MINISTRY OF PUBLIC HEALTH

ORDER

on the introduction into Romania and preservation in the therapeutic circuit of medicinal products manufactured prior to the National Medicines Agency's approval of a marketing authorisation transfer

Taking into account:

- provisions of Law No. 95/2006 on healthcare reform, as amended;

- 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 the organisation and functioning of Ministry of Public Health, on seeing the Approval Report of the Pharmaceutical Sector No. E.N. 8503 of 29 December 2006,

the Minister of Public Health hereby issues the following order:

Article 1. – Medicinal products batches manufactured previously to the approval of the marketing authorisation transfer shall still be introduced into Romania and maintained within the therapeutic circuit one more year after the approval of the National Medicines Agency of the marketing authorisation transfer, if its period of validity has not ceased, following which the new marketing authorisation owner has the duty of withdrawing and destroying them.

Article 2. – The present order shall be published in the Official Gazette of Romania, Part I.

Minister of Public Health Gheorghe Eugen Nicolăescu

Bucharest, 29 December 2006. No. 1810.