

MINISTRY OF HEALTH

ORDER

on approval of Regulations for manufacturing/importation authorisation of manufacturers and importers of medicinal products for human use, including investigational medicinal products and grant of the good manufacturing practice certificate to manufacturers of medicinal products for human use and/or active substances

On seeing the Approval report of the General Directorate for medicinal product strategies and policies No. I.B. 2.663/2009,

having regard to:

- provisions of Law No. 95/2006 on healthcare reform, Title XVII – The medicinal product, 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. 1.718/2008 on the organisation and functioning of the Ministry of Health, as amended,

the minister of health hereby issues the following order:

Art. 1. – Regulations for manufacturing/importation authorisation of manufacturers and importers of medicinal products for human use, including investigational medicinal products and grant of the good manufacturing practice certificate to manufacturers of medicinal products for human use and/or active substances are approved as provided in the Annex¹) which is integral part of this Order.

Art. 2. – On the date of this Order coming into force, Order of the Ministry of Public Health No. 918/2006 on approval of Regulations for manufacturing/importation authorisation of manufacturers and importers of medicinal products for human use, including investigational medicinal products, and of starting materials used in the manufacturing of medicinal products for human use, including investigational medicinal products, published in the Official Gazette of Romania, Part I, No. 719 of 22 august 2006, as amended, shall be repealed.

Art. 3. – The present order is to be published in the Official Gazette of Romania, Part I.

Minister of health,
Ion Bazac

Bucharest, 16 March 2009.
No. 312.

¹ The Annex is to be published later in the Official Gazette of Romania, Part I, No. 198 bis, outside subscription and can be purchased at the Centre for Public Relations of the « Official Gazette » Offices in Bucharest, șos. Panduri nr. 1.