DECISIONS OF THE ROMANIAN GOVERNMENT
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DECISION
on the organisation and operation of the National Agency for Medicines and Medical Devices

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Issued based on Art. 108 of the Romanian Constitution, republished, and on Art. III and VII (1) of Emergency Government Ordinance No. 72/2010 on reorganisation of certain healthcare facilities and amendment of healthcare regulatory acts,

The Romanian Government hereby adopts the following Decision.

CHAPTER I
General matters

Art. 1. – (1) The National Agency for Medicines and Medical Devices is a public institution and legal entity operating under the Ministry of Health, set up in accordance with the law, by merger of the National Medicines Agency and the Technical Office for Medical Devices.

(2) The National Agency for Medicines and Medical Devices, further referred to as *NAMMD,* has its headquarters in Bucharest, 48 Aviator Sănătescu Street, sector 1, and work centres without legal personality for the activities related to medical devices, at 58 Nicolae Titulescu Blvd., sector 1, and 49 Episcop Radu Street, sector 2.

(3) The NAMMD is organised and operated in accordance with legal provisions in force and its own organisation and operation rules, approved through Order of the Minister of Health.

(4) With the approval of the Ministry of Health, the NAMMD may establish territorial units without legal personality for inspection and laboratory control by periodic checks of medical devices.

Art. 2. – (1) The scope of the NAMMD is authorisation of medicinal products for human use, wholesale distribution units for medicinal products for human use, surveillance of manufacturing units, wholesale distribution and quality of medicinal products on the market and in-use control of medicinal products for human use, as well as assessment of medical devices

compliance, certification of management systems, inspection and control of medical devices and of medical engineering units.

(2) The NAMMD issues national strategies and policies in the field of medicinal products and medical devices, in accordance with the law.

Art. 3. – In view of meeting the objectives in its field, the NAMMD performs the following:

a) regulates activities in the field of medicinal products for human use and medical devices, through the Ministry of Health, to ensure establishment of a legal frame and specific regulations;

b) issues the national policies and strategies in the field of medicinal products and medical devices;

c) monitors the enforcement of and compliance with specific regulations in its field, thus ensuring their surveillance and control;

d) represents the state and the Ministry of Health, thus ensuring internal and external representation in its field.

CHAPTER II
NAMMD responsibilities

Art. 4. – (1) In meeting its objectives in its field, the NAMMD cooperates with the Ministry of Health, the National Health Insurance House, professional organisations, as well as with other national and international organisations in the healthcare field.

(2) In the medicinal product domain, in accordance with legal provisions, the NAMMD has the following main responsibilities:

a) sets up mandatory norms, instructions and regulations concerning medicinal products for human use, forwarded to the Ministry of Health for approval;

b) grants marketing authorisations for medicinal products for human use; informs the Ministry of Health on marketing authorisations granted on a monthly basis;

c) supervises and controls the quality of medicinal products for human use, by periodic inspections and planned control undertakings, as well as under all circumstances of alerts about medicinal product quality and effect and responds to requests of the Ministry of Health concerning performance of inspections and activities in its field of competence;

d) authorises and controls ongoing clinical trials and their sites, as the case may be, for medicinal products for human use, in accordance with Good Clinical Practice rules;

e) initiates and/or conducts clinical/preclinical trials and laboratory tests concerning the quality, efficacy and safety of medicinal products for human use, to ensure the health of the general population; in that respect, it cooperates with higher education institutions and scientific research or public health entities;

f) organises, provides guidance to and controls pharmacovigilance activities, performs studies on the use of medicinal products for human use, sets up and edits newsletters concerning the pharmacovigilance activity;

g) approves advertising material for medicinal products for human use, in accordance with regulations in force;

h) elaborates and updates the Index of Medicinal Products for Human Use, specifying the category for each medicinal product, depending on its manner of dispensing, with or without medical prescription;

i) elaborates the "Romanian Pharmacopoeia" and cooperates with national and international bodies in this field;

j) ensures operation of a service for information on medicinal products for human use; elaborates and publishes, in electronic format, the NAMMD Informative Bulletin, specific expert and informative publications;

k) provides, in accordance with the law, on request from medical and pharmaceutical institutions and units, informational material related to medicinal products for human use and establishes the fee for the service provided;

l) cooperates with the Ministry of Health and the National Health Insurance House in setting up the list of medicinal products for human use in the Index of Medicinal Products for Human Use for the benefit of the insured public based on medical prescription, with or without personal contribution;

m) as required, decides on the suspension, recall or modification of marketing authorisations for medicinal products for human use and within 48 hours informs the Ministry of Health on the respective decision, accompanied by an explanatory note;

n) performs various services and activities specific to its units, except for those required by legal entities, for the set up of the dossier for the authorisation of medicinal products for human use, organises training courses;

o) initiates, negotiates and signs agreements and international cooperation documents in the field of medicinal products for human use, within its jurisdiction by the law, organises activities related to international relations and co-operations in the respective field;

p) organises working meetings, courses and scientific events in the field of medicinal products for human use;

q) ascertains violations of legal provisions in its field and enforces the adequate sanctions, in accordance with legislation in force;

r) performs other specific activities in the field of medicinal products for human use, as well as specific activities assigned by the Ministry of Health;

s) grants the certificate of compliance with Good Manufacturing Practice, as well as the manufacturing/import authorisation, based on the inspection carried out by NAMMD inspectors;

ș) grants functioning authorisations to wholesale medicinal product distributors, in accordance with legal provisions, based on the inspection carried out by NAMMD inspectors;

t) identifies other fields for action, in accordance with its responsibilities and scope.

(3) As regards the medical devices field, the NAMMD has the following main responsibilities, in accordance with legal provisions:

a) assesses compliance of medical devices and management systems;

b) provides specialist technical expertise, inspection and/or control services, as required;

c) as part of the technical committees of the Romanian Association of Standardisation (RAS), participates in the elaboration and adoption of standards applicable in its field;

d) collaborates with similar foreign institutions and bodies, establishes and signs mutual recognition protocols or cooperation conventions in accordance with the law, as required;

e) coordinates and performs nationally and/or internationally financed programs in its activity field;

f) trains and assesses qualified medical devices staff;

g) ensures the secretariat of the Commission for medical devices, set up in accordance with Law No. 176/2000 on medical devices as amended, republished;

h) carries out activities related to the documentation, enforcement, research and development in its activity field, to the extent in which such activities do not violate requirements regarding the independence and impartiality needed for the compliance assessment process;

i) performs information activities in its field, as well as elaboration and editing of specialist publications;

j) performs any other activities, by delegation of competences on behalf of the Ministry of Health, according to the law, ensuring compliance with independence and impartiality requirements;

k) ascertains violations of legal provisions in its field and enforces the adequate sanctions, in accordance with legislation in force;

l) performs checks and tests on medical devices and second-hand *in vitro* diagnostic medical devices envisaging their performance and safety in view of approval;

m) performs checks of medical devices in use, by periodic control checks and grants periodic verification bulletins;

n) issues the approval for use of medical devices and second-hand *in vitro* diagnostic medical devices;

o) audits technical and medical units requiring approval for performing activities in the field of medical devices, *in vitro* diagnostic medical devices and active implantable medical devices, as required, to grant the approval, according to the law;

p) audits, as required, technical and medical units providing services in medical devices, *in vitro* diagnostic medical devices and active implantable medical devices, to assess consistent preservation of conditions underlying approval.

(4) Until the new certification body is notified, assessment of medical devices and management systems is still performed by the Technical Office for Medical Devices (*TOMD*)/TOMD Certification, a notified certification body.

Art. 5. – (1) In view of consistent enforcement of legal provisions related to the insurance of quality, efficacy and safety of medicinal products for human use and medical devices, the NAMMD collaborates with various ministries, with other central and local public administration bodies and as such is entitled to request the documents, data and information needed to meet its responsibilities.

(2) When performing its control duties, the empowered personnel in the NAMMD or its territorial units is entitled to request documents which public and private economic agents and units have the duty to provide as well as to respond to other requests necessary in checking the manner in which legislation related to quality of medicinal products for human use and medical devices is enforced.

CHAPTER III
NAMMD policies and strategies

Art. 6. – The NAMMD promotes and implements national policies in its field, by enforcing specific strategies.

Art. 7. – The NAMMD monitors the medicinal product market and ensures control of in-use and medical devices used, as well as control of services performed in the field of medical devices in Romania, for compliance with and enforcement of specific legislation, pursues statistics and forecasts connected to its scope, in view of setting up and proposing regulatory acts.

CHAPTER IV
The organisation and operation of the NAMMD

Art. 8. – (1) The NAMMD is run by a president and 2 vice-presidents concerned with the specific duties and activities in the field of medicinal products for human use and medical devices, respectively, appointed for 3 years, in accordance with the law, through order of the Minister of Health.

(2) As regards payment, the president and vice-presidents are assimilated to the position of general director and deputy director, respectively.

(3) In performance of their duties, the NAMMD president issues decisions and instructions.

(4) The NAMMD president is a tertiary budget manager and represents the institution in its relations with the ministries, public administration authorities, with other national/foreign authorities and public institutions, with natural and legal entities, as well as in court. By means of decisions, the NAMMD president may delegate performance of the responsibility as tertiary budget manager and other duties to one of the two vice-presidents.

(5) The NAMMD is structured in departments organised at directorate level, comprising services, bureaus and units, by decision of the NAMMD president. The maximum number of jobs is 372 positions, the president and the two vice-presidents included.

(6) The organisational structure of territorial inspection and/ or control and surveillance of the medicinal product market units, and of control by means of periodic verification of medical devices is approved through decision of the NAMMD president.

(7) Territorial units for the inspection and/or control and surveillance of the medicinal product market, as well as units performing periodic control of medical devices are all structures without legal personality, in which specialist technical and service personnel carry out activities, employing specialist healthcare, technical and service personnel.

Art. 9. – (1) The NAMMD Administrative Council is set up by order of the Minister of Health and includes the following members:

a) the NAMMD president;

b) the 2 NAMMD vice-presidents;

c) 2 representatives of the Ministry of Health.

(2) The NAMMD president is also the president of the Administrative Council.

(3) The heads of departments within the NAMMD participate in meetings of the Administrative Council, without the right to vote.

Art. 10. – The Administrative Council has the following responsibilities:

a) approves the NAMMD economic and financial policy;

b) approves the income and expense budget and approves its execution;

c) analyses the opportunity and possibilities of signing collaboration and service contracts;

d) approves proposals of tariffs and emergency fees for NAMMD activities, as well as the fee for maintaining marketing authorisation in force, which are to be published in the Official Gazette of Romania, Part I, after approval through order of the Minister of Health;

e) endorses the NAMMD organisational structure, approved through order of the Minister of Health;

f) approves the NAMMD annual activity report;

g) approves the Regulation on NAMMD organisation and operation.

Art. 11. – (1) The Administrative Council is summoned at least once a month or whenever necessary. The summoning date of the Administrative Council is established in the previous meeting of the council. The Administrative Council may be summoned whenever necessary, on summons of the NAMMD president or representatives of the Ministry of Health.

(2) Proposals of the President and the representatives of the Ministry of Health and those meeting the simple majority vote of the entire Administrative Council members have priority on the agenda of the Administrative Council.

(3) The Administrative Council operates legally under simple majority of the entire number of its members.

(4) Decisions are approved in Administrative Councils with a simple majority.

(5) The agenda and its attached documents are transmitted to Administrative Council members at least 7 days prior to the day of the meeting.

(6) Administrative Council decisions are transmitted to the Minister of Health for information.

Art. 12. – (1) The NAMMD Scientific Council is set up through an order of the Minister of Health, on NAMMD president proposal, and it consists of the following:

a) the NAMMD president and two NAMMD members;

b) a representative of the Medical Science Academy;

c) a representative of medicine faculties;

d) a representative of pharmacy faculties;

e) an experienced clinician;

f) a representative of the Minister of Health;

g) a representative of the Romanian College of Pharmacists;

h) a representative of the Romanian College of Physicians;

i) a representative of the Romanian Drug Manufacturers Association;

j) a representative of the Romanian Association of International Medicinal Product Manufacturers;

k) a representative of the medical bioengineering university chair.

(2) Nomination of members mentioned under (1) is performed by the legal representative of institutions involved, on request by the NAMMD president.

(3) The president of the Scientific Council is elected from among its members.

(4) The Scientific Council establishes the NAMMD scientific policy.

(5) The Scientific Council is summoned at least 3 times yearly. The summoning date is established during its meeting. The Scientific Council may be summoned whenever necessary, on request by the NAMMD president, the Ministry of Health or of one third of its members.

(6) The following have priority on the agenda of Scientific Council meetings: the NAMMD scientific activity between two sessions, the manner of NAMMD scientific policy enforcement, proposals of the NAMMD president, the Ministry of Health, the Medical Science Academy or proposals voted by one third of the Scientific Council members.

(7) The Scientific Council may only deliberate if at least one more than half of its members are present.

(8) Scientific Council decisions are approved by simple majority.

(9) Scientific Council decisions of ruling character submitted for approval order of the Minister of Health and is published in the Official Gazette of Romania, Part I; other non-ruling Scientific Council decisions are transmitted to the Ministry of Health for information.

(10) The regulation for Scientific Council organisation and operation is adopted within 30 days as of the date of this decision coming into force and is approved through Decision of the NAMMD president.

Art. 13. – The nominal membership of the Scientific Council is approved for a 3 year mandate, with the possibility of mandate renewal.

Art. 14. – (1) The members of the Scientific Council and the Administrative Council may be granted meeting allowances not exceeding 1% of the president's base salary and their travel/accommodation/per diem expenses may be reimbursed, in accordance with the law.

(2) According to law, individuals who, directly or via their husband/wife or first degree relatives, perform activities or have interests in companies manufacturing, distributing or importing medicinal products are excluded from membership in the Administrative Council.

(3) Before appointment and whenever necessary, or in case of changed relations with such companies, members of the Scientific Council are required to state their personal interests, as well as those of their husband, wife, first degree relatives in the manufacture, distribution or import of medicinal product companies at home or abroad.

(4) Scientific Council members in a conflict of interests as to one of the issues covered during Scientific Council meetings should formally state their abstention from vote and leave the meeting room.

CHAPTER V
Common provisions

Art. 15. – (1) The president and the two vice-presidents put into practice the decisions of the Administrative Council and of the Scientific Council and are responsible for the entire NAMMD activity.

(2) The NAMMD vice-presidents are responsible for the management of quality and implementation into the activity of the institution of European legislation in the field of medicinal products and medical devices.

CHAPTER VI
Funding

Art. 16. – The funding of current and capital NAMMD expenses is done from the state budget.

Art. 17. – Employment and payment of NAMMD staff are performed according to legal provisions in force.

CHAPTER VII
Transitional and final provisions

Art. 18. – (1) All assets and staff of the National Agency for Medicines and of the Technical Office for Medical Devices are taken over by the NAMMD, based on a receipt-delivery protocol.

(2) Maintenance within the maximum number of jobs provided under Art. 8 (5) is achieved by compliance with legal procedure and provisions applicable to contract staff.

(3) Provisions of Art. 8 (2) apply as of the date of expiry of the collective labour contract.

Art. 19. – On the date of this Decision coming into force, Government Decision No. 2.281/2004 on approval of the Regulation on the organisation and operation of the Technical Office for Medical Devices, published in the Official Gazette of Romania, Part I, No. 1.256 of 27 December 2004 is repealed.

PRIME MINISTER,
EMIL BOC

Countersigned:
Minister of Health,
Cseke Attila

Minister of Labour, Family and
Social Welfare**,**
Mihai Constantin Şeitan

Minister of Public Finance,
Sebastian Teodor Gheorghe Vlădescu

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No. 734.