MINISTRY OF PUBLIC HEALTH

ORDER
on approval of Norms relating to examination of an application for the transfer of a marketing authorisation

Taking into account provisions of Title XVII - The medicinal product of Law No. 95/2006 on Healthcare reform and of the Government Ordinance No. 125/1998 on the set up, organisation and functioning of the National Medicines Agency, approved as amended through Law No. 594/2002, as amended ,

based on Government Decision No. 862/2006 on organisation and functioning of the Ministry of Public Health,

on seeing the Approval Report of the Pharmaceutical Directorate No. EN 4714/2006,

the Minister of public health hereby issues the following order:

Article 1. – The norms concerning the manner of dealing with the applications of Marketing Authorisation transfer, in accordance with Annexes 1, 2 and 3 are approved.

Article 2. – Provisions of settled norms in Article 1 refer to Marketing Authorisation Applications transfer which are submitted to the National Medicines Agency after this order coming into force.

Article 3. – Annexes 1, 2 and 3 are integral part of the present order.

Article 4. – On this order coming into force, any contrary disposition shall be repealed.

Article 5. - The present order shall be published in the Official Gazette of Romania, Part I.

Minister of public health,
Gheorghe Eugen Nicolăescu

Bucharest, 2 October 2006.
No. 1206

ANNEX 1

NORMS
concerning the manner of dealing with the applications for the Marketing Authorisation transfer

CHAPTER I
Introduction

Article 1. - The present norms set up the administrative procedure, as well as the manners of examining the Marketing Authorisation Applications transfer for medicinal products for human use, authorised through national procedure.

CHAPTER II
Scope

Article 2. – The present norms are used to applications for the Marketing Authorisation transfer issued by the National Medicines Agency.

Article 3. – The present norms are not used to applications for type IA/1 variations related to the Marketing Authorisation Holder's name change.

CHAPTER III
Definitions

Article 4. - (1) *The Marketing Authorisation transfer* is the procedure which consists in replacing the current (existent) Marketing Authorisation Holder with a new holder.

(2) The new Marketing Authorisation Holder must be settled in Romania or in one of the member states of the European Union.

Article 5. – A Marketing Authorisation transfer may be needed in case of a merge/acquisition, by which the Marketing Authorisation Holder is taken over by another commercial society, thus ceasing to function as a particular juridical body, if a commercial society sells the medicinal product and its rights on that medicinal product to another commercial society or in other circumstances permitted by law.

CHAPTER IV
Administrative procedure related to dealing with the Marketing Authorisation Applications transfer

Article 6. – The Marketing Authorisation Holder, further called *holder,* submits to the National Medicines Agency the Marketing Authorisation Application transfer, in compliance with Annex 3, together with support documentation, in compliance with Annex 2, and with the tariff form, issued in compliance with regulations in force of the National Medicines Agency, concerning the receipt of Marketing Authorisation Applications modifications and encashment of the due tariffs.

Article 7. - An application shall refer to a single Marketing Authorisation.

Article 8. – The Marketing Authorisation Application transfer and the tariff form are submitted for medicinal products which own a Marketing Authorisation in force, issued by the National Medicines Agency.

Article 9. - Concerning medicinal products undergoing a Marketing Authorisation renewal procedure, the transfer application is accompanied by the tariff form only if the applicant demands an evaluation of the transfer application, before the finalisation of the Marketing Authorisation renewal procedure.

Article 10. – If necessary, during the authorisation procedure and the replacement of the initially proposed Marketing Authorisation Holder, the applicant informs the National Medicines Agency about this fact via an address accompanied by a relevant support documentation, issued in compliance with Annex 2.

Article 11. - (1) National Medicines Agency checks whether the application and support documentation are correct and complete.

(2) If the application and documentation are validated according to the administrative aspect, the procedure shall be forwarded.

(3) Unless validated, the application shall be repealed; the procedure may be resumed by the submission of a new application.

Article 12. – The evaluation of the Marketing Authorisation Application transfer takes place following the confirmation of the National Medicines Agency tariff payment by its Department of Economics, in compliance with the National Medicines Agency regulations in force.

Article 13. – The deadline according to which the National Medicines Agency must deal with the Marketing Authorisation Application transfer consists of 30 days from the date of the confirmation of the payment by the Department of Economics.

Article 14. - (1) In case the application submitted to the National Medicines Agency is approved, it informs in written form both the former and new holder on the transfer approval and issues the rectification documents (modification to the Marketing Authorisation, modified parts of the Annexes to the Marketing Authorisation), 30 days after the resolution.

(2) Rectification documents shall only be submitted to the new holder.

Article 15. - (1) The Marketing Authorisation transfer is available starting on the date on which the National Medicines Agency informs both the former and new holder about the approval of the transfer application.

(2) The implementation date of the Marketing Authorisation transfer is the date on which the new holder assumes all his due responsibilities, in compliance with Law No. 95/2006 on healthcare reform. This is established by the National Medicines Agency on grounds of the agreement between the former and new Marketing Authorisation Holder and mentioned in the documents concerning the transfer approval.

Article 16. - In case the documents transmitted for the support of the application for the Marketing Authorisation transfer are incomplete or if the conditions for Marketing Authorisation transfer haven't been met, in compliance with Annex 2, the National Medicines Agency's solution shall consist of the application's rejection.

Article 17. – In case the National Medicines Agency demands the completion of the support documentation of the application for Marketing Authorisation transfer, the answer must be integrally transmitted, 60 days after receiving the address, therefore the development of the procedure being suspended until the submission of supplementary information requested by the National Medicines Agency.

Article 18. - (1) In case the transmitted solicited documents do not meet the demands in view of the transfer application approval, the application shall be repealed; if the documents are not handed out in due time, the application shall be repealed by right.

(2) National Medicines Agency shall inform in written form both holders, current and proposed, about the rejection of the transfer application.

(3) The rejection of the transfer application does not bring forth any prejudice to the right of submitting a new application transfer.

Article 19. - (1) It is recommended that the Marketing Authorisation Holder avoids the submission of variation applications in parallel with the application for Marketing Authorisation transfer.

(2) In case variation applications are submitted during the evaluation procedure of the transfer application, these shall be dealt with regardless of the transfer application.

Article 20. - (1) Modifications operated at the producer(s) level of the finished product, resulted from the marketing authorisation transfer, are not considered part of the transfer procedure.

(2) The respective variations must be submitted separately, at the same time as the transfer application or subsequent to the approval of the transfer application.

(3) The evaluation procedure of the variation applications mentioned in (2) shall be initiated following the approval of the transfer application.

ANNEX 2

DOCUMENTS AND INFORMATION

which must accompany the transfer application of the Marketing Authorisation

1. Name of the medicinal product for which the Marketing Authorisation transfer is requested, the Marketing Authorisation number and availability date of the Marketing Authorisation is available.
2. Identification data (name, address and e-mail address) of the current and proposed holder.
3. A document which attests that the upgraded complete dossier of the product or a copy of this dossier has been made available or transferred to the new Marketing Authorisation Holder.
4. A document concerning the date on which the new Marketing Authorisation Holder takes overall responsibility from the current Marketing Authorisation Holder concerning the medicinal product for which the transfer has been requested; the implementation date of the Marketing Authorisation transfer shall be mentioned.
5. Settlement proof of a new holder in Romania or the European Union.
6. Documents which attest that the new holder is capable of fulfilling all responsibilities required from a Marketing Authorisation Holder, in accordance with the pharmaceutical legislation in force:

a) An identification document of the qualified person, responsible for the pharmacovigilance activities, accompanied by the address, telephone number, fax number, e-mail and curriculum vitae of the qualified person; the qualified person responsible for the pharmacovigilance activity must permanently be at the new holder's service and must be settled in Romania or within the European Union;

b) A document which describes the Scientific Service, service which is responsible for the information concerning the authorised medicinal products, including address, telephone number, fax number;

c) An identification document of the authorised person/company, in view of the communication between the new Marketing Authorisation Holder and the National Medicines Agency, following the approval of the Marketing Authorisation transfer;

d) An identification document of the contact person responsible for further reclamations related to the product, including name, address, telephone number, fax number and e-mail address.

7. A statement, if needed, which attests that the medicinal product for which the Marketing Authorisation transfer is requested hasn't been yet authorised for marketing within the EU, under any of its presentation forms.
8. A statement of the new Marketing Authorisation Holder, in which any outstanding measures or specific obligations are listed; if none of the two aspects is still available, a statement shall be issued which mentions that there are no more outstanding measures or specific obligations to be undertaken.
9. A statement attesting that other modifications have been made concerning the product information, except those who have hinted at the Marketing Authorisation Holder and, if necessary, details on the local representation.
10. New information about the product (package leaflet, Summary of Product Characteristics, label).

NOTE:

Documents mentioned at points 1, 2, 3, 4, 6 and 9 must be signed by the current holder, as well as by the new one.

Documents mentioned at points 7 must be signed by the current holder.

Documents mentioned at points 5 and 8 must be signed by the new holder.

ANNEX No. 3

APPLICATION
for Marketing Authorisation transfer

Commercial name of the medicinal product:
Active substance(s):
Pharmaceutical form :
Strength:
Administration route:
Marketing Authorisation number :

Current Marketing Authorisation Holder:
Name:
Address:
Telephone No.:
Fax No.:
E-mail address:

Proposed Marketing Authorisation Holder:
Name:
Address:
Telephone No.:
Fax No.:
E-mail address:

Name and address of the contact person/representation (for current holder):

Name:
Address:
Telephone No.:
Fax No.:
E-mail address:

Name and address of the contact person/representation (for proposed holder):

Name:
Address:
Telephone No.:
Fax No.:
E-mail address:

Documents attached to the transfer application:

 1. Name of the medicinal product for which the Marketing Authorisation transfer is requested, Marketing Authorisation number and availability date of the Marketing Authorisation.

□ 2. Identification data (name, address and e-mail address) of the current and proposed holder.

□ 3. A document which attests that a complete upgraded dossier of the product or a copy of this dossier has been made available/unavailable or transferred to the new Marketing Authorisation Holder.

□ 4. A document which mentions the date when the new Marketing Authorisation Holder takes overall responsibility from the current holder of the Marketing Authorisation for the medicinal product which must be transferred; implementation date of the Marketing Authorisation transfer will be referred to.

□ 5. Settlement proof of a new holder in Romania or within the European Union *(EU).*

□ 6. Documents that points out the new holder's ability of fulfilling all responsibilities required from a Marketing Authorisation Holder, in accordance with the pharmaceutical legislation in force:

- An identification document of the qualified person, responsible for the pharmacovigilance activity, accompanied by the address, telephone number, fax number, e-mail address and curriculum vitae of the qualified person; the qualified person responsible for the pharmacovigilance activity must permanently be at the new holder's service and must be settled in Romania or within the European Union;

- A document which describes the scientific service, the service which is responsible for the information concerning authorised medicinal products, including address, telephone number, fax number;

- An identification document of the authorised person/company having in view the communication between the new Marketing Authorisation Holder and the NMA, following the approval of the Marketing Authorisation transfer;

- An identification document of the contact person responsible for the further reclamations concerning the product, including name, address, telephone number, fax number and e-mail address.

□ 7. A signed statement, in case the medicinal product for which the Marketing Authorisation transfer is requested has not been yet authorised, for none of its presentation forms.

□ 8. A statement signed by the new Marketing Authorisation Holder, stating any outstanding measures or specific obligations; if none of the two aspects is still available, a letter shall be issued which mentions that there are no more outstanding measures or specific obligations to be undertaken.

□ 9. A signed statement attesting that no other modification has been made to the product information, excepting those which have concerned the Marketing Authorisation Holder and, if necessary, details on local representation.

□ 10. New information on the product (package leaflet, Summary of Product Characteristics, label).

Signatories assume the responsibility according to which the data included in the present application and in the attached transfer documentation are compliant with the Norms in force related to the manner of dealing with the applications for Marketing Authorisation transfer.

Current/Proposed holder

Print name …….....…….

Function…….....……

Signature …….....…..……..

Date ……