THE MINISTRY OF HEALTH

ORDER

on approval of control of medicinal product quality and imported raw materials

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. MC 4.008/2005,

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. – (1) Medicinal products imported from countries that are members of the Pharmaceutical Inspection Co-operation Scheme(PIC/S) or the European Union, authorised for marketing by the National Medicines Agency (NMA), shall be marketed in Romania based on the Statement of Compliance and an analysis bulletin issued by the manufacturer.

(2) Supervising quality of medicinal products mentioned under (1) shall be performed according to an annual sampling plan devised by the NMA.

Article 2. – (1) Imported medicinal products manufactured in PIC/S or EU non-member countries, authorised for marketing by the NMA, shall be analysed by the NMA as follows:

a) biological medicinal products, as defined in Emergency Government Ordinance No. 152/1999 on medicinal products for human use approved with completions and changes through Law No. 336/2002, with further changes and completions, shall undergo batch-to-batch analysis;

b) medicinal products other than biological medicinal products, of higher therapeutic risk (inhalable anaesthetics, plasma substitutes, infusions, contrast substances, radiopharmaceuticals, amynated acid preparations, based preparations, antineoplastic preparations, cardiotonics, heparin, insulin) shall undergo one in three batches analysis;

c) medicinal products other than provided under a) and b) shall undergo one in five batches analysis.

Article 3. – Should the NMA issue two inappropriate analysis bulletins, for a certain medicinal product provided under b) and c) of Article 2, the competent authority shall perform batch-to-batch analysis for the respective medicinal product, the control scheme under b) and c) of Article 2 shall only be resumed after check of 3 consecutive imports.

Article 4. – Representatives of manufacturing companies in PIC/S or EU non-member countries are required to submit to the NMA the status of medicinal product batches imported to Romania during the first 15 days of each quarter.

Article 5. – (1) Raw materials imported by pharmaceutical warehouses for use in preparation of magistral and officinal medicinal products have to meet quality technical requirements as provided in the Norms regarding quality of imported raw materials used in manufacture of Romanian medicinal products, approved through Order of the minister of health No. 1444/05.11.2004 and shall be distributed to warehouses accompanied by analysis bulletins issued by the NMA or a NMA authorised laboratory.

(2) Exception to this provision are raw materials manufactured in PIC/S or EU member countries and imported into Romania.

Article 6. – Expenses incurred by quality control by the NMA are to be paid by importing agents.

Article 7. – Analysis costs are calculated in line with tariffs established through Decision of the NMA Administrative Council in force.

Article 8. – Whenever there are technical possibilities in the NMA to perform certain parameters, the applicant shall submit an application to a NMA authorised control laboratory or other institution with a written recommendation from the NMA, for performance of the respective parameter(s).

Article 9. – Whenever necessary, the applicant shall provide synthesis derived impurities, degradation products and reference substances mentioned in the monograph and/or the approved quality specification at the same time with the samples.

Article 10. – 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 11. – On the date of this order coming into force any contrary provision shall be repealed.

Article 12. – 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. 280.