# PAYMENT FORM
# TARIFF FOR TYPE IA, TYPE IB, TYPE II VARIATIONS OF A MARKETING AUTHORISATION, TRANSFER OF A MARKETING AUTHORISATION AND OTHER CHANGES TO MARKETING AUTHORISATION FOR MEDICINAL PRODUCTS AUTHORISED THROUGH MUTUAL RECOGNITION PROCEDURE OR DECENTRALISED PROCEDURE[1,2]

| **Name of the medicinal product[2]** |
|---|
| |

| **Pharmaceutical form/s, strength/s** | |
|---|---|
| Pharmaceutical form: | |
| Strength: | |

| **Marketing Authorization Holder** | |
|---|---|
| Name: | |
| Address : | |
| City: | |
| Country: | |
| Phone: | |

[1]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.

[2]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/1234/001-001N

| | |
|---|---|
| Fax: | |
| E-mail : | |

**Procedure number***

| | |
|---|---|
| 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 or notification according to Minister of Health Order number 1205/2006 or type P notification (Art. 61(3)).

**Medicinal product status**

| | |
|---|---|
| MA no. ……../ Date of issue | □ |

**Paying Company**

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

**Proposals for payment**

| | |
|---|---|
| Lei : | □ |
| Euro : | □ |

| **Tariffed service*** |
|---|

| **Romania as Reference Member State (RMS)** | | **Amount of tariff in Euro according to MHO no. 888/2014*** ** |
|---|---|---|
| Approval of type IA variation (the principal variation, that defines the type of the variations group) for a medicinal product authorised through mutual recognition procedure or decentralized procedure with Romania as reference member state | □ {number of variations**} | |
| Approval of type IA variation included in the variations group, other than one that defines the type of the group, for a medicinal product authorised through mutual recognition procedure or decentralized procedure with Romania as reference member state | □ {number of variations**} | |
| Approval of type IB variation (the principal variation, that defines the type of the variations group) for a medicinal product authorised through mutual recognition procedure or decentralized procedure with Romania as reference member state | □ {number of variations**} | |
| Approval of type IB variation included in the variations group, other than one that defines the type of the group, for a medicinal product authorised through mutual recognition procedure or decentralized procedure with Romania as reference member state | □ {number of variations**} | |
| Approval of type II variation (the principal variation, that defines the type of the variations group) for a | □ {number of variations**} | |

| | | |
|---|---|---|
| medicinal product authorised through mutual recognition procedure or decentralized procedure with Romania as reference member state | | |
| Approval of type II variation included in the variations group, other than one that defines the type of the group, for a medicinal product authorised through mutual recognition procedure or decentralized procedure with Romania as reference member state | □ {number of variations**} | |

*the service will be tariffed per strength of the medicinal product/pharmaceutical form of the medicinal product.
**number of variations = total number of proposed classified changes (type IA, type IB or type II) x number of marketing authorisations to be varied. A Marketing Authorisation corresponds to a strength/a pharmaceutical form of the medicinal product.
***amount of tariff in euro to be completed by the Applicant, according to MHO no. 888/2014.

| **Tariffed service*** |
|---|

| **Romania as Concerned Member State (CMS)** | | **Amount of tariff in Euro according to MHO no. 888/2014*** |
|---|---|---|
| Approval of type IA variation (principal, that defines the type of the variations group) for a medicinal product authorised through mutual recognition procedure or decentralized procedure with Romania as concerned member state | □ {number of variations**} | |
| Approval of type IA variation included in the variations group, other than one that defines the type of the group, for a medicinal product authorised through mutual recognition procedure or decentralized procedure with Romania as concerned member state | □ {number of variations**} | |

| | | |
|---|---|---|
| Approval of type IB variation (the principal variation, that defines the type of the variations group) for a medicinal product authorised through mutual recognition procedure or decentralized procedure with Romania as concerned member state | □ {number of variations**} | |
| Approval of type IB variation included in the variations group, other than one that defines the type of the group, for a medicinal product authorised through mutual recognition procedure or decentralized procedure with Romania as concerned member state | □ {number of variations**} | |
| Approval of type II variation (the principal variation, that defines the type of the variations group) for a medicinal product authorised through mutual recognition procedure or decentralized procedure with Romania as concerned member state | □ {number of variations**} | |
| Approval of type II variation included in the variations group, other than one that defines the type of the group, for a medicinal product authorised through mutual recognition procedure or decentralized procedure with Romania as concerned member state | □ {number of variations**} | |

*the service will be tariffed per strength of the medicinal product/pharmaceutical form of the medicinal product.
**number of variations = total number of proposed classified changes (type IA, type IB or type II) x number of marketing authorisations to be varied. A Marketing Authorisation corresponds to a strength/a pharmaceutical form of the medicinal product.
***amount of tariff in euro to be completed by the Applicant, according to MHO no. 888/2014.

Note: In case of grouped variations, the final tariff is obtained by summing the corresponding tariff applied to the principal variation (that defines the group) and the corresponding tariff applied for each type of the variation included in that group, calculated for total number of proposed classified changes (number of variations from column II).

| **Tariffed service*** | | |
|---|---|---|
| **Romania as Reference Member State (RMS)<br>or<br>Romania as Concerned Member State (CMS)** | | **Amount of tariff in euro according to MHO no. 888/2014*** ** |
| Approval of Transfer of Marketing Authorisation Application, according to MHO no. 1206/2006, for a medicinal product authorised through mutual recognition procedure or decentralized procedure with Romania as concerned member state/reference member state | □ {number of Applications**} | |
| Approval of Application for changes of the design and labelling of the primary and secondary packaging and changes of the Package Leaflet and Summary of Product Characteristics, others that changes applied through type IA, type IB and type II variations and through Art. 61(3) of Dir. 2001/83/EC, according to MHO no. 1205/2006, for a medicinal product authorised through mutual recognition procedure or decentralized procedure with Romania as concerned member state/reference member state | □ {number of Applications**} | |
| Approval of Application for changes of the labelling of the primary and secondary packaging and changes of the Package Leaflet, others that changes applied through type IA, type IB and type II variations and through MHO no. 1205/2006, according to Art. 61(3) of Dir. 2001/83/EC – **named as type P Notifications**, for a medicinal product authorised through mutual recognition procedure or decentralized procedure with Romania as | □ {number of Applications**} | |

| | | |
|---|---|---|
| concerned member state/reference member state | | |

*the service will be tariffed per strength of the medicinal product/pharmaceutical form of the medicinal product.
**number of Applications = total number of strengths of the medicinal product/pharmaceutical forms of the medicinal product.
***amount of tariff in euro to be completed by the Applicant, according to MHO no. 888/2014.

**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