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| **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 MUTUAL RECOGNITION OR DECENTRALISED PROCEDURE WITH ROMANIA AS REFERENCE MEMBER STATE** |

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| **Name of the medicinal product:** |

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| **Pharmaceutical form, strength, administration route** |

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| Pharmaceutical form: |  |
| Strength: |  |
| Administration route: |  |

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| **Marketing Authorisation Holder** |

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

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| **Status of the medicinal product** |

|  |  |
| --- | --- |
| Authorisation | □ |

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| **Type of authorisation procedure** |

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| --- | --- |
| Mutual recognition procedure | □ |
| Decentralised procedure | □ |

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| **Paying company** |

|  |  |
| --- | --- |
| Name: |  |
| Address: |  |
| City: |  |
| Country: |  |
| Telephone no.: |  |
| Fax no.: |  |
| E-mail address: |  |
| Fiscal code: |  |
| Trade Registry no.: |  |
| IBAN Account no. : |  |
| Bank: |  |

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| **Proposed form of payment** |

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| Lei : | □ |
| Euro : | □ |
| **Tariff for marketing authorisation according to Article 893 of Law no. 95/2006 on healthcare reform, as republished, with the further amendments** | | |

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| For all types of medicinal products mentioned by Law no. 95/2006 on healthcare reform = 5000 € | □ |

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| **Tariff for the assessment of documentation in view of marketing authorisation through European procedures** |

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| **Activity** |  | **The fee in euro currency according to the MHO no. 888/2014\*)** |
| Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State – generic medicinal products [Article 10(1) of Directive 2001/83/EC or Article 704 (1) and (2) of Law 95/2006, as amended] according to Order No. 888/2014, Annex III, letter. B, point. 14  *Note: Article 704 (1) and (2) of Law 95/2006, as amended corresponds to Article 708 (1) and (2) of Law 95/2006, as republished and amended* | □ |  |
| Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State – generic medicinal products – different pharmaceutical form, submitted at the same time as the initial application [Article 10(1) of Directive 2001/83/EC or Article 704 (1) and (2) of Law 95/2006, as amended] according to Order No. 888/2014, Annex III, letter. B, point. 14.a)  *Note: Article 704 (1) and (2)* of Law 95/2006, *as amended corresponds to Article 708 (1) and (2) of Law 95/2006, as republished and amended* |  |  |
| Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State – generic medicinal products – the second and following strengths, submitted at the same time as the initial application [Article 10(1) of Directive 2001/83/EC or Article 704 (1) and (2) of Law 95/2006, as amended] according to Order No. 888/2014, Annex III, letter. B, point. 14.b)  *Note: Article 704 (1) and (2) of Law 95/2006, as amended corresponds to Article 708 (1) and (2) of Law 95/2006, as republished and amended* |  |  |
| Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State - "hybrid" (mixed) application [Article 10(3) of Directive 2001/83/EC or Article 704 (3) of Law 95/2006, as amended] according to Order No. 888/2014, Annex III, letter. B, point. 15.  *Note: Article 704 (3) of Law* *95/2006, as amended corresponds to Article 708 (3) of Law 95/2006, as republished and amended* |  |  |
| Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State - "hybrid" (mixed) application - different pharmaceutical form, submitted at the same time as the initial application [Article 10(3) of Directive 2001/83/EC or Article 704 (3) of Law 95/2006, as amended] according to Order No. 888/2014, Annex III, letter. B, point. 15.a)  *Note: Article 704 (3) of Law 95/2006, as amended corresponds to Article 708 (3) of Law 95/2006, as republished and amended* |  |  |
| Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State - "hybrid" (mixed) application - the second and following strengths, submitted at the same time as the initial application [Article 10(3) of Directive 2001/83/EC or Article 704 (3) of Law 95/2006, as amended] according to Order No. 888/2014, Annex III, letter. B, point. 15.b)  *Note: Article 704 (3) of Law 95/2006, as amended corresponds to Article 708 (3) of Law 95/2006, as republished and amended* |  |  |
| Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State - "biosimilar medicinal product" [Article 10(4) of Directive 2001/83/EC or Article 704 (4) of Law 95/2006, as amended] according to Order No. 888/2014, Annex III, letter. B, point. 16.  *Note: Article 704 (4) of Law 95/2006, as amended corresponds to Article 708 (4) of Law 95/2006, as republished and amended* |  |  |
| Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State - "biosimilar medicinal product" - different pharmaceutical form, submitted at the same time as the initial application [Article 10(4) of Directive 2001/83/EC or Article 704 (4) of Law 95/2006, as amended]  according to Order No. 888/2014, Annex III, letter. B, point. 16.a)  *Note: Article 704 (4) ) of Law 95/2006, as amended corresponds to Article 708 (4) ) of Law 95/2006, as republished and amended* |  |  |
| Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State - "biosimilar medicinal product” – the second and following strengths, submitted at the same time as the initial application [Article 10(4) of Directive 2001/83/EC or Article 704 (4) of Law 95/2006, as amended] according to Order No. 888/2014, Annex III, letter. B, point. 16.b)  *Note: Article 704 (4) of Law 95/2006, as amended corresponds to Article 708 (4) of Law 95/2006, as republished and amended* |  |  |
| Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State - "bibliographic" application [Article 10(a) of Directive 2001/83/EC or Art. 705 of Law 95/2006, as amended] according to Order No. 888/2014, Annex III, letter. B, point. 17.  *Note: Article 705 of Law 95/2006, as amended corresponds to Article 709 of Law 95/2006, as republished and amended* | □ |  |
| Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State - "bibliographic" application - different pharmaceutical form, submitted at the same time as the initial application [Article 10(a) of Directive 2001/83/EC or Article 705 of Law 95/2006, as amended] according to Order No. 888/2014, Annex III, letter. B, point. 17.a)  *Note: Article 705 of Law 95/2006, as amended corresponds to Article 709 of Law 95/2006, as republished and amended* |  |  |
| Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State - "bibliographic" application - the second and following strengths, submitted at the same time as the initial application [Article 10(a) of Directive 2001/83/EC or Article 705 of Law 95/2006, as amended] according to Order No. 888/2014, Annex III, letter. B, point. 17.b)  *Note: Article 705 of Law 95/2006, as amended corresponds to Article 709 of Law 95/2006, as republished and amended* |  |  |
| Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State – fixed combination [Art. 10(b) of Directive 2001/83/EC or Article 706 of Law 95/2006, as amended]  according to Order No. 888/2014, Annex III, letter. B, point. 18.  *Note: Article 706 of Law 95/2006, as* *amended corresponds to Article 710 of Law 95/2006, as republished and amended* | □ |  |
| Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State – fixed combination - different pharmaceutical form, submitted at the same time as the initial application [Article 10(b) of Directive 2001/83/EC or Article 706 of Law 95/2006, as amended] according to Order No. 888/2014, Annex III, letter. B, point. 18.a)  *Note: Article 706 of Law 95/2006, as amended corresponds to Article 710 of Law 95/2006, as republished and amended* |  |  |
| Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State – fixed combination - the second and following strengths, submitted at the same time as the initial application [Article 10(b) of Directive 2001/83/EC or Article 706 of Law 95/2006, as amended] according to Order No. 888/2014, Annex III, letter. B, point. 18.b)  *Note: Article 706 of Law 95/2006, as amended corresponds to Article 710 of Law 95/2006, as republished and amended* |  |  |
| Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State - "informed consent" [Article 10(c) of Directive 2001/83/EC or Article 707 of Law 95/2006, as amended] according to Order No. 888/2014, Annex III, letter. B, point. 19.  *Note: Article 707 of Law 95/2006, as amended corresponds to Article 711 of Law 95/2006, as republished and amended* | □ |  |
| Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State - "informed consent" - different pharmaceutical form, submitted at the same time as the initial application [Article 10(c) of Directive 2001/83/EC or Article 707 of Law 95/2006, as amended] according to Order No. 888/2014, Annex III, letter. B, point. 19.a)  *Note: Article 707 of Law 95/2006, as amended corresponds to Article 711 of Law 95/2006, as republished and amended* |  |  |
| Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State - "informed consent" – the second and following strengths, submitted at the same time as the initial application [Article 10(c) of Directive 2001/83/EC or Article 707 of Law 95/2006, as amended] according to Order No. 888/2014, Annex III, letter. B, point. 19.b)  *Note: Article 707 of Law 95/2006, as amended corresponds to Article 711 of Law 95/2006, as republished and amended* |  |  |

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

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| **Date of application submission (Applicant, NAMMDR)** |

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| **Representative to Romania/Contact person** |

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

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

Date……………….

Marketing Authorisation Holder/Representative to Romania

Name, signature, stamp