

DECISION

No. 33/13.12.2010

on approval of the Regulation on the operation and organisation of the NAMMD Scientific Council

The Scientific Council of the National Agency for Medicines and Medical Devices, established based on Minister of Health Order No. 1123/18.08.2010, reunited on summons of the NAMMD President in the ordinary meeting on 13.12.2010, in accordance with Art. 12(5) of Government Ordinance No. 734/2010 regarding the organisation and operation of the National Agency for Medicines and Medical Devices, as amended, adopts the following

DECISION

Art. 1. - The Regulation on the operation and organisation of the NAMMD Scientific Council is approved, in accordance with the annex which is integral part of this decision.

Art. 2. - At the date of the coming into force of this Decision, NAMMD Scientific Council Decision No. 18/03.09.2011 on approval of the Regulation for organisation and operation of the NAMMD Scientific Council is repealed.

PRESIDENT

of the Scientific Council

of the National Agency for Medicines and Medical Devices,

Acad. Prof. Dr. Leonida Gherasim

**REGULATION FOR ORGANISATION AND OPERATION OF THE
SCIENTIFIC COUNCIL OF THE NATIONAL AGENCY FOR
MEDICINES AND MEDICAL DEVICES**

**CHAPTER 1
General provisions**

Art. 1. - The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD) is part of the organisational structure of the National Agency for Medicines and Medical Devices, in accordance with the provisions of Government Ordinance No. 734 of 21 July 2010 on the organisation and operation of the National Agency for Medicines and Medical Devices, published in the Official Gazette of Romania, Part I, No. 531/29.07.2010.

Art. 2. - The Scientific Council establishes the scientific policy of the National Agency for Medicines and Medical Devices in accordance with Art. 12(4) of Government Ordinance No. 734/2010 on the organisation and operation of the NAMMD.

**CHAPTER 2
Organisation and functioning**

Art. 3. – The setup, name composition, meetings and manner of deliberation of the Scientific Council, establishment of the agenda, manner of approval of Scientific Council Decisions, receipt of indemnities for sessions by Scientific Council members and their reimbursement are in accordance with the provisions of Government Decision No. 734/2010.

Art. 4. - (1) The members of the Scientific Council meet requirements related to conflict of interests and, at the beginning of their mandate, provide a declaration of interests according to the provisions of Art. 14(2), (3) and (4) of Government Decision No. 734/2010.

(2) In case one member of the Scientific Council does not notify existing changes to their declaration of interests, the Scientific Council proposes replacement of that member to the Minister of Public Health.

(3) At the beginning of each Scientific Council meeting, council members in conflict of interests concerning one of the issues on the agenda may take part in debates, however abstaining from voting.

(4) The declarations of interests of Scientific Council members are posted on the NAMMD website.

Art. 5. - (1) The NAMMD Scientific Council President is elected by open vote, with a simple majority.

(2) The Secretariat of the Scientific Council is ensured by the Policies and Strategies Department.

(3) Under certain circumstances, the Scientific Council has the right to resort to NAMMD or academic specialists (in certain fields).

Art. 6. – (1) The agenda of the Scientific Council may include NAMMD activity specific issues requiring analysis and resolution by the Scientific Council as well as various topics proposed for debate/information and projects proposed for in-principle support by Scientific Council members.

(2) Following debate of every issue on the agenda, Scientific Council members sign for their expressed options and votes, in a <Table for formulation of options and votes>, attached in Annex 1 to this Regulation.

Art. 7. – (1) Scientific Council members who, on account of solid grounds, cannot take part in Council meetings, may express their opinions and approve the draft decisions of the Scientific Council by mail, by filling in and signing the <Voting form> attached in Annex 2 to this Regulation and forwarding it to the NAMMD by fax, 2 days prior to the date established for the Scientific Council, as well as by regular mail.

(2) For approval of certain decisions, voting may be done by secret vote on decision by Scientific Council members only.

Art. 8.- (1) The written procedure may be used when circumstances require urgent decisions and summons of a plenary session is not feasible.

(2) In this case, draft decisions are forwarded via e-mail to Scientific Council members, who must confirm receipt thereof.

(3) Scientific Council members may express their opinions and vote for the approval of draft decisions of the Scientific Council through the procedure described under Art. 7 (1), however complaint with the deadline established by the Scientific Council president.

(4) The deadline under (3) is no shorter than 3 working days and not exceeding 7 days.

(5) In the next plenary session of the Scientific Council, the secretariate submits a complete report concerning the written procedure result.

(6) In case of serious complaints, the president of the Scientific Council may decide upon the written procedure and its acceptance in the next plenary session.

(7) If no complaint is issued during the timeframe specified under (4), the draft decision is approved and, if of regulatory nature, it is submitted for approval to the Minister of Public Health.

Art. 9. – (1) Scientific Council Decisions which are not regulatory, approved during a plenary session or under the conditions specified in Art. 7 and Art. 8, come into force as of their posting on the NAMMD website (under the heading *Legislation/Scientific Council Decisions*).

(2) In case the deadline for the coming into force of a Decision is different from the one mentioned in paragraph (1), this is explicitly mentioned in the body of the Decision.

Art. 10. – (1) The president of the Scientific Council chairs the meetings of the Scientific Council; in the absence of the President of the Scientific Council, the meetings are chaired by the NAMMD President or by one of the Scientific Council members assigned thereof.

(2) The president of the Scientific Council leads the meetings of the Scientific Council; when the President of the Scientific Council is missing, the meetings shall be lead by the Vicepresident of the Scientific Council, assigned as shown in paragraph (1).

(3) The President and the Secretariat of the Scientific Council prepare the meetings of the Scientific Council, the agenda and materials to be debated.

Art. 11. – (1) The Secretariate of the Scientific Council receives proposals for the agenda of the Scientific Council meetings, at least one month prior to the ordinary meetings.

(2) The Secretariate of the Scientific Council makes public the date of the Scientific Council meeting, by posting this information on the NAMMD website, minimum 21 days prior to the meeting.

(3) Under certain circumstances requiring summons of an extraordinary meeting of the Scientific Council (in accordance with provisions of Government Decision No. 734/2010), the term mentioned in (2) is different, as required).

(4) The Secretariate of the Scientific Council transmits to the Scientific Council members, in electronic format and/or written form, the agenda, decision drafts and other documents to be debated during the plenary session, at least 10 days prior to the meeting.

(5) Three days prior to the date of the meeting, Scientific Council members forward their remarks/comments/questions related to draft decisions, allowing authors of the respective drafts the time to prepare the answers in due time.

(6) The Scientific Council secretarial assigned person drafts the minutes of the Scientific Council meetings and signs next to all Scientific Council members attending the respective meetings.

(7) The Secretariate of the Scientific Council forwards to the Scientific Council members, in electronic format and/or on paper, the minutes of the Scientific Council meetings; the final form of the minutes is approved in the next meeting of the Council.

(8) Scientific Council meetings are also recorded in audio format and kept as reference for debates and decisions made in each meeting.

Art. 12. - The Secretariat of the Scientific Council manages record of Scientific Council documents: proposals, decisions, minutes, signature lists, declarations of interests, maintained at the NAMMD Secretariate.

Art. 13. - The Secretariat of the Scientific Council elaborates a nominal list with the signatures of all members of the Scientific Council attending each

meeting, used as a basis of the meeting indemnities and reimbursement of transportation, accommodation and daily allowance expenses.

CHAPTER 3

Final provisions

Art. 14. - On the date of the coming into force of the present Regulation for organisation and operation of the NAMMD Scientific Council, the Regulation for organisation and operation of the NAMMD Scientific Council approved through SCD No. 18/03.09.2010 is repealed.

ANNEX 1 to SC Regulation

Proposal/Document/SCD No.

.....

.....

No. crt.	NAMMD SC Members	For information/ debate	Support			Adoption		
			Yes	No	Abstention	Yes	No	Abstention
1.	Acad. prof. dr. L. Gherasim							
2.	Dr. Daniel Boda							
3.	Dr. Pharm. Emese Sipos							
4.	Prof. dr. Ostin C. Mungiu							
5.	Prof. dr. Dan Cheța							
6.	Prof. dr. Ofelia Crișan							
7.	Prof. dr. Dragoș Vinereanu							
8.	Prof. dr. Pharm. D. Lupuliasa							
9.	Prof. dr. Eng. Victor Purcărea							
10.	Senior pharm. Nela Vîlceanu							
11.	Dr. Radu Rășinar							
12.	Dr. Dragoș Damian							
13.	-							
Total								

FORM
to express the vote/options of the NAMMD Scientific Council members

Name and surname:

.....

Title of the Scientific Council

Decision:.....

.....

.....

.....

Vote: Positive

 Negative

 Abstention

Conditioning for vote:

.....

.....

.....

.....

Objections/Recommendations:

.....

.....

.....

.....

.....

Signature:

Date