MINISTRY OF PUBLIC HEALTH

ORDER

on approval of the National Medicines Agency procedure for cancellation of marketing authorisation applications for medicinal products for human use

Taking into account provisions of Title XVII – The medicinal product, of Law no. 95/2006 on healthcare reform, as well as of Government Ordinance no. 125/1998 related to the establishment, organisation and operation 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 operation of the Ministry of Public Health,

on seeing the Approval Report of the Pharmaceutical Directorate no. E.N. 4.711/2006,

the minister of public health hereby issues the following order:

Article 1. – The National Medicines Agency shall cancel marketing authorisation applications for medicinal products for human use where applications cannot be processed for reasons of applicant non-compliance with obligations under the law.

Article 2. – (1) Applications for authorisation shall be canceled in one of the following circumstances:

a) when fees and charges related to an application for marketing authorisation have not been paid within 3 months of the issue of the invoice by the National Medicines Agency;

b) where the applicant has not demonstrated compliance with Good Manufacturing Practice standards of the manufacturing site for the medicinal product subject to application for authorisation by the National Medicines, within one year from the date of registration of the application;

c) when the applicant has not completed documentation in support of the application or has not provided a response to National Medicines Agency requests for clarification within one year of the date for communication of the request letter.

(2) Any amounts paid by the applicant into the National Medicines Agency account shall not be refunded upon cancellation of applications.

Article 3. – (1) Cancellation of the application does not prevent the applicant from submitting a new application for marketing authorisation to the National Medicines Agency.

(2) Submission of a new application for marketing authorisation for products whose application has been cancelled elicits resumption of the entire authorisation procedure, by submission of new documentation in accordance with legal regulations in force, payment of a new authorisation fee, planning, if necessary, of a new Good Manufacturing Practice inspection and setting of a new deadline for completion of the authorisation assessment procedure from the date of amounts due entry into the National Medicines Agency account.

Article 4 – (1) Provisions of this Order shall apply to applications for authorisation already submitted to the National Medicines Agency on the date of entry into force of this Order as well as to applications submitted to the National Medicines Agency after its entry into force, currently or subsequently under circumstances as stipulated under Article 2.

(2) The 3-month deadline mentioned under Article 2 (1) a), i.e. one year, mentioned in Article 2 (1) (b) and (c) shall run from the date of this Order entry into force where the application for authorisation was registered on the date of entry into force of this Order.

Art. 5. – This Order shall be published in the Official Gazette of Romania, Part I.

Minister of public health,

Gheorghe Eugen Nicolăescu

Bucharest, 2 October 2006.

No. 1.203.