

MINISTRY OF PUBLIC HEALTH

ORDER

on withdrawal/suspension by the National Medicines Agency of certain marketing authorisations, prior to Accession

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 4707/2006,

the Minister of public health hereby issues the following order:

Article 1. – Concerning medicinal products which have not undergone the updating procedure of the documentation issued by Minister of public health order No. 1451/2005 on the approval of the Guideline on the updating and modification of the authorisation documentation for The medicinal products for human use authorised in Romania, in order to ensure compliance with the demands of the European Union, published in the Official Gazette of Romania, Part I, No. 66 of 24 January 2006, with through order of Minister of public health No. 92/2006, published in the Official Gazette of Romania, Part I, No. 175 of 23 February 2006, as well as medicinal products which have been authorised by the National Medicines Agency (NMA) on basis of the CADREAC or nCADREAC simplified procedure concerning medicinal products authorised within the European Union through centralised procedure, their Marketing Authorisations shall be withdrawn by the NMA on the last day prior to Accession.

Article 2. – Concerning the medicinal product for whom the documentation in view of updating has been submitted to the NMA, according to the Guideline on the updating and modification of the authorisation documentation of medicinal products for human use authorised in Romania, in order to ensure compliance with the demands of the European Union, and for whom the NMA has requested completions, these not being transmitted by the Marketing Authorisation Holder until the end of 2006, Marketing Authorisations shall be suspended by the NMA on the last day prior to Accession. If, following the NMA transmission and evaluation of the respective completion, the documentation proves to be in compliance with the European legislation, the Marketing Authorisation suspension shall be rejected.

Article 3. – Medicinal product batches manufactured prior to the Marketing Authorisation withdrawal/suspension in accordance with the provisions in Article 1 and Article 2 of the present decision, shall still be able to be imported into Romania and held within the therapeutical circuit one more year after the Marketing Authorisation withdrawal/suspension, in case the availability period is not overcome. Moreover, the Marketing Authorisation Holder has the obligation of withdrawing and destroying them.

Article 4. - (1) Concerning medicinal products which have been authorised by the NMA on basis of the CADREAC / nCADREAC simplified procedure for medicinal products authorised within the European Union through centralised procedure, the term in which they can be held within the therapeutical circuit consists of 2 years, in case the availability period is not overcome. Moreover, the Marketing Authorisation Holder has the obligation of withdrawing and destroying them.

(2) The right of medicinal products which have been authorised by the NMA on basis of the CADREAC / nCADREAC simplified procedure of being introduced and held within the therapeutical circuit depends on the European Commission Decision still being in force.

Article 5. – On this order coming into force, Order of the Minister of public health No. 384/2006 shall be repealed in view of the approval of the withdrawal/suspension method by the National Medicines Agency of certain Marketing Authorisations prior to Romania's Accession to the European Union, published in the Official Gazette of Romania, Part I, No. 353 din 19 April 2006.

Article 6. - 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. 1199.