DECISION

no. 25/03/07/2015

on approval of amendment to Annex to SCD no. 6/22.04.2014 on approval of Regulations for 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. 374/02.04.2014, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 03.07.2015, in accordance with Article 12(5) of Government Decision no. 734/2010 on establishment, organization and operation of the National Agency for Medicines and Medical Devices, as amended, adopts the following:

DECISION

Sole article: The Annex to NAMMD Scientific Council Decision (SCD) no. 6/2014 is amended as follows:

1. Article 13 is supplemented with:

"3) The NAMMD shall make a single request for clarification/supplementation to the applicant;

4) The response to the NAMMD request shall be submitted no later than 30 days; submission of responses that are incomplete/unsatisfactory in terms of content, or failure to submit within the specific timeframe result in rejection of the application for authorisation."

2. Article 17 is amended and shall read as follows:

"The applicant submits to the NAMMD a copy of the favourable opinion expressed by the National Bioethics Committee for Medicines and Medical Devices (CNBMDM) as soon as it becomes available."

3. Article 18 is amended and shall read as follows:

"Clinical trials may only start on condition the NAMMD has granted the authorisation for clinical trial conduct and after grant of a favourable opinion by the National Bioethics Committee for Medicines and Medical Devices (CNBMDM)".

4. Article 26 is supplemented with:

"3) The NAMMD shall make a single request for clarification/supplementation;

4) The response to the NAMMD request shall be submitted no later than 30 days; submission of responses that are incomplete/unsatisfactory in terms of content, or failure to submit within the specific timeframe result in rejection of the application for authorisation."

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