DECISION

No. 1/28.03.2014

on approval of amendment of Scientific Council Decision no. 2 of 22/02/2011 on posting on the NAMMD website of certain data concerning NAMMD authorised clinical trials

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health no. 158/18.02.2013, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 28.03.2014, in accordance with Article 12(5) of Government Decision no. 734/2010 on organisation and operation of the National Agency for Medicines and Medical Devices, as amended, adopts the following

DECISION

Article I.: NAMMD Scientific Council Decision (SCD) no. 2 of 22.02.2011 is amended as follows:

1. Article 5 is amended as follows:

"Article 5. (1) Information from clinical trials for which applications for authorisation have been submitted as of 2014 is made publicly available.

(2) Information from clinical trials, published on the NAMMD website, is subject to monthly update."

2. Article 6 is amended as follows:

"Provisions of this Decision shall enter into force on 1 May 2014".

Article II.: The Annex to Scientific Council Decision no. 2 of 22.02.2011 is replaced with the Annex to this SCD.

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

ANNEX to SCD no. 1 / 28.03.2014

No.	Protocol code number	EudraCT Number	Investigational medicinal product tested	Comparator	Placebo	Therapeutic area	Applicant	Sponsor	International/ national	Name of the trial	Phase	Estimated number of patients for Romania	Number of patients enrolled in Romania	Date of NAMMD authorisation of the clinical trial	Date of Ethics Commission approval	Date of clinical trial start	End of the clinical trial	Temporary closure