DECISION
no. 24/03.07.2015
on approval of amendment of the Annex to SCD no. 2/22.04.2014 on approval of Regulations for authorisation of sites for conduct of clinical trials on medicinal products for human use

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 Council Decision (SCD) no. 2/2014 is amended as follows:

1. Article 5 (2) d) is amended and reads as follows:

"d) - the List of its Standard Operating Procedures (see Annex 2 for the minimal list of Standard Operating Procedures) or certification of implementation of a quality management system in accordance with ISO standards in force for clinical trials;
-certification becomes mandatory as of 1 January 2017;

2. Article 11 d) is amended and reads as follows:

"d) - list of its Standard Operating Procedures (see Annex 2 for the minimal list of Standard Operating Procedures) or certification of implementation of a quality management system in accordance with ISO standards in force for clinical trials;
- ISO certification becomes mandatory as of 1 January 2017;

3. Article 20 d) is amended and reads as follows:
"d) -list of its Standard Operating Procedures (see Annex 2 for the minimal list of Standard Operating Procedures) or certification of implementation of a

quality management system in accordance with ISO standards in force for clinical trials;

- ISO certification becomes mandatory as of 1 January 2017.”

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