APPLICATION FOR TRANSFER OF A MARKETING AUTHORISATION

Name of the medicinal product

Active substance(s)

Pharmaceutical form

Strength

Administration route

Marketing authorisation number

Current marketing authorisation holder

Name:
Address:
Telephone number:
Fax number:
E-mail:

Proposed marketing authorisation holder

Name:
Address:
Telephone number:
Fax number:
E-mail:

Name and address of the representative/contact person (of the current holder) Name: Address: Telephone number: Fax number: E-mail:

Name and address of the representative/contact person (of the proposed holder) Name Address Telephone number Fax number E-mail

Documents attached to the application for transfer:

- 1. Name of the medicinal product for which a marketing authorisation transfer is required, the number of the marketing authorisation and the date before which the marketing authorisation is valid.
- 2. Identification data (name, address and e-mail) of the current holder and the proposed holder
- 3. A document certifying that the full, updated dossier of the medicinal product or a copy thereof has/have been made available or transferred to the new marketing authorisation holder.
- 4. A document on the date when the new marketing authorisation holder takes upon himself all responsibilities from the current marketing authorisation holder regarding the medicinal product for which a marketing authorisation transfer is required; reference shall be made to the implementation date of the marketing authorisation transfer.
- 5. Proof of new marketing authorisation holder establishment in Romania or the European Union (EU).
- 6. Documents certifying that the new holder is capable of fulfilling all responsibilities required from a marketing authorisation holder, in line with pharmaceutical legislation in force:

  - A document for the identification of the qualified person in charge of pharmacovigilance, together with the qualified person’s address, telephone and fax numbers, e-mail and Curriculum Vitae shall be permanently available to the new holder and has to be established in Romania or the EU;

- A document describing the scientific service in charge of the information on medicinal products placed on the market, including address, telephone and fax numbers;

- A document for the identification of the person/company authorised for communication between the new marketing authorisation holder and the National Medicines Agency after approval of marketing authorisation transfer;

- A document for the identification of the contact person in charge of later complaints on medicinal products, including name, address, telephone and fax numbers, e-mail.

☐ 7. Whenever the case, a signed declaration that none of the presentations of the medicinal product for which the marketing authorisation transfer is requested has not been marketed in the EU yet.

☐ 8. A signed letter from the new marketing authorisation holder listing all pending measures or specific obligations; should neither be the case, a declaration is submitted mentioning that there are no pending measures or specific obligations.

☐ 9. A signed declaration that no other changes have been made regarding product information except those envisaging the marketing authorisation holder and, if needed, details on the local representative.

☐ 10. New product information (leaflet, summary of product characteristics, labelling).

The undersigned assume all responsibility that data in this application as well as the attached documentation for transfer are compliant with the Norms in force for the resolution of applications for transfer of marketing authorisation.

Current holder / Proposed holder
Legible name…….
Position ……..
. Signature……..

Date ……