THE MINISTRY OF HEALTH

ORDER

on approval of Norms regarding quality of raw materials used for manufacturing of Romanian medicinal products for human use

Taking into account provisions of Article 10 (9) of Government Ordinance No. 125/1998 related to the set up, organisation and functioning of the National Medicines Agency, approved with changes and completions 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. 4.007/2005,

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. – Advises on Norms regarding quality of raw materials used for manufacturing of Romanian medicinal products for human use, provided in Annex which is an integral part of the order.

Article 2. – The National Medicines Agency shall carry out provisions of the present order.

Article 3. – On the date of this order coming into force, Order of the minister of health No. 1.444/2004, published in the Official Gazette of Romania, Part I, no. 1.077 of 19 November 2004, shall be approved.

Article 4. – 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. 281.

ANNEX

Norms
regarding quality of raw materials used for manufacturing of Romanian medicinal products for human use

Article 1. – Quality of raw materials used for manufacturing of Romanian medicinal products for human use authorised for marketing shall comply with quality approved by the National Medicines Agency on authorisation for marketing of the medicinal products in question.

Article 2. – (1) Quality of raw materials used by Romanian medicinal product manufacturers in experiments in view of preparation of dossiers for marketing authorisation shall comply with provisions of the European Pharmacopoeia edition in force.

(2) Should the European Pharmacopoeia not include the respective monograph, the raw material quality shall comply with provisions of the Romanian Pharmacopoeia edition in force or of any other international pharmacopoeia or the raw material Drug Master File set up by the respective raw material manufacturer in line with European standards.

Article 3. – (1) Quality of raw materials distributed through pharmaceutical warehouses and used for preparation of magistral and officinal medicinal products shall comply with provisions of the European Pharmacopoeia edition in force.

(2) Should the European Pharmacopoeia not include the respective monograph, the raw material quality shall comply with provisions of the Romanian Pharmacopoeia edition in force or of any other international pharmacopoeia or the raw material Drug Master File set up by the respective raw material manufacturer in line with European standards.

Article 4. – Quality of raw materials is confirmed by means of a Statement of Compliance issued by the raw material manufacturer, accompanying raw materials used for manufacturing Romanian medicinal products for human use in their entire circuit.