TAX AND TARIFF PAYMENT FORM AUTHORISATION FOR MEDICINAL PRODUCTS PROPOSED FOR AUTHORISATION THROUGH MUTUAL RECOGNITION PROCEDURE OR DECENTRALISED PROCEDURE WITH ROMANIA AS REFERENCE 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:	□

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 of medicinal products - ***full dossier*** (new active substance, known active substance) [(art. 8(3) of Directive 2001/83/CE or Article 702 (4) of Law 95/2006)]	□
Marketing authorisation of medicinal products - ***full dossier*** (new active substance, known active substance) - ***different pharmaceutical form submitted at the same time with submission of full dossier application*** [(art. 8(3) of Directive 2001/83/CE or Article 702 (4) of Law 95/2006]	
Marketing authorisation of medicinal products - ***full dossier*** (new active substance, known active substance) – ***the second and following strengths submitted at the same time with initial application*** [(art. 8(3) of Directive 2001/83/CE or Article 702 (4) of Law 95/2006]	
Marketing authorisation of medicinal products - ***generic medicinal products*** [(art. 10(1) of Directive 2001/83/CE or Article 704 (1 and 2) of Law 95/2006)]	□
Marketing authorisation of medicinal products - ***generic medicinal products*** - ***different pharmaceutical form submitted at the same time with submission of generic application*** [(art. 10(1) of Directive 2001/83/CE or Article 704 (1 and 2) of Law 95/2006)]	
Marketing authorisation of medicinal products - ***generic medicinal products*** - ***the second and following strengths submitted at the same time with initial application*** [(art. 10(1) of Directive 2001/83/CE or Article 704 (1 and 2) of Law 95/2006)]	
Marketing authorisation of medicinal products - ***"hybrid" (mixed) application*** [(art. 10(3) of Directive 2001/83/CE or Article 704 (3) of Law 95/2006)]	
Marketing authorisation of medicinal products - ***"hybrid" (mixed) application*** - ***different pharmaceutical form submitted at the same time with initial application*** [(art. 10(3) of Directive 2001/83/CE or Article 704 (3) of Law 95/2006)]	
Marketing authorisation of medicinal products - ***"hybrid" (mixed) application*** - ***the second and***	

following strengths submitted at the same time with initial application [(art. 10(3) of Directive 2001/83/CE or Article 704 (3) of Law 95/2006)]	
Marketing authorisation of medicinal products - ***"similar medicinal product"*** [(art. 10(4) of Directive 2001/83/CE or Article 704 (4) of Law 95/2006]	
Marketing authorisation of medicinal products - ***"similar medicinal product"*** - ***different pharmaceutical form submitted at the same time with initial application*** [(art. 10(4) of Directive 2001/83/CE or Article 704 (4) of Law 95/2006)]	
Marketing authorisation of medicinal products - ***"similar medicinal product"*** - ***the second and following strengths submitted at the same time with initial application*** [(art. 10(4) of Directive 2001/83/CE or Article 704 (4) of Law 95/2006)]	
Marketing authorisation of medicinal products - ***"bibliographic" application*** [(art. 10(a) of Directive 2001/83/CE or Article 705 of Law 95/2006)]	□
Marketing authorisation of medicinal products - ***"bibliographic" application*** - ***different pharmaceutical form submitted at the same time with initial application*** [(art. 10(a) of Directive 2001/83/CE or Article 705 of Law 95/2006)]	
Marketing authorisation of medicinal products - ***"bibliographic" application*** - ***the second and following strengths submitted at the same time with initial application*** [(art. 10(a) of Directive 2001/83/CE or Article 705 of Law 95/2006)]	
Marketing authorisation of medicinal products - ***"fixed combination"*** [(art. 10(b) of Directive 2001/83 CE or Article 706 of Law 95/2006)]	□
Marketing authorisation of medicinal products - ***"fixed combination"*** - ***different pharmaceutical form submitted at the same time with initial application*** [(art. 10(b) of Directive 2001/83/CE or Article 706 of Law 95/2006)]	
Marketing authorisation of medicinal products - ***"fixed combination"*** - ***the second and following strengths submitted at the same time with initial application*** [(art. 10(b) of Directive 2001/83/CE or Article 706 of Law 95/2006)]	
Marketing authorisation of medicinal products - ***"informed consent"*** [(art. 10(c) of Directive 2001/83/CE or Article 707 of Law 95/2006)]	□
Marketing authorisation of medicinal products -	

"informed consent" - ***different pharmaceutical form submitted at the same time with initial application*** [(art. 10(c) of Directive 2001/83/CE or Article 707 of Law 95/2006)]	
Marketing authorisation of medicinal products ***"informed consent"*** - ***the second and following strengths submitted at the same time with initial application*** [(art. 10(c) of Directive 2001/83/CE or Article 707 of Law 95/2006)]	

Date of application submission (Applicant, 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