TAX AND TARIFF PAYMENT FORM MARKETING AUTHORISATION / MARKETING AUTHORISATION RENEWAL

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	
Marketing authorisation	□
Marketing authorisation renewal	□
Type of authorisation procedure/marketing authorisation renewal procedure	

National:	□

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:	□

Tax provided for marketing authorisation application according to Article 854 of Law no. 95/2006 on healthcare reform.	
For all types of medicinal products mentioned by Law no. 95/2006 on healthcare reform= 1000 €	□

Tariff for assessment in view of marketing authorisation / marketing authorisation renewal

1. Marketing authorisation of medicinal products submitted - full dossier according to Article 702(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 702(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 702(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 704(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 704(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 704(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 704(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.704(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 704(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 704(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 704(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 704(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 705 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 705 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 705 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 706 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 706 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 706 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 707 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 707 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 707 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 710 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 714 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)	□
11. Marketing authorisation renewal conform Article 730(2) of Law 95/2006, with further amendments and additions, or Article 24 (2) of Directive 2001/83 EC (national procedure)	□
12. Marketing authorisation renewal of homeopathic medicinal products submitted according to Article 710 of Law 95/2006, with further amendments and additions, (Marketing authorisation through simplified procedure) - (national procedure)	□
13. Marketing authorisation renewal a of traditional herbal medicinal products granted according to Article 714 of Law 95/2006, with further amendments and additions (national procedure)	□

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