

DECISION

No. 19/07.11.2008

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

The Scientific Council of the National Medicines Agency, set up based on Order of the Minister of Public Health No. 1027/22.05.2008, reunited on summons of the National Medicines Agency President in the ordinary meeting of 07.11.2008, in line with Article of Government Ordinance No. 125/1998 related to the set up, organisation and functioning of the National Medicines Agency, approved as amended through Law No. 594/2002 as amended, hereby adopts the following

DECISION

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 according to the Annexes, which are integral part of this Decision.

Art. 2. - On the date of this Decision coming into force, Scientific Council Decision No. 15/2006 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, Scientific Council Decision No. 36/2006 and Scientific Council Decision No. 57/2006, amending Scientific Council Decision No. 15/2006 shall be repealed.

Art. 3. - This decision is adopted through Order of the Minister of Public Health and is to be published in the Official Gazette of Romania, Part I.

PRESIDENT
of the Scientific Council
of the National Medicines Agency
Acad. Prof. Dr. Victor Voicu