

DECISION

No. 8/17.04.2012

on approval of amendment of the Annex to Scientific Council Decision No. 29/16.12.2010 on approval of the Regulations on the authorisation by the National Agency for Medicines and Medical Devices of clinical trials/notification to the National Agency for Medicines and Medical Devices of non-interventional studies on medicinal products for human use in Romania

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health No. 1123/18.08.2010, modified through Order of the Minister of Health No. 1601/28.11.2011, in accordance with the Regulation on the organisation and functioning of the NAMMD Scientific Council, Art. 8 (1), adopts by written procedure the following

DECISION

Art. I.: The Annex to the NAMMD Scientific Council Decision (SCD) No. 29/16.12.2010, supplemented through SCD No. 26/13.12.2011, shall be amended as follows:

1. Article 18 is amended as follows:

“Art. 18. – A clinical trial may start only if the NAMMD has authorised its performance and after the receipt of the favourable opinion of the National Ethics Committee, in case of multicentre trials or of the Institutional Ethics Committee, in case of single centre trials.”

2. Article 40 is amended as follows:

„Art. 40. – (1) The application for authorisation of a clinical trial shall be accompanied by the form concerning the skill of each main investigator from the trial sites concerned and his/her commitment to participate in a clinical trial (in accordance with Annex 5 which is integral part of these regulations);

(2) As regards clinical trials implying the existence of differences between the type of trial/therapeutic group of the Investigational Medicinal Product and the expertise of the main investigator, the NAMMD shall request the opinion of the Scientific Council (after validation of the application for authorisation to conduct the clinical trial).

(3) The Scientific Council opinion may be requested either in the Scientific Council meeting or by written procedure, in accordance with the Regulation on the organisation and functioning of the Scientific Council of the National Agency

for Medicines and Medical Devices, approved through SCD No. 33/13.12.2010, as amended.”

Art. II. – The provisions of this Decision shall come into force on the date of their publication on the NAMMD website: www.anmdm.ro

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