DECISION

No. 25/03.09.2010

on approval of the completion of the approval by Order of the Minister of Health procedure of regulatory decisions of the National Medicines Agency Scientific Council

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), set up based on Order of the Minister of Public Health no. 1123/18.08.2010, as amended, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 03.09.2010, in accordance with Article 12(5) of Government Ordinance no. 734/2010 related to the set-up, organisation and operation of the National Medicines Agency, agrees on the following

DECISION

Art. I. – Completion is approved of the administration procedure for approval by Order of the Minister of Health of the following NMA regulatory Scientific Council Decisions (SCDs):

Art. 1. – SCD No. 12/26.06.2009 on the completion of Art. 26 of 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 SCD No. 19/2008 (Order of the Minister of Health No. 312/2009);

Art. 2. – SCD No. 13/26.06.2009 on approval of changes to the Regulations concerning the export of medicinal products for human use, approved through SCD No. 16/2006 (Order of the Minister of Health No. 894/2006);

Art. 3. – SCD No. 14/26.06.2009 on approval of the amendment of the Procedure for the parallel import authorisation for medicinal products for human use, approved through SCD No. 2/2007 (Order of the Minister of Health No. 1962/2008);

Art. 4. – SCD No. 16/27.11.2009 on approval of the changes to the Regulations on marketing authorisation and surveillance of medicinal products for human use, approved through SCD No. 11/31.03.2006 (Order of the Minister of Health No. 895/2006);

Art. 5. – SCD No. 20/27.11.2009 on approval of change of the European templates of the package leaflet, Summary of Product Characteristics and of the

information concerning the labelling of medicinal products authorised for marketing in Romania, approved through SCD No. 2/27.01.2006 (Order of the Minister of Health No. 399/2006);

Art. 6. – SCD No. 21/27.11.2009 on approval of Statements for use in the wording of package leaflet, Summary of Product Characteristics and label information for medicinal products authorised for marketing in Romania, approved through SCD No. 3/27.01.2006 (Order of the Minister of Health No. 400/2006);

Art. 7. – SCD No. 2/23.03.2010 on approval of the amendment to the Guideline on Good Distribution Practice of wholesale medicinal products approved through Order of the Minister of Public Health No. 1963/02.12.2008 (Order of the Minister of Health No. 1963//2009);

Art. 8. – SCD No. 4/23.03.2010 on approval of the Norms of the National Medicines Agency administrative procedure for the handling of variations **(**Order of the Minister of Health No. 874/2006);

Art. 9. – SCD No. 12/07.06.2010 on approval of the Regulations regarding the classification for supply of medicinal products for human use **(**Order of the Minister of Health No. 679/2003).

Art. II. – These decisions (Art. 1-9) are approved through Order of the Minister of Public Health and are published in the Official Gazette of Romania, Part I.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,
Acad. Prof. Dr. Leonida Gherasim