The Parliament of Romania

Law no. 134
of 12 July 2019
on reorganisation of the National Agency for Medicines and Medical Devices and amendment of further ruling provisions

Published in the Official Journal of Romania, Part I, 587 of 17 July 2019

Promulgated by Decree no. 576 of 12 July 2019

The Parliament of Romania hereby adopts this law.

Chapter I
General Provisions

Article 1 - (1) The National Agency for Medicines and Medical Devices of Romania, hereinafter the NAMMDR, is hereby established by reorganisation of the National Agency for Medicines and Medical Devices, to be hereafter dissolved, as a public institution and legal entity, a specialised body of central public administration in the field of medicinal products for human use, medical devices and assessment of health technologies, under the Ministry of Health.

(2) The headquarters of the NAMMDR is located in Bucharest, str. Aviator Sănătescu str. 48, sector 1.

(3) The NAMMDR is organised and operates in accordance with provisions of this law and its own organisation and operation rules, approved by order of the Minister of Health.

(4) For the purpose of its tasks, by decision of the President, the NAMMDR may establish territorial units without legal personality.

Article 2 - The scope of the NAMMDR is:

a) Marketing authorisation of medicinal products for human use, authorisation of manufacturing and wholesale distribution units for medicinal products for human use;

b) Surveillance of manufacturing units and wholesale distribution as well as of the quality of medicinal products on the market and in-use control of medicinal products for human use;

c) Inspection for surveillance of activities conducted in community pharmacies, local distribution units, closed-circuit pharmacies and chemist's shops, at least once every 5 years or whenever required;

d) Regulation of medical devices;

e) Surveillance of the medical device market;

f) Approval of establishments for the trade and servicing of medical devices;

g) Registration of medical devices placed on the market or commissioned in Romania, of domestic manufacturers, authorised representatives, medical device importers and wholesalers;

h) Inspection and control of medical devices in operation;

i) Assessment of health technologies related to medicinal products for human use, high-performance medical devices and equipment.

Article 3. – For its purposes, the NAMMDR performs the following functions:

a) development of national regulations, policies and strategies related to medicinal products for human use, medical devices and health assessment of technologies;

b) control to ensure surveillance and verification of compliance with specific regulations in its field;

c) internal and external representation on behalf of the Romanian state and the Ministry of Health under its scope.

CHAPTER II
NAMMDR duties

Article 4. - (1) For the purpose of specific objectives in its scope, the NAMMDR cooperates with the Ministry of Health, bodies of central and local administration, professional bodies as well as with other healthcare national and international organisations.

(2) For the purpose of its specific tasks, the NAMMDR may work with external experts, in compliance with legal provisions in its field.

(3) In accordance with legal provisions, the NAMMDR has the following main medicinal product related duties:

1. establishing mandatory rules and other regulatory provisions concerning medicinal products for human use, submitted to the Ministry of Health for approval;
2. grant of marketing authorisations, marketing authorisation renewal and variation for medicinal products for human use; grants authorisations for parallel import, their renewal and variation; ensures monthly advising of the Ministry of Health on marketing authorisations granted;
3. surveillance and control of the quality of medicinal products for human use in the frame of their manufacture, import, wholesale and retail, by periodic inspections and planned control operations, as well as under all circumstances of alerts/complaints concerning medicinal product quality and outcomes and responds to requests of the Ministry of Health for performance of inspections and operations in its scope;
4. inspection for surveillance of operations conducted by community pharmacies, local distribution offices, closed circuit pharmacies and chemist's shops at least every 5 years or whenever necessary;
5. authorisation and control of conduct, in accordance with good clinical practice guidelines, of clinical trials on medicinal products for human use as well as of their respective sites, in line with legal provisions if force;
6. performs laboratory testing of the quality of medicinal products for human use for purposes of authorisation, quality monitoring, official batch release, respectively, for immunological or human blood-/plasma-derived medicinal products, as well as on request by other central and local public administration bodies;
7. organisation, guidance and control of pharmacovigilance work, conduct of studies on the use of medicinal products for human use, preparation of notifications on pharmacovigilance operations;
8. approval and control of advertising and readability related to medicinal products for human use, in accordance with regulations in force;
9. development and update of the Index of Medicinal Products for Human Use authorised for marketing in Romania, specifying their respective classification for supply;
10. annual notification of the European Commission and the other Member States on changes operated in the Index of Medicinal Products for Human Use authorised for marketing in Romania;
11. cooperation with national and international bodies for development of the European Pharmacopoeia;
12. operation of a service for information on medicinal products for human use; prepares and publishes, in electronic format, the NAMMDR Newsletter, specific specialist publications and information;

13. cooperation 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 provided on prescription to insurants irrespective of personal contribution;

14. decision on the suspension, recall/withdrawal of marketing authorisations or variation to marketing authorisations terms for medicinal products for human use, as required, as well as notification within 48 hours of the Ministry of Health and the National Health Insurance House on the respective decision;

15. provision of scientific advice and conduct of specific activities within its scope;

16. initiation, negotiation and conclusion of agreements and national and international cooperation documents within its legal scope;

17. organisation of working meetings, training courses, research projects and scientific events in the field of medicinal products for human use;

18. ascertaining of violation of legal provisions in its field and enforcement of appropriate penalties, in accordance with legislation in force;

19. conduct of other specific operations assigned by the Ministry of Health;

20. Good Manufacturing Practice certification of active substance/medicinal product manufacturers in third countries, based on favourable inspection reports by NAMMDR inspectors;

21. authorisation for operation to wholesalers of human medicinal product distributors, or wholesale distribution authorisations in the storage/custody system to wholesalers of medicinal product for human use based on favourable inspection reports by NAMMDR inspectors as well as good distribution practice certification;

22. authorisation of manufacturing/import to Romanian manufacturers/importers of medicinal products/investigational medicinal products for human use based on favourable inspection reports by NAMMDR inspectors as well as Good Manufacturing Practice certification;

23. Good Laboratory Practice certification for sites involved in conduct of non-clinical studies and the bioequivalence studies, respectively, under the law for authorisation of medicinal products for human use;

24. inspection of marketing authorisation holders for verification of compliance with their obligations as regards both pharmacovigilance and other obligations under legislation related to medicinal products for human use;

25. certification of Qualified Persons for applicants meeting conditions under the law;

26. grant of the certificate of pharmaceutical product in the format recommended by the World Health Organisation (WHO) and approval of export declarations for medicinal products for human use;

27. authorisations for supply of special needs medicines;

28. conduct of operations to prevent the entry into the legal supply chain of falsified medicinal products in accordance with legal provisions;

29. conduct of operations related to record and surveillance of brokers of medicinal products for human use;

30. conduct of and participation in assessments of the quality, efficacy and safety of medicines for human use authorised through centralised procedure (as per CAT, PRAC, PDCO, CHMP work), through its own or external experts.

31. participation in meetings and working groups at EU level in the field of medicinal products for human use;

32. enters information on marketing authorisations granted into the European Union database operated by the European Medicines Agency on behalf of the European Union, and provides, on the request of the European Commission or any Member State, all appropriate information on individual marketing authorisations granted;

33. monitoring or the medicinal product market for compliance and enforcement of specific legislation, monitoring of statistics and forecasts related to its scope, for the purpose of developing and proposing regulatory provisions;

34. undertaking of legal steps for ensuring uninterrupted supply of an adequate range of medicines to meet patients' needs;

35. may decide on maintaining/exclusion from the market of products nationally authorised before 2006, only based on marketing authorisation holders' risk-benefit reports and documents submitted in support of the application for authorisation;

36. notification of the Ministry of Health on medicinal product shortages as evident from monthly reports on market placement in in Romania.

(4) As regards the medical devices area, in accordance with legal provisions, the NAMMDR main duties are as follows:

1. development of rules and other mandatory regulations related to medical devices, submitted for Ministry of Health approval;

2. participation as members of inter-ministerial working groups in development of rules for harmonisation and implementation of medical device related regulations, on request by the Ministry of Health;

3. participation in EU medical device related meetings and working groups;

4. technical development of Romania's standpoint and the representation mandate regarding proposals of Community regulatory provisions and topics of European Union working groups related to medical devices, submitted to the Ministry of Health;

5. preparation of the lists of Romanian standards adopting European standards harmonised with European directives on medical devices, submitted for Minister of Health approval;

6. organisation of working meetings, training courses, research projects and scientific events in the field of medical devices;

7. assessment and designation of certification bodies for medical devices, submission to Minister of Health approval of the list of bodies designated and notification of such bodies through the electronic procedure operated by the European Commission;

8. assessment of notified body capability based on methodological rules developed by order of the Minister of Health and withdrawal of notification where the notified body no longer meets specified criteria underlying designation;

9. assessment and approval of entities conducting marketing and servicing of medical devices, in accordance with legislation in force;

10. record of medical devices placed on the market or commissioned in Romania, medical device domestic manufacturers, authorised representatives, importers and wholesalers, according to regulations in force;

11. setup and update of the national data base in accordance with national legislation provisions transposing European directives;

12. provides entry into the Eudamed European database of data entered into the national base, according to provisions of Commission Decision 2010/227/ EU of 19 April 2010 on the European Database on medical devices - Eudamed;

13. decision on medical device classification in the event of disputes between the manufacturer and the conformity assessment responsible body;

14. authorisation, in duly justified cases, of the placing on the market and commissioning of individual medical devices, for the purposes of the health protection policy;

15. authorisation of the conduct of the clinical investigation/assessment of performance procedure with investigational medical devices;

16. surveillance of the medical devices market, according to regulations in force;

17. request of appropriate measures for market withdrawal or prohibition/ restriction of market placement/commissioning medical devices potentially harmful to patients and users' health and/or safety;

18. record and assessment of information on the reported incidents and proposed corrective actions in relation to medical devices and enforcement of the vigilance procedure according to harmonised legislation in force;

19. administrative cooperation with competent authorities of the Member States of the European Union, related to provision of medical device services, through the Ministry of Health and the internal market information system - IMI, established by the European Commission;

20. provision of scientific advice and activities specific in its scope;

21. provision of specialised technical expertise, inspection and/or control, as appropriate;

22. coordination and running of national information programs developed with internal and/or external financing, in its scope;

23. approval, confirmation and certification of registration in accordance with specific legal provisions in force;

24. ascertaining of violation of legal provisions in its field and enforcement of appropriate penalties, in accordance with legislation in force;

25. performance and safety testing and checks for used medical devices;

26. performance and safety testing and checks for used *in vitro* diagnostic medical devices;

27. approval for use of both used medical devices and used *in vitro* diagnostic medical devices;

28. control by periodical verification of medical devices in operation;

29. grant of customs notice, in accordance with specific legislation in force;

30. free sale certification according to the specific legislation in force;

31. upon request, grant of out-of-scope notifications related to classification of certain products as medical devices.

(5) As national competent authority for health technology assessment, the NAMMDR has the following main duties:

1. development and periodical review of national methodological guidelines for assessment of health technologies and formats of health technology assessment reports, in accordance with international standards; development and implementation of priority-setting mechanisms related to health technology assessment, approved by order of the Minister of Health;

2. review and assessment of reports prepared by relevant institutions, organisations, external experts or researchers, on assessment of health technologies for objectivity, validity, compliance and scientific rigour, or request of suppliers or the Ministry of Health;

3. collaboration with professional bodies in the healthcare system and the academia for assessment of health technologies;

4. collection and analysis of statistical data relevant to health technology assessment from all healthcare services;

5. ensuring transparency of the process for substantiation of decisions on health technology assessment;

6. assessment of documentation based on the health technologies assessment mechanism and decides on the inclusion, extension of indications, non-inclusion or exclusion of medicines in/from the List of INNs of on - prescription medicines provided to insurants irrespective of personal contribution, in the healthcare social insurance system, as well as INNs of medicines supplied in the frame of the national health programs;

7. constant development of institutional capacity for health technology assessment, including training activities; organisation of working meetings, training courses, research projects and scientific events in the field;

8. participation in exchange of scientific information, development of models and assessment tools, as well as in studies and development of material in cooperation with Member States of the European network for Health Technology Assessment;

9. participation together with the Ministry of Health in international projects with similar institutions;

10. request from specialised commissions of the Ministry of Health to develop therapeutic protocols;

11. critical examination and approval of therapeutic protocols developed and/or revised by the specialised committees of the Ministry of Health.

Article 5. – (1) The NAMMDR takes adequate steps for the withdrawal, prohibition and/or restriction of market placing of any product intended for human consumption deemed potentially harmful for users' health and/or safety.

(2) When performing its control duties, NAMMDR/NAMMDR territorial units authorised personnel is entitled to demand for documents and public and private economic agents and units are legally required to provide such documents as well as respond to any other requirements necessary to check compliance with legislation on the quality of medicinal products for human use and medical devices.

CHAPTER III
NAMMDR organisation and operation

Article 7. – (1) The NAMMDR is run by a president and 2 vice-presidents appointed in accordance with the law, by order of the Minister of Health.

(2) The Ministry of Health organises a hiring competition for the president and vice-president positions, and the competition methodology is approved by order of the Minister of Health.

(3) As regards their wages, the president and vice-presidents' respective positions are equivalent to the Ministry of Health positions of secretary of state and undersecretary of state, respectively.

(4) In performance of their duties, the NAMMDR president issues decisions and instructions.

(5) The NAMMDR 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.

(6) The NAMMDR structure is approved by its president. By decision of the president, within the approved maximum number of positions, the NAMMDR structure may include services, bureaus, laboratories and compartments, territorial units for inspection and/or control and medicinal products/medical devices market surveillance or medical device in-use surveillance as well as for assessment of medical equipment and control by regular verification of medical devices.

(7) The maximum number of positions is 500 positions, the president and the two vice-presidents included.

(8) The job list is approved by order of the Minister of Health, on proposal by the president and on approval of the Management Board.

(9) Territorial units for inspection and/or control and medicinal products/medical devices market surveillance or medical device in-use surveillance as well as for assessment of medical equipment and control by regular verification of medical devices are entities without legal personality, employing healthcare and/or specialist technical staff.

Article 8. – (1) The NAMMDR Management Board is established by order of the Minister of Health, for a 4-year mandate, and includes the following members:

a) the NAMMDR president;

b) the 2 NAMMDR vice-presidents;

c) 2 representatives of the Ministry of Health.

(2) The NAMMDR president is also the president of the Management Board.

(3) The heads of NAMMDR departments may be invited to meetings of the Management Board, without the right to vote.

Article 9. – The Management Board has the following duties:

a. approval of the NAMMDR economic and financial policy;

b. approval of proposed fees for NAMMDR operations, approved by order of the Minister of Health;

c. approval of the NAMMDR annual report;

d. approval of the income and revenues budget as well as its execution;

e. endorsement of the NAMMDR organisational structure, submitted for approval by order of the Minister of Health;

f. endorsement of the NAMMDR organisation and operation rules, submitted for approval by order of the Minister of Health;

g. endorsement of the NAMMDR job list, submitted for approval by order of the Minister of Health;

Article 10. – (1) The Management Board is summoned by the NAMMDR president or representatives of the Ministry of Health, whenever necessary.

(2) The agenda of Management Board meetings is established by the NAMMDR president, based on proposals by the president, representatives of the Ministry of Health and of such proposals as voted by simple majority of the total number of Management Board members.

(3) The Management Board operates legally under attendance by the simple majority of the total number of its members.

(4) NAMMDR Management Board decisions are approved by vote of a simple majority of the total number of attending members.

(5) The agenda and its attached documents are transmitted to Management Board members within terms established in the Management Board organisation and operation rules.

(6) The Management Board organisation and operation rules is approved by decision of the NAMMDR President within 30 days as of this law coming into force.

(7) NAMMDR Management Board decisions of ruling character are submitted for approval by order of the Minister of Health and published in the Official Journal of Romania, Part I, as appropriate; other non-ruling Management Board decisions are transmitted to the Ministry of Health for information and published on the NAMMDR website.

(8) According to law, persons who, directly or through their spouse or relatives up to the 4th degree included, work or hold interests in companies involved in manufacture, distribution or import of medicinal products for human use or medical devices may not be members of the NAMMDR Management Board.

Article 11. – (1) The NAMMDR Scientific Council is set by order of the Minister of Health, on proposal of the NAMMDR president, and it consists of the following:

a) the NAMMDR president, vice-presidents and three NAMMDR representatives;

b) one representative of medicine faculties as proposed by the Association of Medicine and Pharmacy Universities in Romania;

c) one representative of pharmacy faculties as proposed by the Association of Pharmacy Faculty Deans in Romania;

d) one representative of the Minister of Health;

e) one representative of the College of Pharmacists in Romania;

f) one representative of the College of Physicians in Romania;

g) one representative of the medical Bioengineering university Chair, as proposed by the Association of Medicine Faculty Deans in Romania.

h) one representative of the Public health university Chair medicine faculties as proposed by the associations of medicine and pharmacy universities;

i) one representative of patients' organisations;

(2) Nomination of members mentioned under (1) is performed by the legal representative of institution/organisation involved, as appropriate, on request by the NAMMDR president.

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

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

(5) The Scientific Council shall meet at least 3 times a year or whenever necessary, on summons by the NAMMDR president, one Ministry of Health representative or one third of its members.

(6) The agenda of NAMMDR Scientific Council meetings is established by its president, based on proposals by the president, and primarily consists of the following: the NAMMDR scientific activity between two sessions, approach of NAMMDR scientific policy implementation, proposals of the NAMMDR 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 on condition of attendance by simple majority of the total number of its members.

(8) Scientific Council decisions are approved by simple majority of the total number of its members.

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

(10) The NAMMDR Scientific Council organisation and operation rules are adopted within 30 days as of the date of this decision coming into force.

Article 12. – Membership to the Scientific Council is approved for a 4-year mandate, and the mandate may be renewed.

Article 13. – (1) According to law, persons who, directly or through their spouse or relatives up to the 4th degree included, work or hold interests in companies involved in manufacture, distribution or import of medicinal products for human use or medical devices, may not be members of the NAMMDR Scientific Council.

(2) Before nomination, whenever needed or in the case of changes thereof, members of the Scientific Council shall declare their own interests as well as interests of their spouse or relatives up to the 4th degree included, in companies involved in manufacture, distribution or import of medicinal products for human use or medical devices at home and abroad.

(3) Scientific Council members shall declare their conflicting interests as to one of the issues covered during Scientific Council meetings, abstain from voting and leave the meeting room.

Article 14. – In agreement, the NAMMDR Management Board and Scientific Council develop collaborations between the National Agency and representatives of patients', consumers', economic agents' organisations and the academia, such as participation of the latter in Agency organised events, under terms previously established by the Management board in agreement with the Scientific Council.

CHAPTER IV
Joint provisions

Article 15. – (1) The NAMMDR president and two vice-presidents shall implement decisions of the NAMMDR Management Board and Scientific Council.

Article 16. – On this law entry into force, based on protocol, the NAMMDR shall take over all rights and obligations as well as all other assets currently in NAMMD patrimony.

(2) The NAMMDR shall take over all NAMMD staff, with maintenance of salary rights on takeover date.

(3) Within 30 days from this law entry into force, the NAMMDR organisation and operation rules shall be approved by order of the Minister of Health.

Chapter V
Funding

Article 17. - (1) NAMMDR funding is from its own revenues as resulting from the collection of the fees established according to legislation in force, and a subsidy granted from the state budget.

(2) Revenues obtained from tariffs collected in relation to conduct of its specific activities constitute NAMMDR own revenues.

(3) Revenues obtained from fees collected by the NAMMDR in accordance with legal provisions in force constitute revenues to the state budget.

(4) Unused own revenues are carried over to the next year, with the same purpose.

Chapter V
Staff and payroll

Article 18. - (1) NAMMDR staff consists of staff under contract.

(2) The hiring, promotion to both higher positions and professional degrees/ levels as well as personnel release shall be conducted according to legal provisions in force; staff and its classification and remuneration comply with legal provisions in force related to personnel salary from public funds.

(3) For NAMMDR employees appointed as holders or substitutes in the Management Board of the European Medicines Agency (EMA), scientific committees and working groups of the European Agency, the Heads of Medicines Agencies (HMA), the Coordination Group for the Mutual Recognition and Decentralised Procedures (CMDh), of the European Directorate for the Quality of Medicines (EDQM), of the Council of Europe, of the Council of the European Union, the Pharmaceutical Inspection Co-operation Scheme (PIC/S) and of the European Commission, as well as for the employees nominated, by decision of the President, to participate as members of mixed teams for conduct of specific activities, and staff participating in the process of evaluation-authorisation, supervision and control of medicinal products for human use, health technologies assessment and medical devices related activities, the NAMMDR Management Board may approve grant of monthly financial incentives, within the amount of two gross national minimum wages, within the approved budget, according to article 193 (61) of Law no. 95/2006 on healthcare reform, republished as amended.

Article 19. - The following shall be repealed on this law entry into force:

a) article III of Government Emergency Ordinance on reorganisation of healthcare facilities and amendment of public health legislation and amendment of healthcare regulatory provisions, published in the Official Journal of Romania, Part I, no. 452 of July 2, 2010;

b) Government Decision no. 734/2010 on the organisation and operation of the National Agency for Medicines and Medical Devices, published in the Official Journal of Romania, Part I, no. 531 of July 29, 2010, as amended as well as any provisions to the contrary.

Article 20. - Within 30 days as of this law entry into force, the Ministry of Health shall develop rules for implementation of provisions provided in article 5 of this law.

Article 21. - Throughout Law no. 95/2006 on healthcare reform, republished as amended in the Official Journal of Romania, Part I, no. 652 of August 28, 2015, the phrase "National Agency for Medicines and Medical Devices" shall be replaced with "National Agency for

Medicines and Medical Devices of Romania", whereas the phrase "NAMMD", shall be replaced with "NAMMDR".

This law has been adopted by the Parliament of Romania, pursuant to provisions of article 75 and of article 76 (2) of the Constitution of Romania, as republished.

PRESIDENT OF THE CHAMBER OF DEPUTIES
ION-MARCEL CIOLACU

PRESIDENT OF THE SENATE
CĂLIN-CONSTANTIN-ANTON POPESCU-TĂRICEANU