

ORDER

for supplementations 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, approved through Minister of Health Order No. 312/2009

On seeing the common report for approval No. Cs. A. 13.119/15.12.2010 of the Medicinal Product Policy Directorate,

Taking into account:

- the provisions of Law No. 95/2006 on healthcare reform, as amended,
 - Government Decision No. 734/2010 on organisation and functioning of the National Agency for Medicines and Medical Devices,
- based on Government Decision No. 144/2010 on organisation and functioning of the Ministry of Health, as amended,

the minister of health hereby issues the following order:

Art. I. – The 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, approved through Minister of Health Order No. 312/2009, published in the Official Gazette of Romania, Part I, No. 198 and 198 bis of 30 March 2009, are amended as follows:

1. Under Art. 26 (1), a new paragraph is introduced after h), namely i), which reads as follows:

"i) for medicinal products centrally authorised in the European Union – based on the import authorisation and on the European Commission decision."

2. Under Art. 26 (2), a new paragraph is introduced after k), namely l), which reads as follows:

"l) for nationally authorised medicinal products in Romania – based on the wholesale distribution authorisation and the marketing authorisation released by the National Agency for Medicines and Medical Devices."

Art. II. – This Order is to be published in the Official Gazette of Romania, Part I.

Minister of Health,

Cseke Attila

Bucharest, 14 January 2011.

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