

**PAYMENT FORM**  
**TARIFF FOR VARIATIONS OF A MARKETING**  
**AUTORISATION, TRANSFER OF A MARKETING**  
**AUTORISATION AND OTHER CHANGES TO**  
**MARKETING AUTHORISATION FOR**  
**MEDICINAL PRODUCTS AUTHORISED**  
**THROUGH MUTUAL RECOGNITION**  
**PROCEDURE OR DECENTRALISED**  
**PROCEDURE<sup>1,2</sup>**

**Name of the medicinal product<sup>2</sup>**

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**Pharmaceutical form/s, strength/s**

Pharmaceutical form:	
Strength:	

**Marketing Authorization Holder**

Name:	
Address :	
City:	
Country:	
Phone:	
Fax:	

<sup>1</sup>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.

<sup>2</sup>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-n

E-mail :	
<b>Procedure number*</b>	

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 and notification according to Minister of Health Order number 1205/2006, only.

<b>Medicinal product status</b>
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MA no. .... / Data	<input type="checkbox"/>
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<b>Paying Company</b>
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Name:	
Address :	
City:	
Country:	
Phone:	
Fax :	
E-mail :	
Fiscal Code:	
Trade Registry	
IBAN Account :	
Bank :	

<b>Proposals for payment</b>
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Lei :	<input type="checkbox"/>
Euro :	<input type="checkbox"/>

**Paid service**

Assessment of Type IA notification/ Type IA variation that defines the type of a grouped notification	<input type="checkbox"/> {number of variations*}
Assessment of Type IB notification/ Type IB variation that defines the type of a grouped notification	<input type="checkbox"/> {number of variations*}
Assessment of Type II variation/ Type II variation that defines the type of a grouped application	<input type="checkbox"/> {number of variations*}
Assessment of Type IA variation included in a grouped notification/application	<input type="checkbox"/> {number of variations*}
Assessment of Type IB variation included in a grouped notification/application	<input type="checkbox"/> {number of variations*}
Assessment of Type II variation included in a grouped application	<input type="checkbox"/> {number of variations*}
Assessment of transfer of marketing authorisation application	<input type="checkbox"/>
Assessment of application for changes in primary and secondary packing design and inscription/labelling, regarding changes to Leaflet, other than resulting from Type IA, IB and II application under Article 61(3) of Directive 2001/83/EC or Minister of Health Order number 1205/2006	<input type="checkbox"/>

\*number of variations = number of changes (type IA, IB or II) x number of marketing authorisations to be varied

**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.....

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