MINISTRY OF PUBLIC HEALTH

ORDER
for approval of the management of applications for proposed changes in design and wording of the package of medicinal products for human use, as well as changes in leaflet and Summary of Product Characteristics, other than caused by Type IA, IB and II variations

Taking into account provisions of Title XVII - The medicinal product of Law No. 95/2006 on healthcare reform and of 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 4713/2006,

the Minister of public health hereby issues the following order:

Article 1. - All modifications related to the design and package labelling, as well as to the package leaflet and Summary of Product Characteristics (SPC) modifications of the medicinal product for human use, shall be presented to the National Medicines Agency by the Marketing Authorisation Holder, further called *holder*.

Article 2. – In view of the approval of modifications to Article 1, the holder submits to the National Medicines Agency the following:

a) application, which contains an overall description of the submitted modification, along with the payment form set up in accordance with the National Medicines Agency regulations in force related to the receiving of the applications for the modifications brought to the Marketing Authorisation and of the encashment of the due tariffs;

b) package leaflet and SPC (on paper and in electronic format), set up in accordance with the regulations in force concerning the package leaflet and the SPC of the medicinal product for human use (suggested current package leaflet and SPC/package leaflet and SPC).

The proposed modifications shall be clearly specified, by underlying the modified terms.

c) If the documentation is submitted in other language than Romanian, the package leaflet and the SPC shall be submitted with the underlined suggested modifications, in an accurate translation into English.

d) primary and/or secondary package layouts, as required, imprinted according to the regulations in force, regarding the labelling of the medicinal product for human use, respectively current/suggested label.

Article 3. - (1) The application and payment form shall be submitted for the medicines which own Marketing Authorisation in force, issued by the National Medicines Agency.

(2) A payment form shall be submitted for the medicinal product undergoing a renewal procedure of the marketing authorisation only if the applicant demands the evaluation of the application before the finalisation of the renewal procedure.

Article 4. – The deadline for dealing with the applications on the design modification and package labelling, modification of the package leaflet and package labelling, as well as the modification of the package leaflet and SPC consists of 60 days after the confirmation of the fee by the Economics Department, after the date of NMA tariff payment confirmation by its Economics Department.

Article 5. – If the National Medicines Agency hasn’t issued any demand within the time frame mentioned in Article 4, this notification shall be considered accepted.

Article 6. - National Medicines Agency informs the holder on approval of the application and issues the rectification documents, as required, modifications on Marketing Authorisation, annexes to the modified Marketing Authorisations or modified parts of annexes to Marketing Authorisation, 30 days after the resolution.

Article 7. - (1) In case the National Medicines Agency requires supplementary information concerning the application in view of the modification of the design and package labelling, package leaflet and SPC modification, the holder shall answer the applications 60 days after receiving the address.

(2) In this given situation, the development of this procedure is blocked until the submission of supplementary information solicited to the National Medicines Agency.

Article 8. - (1) In case the conditions in view of the application approval are not fulfilled, the present Order shall be repealed; if the holder does not provide the solicited information in due time, the application is considered repealed by right on its expiry date.

(2) The National Medicines Agency informs the holder on the repealment of the application.

(3) The repealment of the application does not imply any prejudice to the holder's right of submitting a new application.

Article 9. – Provisions of the present Order refer to applications for the modifications of design and package labelling of medicinal products for human use, as well as for the modifications of the package leaflet and the SPCs, others than those caused by Type IA, IB and II variations, submitted to the National Medicines Agency after this order coming into force.

Article 10. - On this order coming into force, the NMA Order No. 1,126/2003 shall be repealed, in view of the manner of dealing with the applications for modifications of design and package labelling, as well as the modifications of the package leaflet, others than those caused by Type IA, IB and II variations, published in the Official Gazette of Romania, Part I, No. 908/19.12.2003.

Article 11. - 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. 1205.