MINISTRY OF PUBLIC HEALTH

ORDER
on approval of the Norms concerning handling of modifications to the marketing authorisation during marketing authorisation renewal procedure

on seeing the Approval Report of the Pharmaceutical Directorate No. E.N. 10.752/2008,

taking into account:

- provisions of Law No. 95/2006 on healthcare reform, Title XVII ,,The medicinal product", with further amendments and supplementations;

- Government Ordinance No. 125/1998 on the set up, organisation and functioning of the National Medicines Agency, approved through Law No. 594/2002, with further amendments and supplementations,

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

the Minister of Public Health hereby issues the following Order:

Art. 1. – The Norms concerning handling of modifications to the marketing authorisation during marketing authorisation renewal procedure are approved, in accordance with the Annex which is integral part of this Order.

Art. 2. – The Norms concerning handling of modifications to the marketing authorisation during marketing authorisation renewal procedure apply to the applications for modification submitted to the National Medicines Agency after the date of the present Order coming into force.

Art. 3. – On the date of this Order coming into force, any contrary disposition is abridged.

Art. 4. - This Order is published in the Official Gazette of Romania, Part I.

Minister of Public Health,
Gheorghe Eugen Nicolăescu

Bucharest, 14 October 2008.
No. 1.732.

ANNEX

NORMS
concerning handling of modifications to the marketing authorisation during marketing authorisation renewal procedure

Art. 1. - These Norms establish the handling manner of modifications to marketing authorisation during the renewal procedure of marketing authorisation for medicinal products for human use authorised through national procedure.

Art. 2. - These Norms apply to applications concerning type IA, IB, II variations, transfer of marketing authorisation, modification of the design and printing of the product package, as well as to applications concerning the exception from the necessity of the presence of certain data on the label and leaflet and from the necessity of the leaflet being written in Romanian, in case of medicinal products for human use which are not meant to directly released to the patient.

Art. 3. - All modifications intervening during the availability period of the marketing authorisation should be submitted to the National Medicines Agency and assessed in accordance with the specific regulations, approved through Minister of Public Health Orders.

Art. 4. - (1) If, due to objective and justified reasons, the marketing authorisation cannot be renewed under the given conditions (e.g. the necessity of bringing some modifications to the Summary of Product Characteristics, the leaflet and label, in order to meet some new requirements imposed by the legislation or guidelines), the Marketing Authorisation Holder may submit additional information and/or bring modifications to the medicinal product via its renewal application.

(2) Section "present/proposed situation" in the renewal application should clearly state all modifications brought to the information concerning the medicinal product.

(3) Alternately, the listing of modifications may be transmitted as a separate document, attached to the renewal authorisation.

(4) This type of modifications does not require the triggering of segregated assessment procedures.

(5) The modifications not mentioned on this list shall not be taken into consideration as part of the renewal authorisation.

Art. 5. - (1) For those cases where the need for transmission has been identified, during the renewal procedure, with respect to the applications for various types of changes, as stated under Art. 2, segregated assessment

procedures shall be implemented, in accordance with the specific regulations in force.

(2) The respective applications shall be accompanied by the tariff forms specific to the proposed change.

Art. 6. - (1) In case a type IA/IB/II variation affects the information on the medicinal product and is not finished at the moment of the submission of a renewal application, the latest version of the information on the product, approved in its country of origin, is used.

(2) In case the assessment procedure of a type IA/IB/II variation ends prior to or at the moment of the renewal procedure ending, the changes accepted via variation should be reflected in the renewed information on the respective product.

Art. 7. - All applications concerning the various changes occurred in medicinal products, not completed before finalisation of the renewal procedure, as well as applications submitted by the MAH during the renewal procedure should be solved before finalisation of the renewal procedure, so that the marketing authorisation and annexes may reflect the new data on the given medicinal product, where required.

Art. 8. - Changes to the timeframe when the marketing authorisation renewal takes place may occur, if, when assessing some applications for variation submitted prior to the renewal application or during the renewal procedure, requests for completion of the support documentation or clarification of terms have resulted.

Art. 9. – The principles representing the basis of the present Norms are issued in the CHMP Guideline on the post-authorisation for medicinal products for human use (Post-Authorisation Guidance - Human Medicinal Products) (Ref. Doc: EMEA/310007/2006 Rev 08). The principles which represent the basis of these Norms are issued in the CHMP Post-Authorisation Guidance - Human Medicinal Products (Doc. Ref: EMEA/310007/2006 Rev 08).

Abbreviations

CHMP - Committee for Human Medicinal Products
EMEA – European Medicines Agency