THE MINISTRY OF HEALTH

ORDER

on approval of implementation of changes to marketing authorisations approved by the National Medicines Agency

Taking into account provisions of Article 10 (9) of Government Ordinance No. 125/1998 on the setting up, organisation and functioning of the National Medicines Agency, approved and modified through Law No. 594/2002, with further changes and completions, and of Government Emergency Ordinance No. 152/1999 on medicinal products for human use, approved with changes and completions through Law No. 336/2002, with further changes and completions,

on seeing The Approval Report of the General Pharmaceutical and Medical Devices Directorate No. M.C. 4.011/2005,

based on Government Decision No. 168/2005 on organisation and functioning of the Ministry of Health,

the minister of health hereby issues the following order:

Article 1. – Changes to marketing authorisations approved by the NMA on renewal of medicinal product marketing authorisation or on approval of an application for variation/notification of variation, shall be implemented by the marketing authorisation holder no later than 6 months since the issuance of documents certifying approval of respective changes.

Article 2. – At the same time with distribution of the first batch of the medicinal product manufactured in line with new provisions approved by the NMA, the marketing authorisation holder shall notify distributors in writing on changes introduced.

Article 3. – Before expiry of the 6 months deadline provided for in Article 1., the manufacturer may put on the market new batches of medicinal products manufactured in line with provisions previous to issuance of documents certifying approval of respective changes.

Article 4. – (1) Batches manufactured in line with the initial marketing authorisation may be maintained in the therapeutic circuit for no longer than two years since issuance of the new documents, depending on the expiry date mentioned on the medicinal product packaging manufactured in respect of the initial authorisation.

(2) On expiry of the two – year period mentioned under (1), the marketing authorisation holder shall withdraw the respective medicinal product batches from the market.

Article 5. – Through its Pharmaceutical Inspection Department, the NMA shall check compliance with provisions of the present Decision.

Article 6. – Should provisions of the present order be disregarded, provisions of Article 100 (1) (e) of Emergency Government Ordinance No. 152/1999 on medicinal products for human use approved with changes and completions through Law No. 336/2002, with further changes and completions shall be applied.

Article 7. – The present order is to be published in the Official Gazette of Romania, Part I.

Minister of Health,
Mircea Cinteză

Bucharest, 30 March 2005.
No. 279.