 on healthcare reform, with further amendments and additions, or Article 8 (3) of Directive 2001/83 EC (national procedure)	□	
1.a) Marketing authorisation of medicinal products submitted - full dossier, according to Article 706(4), of Law 95/2006, with further amendments and additions, or Article 8 (3) of Directive 2001/83 EC – different pharmaceutical form submitted at the same time with submission of full dossier application (national procedure)	□	
1.b) Marketing authorisation of medicinal products submitted - full dossier, according to Article 706(4), of Law 95/2006, with further amendments and additions, or Article 8 (3) of Directive 2001/83 EC – the second and following strengths submitted at the same time with initial application (national procedure)	□	
2. Marketing authorisation of generic medicinal products submitted according to Article 708(1) and (2) of Law 95/2006, with further amendments and additions, or Article 10 (1) of Directive 2001/83 EC *(national procedure)*	□	
2.a) Marketing authorisation of generic medicinal products submitted according to Article 708(1) and (2) of Law 95/2006, with further amendments and additions, or Article 10 (1) of Directive 2001/83 EC – different pharmaceutical form submitted at the same time with submission of generic application (national procedure)	□	
2.b) Marketing authorisation of generic medicinal products submitted according to Article 708(1) and (2) of Law 95/2006, with further amendments and additions, or Article 10 (1) of Directive 2001/83 EC – the second and following strengths submitted at the same time with initial application (national procedure)	□	

3. Marketing authorisation of medicinal products submitted - *"hybrid" (mixed) application* according to Article 708(3) of Law 95/2006, with further amendments and additions, or Article 10 (3) of Directive 2001/83 EC (national procedure)	□	
3.a) Marketing authorisation of medicinal products submitted - *"hybrid" (mixed) application* according to art.708(3) of Law 95/2006, with further amendments and additions, or Article 10 (3) of Directive 2001/83 CE, different pharmaceutical form submitted at the same time with initial "hybrid" (mixed) application (national procedure)	□	
3.b) Marketing authorisation of medicinal products submitted - *"hybrid" (mixed) application* according to Article 708(3) of Law 95/2006, with further amendments and additions, or Article 10 (3) of Directive 2001/83 CE, *the second and following strengths submitted at the same time with initial application* (national procedure)	□	
4. Marketing authorisation of "similar medicinal products" submitted according to Article 708(4) of Law 95/2006, with further amendments and additions, or Article 10 (4) of Directive 2001/83 EC *(national procedure)*	□	
4.a) Marketing authorisation of "similar medicinal products" submitted according to Article 708(4) of Law 95/2006, with further amendments and additions, or Article 10 (4) of Directive 2001/83 CE, different pharmaceutical form submitted at the same time with initial "hybrid" (mixed) application(national procedure)	□	
4.b) Marketing authorisation of "similar medicinal products" submitted according to Article 708(4) of Law 95/2006, with further amendments and additions, or Article 10 (4) of Directive 2001/83 CE, the second and following strengths submitted at the same time with initial application (national procedure)	□	

5. Marketing authorisation of “well-established use” medicinal products submitted according to Article 709 of Law 95/2006, with further amendments and additions, or Article 10 (a) of Directive 2001/83 EC (“bibliographic” application) (national procedure)	□	
5.a) Marketing authorisation of “well-established use” medicinal products submitted according to Article 709 of Law 95/2006, with further amendments and additions, or Article 10 (a) of Directive 2001/83 EC (“bibliographic” application), different pharmaceutical form submitted at the same time with initial “hybrid” (mixed) application (national procedure)	□	
5.b) Marketing authorisation of “well-established use” medicinal products submitted according to Article 709 of Law 95/2006, with further amendments and additions, or Article 10 (a) of Directive 2001/83 EC (“bibliographic” application), the second and following strengths submitted at the same time with initial application (national procedure)	□	
6. Marketing authorisation of “fixed combination” medicinal products - submitted according to Article 710 of Law 95/2006, with further amendments and additions, or Article 10 (b) of Directive 2001/83 EC (national procedure)	□	
6. a) Marketing authorisation of “fixed combination” medicinal products - submitted according to Article 710 of Law 95/2006, with further amendments and additions, or Article 10 (b) of Directive 2001/83 CE, different pharmaceutical form submitted at the same time with initial “fixed combination” application (national procedure)	□	
6.b) Marketing authorisation of “fixed combination” medicinal products - submitted according to Article 710 of Law 95/2006, with further amendments and additions, or Article 10 (b) of Directive 2001/83 CE, the second and following strengths submitted at the same time with	□	

initial “fixed combination” application (national procedure)		
7. Marketing authorisation of “informed consent” medicinal products according to Article 711 of Law 95/2006, with further amendments and additions, or Article 10 (c) of Directive 2001/83 EC (national procedure)	□	
7.a) Marketing authorisation of “informed consent” medicinal products according to Article 711 of Law 95/2006, with further amendments and additions, or Article 10 (c) of Directive 2001/83 CE, different pharmaceutical form submitted at the same time with initial application (national procedure)	□	
7.b) Marketing authorisation of “informed consent” medicinal products according to Article 711 of Law 95/2006, with further amendments and additions, or Article 10 (c) of Directive 2001/83 CE, the second and following strengths submitted at the same time with initial application (national procedure)	□	
8. Marketing authorisation of homeopathic medicinal products submitted according to Article 714 of Law 95/2006, with further amendments and additions, (Marketing authorisation through simplified procedure - national procedure)	□	
9. Marketing authorisation of traditional herbal medicinal products conform Article 718 of Law 95/2006, with further amendments and additions, (national procedure)	□	
10. Marketing authorisation of medicinal products submitted as line extensions of an already authorised medicinal product (national procedure)	□	

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

Date of application submission (Proposer, NMA)

Representative to Romania/Contact person

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

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

Date…….

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