The Ministry of Health

ORDER No. 857
of 22 March 2022
on approval of the Regulation on the organisation and operation of the National Agency for Medicines and Medical Devices of Romania (ANMDMR)

Published in: The Official Gazette no. 283 of 24 March 2022

On seeing:

- The Report of the General Directorate of Human Resources, Salary Structures and Policies, Management Service and Healthcare Structures, Salary Rights Management Office no. AR 4698 of 22.03.2022;
- notifications no. 59274 E of 8.07.2021, no. 59274 E of 21.07.2021, no. 61614 of 26.08.2021, no. 59274 E of 19.10.2021, no. 59274 E of 30.12.2021 and no. 59274 E of 27.01.2022 of the National Agency for Medicines and Medical Devices of Romania, registered at the Ministry of Health with no. Reg 2/17.061 of 12.07.2021, Reg 2/17.061 of 22.07.2021, Reg 2/38.299 of 30.12.2021, SMSS 1.244 of 26.08.2021, SMSS 2.189 of 20.10.2021, SMSS 4.413 of 3 0.12.2021 and SMSS 647 of 27.01.2022,

Considering the provisions of Article 9 f) of Law 134/2019 on the reorganisation and operation of the National Agency for Medicines and Medical Devices, as well as for the amendment of some regulatory documents, as further amended and supplemented,

pursuant to the provisions of Article 7 (4) and Article 14 (3) of Government Decision no. 144/2010 on the organisation and operation of the Ministry of Health, as further amended and supplemented,

the minister of health hereby issues the following order:

Art. 1 - The Regulation on the organisation and operation of the National Agency for Medicines and Medical Devices of Romania, as provided in the Annex which is an integral part of this Order, is approved.

Art. 2 – On this order's entry into force, Order of the Minister of Health no. 1.522/2019 on approval of the Regulation on the organisation and operation of the National Agency for Medicines and Medical Devices of Romania, published in the Official Gazette of Romania, Part I, no. 841 and 841 bis of 16 October 2019, shall be repealed.

Art. 3 - The specialized structures of the Ministry of Health and the National Agency for Medicines and Medical Devices of Romania shall carry out the provisions of this Order.

Art. 4 - This Order shall be published in the Official Gazette of Romania, Part I.

Minister of Health,
Alexandru Rafila

ANNEX

REGULATION ON THE ORGANISATION AND OPERATION OF THE NATIONAL AGENCY FOR MEDICINES AND MEDICAL DEVICES OF ROMANIA

SECTION I
General provisions

Art. 1 - (1) The National Agency for Medicines and Medical Devices of Romania, hereinafter referred to as the ANMDMR, is a public institution with legal personality, a specialized body of the central public administration in the field of medicinal products for human use, medical devices and health technologies assessment, subordinated to the Ministry of Health.

(2) The ANMDMR is headquartered in Bucharest, 48 Aviator Sănătescu, sector 1.

(3) The ANMDMR was established based on Law 134/2019 on the reorganisation of the National Agency for Medicines and Medical Devices, as well as for the Amendment of some regulatory documents, as further amended and supplemented, and is financed from its personal revenues and from a subsidy granted from the state budget.

Art. 2 - (1) The scope of the ANMDMR consists of:

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.

j) issuance of customs approvals, according to the provisions of art. 12 b) of Order of the Minister of Health no. 1.009/2016 regarding the registration of medical devices into the national database, as further amended and supplemented;

k) assessment, designation and monitoring of bodies ensuring compliance assessment in the field of medical devices;

l) assessment of health technologies of medicinal products for human use, devices and high-performance medical equipment;

m) authorisation of clinical investigations for medical devices and assessment of performance of in vitro diagnostic medical devices;

n) the authorisation of clinical trials with medicinal products for human use, as well as authorisation of the site where they are carried out;

o) monitoring the safety of medicinal products for human use through pharmacovigilance activity.

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

Art. 3 - For its purposes, the ANMDMR 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.

Art. 4 - (1) The ANMDMR 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 variations; 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, through periodic inspections and planned/unexpected 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. conducts studies on the use of medicinal products for human use;

7. performs laboratory testing of the quality of medicinal products for human use for purposes of authorisation, quality surveillance, 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;

8. organisation and control of pharmacovigilance work, preparation of notifications on pharmacovigilance operations;

9. approval and control of advertising and readability related to medicinal products for human use, in accordance with regulations in force;

10. development and update of the Index of Medicinal Products for Human Use authorised for marketing in Romania, specifying their respective classification for supply;

11. annual notification of the European Commission and the other EU Member States on changes operated in the Index of Medicinal Products for Human Use authorised for marketing in Romania;

12. cooperation with national and international bodies for development of the European Pharmacopoeia;

13. operation of a service for information on medicinal products for human use; prepares and publishes, in electronic format, the ANMDMR Newsletter, specific specialist publications and information;

14. 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;

15. decision on the suspension, recall/withdrawal of marketing authorisations of 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;

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

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

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

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

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

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

22. authorisation for operation to wholesalers of human medicinal product distributors of medicinal product for human use based on favourable inspection reports by the ANMDMR inspectors as well as Good Distribution Practice certification;

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

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

25. 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;

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

27. 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;

28. authorisations for supply of medicinal products for special needs;

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

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

31. carries out activities regarding the registration of manufacturers, importers and distributors of active substances that will be used as starting materials for medicinal products for human use;

32. issues approvals for donations of medicinal products for human use to the applicants;

33. decides, as the case may be, the suspension, withdrawal of manufacturing authorisations/certificates of compliance with good manufacturing practice, wholesale distribution authorisations/good distribution practice certificates, good laboratory practice certificates, certificates attesting to the “qualified person” status;

34. conduct of and participation in assessments of the quality, efficacy and safety of medicinal products for human use authorised through centralised procedure (CAT, PRAC, PDCO, CHMP etc.), through its own or external experts.

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

36. 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, upon request of the European Commission or any Member State, all appropriate information on individual marketing authorisations granted;

37. monitoring of 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;

38. the legal steps in order to permanently ensure by the marketing authorisation holder/the representative of the marketing authorisation holder and the wholesale distributor an adequate range of medicinal products that meet the needs of patients;

39. 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;

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

41. undertakes legal steps in order to prevent or alleviate the shortage in the supply of medicinal products;

42. ensures administrative cooperation with the competent authorities of the member states of the European Union, regarding the provision of services in the field of medicinal products for human use, through the Ministry of Health and the information system of the internal market - IMI, established by the European Commission.

(2) As regards the medical devices area, in accordance with legal provisions, the ANMDMR 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 the 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 database 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 of medical devices - Eudamed;

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

14. authorisation, in duly justified cases, of the placing on the market and commissioning of individual medical devices, for the purposes of the healthcare 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 placing on the market/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 (second-hand) 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;
32. issues medical device donation notices to applicants;
33. approves and controls advertising for medical devices.

(3) The ANMDMR is the national competent authority in the field of health technologies assessment, in accordance with the legal provisions, and has the following main attributions:

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, upon 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 medicinal products in/from the List of international non-proprietary names (INNs) of on - prescription medicinal products provided to insurants irrespective of personal contribution, in the healthcare social insurance system, as well as INNs of medicinal products supplied in the frame of 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 development of studies and 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.

(4) To fulfil its tasks, the ANMDMR can collaborate with external experts, in compliance with the legal provisions in the field.

Art. 5 - The ANMDMR takes adequate steps for the withdrawal, prohibition and/or restriction of placement on the market of medicinal products for human use and medical devices deemed potentially harmful for users' health and/or safety.

Art. 6 - When performing its control duties, ANMDMR authorised personnel/ANMDMR 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.

Art. 7 - The ANMDMR pursues the fulfilment of the commitments assumed by Romania in the institution's areas of expertise, as well as of the measures resulting from the participation in working groups of the European Union bodies in the specific field of activity.

SECTION II

Management and organisational structure of the National Agency for Medicines and Medical Devices of Romania

Art. 8 - (1) The ANMDMR is run by a president and 2 vice-presidents appointed in accordance with the law, by order of the Minister of Health.

(2) In performance of their duties, the ANMDMR president issues decisions and instructions.

(3) The ANMDMR 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. The ANMDMR president can delegate, by decision, to one of the 2 vice-presidents the exercise of the attribution of tertiary credit ordinator, as well as other attributions, during his temporary absence from the institution, expressly mentioned in the delegation decision.

(4) As a waiver from the provisions of paragraph (3), the vice-presidents of the ANMDMR fulfil the capacity of tertiary credit ordinator and legal representative, during the vacancy of the "ANMDMR president" position or in the situation where the president is in the absolute impossibility of exercising his duties, for the fields of activity specific to the organisational structures that they coordinate, as appropriate. In the situation where a single vice-president is appointed by Order of the Minister of Health, he/she fulfils the capacity of tertiary credit ordinator and legal representative, during the vacancy of the president position or in the situation where he/she is in the absolute impossibility of exercising his/her duties.

(5) Vice-presidents are subordinated to the ANMDMR president and exercise the duties established by decision of the ANMDMR president regarding the specific scientific activities in the field of medicinal products for human use and medical devices, namely those regarding the technical-administrative activities which support the specific scientific activities.

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

(7) The ANMDMR organisational structure is approved through Order of the Minister of Health, at the proposal of the ANMDMR president and with the approval of the administration board. The ANMDMR structure includes general directorates, directorates, services, bureaus and compartments. Within the organisational structure, the following can be set up through decision of the ANMDMR president: laboratories, 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, while respecting the maximum approved number of positions.

(8) The organisational structure of the ANMDMR must comply with the following requirements:

a) a minimum number of 5 execution positions is necessary for the establishment of an office;

b) a minimum number of 5 execution positions is necessary for the establishment of a laboratory;

c) a minimum number of 7 execution positions is necessary for the establishment of a service;

d) a minimum number of 15 execution positions is necessary for the establishment of a directorate;

e) a minimum number of 25 execution positions is necessary for the establishment of a general directorate;

(8) The job list is approved by order of the Minister of Health, on proposal of 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.

Art. 9 - (1) The ANMDMR Management Board is established by Order of the Minister of Health, for a 4-year mandate, and includes the following members:

a) the ANMDMR president;

b) the 2 ANMDMR vice-presidents;

c) 2 representatives of the Ministry of Health.

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

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

Art. 10 - The Management Board has the following duties:

a) approval of the ANMDMR economic and financial policy;

b) approval of proposed fees for ANMDMR activities, approved by Order of the Minister of Health;

c) approval of the ANMDMR annual report;

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

e) endorsement of the ANMDMR organisational structure, submitted for approval by Order of the Minister of Health;

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

g) endorsement of the ANMDMR job list, submitted for approval by Order of the Minister of Health;

h) approves the proposals regarding the administration of the patrimony, regarding the updating of the situation and the identification data of the fixed assets that are part of the public domain of the state and which are under the administration of the ANMDMR, the maintenance, ensuring the safeguard, protection and preservation of these assets.

Art. 11 - (1) The Management Board is summoned by the ANMDMR president or representatives of the Ministry of Health, whenever necessary.

(2) The agenda of Management Board meetings is established by the ANMDMR 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) ANMDMR 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 regulation for organisation and operation of the administration board is approved according to the provisions of Art. 11 paragraph (10) of Law 134/2019, as further amended and supplemented.

(7) ANMDMR Management Board decisions of ruling character are submitted for approval by order of the Minister of Health and published in the Official Gazette 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 ANMDMR 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 cannot be members of the ANMDMR Management Board.

Art. 12 - (1) The ANMDMR Scientific Council is set by order of the Minister of Health, on proposal of the ANMDMR president, and it consists of the following:

a) the ANMDMR president, vice-presidents and two ANMDMR 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 proposed by the G6 University Alliance Association – the University of Medicine and Pharmacy (UMF);

e) one representative of the Minister of Health;

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

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

h) one representative of the National School of Public Health, Management and Improvement in the Healthcare Field.

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

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

(4) The persons who hold management positions within the ANMDMR and a representative of the representative associations of the pharmaceutical and medical device industry can participate as guests in the meetings of the ANMDMR scientific council, at the proposal of the president of the scientific council, without the right to vote.

(5) The Scientific Council establishes the ANMDMR scientific policy.

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

(7) The agenda of ANMDMR Scientific Council meetings is established by its president, and primarily consists of the following: the ANMDMR scientific

activity between two sessions, approach of ANMDMR scientific policy implementation, proposals of the ANMDMR president, the Ministry of Health, the Medical Science Academy or proposals voted by one third of the Scientific Council members.

(8) The Scientific Council may only deliberate on condition of attendance by simple majority of the total number of its members.

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

(10) The decisions of the scientific council are sent for information to the Minister of Health and posted on the ANMDMR website.

(11) The regulation for organisation and operation of the scientific council is approved according to the provisions of art. 11 paragraph (10) of Law no. 134/2019, with further amendments and supplementations.

Art. 13 - The nominal composition of the scientific council is approved for a 4-year period, with the possibility of renewing the mandate.

Art. 14 - (1) Persons who, directly or through their spouse or relatives up to the fourth degree inclusively, carry out activities or hold interests in commercial companies manufacturing, distributing or importing medicinal products for human use or devices cannot be members of the scientific council, according to the law.

(2) The members of the scientific council are obliged to declare the personal interests that they, the husband, the wife, as well as their relatives up to the 4th degree inclusively, have towards the commercial companies manufacturing, distributing or importing medicinal products for human use or medical devices from their country or from abroad, before being appointed and whenever the need arises or there are changes in the relationship with them.

(3) The members of the scientific council have the obligation to declare possible conflicts of interest regarding one of the issues debated in the scientific council meetings, to abstain from voting and to leave the meeting room.

Art. 15 - The administration board, in agreement with the scientific board, develops collaborative relationships between the agency and representatives of patients, consumers, economic operators and academic institutions; collaborative relationships may include their participation in the agency's activities, under the conditions established in advance by the administration board, in agreement with the scientific board.

Art. 16 - (1) The National Agency for Medicines and Medical Devices of Romania has the following organisational structure, according to the provisions of the interim Order of the Minister of Health no. 2318/2021 on approval of the organisational structure of the National Agency for Medicines and Medical Devices of Romania:

1. ANMDMR president;
2. Vice-president with duties regarding specific scientific activities;
3. Vice-president with duties regarding technical and administrative activities;

4. The Administration Council (CA);
5. The Scientific Council (CS);
6. The Secretariat (S);
7. The Compartment for specific scientific activities (CASS);
8. The Compartment for technical-administrative activities (CATA);
9. The Internal Audit Bureau (BAI);
10. The Monitoring and Reporting Bureau (BMR);
11. The General Directorate for Evaluation and Authorisation (DGEA);
12. The National Procedure Directorate[1]) (DPN);
13. The National Procedure Administration Service[2]) (SAPN);
14. The administration validation bureau[3]) (BVA);
15. The National Procedure Evaluation Service[2]) (SEPN);
16. The Compartment for Medicinal Product Quality[4]) (CCM);
17. The Compartment for Non-clinical safety and efficacy[4]) (CESNC);
18. The Compartment for Medicinal Product Information[4]) (CIM);
19. The National Procedure Variation Service[2]) (SVPN);
20. The Bureau for Variation Assessment and Validation[5]) (BEVV);
21. The European Procedures Directorate[1]) (DPE);
22. The Service for European Procedures Administration[6]) (SAPE);
23. The Compartment for Procedure Administration[7]) (CAP);
24. The Compartment for Centralised Procedure Administration[7]) (CAPC);
25. The Compartment for Variation Validation and Administration[7]) (CVAV);
26. The Service for European Procedures Evaluation[6]) (SEPE);
27. The Compartment for Medicinal Product Quality[8]) (CCM);
28. The Compartment for Non-clinical safety and efficacy[8]) (CESNC);
29. The Compartment for Medicinal Product Information[8]) (CIM);
30. The Compartment for Centralised Procedure Evaluation[8]);
31. The Pharmacovigilance and Risk Management Directorate[1]) (DFVMR);
32. The Evaluation Service[9]) (SE);
33. The Data Management Bureau[9]) (BGD);
34. The Authorisation Issuance Service[1]) (SEA);
35. The Legibility Compartment[1]) (CL);
36. The Medicinal Product Index Service[1]) (SN);
37. The Directorate for Health Technologies Assessment (DETM);
38. The Medical Assessment Compartment[10]) (CEM);
39. The Compartment for Medical Data Analysis and Validation[10]) (CVADM);
40. The Clinical Trials Directorate (DSC);
41. The Compartment for Administration - validation of clinical trials with medicinal products for human use [11]) (CAVSCMUU);
42. The compartment for clinical and non-clinical evaluation of clinical trials with medicinal products for human use [11]) (CECNSCMUU);
43. The Compartment for Quality Evaluation of Clinical Trials with Medicinal Products for human use[11]) (CECSCMUU);

44. The Directorate for Medicinal Product Quality Assessment and Control (DECCM);

45. The Compartment for Procedure Administration and Medicinal Product Quality Control[12]) (CAPCCM);

46. The Laboratory Service for Physical-chemical, Immunochemical and Serological Determinations on Biological Medicinal Products and Pharmacotoxicology[12]) (LDFCISMBF);

47. The Laboratory Service for Determinations on Cell Cultures and Microbiology[12]) (LDCCM);

48. The Service for Physical-Chemical and Instrumental Determinations on Synthetic Medicinal Products[12]) (LDFCIMS);

49. The Compartment for Control of Radiopharmaceutical Products[12]) (CCPR);

50. The Compartment for Biological Products Assessment[12]) (CEPB);

51. The General Directorate for Pharmaceutical Inspection (DGIF);

52. The Directorate for Administration of DGIF Processes [13]) (BAPDGIF);

53. The Directorate for Inspection of Good Manufacturing Practice, Good Laboratory Practice, Good Analytical Laboratory Practice, Good clinical practice and Good Pharmacovigilance Practice[13]) (DIBPFLLASCFV);

54. The Directorate for Good Distribution Practice Inspection[13]) (DIBPD);

55. The Directorate for Quality Supervision of Medicinal Products, Alerts and Territorial Units[13]) (DSCMAUT);

56. The Falsified Medicinal Products Bureau[14]) (BAMF);

57. Territorial Inspection Unit - Iaşi[14]) (UTII);

58. Territorial Inspection Unit - Bacău[14]) (UTIB);

59. Territorial Inspection Unit - Galaţi[14]) (UTIG);

60. Territorial Inspection Unit - Piteşti[14]) (UTIP);

61. Territorial Inspection Unit - Satu-Mare[14]) (UTISM);

62. Territorial Inspection Unit - Cluj[14]) (UTIC);

63. Territorial Inspection Unit - Oradea[14]) (UTIO);

64. Territorial Inspection Unit - Deva[14]) (UTID);

65. Territorial Inspection Unit - Mureş[14]) (UTIM);

66. Territorial Inspection Unit - Timişoara[14]) (UTIT);

67. Territorial Inspection Unit - Craiova[14]) (UTIC);

68. Territorial Inspection Unit - Constanţa[14]) (UTICO);

69. The General Directorate for Medical Devices (DGDM);

70. The Regulatory Market Surveillance Directorate[15]) (DRSP);

71. The Regulation Service[16]) (SR);

72. The Compartment for Clinical Investigation and Medical Devices[17]) (CICDM);

73. The Market Surveillance Service[16]) (SSP);

74. The Vigilance Compartment[18]) (CV);

75. Territorial Inspection Unit - Iaşi[16]) (UTII);

76. Territorial Inspection Unit - Cluj [16]) (UTIC);

77. Territorial Inspection Unit - Oradea[16]) (UTIO);
78. Territorial Inspection Unit - Deva[16]) (UTID);
79. Territorial Inspection Unit - Mureş[16]) (UTIM);
80. Territorial Inspection Unit - Timişoara[16]) (UTIT);
81. Territorial Inspection Unit - Craiova[16]) (UTIC);
82. The Technical-Laboratories Directorate[15]) (DTL);
83. The Nuclear Unit Service[19]) (SUN);
84. The Tests and Checks Service[19]) (SIV);
85. The Directorate for Approval[15]) (DA);
86. The Advertising Service (SP);
87. The Scientific Advice Bureau (BCS);
88. The Directorate for Human Resources and Quality Management (DRUMC);
89. The Quality Assurance and Registry Service[20]) (SACR);
100. The Compartment for Quality Assurance, Ethics and Integrity[21]) (CACEI);
101. The Registry and Archive Compartment[21]) (CRA);
102. The Staff - Payroll Service[20]) (SPS);
103. The Staff Compartment[22]) (CP);
104. The Payroll Compartment[22]) (CS);
105. The Directorate for Legal, European Affairs and International Relations (DJAERI);
106. The Service for General Legal Assistance, Debt Tracking and Administrative Litigation[23]) (SAJGUDCA);
107. The Service for Legislation, Referrals, European Affairs and International Relations [23]) (SLSAERI);
108. The Communication and Public Relations Service (SCRP);
109. The Bureau for Communication with the Press, Stakeholders and Social Media[24]) (BCPAPISM);
110. The Translations Compartment[24]) (CT);
111. The Directorate for Economy and Public Procurement (DEAP);
112. The Budget, Finance and Accounting Service[25]) (SBFC);
113. The Bureau for Public Procurement and Protocol[25]) (BAPP);
114. The Directorate for General Administration and External Financial Assistance (DAGAFE);
115. The Administrative and Heritage Compartment[26]) (CAP);
116. The Information and Communication Technology Service (STIC);
117. The Bureau for Development of Information and Communication Technology projects, infrastructure and technical support[27]) (BDPTICIST);
118. The Design and Webpages Compartment[27]) (CDPI);
119. The Compartment for Critical National Infrastructures (CICN);
120. The Prevention and Protection Directorate (CPP).

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[1]) Is subordinated to the General Directorate for Evaluation and Authorisation.
[2]) Is subordinated to the National Procedure Directorate.
[3]) Is subordinated to the National Procedure Administration Service.
[4]) Is subordinated to the Service for European Procedures Evaluation.
[5]) Is subordinated to the National Procedure Variations Service.
[6]) Is subordinated to the European Procedures Directorate.
[7]) Is subordinated to the Service for Administration of European Procedures.
[8]) Is subordinated to the Service for Assessment of European Procedures.
[9]) Is subordinated to the Pharmacovigilance and Risk Management Directorate
[10]) Is subordinated to the Directorate for Health Technologies Assessment.
[11]) Is subordinated to the Clinical Trials Directorate.
[12]) Is subordinated to the Directorate for Medicinal Product Evaluation and Quality Control.
[13]) Is subordinated to the General Directorate for Pharmaceutical Inspection.
[14]) Is subordinated to the Directorate for Quality Supervision of Medicinal Products, Alerts and Territorial Units.
[15]) Is subordinated to the General Directorate for Medical Devices.
[16]) Is subordinated to the Medical Devices Regulation and Market Surveillance Directorate.
[17]) Is subordinated to the Regulatory Service.
[18]) Is subordinated to the Market Surveillance Service.
[19]) Is subordinated to the Technical Laboratories Directorate.
[20]) Is subordinated to the Directorate for Human Resources, Quality Management and Administration.
[21]) Is subordinated to the Quality Assurance and Registry Service.
[22]) Is subordinated to the Staff-Payroll Service.
[23]) Is subordinated to the Directorate for Legal, European Affairs and International Relations.
[24]) Is subordinated to the Communication and Public Relations Service.
[25]) Is subordinated to the Directorate for Economy and Public Procurement.
[26]) Is subordinated to the Directorate for General Administration and External Financial Assistance.
[27]) Is subordinated to the Information and Communication Technology Service.

(2) The structures/functions provided for in paragraph (1) points 2, 3 and 6 - 10 are organisationally subordinated directly to the ANMDMR president, the structures provided for in paragraph (1) points 11, 37, 40, 44, 51, 69, 86 and 87 are organisationally subordinated to the vice-ANMDMR president with attributions regarding specific scientific activities in the field of medicinal products for human use and medical devices, the structures provided for in paragraph (1) points 88, 105, 108, 111, 114, 116, 119, 120 are organisationally

subordinated to the vice-president of the ANMDMR with attributions regarding technical-administrative activities which support specific scientific activities.

SECTION III
Attributions of the ANMDMR management

Art. 17 - (1) The president and the two vice-presidents, as the case may be, are responsible for the entire activity of the ANMDMR and carry out the decisions of the administration board and the scientific council.

(2) The ANMDMR vice-presidents are responsible for quality management and the implementation of European legislation in the field of medicinal products for human use and medical devices in the institution's activity.

(3) The ANMDMR management acts with the diligence that a good owner puts into the administration of his assets and is responsible for the integrity of the patrimony, as well as for the preparation and presentation, at the established terms, of its situation, in accordance with the legal provisions in force.

Art. 18 - (1) **The ANMDMR President** performs the following duties:

1. represents the institution in its relations with natural persons, with the Ministry of Health or with other legal persons from the country and abroad, as well as in court;
2. manages, organises, supervises and is responsible, according to the law, for the entire activity of the institution, having the capacity of tertiary credit ordinator;
3. is responsible for compliance with the legal deadlines for the supplementation of institution-specific works, compliance with the confidentiality of information managed by the institution, identification and management of potential conflicts of interest;
4. organises and coordinates the administration board of the ANMDMR, as president of the administration board, according to the law;
5. carries out the decisions of the administration board and of the scientific council;
6. coordinates, plans, manages and is directly responsible for the activity of the two vice-presidents, the Secretariat, the president's advisers, the internal audit office and the monitoring and reporting office, according to the institution’s organisational chart;
7. issues decisions and instructions;
8. supervises and signs all exit documents from the institution;
9. proposes to the Ministry of Health for approval, in accordance with the law, the draft revenue and expenditure budget and is responsible for the execution of the approved budget during the budget exercise, according to the legal provisions;

10. approves the quarterly and annual financial statements on the execution of the budget of revenues and expenses according to the regulations issued by the Ministry of Public Finance and presents them to the main credit ordinator;

11. controls and supervises the financial resources required to fulfil the institution's duties;

12. ensures the organisation of the preventive financial control of the ANMDMR and the record of commitments, the observance of financial-budgetary discipline, the management of funds and patrimony;

13. approves the annual public procurement plan as well as the annual public procurement strategy;

14. proposes the optimal organisational structure in order to ensure the smooth running of the institution's activity;

15. orders by decision the organisation of services, offices, laboratories, compartments and territorial units;

16. approves the assignment, modification, suspension or termination of employment relationships for the ANMDMR staff, in accordance with the law;

17. establishes the attributions/tasks/responsibilities of the ANMDMR staff and approves the job descriptions for the staff directly subordinated;

18. establishes responsibilities at each managerial level;

19. plans staff training;

20. ensures an adequate work climate that stimulates the motivation, satisfaction, development and performance of the ANMDMR staff;

21. ensures the adequate infrastructure for the fulfilment of ANMDMR attributions;

22. identifies the needs and expectations of the interested parties;

23. organises consultations with interested parties regarding the processes carried out in the institution;

24. monitors the implementation and development of the internal managerial control system and ensures the continuous improvement of the quality management system within the institution;

25. approves the annual internal audit plan;

26. ensures the exchange of information between ANMDMR structures;

27. proposes solutions to optimize the ANMDMR activity.

Art. 19 - The ANMDMR vice-presidents fulfil the following duties:

1. exercise the powers conferred by the ANMDMR president for the specific scientific activities in the field of medicinal products for human use and medical devices or for the technical-administrative activities which support the specific scientific activities, as the case may be, as well as any other powers conferred by decision of the president;

2. represent the institution in its relations with natural persons, with the Ministry of Health or with other legal persons from the country and abroad, as well as in court, at its level of competence;

3. manage, organise, supervise and are responsible, according to the law, for the activity of the institution, according to the powers conferred by the ANMDMR president;

4. are responsible for compliance with the legal deadlines for supplementation of institution-specific works, compliance with the confidentiality of information managed by the institution, identification and management of potential conflicts of interest, according to the powers conferred onto them by the ANMDMR president;

5. carry out the decisions of the administration council and of the scientific council;

6. supervise and sign the exit documents from the institution, effectively delegating this task by decision of the president;

7. propose to the ANMDMR president the optimal organisational structure in order to ensure the smooth running of the activity of subordinate organisational structures;

8. plan the activity of subordinate organisational structures;

9. establish the attributions/tasks/responsibilities of subordinate staff within the structures they coordinate, other than those established by the ANMDMR president;

10. plan the training of the staff in the structures they coordinate;

11. identify the needs and expectations of interested parties;

12. organise consultations with interested parties regarding the processes carried out in the institution;

13. ensure continuous improvement of the quality management system within the institution;

14. are responsible for the implementation of the European legislation in the field of competence in the activity of the institution;

15. fulfils any other attribution provided by law or, as the case may be, established by the ANMDMR president.

SECTION IV
The attributions of ANMDMR organisational structures

Art. 20 - (1) The general directorates, departments, services, offices, laboratories, departments and territorial units within the ANMDMR are specialised structures and have the attributions provided by law for hiring, liquidating and ordering expenses, as well as for public procurement.

(2) Authorised persons within the ANMDMR specialised structures with right to sign for employment, liquidation, ordering and payment are nominated by decision of the ANMDMR president.

(3) The preventive control activity within the ANMDMR is organised and carried out by the Directorate for Economy and Public Procurement. In relation to the types of the operations, the ANMDMR president can decide to extend it to other specialised structures where payment obligations or other patrimonial obligations are initiated, through legal documents.

(4) The persons granting the preventive financial control visa are proposed by the ANMDMR president, and the proposals are approved by the Ministry of Health.

(5) General managers, directors, heads of services, heads of offices, heads of laboratories, heads of departments and heads of territorial units have the following attributions:

a) they lead and are responsible for the activity of subordinate staff and monitor the fulfilment of their tasks, according to the legal regulations in force. Work duties are assigned individually;

b) responsible for fulfilment in due time of the duties entrusted by the ANMDMR management;

c) prepare the job descriptions for subordinate staff and are responsible for the balanced and fair distribution of tasks. In case of non-distribution of tasks by job description, they fully fall to the general managers, directors, heads of services, heads of offices, heads of laboratories, heads of departments and heads of territorial units and they are responsible for the performance or failure to perform these tasks;

d) draw up or countersign, as the case may be, the individual professional performance evaluation sheets of the persons with management or execution positions in the managed structure:

e) carry out the periodic analysis of the activity within the organisational structure and follow the fulfilment of performance indicators established for the activities of the organisational structure they lead;

f) the identification and implementation of ways to improve the activity within the organisational structure that they lead based on the results of their own periodical analyses, respectively based on the results of internal/external audits;

g) nominate the persons responsible for archiving the structures' documents and establish their attributions and tasks through the job description;

h) to ensure the implementation and development of the internal management control system and the implementation and handling of the quality management system in their organisational structure;

i) ensures the preparation of the annual activity reports of the organisational structure they manage;

j) fulfils any other duties established by the ANMDMR management.

Art. 21 - The **secretariat** is directly subordinated to the ANMDMR president, is managed by the ANMDMR president and has the following attributions:

1. drawing up and updating the agenda and the hearings of the ANMDMR president;

2. receiving and submitting for approval/approving the documents issued by the organisational structures within the ANMDMR;

3. the prompt distribution of documents endorsed/approved by the ANMDMR president;

4. ensuring telephone connections with the ANMDMR president or connections requested by him;

5. keeping and using the stamps provided in accordance with the legal provisions;

6. fulfilling any duties established by the ANMDMR president.

Art. 22 - The Compartment for specific scientific activities is directly subordinated to the ANMDMR president, is led by the ANMDMR president and has the following responsibilities:

1. provides advice to the ANMDMR President on specific scientific activities in the field of medicinal products for human use and medical devices:
2. analyses the correspondence registered with the ANMDMR on specific scientific activities in the field of medicinal products for human use and medical devices and submits it for resolution to the ANMDMR President;
3. analyses the documents submitted by the institution's organisational structures on specific scientific activities in the field of medicinal products for human use and medical devices, in order to present them for signature to the ANMDM President;
4. monitors the preparation of materials and documentation initiated by the organisational structures, regarding specific scientific activities in the field of medicinal products for human use and medical devices, necessary for the participation of the ANMDMR president in working sessions, symposia, other meetings;
5. drafts papers on specific scientific activities in the field of medicinal products for human use and medical devices, in accordance with the provisions of the ANMDMR President;
6. ensures the relationship between the ANMDMR President, the organisational structures of the institution that carries out specific scientific activities in the field of medicinal products for human use and medical devices, other national or international institutions and organisations;
7. monitors the implementation of the ANMDMR communication strategy on specific scientific activities in the field of medicinal products for human use and medical devices;
8. ensuring optimal collaboration with all ANMDMR organisational structures, which carry out specific scientific activities in the field of medicinal products for human use and medical devices, as well as optimal relations with other authorities and public institutions;
9. fulfils any other duties established by the ANMDMR management.

Art. 23 - The Compartment for technical-administrative activities is directly subordinated to the ANMDMR President, is led by the president and has the following responsibilities:
1. provides advice to the ANMDMR president on technical-administrative activities which support specific scientific activities;
2. analyses the correspondence registered with the ANMDMR regarding technical-administrative activities which support specific scientific activities and submits them for resolution to the ANMDMR president;
3. analyses the documents submitted by the organisational structures of the institution, which carry out technical-administrative activities which support specific scientific activities, in order to be signed by the ANMDMR president;
4. monitors the preparation of materials and documentation initiated by the organisational structures, regarding technical-administrative activities which support the specific scientific activities required for participation of the ANMDMR president in working sessions, symposia, other meetings;
5. drafts scientific papers, regarding technical-administrative activities which support the specific scientific activities, in accordance with the provisions of the ANMDMR president;
6. ensures the relationship between the ANMDMR president, the organisational structures of the institution, other national or international institutions and organisations;
7. monitors the implementation of the ANMDMR communication strategy, regarding the technical-administrative activities which support the specific scientific activities;
8. ensures optimal collaboration with all organisational structures of the ANMDMR, which carry out technical-administrative activities supporting the specific scientific activities as well as effectively ensures relations with other authorities and public institutions;
9. fulfils any other duties established by the ANMDMR management.

Art. 24 - The Internal Audit Bureau is directly subordinated to the ANMDMR president, is led by a head of bureau and has the following responsibilities:
1. applying the specific methodological rules regarding the exercise of internal public audit and the internal audit charter according to Order of the Ministry of Health no. 683/2014;
2. developing the draft multi-annual internal public audit plan and, based on it, the draft annual internal public audit plan;
3. carrying out internal public audit activities/missions to assess whether the financial management and control systems of the ANMDMR are transparent and comply with the rules of legality, regularity, economy, efficiency and effectiveness;

4. exercising internal audit over all activities carried out within the ANMDMR, regarding the formation and use of public funds, as well as the administration of public assets;
5. auditing, at least once every 3 years, without being limited to these, for:
- financial activities or those with financial implications carried out by the ANMDMR from the moment of establishment of commitments until the use of funds by final beneficiaries, including funds from external financing;
- payments assumed through budgetary and legal commitments, including from community funds;
- administration of the patrimony, as well as the sale, pledge, concession or rental of property belonging to the private domain of the state or of the administrative-territorial units;
- concession or rental of goods from the public domain of the state or of administrative-territorial units;
- establishment of public revenues, respectively the method of authorising and establishing debt securities, as well as the facilities granted for their collection;
- allocation of budget appropriations;
- the accounting system and its reliability;
- the decision-making system;
- management and control systems, as well as the risks associated with such systems;
- information systems.
6. including the missions ordered by the Public Internal Audit Compartment of the Ministry of Health in the annual internal public audit plan of the Internal Audit Office, carrying them out in good conditions and reporting within the set deadlines;
7. complying with the procedure established by the Romanian Central Harmonisation Unit for Public Internal Audit (UCAAPI) for the planning, progress, implementation and reporting method;
8. informing the Public Internal Audit Compartment of the Ministry of Health about the recommendations not adopted by the head of the audited structure;
9. sending to the Public Internal Audit Compartment of the Ministry of Health summaries of the recommendations not adopted by the head of the audited structure and the consequences of their non-implementation, accompanied by relevant documentation;
10. periodically reporting to the UCAAPI, through the public internal audit compartments of the Ministry of Health, on the findings, conclusions and recommendations;
11. preparing the annual report of the public internal audit activity which presents the way in which the objectives of the Internal Audit Bureau are achieved;
12. ensuring that the annual report of the internal public audit activity includes at least the following information:
- findings;

- recommendations and conclusions resulting from the public internal audit activity;
- progress made in implementing the recommendations;
- irregularities or possible prejudices found during public internal audit missions;
- information regarding professional training.

13. sending the Ministry of Health the annual report on the internal audit activity by the 30th of January of the following year, for the year ended;
14. immediately reporting irregularities or possible damages identified in the performance of internal public audit missions to the ANMDMR president and the authorised internal control structure;
15. proposing, as appropriate, the suspension of the internal public audit mission in the event of identification of irregularities or possible damages, with the agreement of the ANMDMR president, who approved the mission, if from the preliminary analysis of the checks performed it is estimated that, by continuing it, internal audit objectives will not be achieved (access limitation, insufficient information, etc.);
16. inclusion in periodic and annual reports of cases of irregularities or possible damages identified;
17. verification of compliance with the norms, instructions, as well as the code of conduct of the internal auditor, which is carried out through planned or ad-hoc evaluation missions of the public internal audit activity;
18. advising and carrying out thematic verifications at the suggestion of the president of the ANMDMR, of the Internal Public Audit Department of the Ministry of Health;
19. formulating recommendations for improving the operation of ANMDMR activities in terms of efficiency and effectiveness;
20. assessing the existence of adequate, sufficient and effective processes in the field of risk management;
21. supporting the ANMDMR president in identifying and assessing risks and contributing to the improvement of the internal/managerial control system;
22. evaluating internal control systems by helping the institution maintain an appropriate internal/managerial control system, assessing its efficiency and effectiveness and ensuring its improvement;
23. evaluating the implementation of the National Anti-Corruption System at ANMDMR level;
24. participation, through representatives nominated by the ANMDMR management, in committees within the ANMDMR, in meetings of various working groups of public authorities and institutions, as well as in meetings of other European bodies competent in the field of internal audit;
25. ensuring professional training of personnel through internal/external training, participation in advanced training and specialisation courses, experience exchanges, participation in national and international scientific events in the field of internal audit;

26. professional collaboration with all organisational structures within the ANMDMR;
27. fulfils any other duties established by the ANMDMR management.

Art. 25 - The Monitoring and Reporting Bureau is directly subordinated to the ANMDMR president, is led by a head of bureau and has the following responsibilities:
1. keeping records of documents distributed by the ANMDMR president and monitoring compliance with the deadlines for resolution of various issues, which have certain deadlines;
2. is responsible for timely fulfilment of the duties assigned to the heads of organisational structures by the ANMDMR president;
3. periodically analysing the activities of organisational structures and monitoring the fulfilment of performance indicators, based on which it identifies and implements ways to improve and streamline the activity of organisational structures;
4. monitoring the activity of the organisational structures and sending reports on the activity carried out by these structures to the ANMDMR president;
5. preparing periodic reporting documents on the status of project implementation, project monitoring and assessment reports, in line with the procedures;
6. monitoring periodic reporting documents on the status of project implementation, project monitoring and assessment reports, in line with the procedures;
7. participation, through representatives appointed by the ANMDMR management, in committees of the ANMDMR, in meetings of various working groups of public authorities and institutions, as well as of other European bodies competent in the field of medicinal products and medical devices;
8. providing, within the legal term, responses to the notices of the Ministry of Health, other public authorities and institutions, to petitions, as well as to requests for information of public interest, through the authorised organisational structure;
9. ensuring professional training of staff through internal/external training, participation in advanced training and specialisation courses, experience exchanges, participation in national and international scientific events in the field of the medicinal product;
10. professional collaboration with all organisational structures of the ANMDMR;
11. fulfils any other duties established by the ANMDMR management.

Art. 26 - (1) **The General Directorate for Evaluation and Authorisation** is directly subordinated to the Vice-President of the ANMDMR with responsibilities regarding specific scientific activities in the field of medicinal products for human use and medical devices, is led by a general director and has the following structure:

a) The National Procedure Directorate, with its subordinated structures:

a1) The National Procedure Administration Service with its subordinated structure, the Validation-Administration Bureau;

a2) The National Procedure Evaluation Service with its subordinated structures: The Medicinal Products Quality Compartment, the Compartment for Non-clinical safety and efficacy and the Compartment for Medicinal Product Information;

a3) The National Procedure Variation Service with its subordinated structure, the Bureau for Variation Assessment and Validation.

b) The European Procedures Directorate with its subordinated structures:

b1) The Service for European Procedures Administration with its subordinated structures: The Compartment for Procedure Administration, the Compartment for Centralised Procedure Administration and the Compartment for Variation Validation and Administration.

b2) The Service for European Procedures Evaluation with its subordinated structures: The Medicinal Products Quality Compartment, The Compartment for Non-clinical safety and efficacy, Compartment for Medicinal Product Information and the Compartment for Centralised Procedure Evaluation.

c) The Pharmacovigilance and Risk Management Directorate with its subordinated structures:

c1) The Evaluation Service;

c2) The Data Management Bureau.

d) The Authorisation Issuance Service;

e) The Legibility Compartment;

f) The Medicinal Product Index Service;

(2) **The National Procedure Directorate** is headed by a director, is subordinated to the general director of the General Directorate for Evaluation and Authorisation and has the following duties:

1. coordinating the marketing authorisation (MA)/marketing authorisation (MA) renewal activity, including post-authorisation activities of medicinal products for human use submitted through the national procedure;

2. is responsible for fulfilling the tasks/responsibilities/activities of the DPN, within the legal deadlines in force;

3. receiving payment confirmations for the files submitted for marketing authorisation/marketing authorisation renewal and their registration;

4. performing administrative verification in order to validate the documentation submitted for the marketing authorisation/the marketing authorisation renewal through "purely" national procedure;

5. drafting positive/negative response notices or with requests for supplementation to applicants, in order to validate the documentation (drafting, technical editing, printing, recording and distributing validation/invalidation/supplementation notices);

6. managing notices for validation/invalidation/supplementation;

7. receiving documentation related to applications for marketing authorisation/marketing authorisation (MA) renewal, as well as various requests for supplementation of documentation during their evaluation, registered with the ANMDMR;

8. technical editing/recording and sending distribution addresses for validated products (validated files, supplementations) to the structures involved in the evaluation;

9. receiving documentation assessment reports and, where appropriate, analysis bulletins and placing them into databases;

10. drawing up/completing "medicinal product record sheets" containing medicinal product identification data (trade name, pharmaceutical form, strength), legal basis, MAH holder, entry number, date of entry of the medicinal product, number and date of the distribution notice to the services involved, date of reports with final requests, date of discussion in the marketing authorisation committee);

11. preparing the medicinal product authorisation/authorisation renewal file to be submitted to the CAPP in order to formulate an opinion on its authorisation/authorisation renewal;

12. organising meetings and drawing up minutes of the committee for marketing authorisation through national procedure (CAPP PN); developing the list of medicinal products proposed for discussion during CAPP PN meetings;

13. presenting medicinal products proposed for MA/MA renewal of the MA through national procedure to the CAPP PN, upon supplementation of the procedure;

14. registering and distributing interruption notices to the services involved in the evaluation of the documentation;

15. checking and updating the databases relating to the files in progress and the authorised products;

16. preparing and submitting reports in authorisation files and authorisation/renewal files, in view of archiving;

17. coordinating the "parallel import and export" activity (administrative validation, evaluation, evaluation of variations to the terms of the parallel import authorisation (AIP), technical editing of changes to the terms of the AIP, provision, upon request, of MA information to competent national authorities in the EU where applications for authorisation through parallel import have been submitted);

18. preparing and drafting notices regarding requests for supplementation of the authorisation documentation in order to issue the parallel import authorisation;

19. coordinating the activity regarding variations to the terms of the marketing authorisations of medicinal products for human use through the "purely" national procedure;

20. coordinating the activity regarding changes to the design and labelling, packaging of medicinal products for human use, as well as changes to the package

leaflet, other than those due to type IA, IB and II variations, through the "purely" national procedure;

21. validation of chemical-pharmaceutical type IB and II variations to the terms of marketing authorisations for medicinal products for human use authorised "through national procedure" or undergoing MA renewal procedure;

22. evaluation of the supporting documentation of applications for variations to the marketing authorisations (type IA, type IB, type II - except for clinical variations), for transfer of the marketing authorisation, for change of the design and labelling of the packaging for medicinal products for human use authorised through "purely" national procedure or under the procedure of marketing authorisation renewal;

23. preparation of the assessment report of chemical-pharmaceutical type II variations, in accordance with the specific standard operating procedure (PSO);

24. drafting documents addressed to the applicant (approval letters, notices requesting supplementation of supporting documentation, rejection letters, corrective documents of the MA - modification of the MA, modifications of MA annexes or revised MA annexes, explanatory notes, tariff adjustment letters, if applicable) following the evaluation of the supporting documentation of applications for variations to the MA (type IA, type IB, type II - except for clinical variations), for MA transfer, for modification of the design and labelling of the packaging of medicinal products for human use authorised through national procedure or under the MA renewal procedure;

25. introducing the corrective documents into specific databases, to ensure traceability during the validity period of the MA;

26. recording the result of the evaluation of specific requests into the variation database;

27. drafting official replies to various requests made by proposers on the subject of variations to the MA;

28. coordinating the assessment of the chemical-pharmaceutical documentation and the standard dossier of the active substance (ASMF/DMF), the documentation on clinical efficacy and safety, the documentation on bioequivalence/bioavailability studies, the pharmacotoxicological documentation, as well as the information on medicinal products for human use proposed for authorisation/renewal of the MA through national procedure;

29. distribution of the assessment of the chemical-pharmaceutical documentation and the active substance master file (ASMF/DMP), the documentation on clinical efficacy and safety, the documentation on bioequivalence/bioavailability studies, the pharmacotoxicological documentation, the information on medicinal products;

30. collaboration with other structures involved in the assessment in order to finalize them (the DFVMR, the DCCM, the CEPB, etc.);

31. evaluation of administrative matters, the chemical-pharmaceutical documentation, the documentation on non-clinical efficacy and safety, the

documentation on bioequivalence/bioavailability studies on medicinal products for human use proposed for marketing authorisation/marketing authorisation renewal through the "purely" national procedure;

32. preparing assessment reports of the chemical-pharmaceutical documentation, the active substance master file (ASMF/DMF), the documentation regarding clinical efficacy and safety, the pharmacotoxicological documentation, as well as submitting requests for documentation supplementation to the SAPN, when applicable;

33. evaluating clinical documentation for approval of type II clinical variations;

34. evaluating the documentation for approval of clinical trials of bioequivalence/bioavailability, drafting the assessment reports and submitting requests for supplementation of the documentation, when necessary;

35. managing payment confirmations for approval of clinical trials of bioequivalence/bioavailability and drafting the tariff adjustment addresses when necessary;

36. drafting and technical editing the authorisation of the bioequivalence/bioavailability clinical trial and its amendments;

37. evaluating the content and, where appropriate, the quality of the translation into Romanian of draft summaries of product characteristics (SmPCs), package leaflets and labelling information proposed by applicants for marketing authorisation/marketing authorisation renewal through national procedure and drafting the response to applicants for transmission of requests for supplementation or modification, as appropriate;

38. administrative validation of clinical variations of type IB and II, with the preparation of validation, invalidation addresses, as appropriate;

39. preparation of notices for standardisation of the tariff of clinical variations of type IA, IB, II (if applicable);

40. evaluating the content of draft amendments to the SmPC, leaflets and labelling information proposed by applicants within the framework of type IA, IB, II clinical variations, within the national procedure, and drafting notices with requests for additions or amendments, as appropriate;

41. evaluating the content of draft amendments to the SmPC, leaflets and labelling information proposed by applicants within the framework of amendments to the leaflet and the SmPC, other than those due to type II variations, within the national procedure, and drafting addresses with requests for additions or amendments, as appropriate;

42. developing and drafting annexes 1 - 3 (leaflet, SmPC and labelling information approved by the ANMDMR) for medicinal products for human use upon marketing authorisation/marketing authorisation renewal through national procedure;

43. developing and drafting amendments to Annexes 1 - 3 (leaflet, SmPC and labelling information approved by the ANMDMR) within the framework of

type II clinical variations and other amendments to these annexes other than those due to type II variations within the national procedure;

44. managing the database with the evidence of type IA, IB, II clinical variations or other amendments to the information of the package leaflet and of the SmPC for medicinal products authorised through national procedure;

45. maintaining electronic records of products under evaluation;

46. managing the records of medicinal products approved for marketing authorisation/renewal of marketing authorisation;

47. managing decisions of the European Commission and the Coordination Group regarding referrals;

48. sending by e-mail requests for implementation of the outcome of the referral procedure (submission of variations) to the MAHs involved in the referral;

49. monitoring compliance by the MAH of the submission of variations for the implementation of the outcome of the referral procedures;

50. evaluating the documentation submitted in order to change the classification for release of medicinal products for human use authorised through a "purely" national or decentralised procedure, of mutual recognition; drawing up the assessment report and presenting it at the meeting of the Scientific Council;

51. maintaining the database with the distribution and status of works within the SEPN;

52. archiving the prepared reports and addresses;

53. evaluating the documentation submitted by applicants for authorisation of the supply of medicinal products for special needs; preparing the assessment report and sending requests for supplementation/clarification of the documentation to applicants;

54. participating in the evaluation of the documentation submitted by applicants for authorisation of the use of a medicinal product as a last resort treatment; participating in the preparation of the assessment report and sending requests for supplementation/clarification of the documentation to applicants;

55. managing documents and specific databases;

56. participating in the meetings of the inspection committee for good manufacturing practice (GMP), good laboratory practice (GLP), good analytical laboratory practice (GALP), good clinical practice (GCP) and good pharmacovigilance practice (GVP), good wholesale distribution practice (GDP);

57. participating in the meetings of the committee for evaluation and authorisation of units which can conduct clinical trials in the field of medicinal products for human use;

58. collaborating with the DGIF to resolve issues of non-compliance with the GMP, GCP, which arise during the evaluation of the documentation;

59. participating in the meetings of the committee for the management of crisis situations caused by quality, safety and/or efficacy issues related to medicinal products;

60. participation in the development and review of regulations regarding authorisation/renewal of authorisation, variations to the terms of the MA and related activities (e.g. parallel import);

61. participation, through representatives appointed by the ANMDMR, in meetings of committees and working groups in the field of medicinal products for human use from the European Commission, the EMA, the European Council, the Council of Europe, the European Directorate for the Quality of Medicines (EDQM), etc.;

62. participation in working groups of the EMA, EDQM, European Commission, Council of Europe;

63. transmission of data requested by Romania to the European Commission, the Council of Europe, the EMA, the HMA, the EDQM;

64. ensuring the administration of databases by the responsible persons, in accordance with the decisions of the president;

65. participating in the updating of tariffs for services provided by the directorate;

66. preparing and publishing public assessment reports;

67. identifying manufacturers of active substances and medicinal products for which the certificate of good manufacturing practice (GMP) has been suspended;

68. analysing requests for temporary exemption from the manner of labelling the packaging and leaflet approved in the MA/authorisations for supply of medicinal products for special needs and managing the related documentation;

69. evaluating the application submitted to the ANMDMR in order to obtain the scientific opinion on the quality and safety of the active substance(s) with auxiliary action in the medical device in which it/they is/are incorporated as an integral part (hereinafter referred to as "ancillary active substance(s)");

70. evaluation of documentation and preparation of assessment reports of the active substance master file (ASMF), through the national procedure and/or European procedures within the marketing authorisation procedure, and entry of reports into the ANMDMR centralised database;

71. evaluation of documentation and preparation of assessment reports of the active substance master file (ASMF), submitted within the framework of type II variations;

72. participation in updating the tariffs for the services provided by the directorate;

73. participation, through representatives appointed by the ANMDMR management, in committees within the ANMDMR, in meetings of various working groups of public authorities and institutions, as well as of other European bodies competent in the field of medicinal products;

74. ensuring professional training of staff through internal-external training, participation in advanced training and specialisation courses, experience

exchanges, participation in national and international scientific events in the field of medicinal products;

75. providing within the legal term responses to the notices of the Ministry of Health, other authorities and public institutions, to petitions, as well as to requests for information of public interest, through the authorised organisational structure;

76. participating in the development and revision of legislation in its field of activity;

77. professional collaboration with all organisational structures of the ANMDMR;

78. fulfils any other duties established by the management of the ANMDMR.

(3) **The European Procedures Directorate** is headed by a director, is subordinated to the general director of DGEA and has the following duties:

1. coordinating the authorisation/renewal of the marketing authorisation (MA), including post-authorisation activities of medicinal products for human use submitted through European procedures [centralised procedure (CP), decentralised procedure (DCP) and mutual recognition procedure (MRP)] in which Romania acts as interested member state (SMI), reference member state (RMS), Rapporteur/Co-Rapporteur, as appropriate;

2. receiving letters of intent and receiving and verifying payment confirmations for applications submitted for the authorisation/renewal of the MA, their registration and preparation of notices for regularisation, as appropriate;

3. evaluating for validation/invalidation of applications for marketing authorisation/marketing authorisation renewal for medicinal products for human use through European procedures or with requests for supplementation to applicants in order to validate the documentation (preparation, technical editing, printing, registration and distribution of notices for validation/invalidation/supplementation);

4. establishing the DCP/MRP procedure number for procedures in which Romania is the SMR, opening procedures in the Communication Tracking System (CTS) for procedures in which Romania is the reference member state/interested member state (SMR/SMI);

5. managing the schedule for procedures in which Romania is the SMR/SMI and establishing the schedule for procedures in which Romania is the SMR initially or by subsequently taking over the responsibilities as SMR;

6. receiving documentation related to applications for authorisation/renewal of the marketing authorisation, as well as various requests for supplementation of documentation on specific days of the procedures, receiving SMR reports and SMI comments and questions;

7. editing, printing, signing, registering and sending distribution addresses for validated applications (validated initial applications or supplementations), as well as for restarts or changes to the schedule of procedures to the evaluators in the structures involved in the evaluation stages;

8. registering and distributing notices for interruption of the procedure to the services involved in the evaluation of the documentation;

9. checking and updating the databases relating to applications in progress and authorised/renewed products;

10. preparing the reports for the Directorate for Economy and Public Procurement (DEAP) following the decisions for deletion/interruption of marketing authorisation/marketing authorisation renewal applications;

11. preparing the medicinal product authorisation dossier to be presented to the committee for the approval of marketing authorisation through European procedures (CAPP-PE) in order to formulate an opinion on its authorisation/renewal, drawing up the authorisation conditions, mentioning the post-authorisation conditions and/or commitments, establishing the DCR (common renewal date) and the frequency of submission of the RPAS (periodic safety update report - PSUR) in accordance with the EURD (European reference date);

12. organising meetings, drawing up the CAPP-PE agenda for medicinal products proposed for marketing authorisation/marketing authorisation renewal, after conclusion of the procedure by the SMR, as well as distributing the agenda to committee members;

13. drawing up the database and archiving the files of authorised products;

14. managing the "national phase" of European DCP/MRP procedures (receiving documents from applicants, distributing them to assessors and communicating comments following assessment), maintaining the updated status of the translations of Annexes 1 - 3 of the MA;

15. evaluation of the scientific (chemical-pharmaceutical, pharmacotoxicological, clinical) documentation developed by the manufacturer, and of the reports prepared by the SMR for the submitted procedure, respecting each stage of the established schedule for marketing authorisation/marketing authorisation renewal and amendment of the marketing authorisation for medicinal products for human use, through European procedures;

16. preparing scientific reports on the evaluation of the documentation and, where appropriate, lists of requests for supplementation by all departments at each specific stage of the procedure, introducing them into databases and sending consolidated reports with the requests and comments of the evaluators to the SMR and to applicants; evaluating the replies received to requests and the supplementations made to the documentation and issuing updated assessment reports;

17. preparing the report summarising the conditions for release of the MA and its Annexes, as well as the amendments to the MA and the revised annexes;

18. preparing the global assessment report for posting it in the CTS at the Index of medicinal products authorised through European procedures on the HMA/CMDh website, for procedures in which Romania is the SMR;

19. preparing and updating the database of bioequivalence trials;

20. framing the classification of medicinal products for human use according to their manner of release;

21. registration of the anatomical, therapeutic, chemical (ATC) code established by the World Health Organisation (OMS);

22. approval of the information specific to Romania in the blue box of the packaging of medicinal products authorised through the centralised procedure;

23. participation in the activities of the CHMP (EMA's Committee for Medicinal Products for Human Use);

24. administration of the documentation for the centralised procedure;

25. assessment of applications through the centralised procedure as Rapporteur/Co-Rapporteur, preparation of reports as Rapporteur/Co-Rapporteur, as appropriate;

26. participation in the assessment of applications for authorisation/line extensions/variations through centralised procedure, with the submission of comments, according to the specific schedule;

27. verification of the translations of Annexes 1 - 3 of the MA, following CHMP's opinions;

28. participation in professional activities imposed by the requirements of the Paediatric Regulation;

29. participation in the assessment, preparation of the report and presentation in the plenary of PDCO meetings of the paediatric investigation plan (PIP), of the amendments to the MP agreed by the Paediatric Committee (PDCO) of the EMA (European Medicines Agency) and assessment of the compliance of paediatric clinical trials completed with the PIP approved by the EMA;

30. participation in the assessment of applications for extrapolation of clinical trials for approval of the paediatric investigation plan (PIP) within the PDCO Extrapolation Group, according to the (EU) Paediatric Regulation;

31. participation in the preparation of Scientific Classifications as advanced therapy medicinal products and the scientific opinion of the Committee for Advanced Therapies (CAT) to the Scientific Advice Working Party (SAWP) of the European Medicines Agency;

32. participation alongside the rapporteur or peer reviewer in TCs organised by the EMA to clarify aspects of the PIP proposed by applicants;

33. participation in professional activities imposed by the requirements of the Orphan Medicinal Products Regulation by evaluation of the documentation for designation of orphan substances and medicinal products within the EMA Committee for Orphan Medicinal Products (COMP);

34. participation in the meetings and activities of the Coordination Group of the mutual recognition procedure and the decentralised procedure for medicinal products for human use;

35. participates in the performance of the duties of examining issues related to marketing authorisations, variations of the MA, ensures coordination between the

activity and decisions of the Coordination Group and the ANMDMR, ensures the update of documents and forwards Romania's opinion in referral procedures;

36. coordinating the approval of amendments (variations) to the marketing authorisation (MA) of medicinal products for human use submitted through European procedures [decentralised procedure (DCP) and mutual recognition procedure (MRP)] in which Romania acts as an interested member state (IMS) or reference member state (RMS);

37. receiving and verifying payment confirmations for the files submitted for MA amendment, registering them and drawing up regularisation notices, as appropriate;

38. scientific evaluation of the documentation submitted with the applications for variations of medicinal products for human use through European procedures and/or of the request for supplementation sent to applicants in order to validate the documentation and accept the variation (preparation, technical editing, printing, registration and distribution of validation/invalidation/supplementation addresses);

39. establishing the DCP/MRP procedure number for procedures in which Romania is the SMR, opening the procedures in the CTS (Communication Tracking System), for procedures in which Romania is the SMR/SMI;

40. management of the procedure schedule for procedures in which Romania is the SMR/SMI and establishment of the procedure schedule for procedures in which Romania is the SMR initially or by subsequent assumption of responsibilities as SMR;

41. technical editing, printing, signing, recording and sending distribution addresses for validated requests (validated initial variation applications or supplementations), as well as for restarts or changes to the procedure schedule to the structures involved in the assessment;

42. record and distribution of notices for interruption of the procedure to the services involved in assessment of the documentation;

43. checking and updating databases of ongoing variation applications and authorised/renewed products;

44. evaluating the documentation for variations, for marketing authorisation transfer, for other types of changes in view of approval for medicinal products for human use, submitted through European procedures;

45. drafting, editing and printing approval letters for variation applications and amendments to Marketing Authorisations and their Annexes;

46. updating the APP and its annexes in the files of the ANMDMR server as a result of approved changes;

47. managing the database with evidence of variations or other changes to the MAs for medicinal products authorised through European procedures and archiving the files;

48. ensuring Pharmacopoeia-related activities, by:

a) translation into Romanian and revision of previous translations of the Standard Terms approved by the European Pharmacopoeia Commission for Pharmaceutical Dosage Forms, Routes and Methods of Administration, Packaging (Containers, Closures and Administration Devices), Combined Standard Terms (Combined Pharmaceutical Dosage Forms, Combined Terms and Packaging Combinations) and their submission for approval to the ANMDMR Scientific Council;

b) online transmission (by the translator authorised by the EDQM, within the DCRPAE) directly to the EDQM Standard Terms database, of the Romanian version, after approval by Decision of the ANMDMR Scientific Council;

c) setup and update of the "Standard Terms" section on the ANMDMR website;

d) coordination of technical-scientific activities resulting from Romania's accession to the "Convention for the Elaboration of the European Pharmacopoeia" within the Council of Europe and participation, through the representative appointed by the ANMDMR management, in the Sessions of the European Pharmacopoeia Commission, with "member" status;

e) ensuring participation in the annual meeting of the Secretariats of the National Pharmacopoeias;

f) maintenance and update of the "INFO-Pharmacopoeia Service" database, on the ANMDMR intranet, which contains the electronic versions of the documentation records, the developed FRX Supplements, the Standard Terms in Romanian (prior to complete revision and respectively adoption of Version 1.0.0 – 14 November 2014 of the EDQM Database for Standard Terms) and other useful information;

49. participation in the meetings of the inspection committee for good manufacturing practice (GMP), good laboratory practice (GLP), good analytical laboratory practice (GLP), good clinical practice (GCP), good pharmacovigilance practice and good wholesale distribution practice;

50. participation in the meetings of the committee for the management of crisis situations caused by quality, safety and/or efficacy issues of medicinal products or issues related to the lack of medicinal products on the market;

51. participation in the meetings of the committee for authorisation of medicinal products used as last-resort treatments;

52. professional collaboration with all organisational structures of the ANMDMR;

53. professional collaboration with the DGIF by checking databases and sending information to solve issues of non-compliance with good manufacturing practices, good clinical practices, good laboratory practices, good analytical laboratory practices notified by the DGIF or other inspection authorities, submitting proposals for drawing up the annual sampling plan or transmitting opinions in response to certain complaints or notifications;

54. participation in the development and review of regulations regarding the authorisation of medicinal products for human use and related activities;

55. participation, through representatives appointed by the ANMDMR, in meetings of scientific committees and working groups in the field of medicinal products for human use from the European Commission, the European Council, the Council of Europe, the European Medicines Agency (EMA), the "Heads of Medicines Agencies" (HMA), etc.;

56. contributes to the implementation of decisions of the committees at agency level;

57. evaluation of the documentation and preparation of assessment reports of the active substance master file (ASMF) through national procedure and/or European procedures within the framework of the marketing authorisation procedure, and introduces the reports into the centralised database of the ANMDMR;

58. evaluation of documentation and preparation of assessment reports of the standard dossier of the active substance (ASMF), submitted within the framework of type II variations;

59. participation in updating the tariffs for the services provided by the department;

60. participation, through representatives appointed by the ANMDMR management, in committees of the ANMDMR, in meetings of various working groups of public authorities and institutions, as well as of other European bodies competent in the field of medicinal products;

61. providing within the legal term responses to the notices of the Ministry of Health, other authorities and public institutions, to petitions, as well as to requests for information of public interest, through the authorised organisational structure;

62. ensuring professional training of personnel through internal/external training, participation in advanced training and specialisation courses, experience exchanges, participation in national and international scientific events in the field of the medicinal product for human use;

63. participating in the development and revision of legislation in its field of activity;

64. professional collaboration with all organisational structures of the ANMDMR;

65. fulfils any other duties established by the ANMDMR management.

(4) **The Pharmacovigilance and Risk Management Directorate** is headed by a director, is subordinated to the general director of DGEA and has the following duties:

1. management of adverse reaction/serious and non-serious reports, originating from spontaneous reporting and from non-interventional clinical studies, in written and/or electronic format;

2. management of undesirable post-vaccination adverse reactions (RAPI) based on permanent collaboration protocol between the ANMDMR through the DFMR and the National Institute of Public Health (INSP), through the National Centre for Surveillance and Control of Communicable Diseases (CNSCBT), with the objective of mutual information regarding RAPIs reported by physicians and patients;

3. developing and drafting information notices for the Romanian College of Physicians, the Romanian College of Pharmacists and physicians and pharmacists in the healthcare network, regarding adverse reactions validated by the ANMDMR, within the framework of the National Continuing Medical Education Programme, for the purpose of crediting;

4. evaluating periodic safety update reports (PSURs) within the framework of Periodic safety update report single assessments (PSUSAs), for which Romania was nominated as the reference member state (Lead Member State - LMS) as well as the PSURs submitted for medicinal products authorised only in Romania which contain the active substance(s) not found in the EURD list (non-PSUSA procedure);

5. assessment of the summary of the pharmacovigilance system, the risk management plans, submitted by applicants for authorisation for marketing of medicinal products through national procedure, mutual recognition procedure/decentralised procedure and centralised procedure;

6. assessment of the safety documentation - Periodic Benefit-Risk Assessment report (PBRER)/Annex to Clinical Overview, submitted by marketing authorisation holders for renewal of the MA through national procedure, mutual recognition procedure/decentralised procedure and centralised procedure;

7. evaluation of pharmacovigilance documentation (summary of the pharmacovigilance system master file and risk management plan), introduced by variation to medicinal products authorised through the national procedure and the mutual recognition procedure/decentralised procedure;

8. evaluation of documentation for post-authorisation safety studies (PASS) (protocol, interim reports, final study report) - in collaboration with the Clinical Trials Directorate;

9. evaluation of educational materials for healthcare professionals and patients proposed as additional risk minimisation measures in the risk management plan;

10. evaluation and approval of "Direct Healthcare Professional Communications" and sending information letters regarding Direct Healthcare Professional Communications to the National Health Insurance House, the Ministry of Health, the Romanian College of Physicians and the Romanian College of Pharmacists and posting them on the ANMDMR website;

11. detecting safety signals for substances that Romania must monitor in the European Eudravigilance database and for substances for which safety concerns are identified at national level;

12. verifying the translation of press releases with/without questions and answers (Q & A) documents of the European Medicines Agency (EMA), issued following the recommendations of the Pharmacovigilance Risk Assessment Committee (PRAC) or EMA recommendations on the safety of medicinal products for human use;

13. communicating pharmacovigilance (FV) issues in the European Union (rapid alert, urgent safety restrictions) to the ANMDMR, for medicinal products authorised through the national procedure, the mutual recognition procedure/decentralised procedure and the centralised procedure;

14. drafting the replies to requests for information for certain medicinal products or classes of medicinal products, received from other Member States, and transmitting them via the Rapid Alert System/non-urgent information;

15. maintaining and managing the adverse reactions database, recording and archiving adverse reactions reported on the Romanian territory, electronically and on paper;

16. working with stakeholders to train healthcare professionals and patients in reporting adverse reactions to medicinal products for human use;

17. participating, through nominated representatives, in meetings of EMA's Pharmacovigilance Risk Assessment Committee (PRAC) and other relevant meetings;

18. participation in updating the tariffs for the services provided by the directorate;

19. participation, through representatives appointed by the ANMDMR management, in committees of the ANMDMR, in meetings of various working groups of public authorities and institutions, as well as other European bodies competent in the field of the medicinal product for human use;

20. ensuring professional training of staff through internal/external training, participation in advanced training and specialisation courses, experience exchanges, participation in national and international scientific events in the field of the medicinal product for human use;

21. providing within the legal term replies to the notices of the Ministry of Health, other public authorities and institutions, to petitions, as well as to requests for information of public interest, through the authorised organisational structure;

22. participation in the development and revision of legislation in its field of activity;

23. professional collaboration with all organisational structures within the ANMDMR;

24. performs any other duties established by the ANMDMR management.

(5) **The Authorisation Issuance Service** is headed by a head of service, subordinated to the Director General of the DGEA and has the following duties:

1. registration and issuance of marketing authorisations and annexes to the authorisation;

2. management of the "Registration" database and its update with the medicinal products for which the issuance of a marketing authorisation has been approved by the marketing authorisation committee;

3. management and updating of the "Post-authorisation requests" database;

4. archiving of marketing authorisations and their annexes in the files on the ANMDMR server, following authorisation/renewal;

5. monthly transmits the list of marketing authorisations to the Ministry of Health;

6. preparation and transmission of the statements to the Directorate for Economy and Public Procurement following authorisation, in order to invoice the fee for registration of marketing authorisations in the Index of Medicinal Products for Human Use;

7. preparation of amending documents of marketing authorisations and their annexes;

8. forwarding correspondence related to marketing authorisations to applicants who do not have a representative in Romania;

9. participating in the meetings of marketing authorisation, special needs and parallel import committees and drawing up the minutes;

10. issuing special needs authorisations and parallel import authorisations;

11. registration and archiving of special needs authorisations, parallel import authorisations and the documentation which represented the basis for their issuance;

12. registration, issuance of the scientific opinion for active substances incorporated and with auxiliary action in medical devices and archiving of the documentation which represented the basis for its issuance;

13. issuance of the product certificate according to the World Health Organisation (WHO) format;

14. management and updating of the "WHO Certificates" database;

15. participation in updating the tariffs for services provided by the Authorisation Issuance Service;

16. participation, through representatives nominated by the ANMDMR management, in committees of the ANMDMR, in meetings of various working groups of public authorities and institutions, as well as of other European bodies competent in the field of the medicinal product for human use;

17. ensuring professional training of personnel through internal/external training, participation in advanced training and specialisation courses, experience exchanges, participation in national and international scientific events in the field of the medicinal product for human use;

18. providing, within the legal deadline, replies to the notices of the Ministry of Health, other authorities and public institutions, to petitions, as well

as to requests for information of public interest, through the authorised organisational structure;

19. participating in the development and revision of legislation in its field of activity;

20. professional collaboration with all organisational structures of the ANMDMR;

21. fulfils any other duties established by the ANMDMR management.

(6) **The Legibility Compartment** is headed by the director general of the General Directorate for Evaluation and Authorisation and has the following duties:

1. evaluation of readability tests submitted within the framework of authorisation procedures within the national procedure;

2. evaluation of readability tests submitted within the framework of authorisation renewal procedures through an application regarding the modification of the design and inscription of the packaging of medicinal products for human use, as well as modifications of the package leaflet and summary of product characteristics, other than those due to type IA, IB and II variations, according to legal regulations in force within the national procedure;

3. evaluation of readability tests submitted within the framework of authorisation or authorisation renewal procedures within the framework of European procedures;

4. participation in the updating of tariffs for services performed by the bureau;

5. accreditation of economic operators performing readability tests by evaluating the documentation submitted for obtaining the accreditation certificate, in order to carry out inspections at their premises and readability tests;

6. participation, through representatives nominated by the ANMDMR management, in committees of the ANMDMR, in meetings of various working groups of public authorities and institutions, as well as of other European bodies competent in the field of the medicinal product for human use;

7. ensuring professional training of personnel through internal/external training, participation in advanced training and specialisation courses, experience exchanges, participation in national and international scientific events in the field of the medicinal product for human use;

8. providing within the legal term replies to the notices of the Ministry of Health, other public authorities and institutions, to petitions, as well as to requests for information of public interest, through the authorised organisational structure;

9. participation in the development and revision of legislation in its field of activity;

10. professional collaboration with all organisational structures within the ANMDMR;

11. fulfils any other duties established by the ANMDMR management.

(7) **The Medicinal Product Index Service** is headed by a head of service, subordinated to the Director General of the DGEA and has the following duties:

1. drawing up the list of medicinal products released by medical prescription on the Romanian territory, specifying, if applicable, the classification category; this list is updated on a yearly basis;

2. drawing up and updating the Index of medicinal products, including medicinal products authorised for marketing in Romania, specifying for each product the classification for release;

3. registering into the "Index" application the medicinal products authorised through the: national/European/centralised procedure regarding the supply of medicinal products for special needs (ANS);

4. registering into the "AIP Index" application the medicinal products authorised through the national procedure for issuing parallel import authorisations (AIP);

5. evaluating requests and drafting notices regarding the decision to suspend/withdraw (terminate) the marketing authorisation; sending them to the applicant and the services involved, notifying the Ministry of Health, the National Health Insurance Fund, professional organisations (as appropriate);

6. permanent update of data on the ANMDMR website, related to medicinal products authorised for marketing in Romania: APP/ANS/EC Decisions (the Index section) and upon request for parallel import authorisations - AIPs (section “Parallel import authorisations for which a CIM/xls was requested”);

7. drawing up the reports concerning medicinal products with the right to circulate, as a result of the interruption of the renewal procedure, respectively of the decisions to withdraw the marketing authorisation, as well as introducing these products into the ANMDMR registry for European procedures;

8. drawing up and constantly updating, in collaboration with the Directorate for Economy and Public Procurement, the reports concerning medicinal products with marketing authorisation or for which decisions have been issued to cancel authorisation/renewal applications or for which decisions have been issued to withdraw the marketing authorisation, in order to pay the fee for drawing up and updating the Index of medicinal products for human use;

9. managing and communicating the decisions of the European Commission and the Coordination Group applicable to medicinal products authorised on the Romanian territory, to the organisational structures with responsibilities regarding the specific scientific activities referred to in the decisions, in view of their implementation;

10. managing the decisions of the European Commission regarding medicinal products for human use authorised on the Romanian territory, in order to update the information in the Index of medicinal products for human use, according to the notifications received from the MAH;

11. monitoring the way in which the MAH complies with the decisions of the European Commission and the Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh), CMDh, applicable to medicinal products authorised through the decentralised and centralised mutual recognition procedures;

12. monitoring of European Commission (EC) Decisions in the Community Register and management of notifications received from the Ministry of Foreign Affairs/Ministry of Health regarding the issuance of EC Decisions on the conditional authorisation of certain medicinal products, on the suspension/withdrawal/modification of the Marketing Authorisation;

13. posting of EC decisions and positions adopted by consensus by the European Procedures Coordination Group (CMDh) on the Romsys/anm/EC decisions/Implementation status server and forwarding them to the ANMDMR specialists nominated to complete the registration of decisions on the Romsys Server and their implementation;

14. drawing up and forwarding to the Ministry of Health and the National Health Insurance House, upon request, the list of amendments brought to the Marketing Authorisations issued by the ANMDMR;

15. drawing up and submitting, upon request of the Ministry of Health or the National Health Insurance House, periodic statements about authorised medicinal products, in the process of renewing the APP/ANS/EC Decision/AIP;

16. processing the information received from the Ministry of Health and the National Health Insurance House to ensure technical support in finishing the annexes to the project for periodic updating or amendment of the List of International Non-proprietary Names of on-prescription medicinal products as provided to insurants, irrespective of personal contribution, in the frame of the health insurance system, as well as of International Non-proprietary Names of medicinal products provided in national health insurance programs;

17. drafting of notices regarding the decision to amend/suspend/withdraw marketing authorisations and sending them to the Authorisation Issuance Service;

18. monthly verification (or whenever necessary) of medicinal products newly included into the national price catalogue for medicinal products authorised for marketing in Romania (Canamed);

19. evaluating and issuing notices regarding the status of medicinal products in the Canamed, in line with the provisions of Law no. 95/2006 on healthcare reform, republished, as further amended and supplemented, and of Order of the Minister of Health no. 368/2017 on approval of the Rules regarding the calculation method and the procedure for approving the maximum prices of medicinal products for human use, as further amended and supplemented;

20. completing the classification of medicinal products into the Canamed, upon request of the Ministry of Health, for implementation of the provisions of Emergency Government ordinance no. 77/2011 on establishment of contributions for the financing of health expenditures, as further amended and supplemented;

21. evaluating and managing information for compliance with the legal provisions in force relating to the "sunset clause" regarding the marketing of the medicinal product (this implies the withdrawal of the MA after 3 years, if the medicinal product has not been marketed) and drafting the response to requests for exemption from these provisions; drafting notices to the MAH informing of the failure to meet legal requirements and apply the MA sunset clause;

22. providing information regarding: whether or not to place the medicinal product on the market, the fact of not placing the medicinal product on the market, temporary interruption of placing the medicinal product on the market, permanent termination of placing the medicinal product on the market, resumption of marketing of the medicinal product, to the Communication and Public Relations Service, in order to formulate a response to the notifications received at the address lipasmedicament@anm.ro, including those redirected from the website http://medicamentelipsa.ms.ro/.

23. drawing up various reports based on the data contained in the ANMDMR Index: processing information received from specialised commissions/directorates of the Ministry of Health and drawing up lists of medicinal products/INNs for national auctions/etc.;

24. collaboration with the DGIF in assessing the situation regarding compliance with the provisions of Art. 804 of Law no. 95/2006, republished, as further amended and supplemented;

25. weekly provision of information to the DGIF, and upon request, for the purpose of analysing intra-community delivery notifications;

26. monthly information of the Ministry of Health regarding the "situation of medicinal products" in order to meet the obligations of the ANMDMR regulated by provisions of Art. 804 of Law no. 95/2006, republished, as further amended and supplemented;

27. carrying out, upon request of the ANMDMR management, the following activities:

a) monitoring the Romanian medicinal product market, the share of pharmaceutical companies, the share of the main therapeutic groups;

b) analysing and producing synthetic information on the share of pharmaceutical companies on the Romanian medicinal product market;

c) analysing and producing synthetic information on the share of the main therapeutic groups on the Romanian medicinal product market;

d) analysing and producing synthetic information on the share represented by local producers in relation to multinational companies;

e) producing synthetic information on the evolution of the Romanian pharmaceutical market.

28. processing information and drawing up various reports (based on the data contained in the Index of Medicinal Products for Human Use) requested by the specialised commissions/directorates within the Ministry of Health, the

National Health Insurance House, the organisational structures of the ANMDMR, etc.;

29. preparing and submitting, upon request of the European Medicines Agency (EMA), the report on authorised or under authorisation, within the framework of referral procedures and the Periodic safety update report single assessments (PSUSA);

30. managing the decisions of the European Commission and the Coordination Group regarding referrals;

31. monitoring fulfilment by the MAH of the conditions imposed as a result of referral procedures;

32. monitoring the medicinal product market in order to comply with and apply specific legislation, monitoring statistics and forecasts related to the object of activity, in order to develop and propose ruling provisions;

33. drawing up the list of medicinal products authorised for marketing by the ANMDMR, the list of medicinal products authorised for marketing through centralised procedure and the list of therapeutic groups of medicinal products subject to marketing authorisation/marketing authorisation renewal applications, quarterly, to the Communication and Public Relations Service;

34. collaborating with the Ministry of Health and the National Health Insurance House to prepare various documentary materials necessary for the development of: the Index of medicinal products for human use, the list of medicinal products released with/without personal contribution, OTC products;

35. making changes to the Index of medicinal products for human use after identifying the manufacturers of active substances and medicinal products for which the certificate of good manufacturing practice has been suspended.

36. participating in updating the tariffs for the services provided by the bureau;

37. participating, through representatives nominated by the ANMDMR management, in committees of the ANMDMR, in meetings of various working groups of public authorities and institutions, as well as other European bodies competent in the field of medicinal products;

38. ensuring professional training of personnel through internal/external training, participation in advanced training and specialisation courses, experience exchanges, participation in national and international scientific events in the field of medicinal products;

39. providing, within the legal deadline, responses to the notices of the Ministry of Health, other authorities and public institutions, to petitions, as well as to requests for information of public interest, through the authorised organisational structure;

40. participating in the development and revision of the legislation in its field of activity;

41. professional collaboration with all organisational structures of the ANMDMR;

42. fulfils any other duties established by the ANMDMR management.

Art. 27 - The Directorate for Health Technologies Assessment is directly subordinated to the Vice-President of the ANMDMR with responsibilities regarding specific scientific activities in the field of medicinal products for human use and medical devices, is led by a director, has under its control the Medical Assessment Compartment and the Compartment for Medical Data Analysis and Validation and has the following duties:

1. medical technologies assessment of medicinal products for human use, high-performance medical devices and equipment;

2. develops and periodically reviews the national methodology and criteria for medical technologies assessment and the formats of medical technologies assessment reports, in line with international standards; develops and implements prioritisation mechanisms for the purpose of health technologies assessment approved through Order of the Minister of Health;

3. analyses and evaluates reports drafted by authorised institutions, organisations, external experts or researchers, regarding the evaluation of health technologies, for objectivity, validity, compliance and scientific rigor, upon request of suppliers or the Ministry of Health;

4. collaborates with professional bodies in the health system and academic institutions in order to assess health technologies;

5. collects and analyses statistical data relevant to the assessment of health technologies from all institutions in the health system;

6. collects and analyses statistical data relevant to the assessment of health technologies from all institutions in the health system;

7. develops and implements prioritisation mechanisms for assessment of health technologies, with the approval of the Ministry of Health;

8. ensuring transparency of the decision-making process regarding health technologies assessment;

9. implementing a rapid assessment mechanism for health technologies, carried out by authorised scientific research institutions, based on analyses and assessment reports from European Union member countries, in order to make a decision, with the approval of the Ministry of Health;

10. continuously develops institutional capacity in the field of health technology assessment, including through professional training activities; organises working meetings, training courses, training and advanced training courses, research projects and scientific events in the field;

11. participates in exchanges of scientific information, in development of assessment models and tools, as well as in the production of studies and materials, in collaboration with member states of the European Network for Health Technology Assessment;

12. participates together with the Ministry of Health in international collaboration projects with other institutions in the field;

13. requesting the specialised committees of the Ministry of Health to develop therapeutic protocols;

14. critically analysing and approving the therapeutic protocols developed and/or amended by specialised committees;

15. organising, coordinating and controlling, at its level of competence, under the authority of the ANMDMR President, the process of health technologies assessment in order to support the inclusion of new international non-proprietary names (INNs), compensated international non-proprietary names with extension of indication, fixed-dose combinations, generics without a compensated international non-proprietary name, biosimilars without a compensated international non-proprietary name in the List of International Non-proprietary Names of on-prescription medicinal products as provided to insurants, irrespective of personal contribution, in the frame of the health insurance system, as well as of International Non-proprietary Names of medicinal products provided in national health insurance programs;

16. participation in the calculation and establishment of the costs of therapies for health technologies subject to evaluation regarding the inclusion, extension of indications, non-inclusion into or exclusion from the List of International Non-proprietary Names of on-prescription medicinal products as provided to insurants, irrespective of personal contribution, in the frame of the health insurance system, as well as of International Non-proprietary Names of medicinal products provided in national health insurance programs;

17. is responsible for the entire process of health technologies assessment in order to support the inclusion of new international non-proprietary names (INNs), compensated international non-proprietary names with indication extension, fixed-dose combinations, generics without a compensated international non-proprietary name, biosimilars without a compensated international non-proprietary name in the List of International Non-proprietary Names of on-prescription medicinal products as provided to insurants, irrespective of personal contribution, in the frame of the health insurance system, as well as of International Non-proprietary Names of medicinal products provided in national health insurance programs;

18. ensures and is responsible for the compliance and application, according to legal provisions in force, together with subordinate employees, of:

a) the criteria for health technologies assessment regarding the inclusion, extension of indications, non-inclusion into or exclusion from the List of International Non-proprietary Names of on-prescription medicinal products as provided to insurants, irrespective of personal contribution, in the frame of the health insurance system, as well as of International Non-proprietary Names of medicinal products provided in national health insurance programs;

b) the methodology for health technologies assessment regarding the inclusion, extension of indications, non-inclusion into or exclusion from the List of International Non-proprietary Names of on-prescription medicinal products as

provided to insurants, irrespective of personal contribution, in the frame of the health insurance system, as well as of International Non-proprietary Names of medicinal products provided in national health insurance programs;

c) the documentation to be submitted by applicants, the methodological tools used in the evaluation process regarding the inclusion, extension of indications, non-inclusion into or exclusion from the List of International Non-proprietary Names of on-prescription medicinal products as provided to insurants, irrespective of personal contribution, in the frame of the health insurance system, as well as of International Non-proprietary Names of medicinal products provided in national health insurance programs;

d) the general framework regarding conditional inclusion into the List of International Non-proprietary Names of on-prescription medicinal products as provided to insurants, irrespective of personal contribution, in the frame of the health insurance system, as well as of International Non-proprietary Names of medicinal products provided in national health insurance programs, based on cost-volume/cost-volume-result contracts;

19. evaluates the documentation based on the medical technologies assessment mechanism and issues the decision on the inclusion, extension of indications, non-inclusion into or exclusion from the List of International Non-proprietary Names of on-prescription medicinal products as provided to insurants, irrespective of personal contribution, in the frame of the health insurance system, as well as of International Non-proprietary Names of medicinal products provided in national health insurance programs;

20. proposes to the ANMDMR President to issue decisions regarding the inclusion, extension of indications, non-inclusion into or exclusion from the List of International Non-proprietary Names of on-prescription medicinal products as provided to insurants, irrespective of personal contribution, in the frame of the health insurance system, as well as of International Non-proprietary Names of medicinal products provided in national health insurance programs;

21. may be designated as a representative in the negotiation committee of cost-volume/cost-volume-result type contracts, based on which medicinal products will be conditionally included in the List of International Non-proprietary Names of on-prescription medicinal products as provided to insurants, irrespective of personal contribution, in the frame of the health insurance system, as well as of International Non-proprietary Names of medicinal products provided in national health insurance programs;

22. participates in updating the tariffs for the services provided by the directorate;

23. participation, through representatives nominated by the ANMDMR management, in committees of the ANMDMR, in meetings of various working groups of public authorities and institutions, as well as other European bodies competent in the field of medicinal products for human use, health technologies and medical devices;

24. ensuring professional training of staff through internal/external training, participation in specialised training courses, exchanges of experience, participation in national and international scientific events in the field of medicinal products for human use, medical technologies and medical devices;

25. providing within the legal deadline replies to the notices of the Ministry of Health, other public authorities and institutions, to petitions, as well as to requests for information of public interest, through the authorised organisational structure;

26. participating in the development and revision of legislation in its field of activity;

27. professional collaboration with all organisational structures of the ANMDMR;

28. fulfils any other duties established by management of the ANMDMR.

Art. 28 - The Clinical Trials Directorate is directly subordinated to the vice-president of the ANMDMR with responsibilities regarding specific scientific activities in the field of medicinal products for human use and medical devices, is led by a director, has in its service the Compartment for Administration - validation of clinical trials with medicinal products for human use, the Compartment for clinical and non-clinical evaluation of clinical trials with medicinal products for human use and the Compartment for Quality Evaluation of Clinical Trials with Medicinal Products for human use and has the following duties:

1. evaluation and authorisation of clinical trials with medicinal products for human use by:

a) validation of the documentation submitted for authorisation of clinical trials with medicinal products for human use and technical editing of validation addresses;

b) evaluation of the documentation for authorisation of clinical trials with medicinal products for human use, drafting of evaluation reports, transmission of requests for supplementation of the documentation, when applicable, and evaluation of responses to requests;

c) authorisation of clinical trials with medicinal products for human use and drafting of rejection addresses, as applicable.

2. evaluation and approval of amendments to clinical trials with medicinal products for human use by:

a) validation of the documentation submitted for approval of important amendments;

b) evaluation of the documentation submitted for approval of amendments and drafting of evaluation reports, sending requests for supplementation of documentation, when applicable, and evaluation of responses to requests;

c) drafting and technical editing of the response approving/rejecting the amendment;

3. evaluation and approval of observational studies of any type:

- evaluation of observational studies;

- transmission of the response to the applicant;

- record keeping;

4. managing notifications sent by applicants, in accordance with the legal provisions in force regarding clinical trials with medicinal products for human use;

5. managing databases (entering electronic documentation into the Romsys server and maintaining records of requests, notifications or any information received concerning clinical trials/investigations and bioequivalence trials);

6. managing European databases and completing the requested information;

7. managing notices for tariff adjustment, when necessary;

8. managing and/or downloading XML files of clinical trials assessed in the EudraCT clinical trials database;

9. publishing information from clinical trials/clinical investigations/bioequivalence trials, preparing documents for publication;

10. managing the VHP (Voluntary Harmonized Procedure);

11. evaluation and authorisation of healthcare units for conducting clinical trials with medicinal products for human use by:

- evaluation and preparation of evaluation reports;

- participation through designated representatives in the meetings of the evaluation and authorisation committee of the units which may conduct clinical trials in the field of medicinal products for human use;

- organisation of meetings of the evaluation and authorisation committee of the units which may conduct clinical trials in the field of medicinal products for human use;

- authorisation of conducting clinical trials with medicinal products for human use by healthcare units and drafting rejection letters, as appropriate;

- keeping records of applications, evaluation status, authorised units.

12. collaborating with the DGIF to prepare good clinical practice inspections and solve issues regarding good manufacturing practice, arising during evaluation of the documentation;

13. participating in meetings of the inspection committee for good clinical practice (BPSC);

14. submitting for archiving the files sent by applicants, related to clinical trials with medicinal products for human use, and amendments, notifications as well as the files sent by applicants for authorisation of health units for conduct of clinical trials;

15. management of safety reports in clinical trials (RAGNS, periodic safety reports and Development Safety Update Reports - DSURs),

16. participation in updating the tariffs for the services provided by the directorate;

17. participation, through representatives nominated by the ANMDMR management to the committees of the ANMDMR, in meetings of various working groups of public authorities and institutions, as well as other European bodies competent in the field of medicinal products for human use;

18. ensuring professional training of personnel through internal/external training, participation in advanced training and specialisation courses, experience exchanges, participation in national and international scientific events in the field of medicinal products for human use;

19. providing, within the legal deadline, replies to the notices of the Ministry of Health, other authorities and public institutions, to petitions, as well as to requests for information of public interest, through the authorised organisational structure;

20. participating in the development and revision of legislation in its field of activity;

21. professional collaboration with all organisational structures of the ANMDMR;

22. fulfils any other duties established by the management of the ANMDMR.

Art. 29 - The Directorate for Medicinal Product Evaluation and Quality Control is directly subordinated to the vice-president of the ANMDMR with responsibilities regarding specific scientific activities in the field of medicinal products for human use and medical devices, is led by a director and has in its service: The Compartment for Procedure Administration and Medicinal Product Quality Control, the Laboratory Service for Physical-chemical, Immunochemical and Serological Determinations on Biological Medicinal Products and Pharmacotoxicology, the Laboratory Service for Determinations on Cell Cultures and Microbiology, the Service for Physical-Chemical and Instrumental Determinations on Synthetic Medicinal Products, the Compartment for Control of Radiopharmaceutical Products and the Compartment for Biological Products Assessment and has the following duties:

1. supports the competent authority in the activity regarding the complex control of the quality, safety and efficacy of medicinal products for human use by analysing medicinal products within the framework of pre- and post-authorisation activities, market surveillance and official batch release in the case of biological medicinal products;

2. performs laboratory analyses during the marketing authorisation/renewal of the MA procedure, scientific evaluation of the documentation regarding the control methods in the authorisation documentation and issuing certificates of analysis/certificates of compliance;

3. performs routine laboratory control of domestic (batch by batch) and imported biological medicinal products for human use (in special cases, in line with the specific procedure in force), together with the analysis of quality certificates and the evaluation of batch protocol summaries, followed by the

release of analysis certificates and, if all conditions are met, the release of the official batch release certificate, as an Official Medicines Control Laboratory (OMCL). Within the framework of the Official Control Authority Batch Release (OCABR) of biological medicinal products, physicochemical, serological, immunochemical, cell culture, pharmacological and microbiological laboratory determinations are performed; also, the analysis of trend data of laboratory results is performed;

4. carrying out specific sample reception and administrative activities associated with laboratory control: specific receipt and verification, registration, appropriate storage and distribution of samples and related documentation for testing in the DCCM; carrying out preparatory stages and planning before testing; issuing, verifying and centralising certificates of analysis in order to prepare and issue certificates of analysis/compliance, the certificate of official batch release or the non-compliance certificate, as the case may be;

5. assessment, within the European Union administrative procedure for official batch release, of the following documents, for batches of immunological products and products derived from human blood or plasma, for which the official batch release was carried out in the EU: information on the intention for marketing and the official batch release certificate;

6. carrying out laboratory analyses for medicinal products included in the national market surveillance programme, medicinal products authorised through the special needs procedure, medicinal products claimed from the territory by healthcare units, by natural or legal persons, in collaboration with the DGIF;

7. providing expertise for the control of medicinal products with quality deficiencies or which are suspected of being harmful to public health (falsified medicinal products and illegal medicinal products/products/samples);

8. acting as an Official Medicines Control Laboratory (OMCL) in the interest of the ANMDMR;

9. participating in activities and programmes carried out within the European OMCL network, aiming to harmonise administrative and technical activities of these laboratories and to improve the quality management system;

10. performing laboratory analyses on the quality of medicinal products, coordinated by the EDQM: proficiency testing programmes (PTSs), standardisation studies of chemical reference substances (SCR), market surveillance studies (Marketing Surveillance Studies - MSS), testing of samples of medicinal products authorised for marketing by the EMA through centralised procedure, testing of samples of medicinal products authorised for marketing by the ANMDMR through European procedures, through mutual/decentralised recognition procedures (MRP/DCP);

11. managing the EDQM databases, as a member of the European Network of Official Medicines Control Laboratories (OMCL) (the European network of OMCLs);

12. participating in studies coordinated by the International Pharmaceutical Federation (Fédération Internationale Pharmaceutique - FIP), as a member of this federation;

13. participating in the creation/update of tariff sheets for services provided in the directorate, according to its competences;

14. implementation and continuous improvement of the quality management system in the directorate, implementation of EDQM requirements, as part of the European Network of Official Medicines Control Laboratories (OMCL) (the European network of OMCLs);

15. evaluation of quality documentation for biological medicinal products submitted for marketing authorisation, respectively for renewal of the marketing authorisation (MA), through national procedure, approval of Type I and II variations submitted through national procedure, the European mutual recognition procedure, the decentralised and centralised procedure; approval of design changes submitted through national procedure; approval of marketing authorisation transfers submitted through national procedure; approval of the application for conducting clinical trials submitted through national/VHP procedure;

16. performing administrative activities associated with the evaluation of quality documentation: receiving, registering and distributing evaluation requests and related documentation from the process owner directorate/applicants; drafting evaluation reports and approval/rejection letters, registering and sending evaluation reports, as well as supporting reports developed within the marketing authorisation committee;

17. assessing the quality documentation within the exemption procedures for biological medicinal products for human use, at the request of the organisational structure managing these procedures;

18. amending the terms of marketing authorisations for biological medicinal products for human use, following approval of Type I or II variations in the national procedure, the approval of design changes, the approval of MA transfer or following editorial corrections;

19. validating applications for approval of type IB/II variations for biological medicinal products submitted through national procedure and issuance of corresponding addresses;

20. evaluation of quality documentation within the authorisation procedures for supply of medicinal products for special needs, compassionate use and biological medicinal products for human use;

21. evaluation of documentation and preparation of evaluation reports of the active substance master file (ASMF), through European procedures within the marketing authorisation procedure, in collaboration with The European Procedures Directorate;

22. evaluation of documentation and preparation of evaluation reports of the active substance master file (ASMF), through European procedures, for type II variations, in collaboration with the European Procedures Directorate;

23. participates, in collaboration with the DGIF, in inspections monitoring compliance with GLP, GMP rules, at the sites of manufacturing units of medicinal products for human use, as experts in the field of biological medicinal products.

24. development of regulations specific to the activity carried out by the directorate;

25. administration of databases, by responsible persons, appointed by internal decisions of the ANMDMR management;

26. participation in updating the tariffs for the services provided by the directorate;

27. participation, through representatives nominated by the ANMDMR management, in committees of the ANMDMR, in meetings of various working groups of public authorities and institutions, as well as of other European bodies competent in the field of medicinal products;

28. ensuring professional training of personnel through internal/external training, participation in advanced training and specialisation courses, experience exchanges, participation in national and international scientific events in the field of medicinal products for human use;

29. providing within the legal term responses to the notices of the Ministry of Health, other public authorities and institutions, to petitions, as well as to requests for information of public interest, through the authorised organisational structure;

30. participation in the development and revision of legislation in its field of activity;

31. professional collaboration with all organisational structures of the ANMDMR;

32. fulfils any other duties established by the ANMDMR management.

Art. 30 - (1) **The General Directorate for Pharmaceutical Inspection** is directly subordinated to the Vice-President of the ANMDMR with responsibilities regarding specific scientific activities in the field of medicinal products for human use and medical devices, is led by a general director and is structured as follows:

a) The Directorate for Administration of DGIF Processes;

b) The Directorate for Inspection of Good Manufacturing Practice, Good Laboratory Practice, Good Analytical Laboratory Practice, Good clinical practice and Good Pharmacovigilance Practice;

c) The Directorate for Good Distribution Practice Inspection;

d) The Directorate for Quality Supervision of Medicinal Products, Alerts and Territorial Units with its subordinated structures: The Falsified Medicinal Products Bureau, the Territorial Inspection Unit - Iaşi, the Territorial Inspection

Unit - Bacău, the Territorial Inspection Unit - Galaţi, the Territorial Inspection Unit - Piteşti, the Territorial Inspection Unit - Satu-Mare, the Territorial Inspection Unit - Cluj, the Territorial Inspection Unit - Oradea, the Territorial Inspection Unit - Deva, the Territorial Inspection Unit - Mureş, the Territorial Inspection Unit - Timişoara, the Territorial Inspection Unit - Craiova and the Territorial Inspection Unit - Constanţa.

(2) **The Directorate for Administration of DGIF Processes** is headed by a director, is subordinated to the general director of DGIF and has the following duties:

1. drawing up, issuing and administering certificates attesting to the status of qualified person for batch release;

2. administering national databases relating to inspection coding, dynamics of manufacturing/import units, wholesale distribution units and certified third-country manufacturers;

3. periodically updating electronic records relating to the scheduling and performance of inspections;

4. carrying out pre- and post-marketing authorisation inspections, at the request of the DPN/DPE or the CAPP;

5. organising meetings of the GMP, GDP, GLP, GALP, GCP, pharmacovigilance Inspection Commission in order to present the inspection reports of the DGIF;

6. participating in joint actions organised by the Pharmacy Inspection Convention (PIC) - the Pharmaceutical Inspection Cooperation Scheme (PIC/S) to which Romania is affiliated;

7. drawing up the annual program of activities of the DGIF, with Annexes (annual inspection programmes);

8. participating in joint actions organised by the Pharmacy Inspection Convention (PIC) - the Pharmaceutical Inspection Cooperation Scheme (PIC/S) to which Romania is affiliated;

9. ensuring, through nominated persons, the registration of entries/exits of all documents addressed to/issued by the DGIF;

10. ensuring, through the nominated person (the person responsible for goods), the supply and administration of fixed assets and consumables required by the DGIF;

11. participating in the updating of tariffs for the services provided by the directorate;

12. participating, through representatives nominated by the ANMDMR management, in committees of the ANMDMR, in meetings of various working groups of authorities and public institutions, as well as of other European bodies competent in the field of pharmaceutical inspection;

13. ensuring professional training of personnel through internal/external training, participation in advanced training and specialisation courses, experience

exchanges, participation in national and international scientific events in the field of pharmaceutical inspection;

14. providing, within the legal deadline, responses to the notices of the Ministry of Health, other authorities and public institutions, to petitions, as well as to requests for information of public interest, through the authorised organisational structure;

15. participating in the development and revision of guidelines and legislation in its field of activity;

16. professional collaboration with all organisational structures of the ANMDMR;

17. fulfils any other duties established by the ANMDMR management.

(3) **The Directorate for Inspection of Good Manufacturing Practice, Good Laboratory Practice, Good Analytical Laboratory Practice, Good clinical practice and Good Pharmacovigilance Practice** is headed by a director, is subordinated to the general director of DGIF and has the following duties:

1. carrying out authorisation inspections, respectively certification of good manufacturing practice (GMP) for the manufacture/import of medicinal products for human use, including those for clinical investigation;

2. receiving, registering, sending correspondence regarding the inspection activity [(good manufacturing practice (GMP), good laboratory practice (GLP), good analytical laboratory practice (GALP), good clinical practice (GCP) and pharmacovigilance (PVP)];

3. verifying the existence of complete documentation necessary for carrying out inspections, calculating inspection fees (GMP, GLP, PVP, PVP, PVP, PVP) and following up on their payment in accordance with the operational procedure of the DGIF;

4. preparing, issuing and administering manufacturing/import authorisations, GMP certificates, GLP certificates, authorisations for independent control units;

5. carrying out GMP, GLP, GALP, PhV inspections at the sites of marketing authorisation holders (MAHs) to verify compliance with their obligations in the field of activities incumbent on them as marketing authorisation holders for medicinal products for human use, provided for by law, other than pharmacovigilance;

6. carrying out follow-up inspections on the resolution of deficiencies for all types of inspections, as well as carrying out unannounced inspections;

7. conducting GMP certification inspections at the sites of manufacturers/importers of starting materials in Romania and third countries;

8. conducting GMP certification inspections at the sites of manufacturers of medicinal products in third countries;

9. conducting inspections of good analytical laboratory practice (GALP) for the authorisation of independent medicinal product quality control units;

10. conducting inspections of good clinical practice (GCP) in clinical investigation centers and contract research organisations (CROs) involved in the conduct of clinical trials with medicinal products for human use, inspections of clinical trials authorised in Romania to verify compliance with the Guideline on good clinical practice, as well as inspections of clinical investigations authorised in Romania;

11. inspecting medical units authorised by the ANMDMR to conduct clinical trials of medicinal products and clinical investigations for medical devices;

12. performing inspections for certification of good laboratory practice (GLP);

13. performing pharmacovigilance inspections at the sites of MAHs or their partners;

14. performing inspections at the sites of MAHs to verify compliance with their obligations in the field of activities incumbent on them as holders of marketing authorisations for medicinal products for human use provided for by legislation, other than pharmacovigilance (FV);

15. carrying out pre- and post-marketing authorisation inspections, at the request of the DPN/DPE or the CAPP;

16. conducting inspections to monitor the resolution of deficiencies for all types of inspections, as well as conducting unannounced inspections, for all types of inspections;

17. maintaining national databases on approved export declarations, certificates issued to qualified persons;

18. entering into the EudraGMP the information included in the manufacturing/import/wholesale distribution authorisations and in the issued GMP certificates;

19. entering into the EudraGMDP information about inspections carried out by good clinical practice (GCP) inspectors from the ANMDMR in relation to applications submitted to the EMA for centrally authorised products;

20. approving export declarations, following assessment of submitted documents, in accordance with the legislation in force;

21. issuing donation notices for medicinal products for human use;

22. approving the provision of free medical samples and maintaining electronic records of the MAH's periodic reports on the provision of free medical samples;

23. preparing and managing essential documents for each inspection performed;

24. implementing, maintaining and continuously improving the quality management system by: developing/revising the Inspectorate's Quality Manual, which states the quality policy, objectives and responsibilities in achieving them;

25. participation in joint actions organised by The Pharmaceutical Inspection Convention (PIC) - the Pharmaceutical Inspection Cooperation Scheme (PIC/S) to which Romania is affiliated;

26. participation in meetings of the PIC/S Officials Committee;

27. participation, through representatives nominated by the ANMDMR, in meetings of EMA working groups in the field of GMP, GLP, GCP and PhV inspections;

28. communication and participation in joint activities with inspectorates from EU Member States and with those of PIC/S participating authorities, on inspection issues;

29. participation in joint actions organised by the Pharmacy Inspection Convention (PIC) - Pharmacy Inspection Cooperation Scheme (PIC/S) to which Romania is affiliated;

30. participation in implementation of the EMA inspection programme in relation to centrally authorised products (GMP and GCP inspections), respectively in the inspection programme of the European Directorate for the Quality of Medicines & HealthCare (EDQM), in the case of active substances;

31. participation in updating tariffs for the services provided by the Directorate;

32. participation, through representatives nominated by the ANMDMR management, in committees of the ANMDMR, in meetings of various working groups of public authorities and institutions, as well as of other European bodies competent in the field of pharmaceutical inspection;

33. ensuring professional training of personnel through internal/external training, participation in advanced training and specialisation courses, experience exchanges, participation in national and international scientific events in the field of pharmaceutical inspection;

34. providing within the legal deadline replies to the notices of the Ministry of Health, other authorities and public institutions, to petitions, as well as to requests for information of public interest, through the authorised organisational structure;

35. participating in the development and revision of guidelines and legislation in its field of activity;

36. professional collaboration with all organisational structures of the ANMDMR;

37. fulfils any other duties established by the ANMDMR management.

(4) **The Directorate for Good Distribution Practice Inspection** is headed by a head of service, is subordinated to the Director General of the DGIF and has the following duties:

1. verifying the existence of the complete documentation needed for performing Good Distribution Practice (GDP) inspections, and following up on the payment of fees for these;

2. receiving, registering, sending correspondence related to the GDP inspection activity;

3. verifying the existence of complete documentation needed for performing inspections, calculating GDP inspection fees and following up on their payment in accordance with the operating procedure of the DGIF;

4. performing GDP inspections at the sites of marketing authorisation holders (MAHs);

5. conducting inspections to monitor the resolution of deficiencies for all types of inspections, as well as conducting unannounced inspections;

6. preparing, issuing and administering wholesale distribution authorisations and GDP certificates;

7. conducting inspections for authorisation, respectively GDP certification of wholesale medicinal product distribution units;

8. conducting inspections to verify the activity of registered brokers of medicinal products;

9. carrying out inspections to verify the activity of wholesale distributors of starting materials used in the manufacture of medicinal products for human use;

10. carrying out inspections to monitor the resolution of deficiencies, as well as carrying out unannounced inspections;

11. entering into the EudraGMDP the information included in the wholesale distribution authorisations and in the issued GDP certificates;

12. drawing up and managing essential documents for each inspection performed;

13. managing notifications regarding intra-community deliveries and monthly reports submitted by wholesale distributors/manufacturers/importers, according to the legislation in force;

14. participating in joint actions organised by the Pharmacy Inspection Convention (PIC) - Pharmacy Inspection Cooperation Scheme (PIC/S) to which Romania is affiliated;

15. participating in meetings of the PIC/S Officials Committee;

16. communication and participation in joint activities with the inspectorates of the EU Member States and those of the PIC/S participating authorities, for inspection issues;

17. participation in joint actions organised by the Pharmacy Inspection Convention (PIC) - Pharmacy Inspection Cooperation Scheme (PIC/S) to which Romania is affiliated;

18. participation in updating the tariffs for the services provided by the directorate;

19. participation, through representatives nominated by the ANMDMR management, in committees of the ANMDMR, in meetings of various working groups of public authorities and institutions, as well as of other European bodies competent in the field of pharmaceutical inspection;

20. ensuring professional training of personnel through internal/external training, participation in advanced training and specialisation courses, experience exchanges, participation in national and international scientific events in the field of pharmaceutical inspection;

21. providing within the legal deadline replies to the notices of the Ministry of Health, other public authorities and institutions, to petitions, as well as to requests for information of public interest, through the authorised organisational structure;

22. participating in the development and revision of guidelines and legislation in its field of activity;

23. professional collaboration with all organisational structures of the ANMDMR;

24. fulfils any other duties established by the ANMDMR management.

(5) The Directorate for Quality Supervision of Medicinal Products, Alerts and Territorial Units is headed by a director, is subordinated to the general director of DGIF and has the following duties:

1. receiving, registering, sending correspondence regarding the inspection activity for supervision of the quality of medicinal products and the verification of compliance with the Good Practice rules (RBPX) at the sites of manufacturers, importers, wholesale distributors, holders of marketing authorisations for medicinal products for human use, investigation centers/contract research organisations and supervision of the activity of pharmacies;

2. verifying the existence of complete documentation needed for performing inspections, calculating inspection fees and following up on their payment in accordance with the operating procedure of the DGIF;

3. carrying out unannounced inspections to supervise the quality of medicines and verify compliance with the rules of good practice (RBPX) at manufacturers, importers, wholesale distributors, marketing authorisation holders for medicinal products for human use, investigation centers/contract research organisations;

4. conducting inspections for surveillance of the activity of pharmacies;

5. conducting inspections to monitor the resolution of deficiencies for all types of inspections carried out, as well as conducting unannounced inspections in the field of activity of the directorate;

6. preparing a quarterly report on medicinal products withdrawn due to quality non-compliances detected through inspection activity, which is published in the agency's information materials and on the ANMDMR website;

7. surveillance of medicinal product quality through:

a) annual sampling plan;

b) thematic plans for surveillance inspections;

c) resolution of notifications regarding quality non-compliances of medicinal products;

8. performance of activities preventing entry into the legal supply chain of some medicinal products, in accordance with legal provisions;

9. participation, through the contact person from the DGIF nominated for the PIC/S, EU, EMA, WHO databases, in solving rapid alerts regarding falsified medicinal products, in pan-European programmes regarding medicinal product counterfeiting;

10. initiating and/or participating in rapid alert actions by the nominated inspector to warn about major non-compliances of (class 1 and class 2) medicinal products in the PIC/S, EU, WHO Rapid Alert System;

11. managing rapid alerts on counterfeit/stolen medicinal products and taking measures to prevent counterfeit medicinal products from entering the legal supply chain, in accordance with legal provisions;

12. receiving and processing rapid alerts, information on substandard, falsified or stolen medicinal products from Member States of the European Economic Area and partners of the Mutual Recognition Agreement and notifying them of the possible presence in the distribution network of falsified/stolen medicinal products, products resulting from fraud in the manufacturing, packaging, distribution or promotion of medicinal products containing falsified raw materials;

13. accessing the National Medicines Verification System for the purpose of supervising the operation of repositories and investigating potential incidents related to falsification;

14. notifying the Romanian Organisation for Serialisation of Medicinal Products (OSMR) when suspending/withdrawing a manufacturing authorisation or a wholesale distribution authorisation; if the suspension of the manufacturing or wholesale distribution authorisation is revoked or the authorisation is withdrawn, the ANMDMR shall again notify the OSMR thereof;

15. informing, through the Directorate for Legal, European Affairs and International Relations, the customs authorities and the criminal investigation and prosecution bodies, regarding fraud or counterfeit/stolen medicinal products;

16. monitoring the correctness of the withdrawal of counterfeit/stolen medicinal products;

17. conducting investigations in the online environment regarding the detection of sites that sell suspected counterfeit medicinal products;

18. participating in joint actions organised by The Pharmaceutical Inspection Convention (PIC) - the Pharmaceutical Inspection Cooperation Scheme (PIC/S) to which Romania is affiliated;

19. communication and participation in joint activities with the inspectorates of European Union Member States and those of PIC/S participating authorities, for inspection issues;

20. coordination of the activity of territorial inspection units;

21. provision of pharmacovigilance consultancy in the territory, with the participation of territorial inspection units;

22. participation in updating the tariffs for the services provided by the department;

23. participation, through representatives nominated by the ANMDMR management, in the committees within the ANMDMR, in the meetings of various working groups of public authorities and institutions, as well as other European bodies competent in the field of pharmaceutical inspection;

24. ensuring professional training of personnel through internal/external training, participation in advanced training and specialisation courses, experience exchanges, participation in national and international scientific events in the field of pharmaceutical inspection;

25. providing within the legal term responses to the notices of the Ministry of Health, other authorities and public institutions, to petitions, as well as to requests for information of public interest, through the authorised organisational structure;

26. participating in the development and revision of guidelines and legislation in its field of activity;

27. professional collaboration with all organisational structures of the ANMDMR;

28. fulfils any other duties established by the ANMDMR management.

Art. 31 - (1) The General Directorate for Medical Devices is directly subordinated to the Vice-President of the ANMDMR with responsibilities regarding specific scientific activities in the field of medicinal products for human use and medical devices, is led by a general director and has the following structure:

a) The Regulatory Market Surveillance Directorate with its subordinated structures the Regulation Service with its subordinated structure The Compartment for Clinical Investigation and Medical Devices, the Market Surveillance Service with its subordinated structure the Vigilance Compartment, as well as the Territorial Inspection Unit - Iaşi, Territorial Inspection Unit - Cluj, Territorial Inspection Unit - Oradea, Territorial Inspection Unit - Deva, Territorial Inspection Unit - Mureş, Territorial Inspection Unit - Timişoara, Territorial Inspection Unit - Craiova;

b) The Technical Laboratories Directorate with its subordinated structures, the Nuclear Unit Service and the Tests and Checks Service;

c) The Directorate for Approval.

(2) **The Regulatory Market Surveillance Directorate** is headed by a director, is subordinated to the general director of DGDM and has the following duties:

1. proposes draft regulatory documents to transpose European directives in the field of medical devices or to create the framework for the application of EU regulations in the field of medical devices, which it submits for approval to the Directorate for Legal, European Affairs and International Relations;

2. participates in interministerial working groups in the development of documents for harmonisation and implementation of regulations in the field of

medical devices and service provision, at the request of the Ministry of Health and the proposal of the ANMDMR management;

3. participates in meetings and working groups in the field of medical devices at the European Union level;

4. elaborates, from a technical point of view, Romania's position and the mandate of representation regarding the proposals for Community legislative provisions and the topics of the working groups at the European Union level in the field of medical devices and transmits them to the Ministry of Health through the Legal, European Affairs and International Relations Directorate, with the approval of the ANMDMR management;

5. elaborates methodological rules regarding the organisation and operation of the medical devices sector;

6. draws up lists of Romanian standards which adopt European standards harmonised with European directives in the field of medical devices;

7. participates in the technical committees of the Romanian Standards Association (ASRO) in the development and adoption of standards applicable in its field of activity;

8. nominates certification bodies in the field of medical devices, submits the list of nominated bodies to the approval of the Minister of Health and notifies these bodies through the electronic procedure managed by the European Commission;

9. supervises notified bodies and orders appropriate measures;

10. registers medical devices placed on the market or put into service in Romania, domestic manufacturers, authorised representatives, importers and distributors of medical devices, according to the regulations in force;

11. creates and updates the national database in accordance with the provisions of national legislation transposing European directives;

12. ensures the entry of data from the national database into the European database (Eudamed);

13. decides on the classification of a medical device in the event of a dispute between the manufacturer and the body responsible for assessment of compliance;

14. authorises, in well-justified cases, the placing on the market and putting into service of single medical devices, when this is in the interest of health safeguard policy;

15. develops specific technical procedures in the field of medical devices;

16. ensures administrative cooperation with competent authorities of EU Member States regarding the provision of services in the field of medical devices;

17. issues certificates of free sale, following evaluation of submitted documents, in accordance with the legislation in force;

18. issues customs notices, following the evaluation of the submitted documents, in accordance with the legislation in force;

19. issues donation notices, following the evaluation of the submitted documents, in accordance with the legislation in force;

20. issues out-of-scope notices, following evaluation of the submitted documents, in accordance with the legislation in force;

21. carries out any other activities by delegation of powers from the Ministry of Health, according to the law;

22. carries out the activities arising from the attribution of supervision of the medical devices market, according to legal regulations;

23. orders appropriate measures for withdrawal from the market or for prohibition or restriction of placing on the market/putting into service of medical devices which may compromise the health and/or safety of patients and users;

24. records and evaluates information on incidents and corrective actions reported in relation to medical devices and implements the vigilance procedure, in accordance with the harmonised legislation in force;

25. ascertains the violation of legal provisions in the field of medical devices and applies appropriate sanctions in accordance with the legislation in force;

26. ensures, in a centralised manner, the recording and evaluation of any information received in accordance with the law and concerning the reporting of an incident related to medical devices;

27. informs the European Commission and the other Member States of the European Union of the measures which have been taken or which are being considered to minimise the risk of recurrence of incidents;

28. evaluates and authorizes clinical investigations for medical devices;

a) evaluates the documentation for approval of clinical investigations, drafting of evaluation reports, transmission of requests for supplementation of documentation, when applicable, and evaluation of responses to requests;

b) authorizes clinical investigations, setup and technical editing of clinical investigation authorisations and rejection letters.

29. evaluates and approves amendments to clinical investigations for approved medical devices through:

a) evaluating amendments and drafting evaluation reports, submitting requests for supplementation of documentation, when applicable, and evaluating replies to requests;

b) drafting and technical editing of the reply approving/rejecting the amendment;

30. receives and manages any type of amendments to clinical investigations for medical devices, various notifications, notices with requests for various information;

31. manages databases for clinical investigations for medical devices;

32. manages European databases and supplements the requested information;

33. manages tariff adjustment notices, when necessary;

34. publishes information from clinical investigations for medical devices, prepares documents for publication.

35. submits for archiving the documentation submitted for approval of clinical investigations for medical devices and all subsequent documents;

36. collaborates with other departments within the ANMDMR in case the clinical investigation involves medicinal products as well, to solve issues that arise during evaluation of the documentation;

37. evaluates performance of in vitro diagnostic medical devices;

38. manages reports of serious and non-serious adverse reactions, originating from clinical investigations for medical devices, in written and/or electronic format;

39. participates in the development and review of regulations on the authorisation of clinical investigations for medical devices;

40. manages the electronic system on clinical investigations for medical devices/evaluates the performance of in vitro diagnostic medical devices (electronic procedure for evaluation/analysis of clinical investigation requests carried out in Romania, and evaluation of clinical investigations from other Member States, etc.);

41. reports serious adverse events, which shall be entered into the electronic system for clinical investigations for medical devices/ evaluation of performance of in vitro diagnostic medical devices;

42. participates in updating the tariffs for services provided by the directorate;

43. participates, through representatives designated by the ANMDMR management, in the committees within the ANMDMR, in the meetings of various working groups of public authorities and institutions, as well as other European bodies competent in the field of medical devices;

44. ensures professional training of personnel through internal/external training, participation in advanced training and specialisation courses, experience exchanges, participation in national and international scientific events in the field of medical devices;

45. provides within the legal term replies to the notices of the Ministry of Health, other authorities and public institutions, petitions, as well as to requests for information of public interest, through the authorised organisational structure;

46. participates in the development and revision of legislation in its field of activity;

47. professional collaboration with all organisational structures of the ANMDMR;

48. fulfils any other duties established by the ANMDMR management.

(3) **The Technical-Laboratories Directorate** is headed by a director, is subordinated to the general director of the DGDM and has the following duties:

1. carrying out tests and verifications for medical devices, medical devices which use ionising radiation, magnetic resonance imaging equipment and radiological protection equipment, at the request of third parties;

2. carrying out tests and verifications for medical devices and in vitro diagnostic medical devices, medical devices which use ionising radiation, magnetic resonance imaging equipment and second-hand radiological protection equipment, regarding performance and safety in view of approval;

3. issuing approvals for use of medical devices and in vitro diagnostic medical devices, medical devices which use ionising radiation, magnetic resonance imaging equipment and second-hand radiological protection equipment;

4. controlling medical devices in use, through periodic control checks and issuing periodic check bulletins for medical devices which use ionising radiation, magnetic resonance imaging equipment and radiological protection equipment;

5. providing specialised technical expertise services;

6. participating in the technical committees of the Romanian Standards Association (ASRO) in the development and adoption of standards applicable in its field of activity;

7. carrying out any other activities, by delegation of powers from the Ministry of Health, according to the law;

8. participation in updating the tariffs for the services provided by the directorate;

9. participation, through representatives appointed by the ANMDMR management, in committees of the ANMDMR, in meetings of various working groups of public authorities and institutions, as well as of other European bodies competent in the field of medical devices;

10. ensuring professional training of staff through internal/external training, participation in training courses, specialisation, experience exchanges, participation in national and international scientific events in the field of medical devices;

11. providing, within the legal term, responses to the notices of the Ministry of Health, other public authorities and institutions, to petitions, as well as to requests for information of public interest, through the authorised organisational structure;

12. participates in the development and revision of legislation in its field of activity;

13. professional collaboration with all organisational structures of the ANMDMR;

14. fulfils any other duties established by the ANMDMR management.

(4) **The Directorate for Approval** is headed by a director, is subordinated to the general director of DGDM and has the following duties:

1. assessing economic operators, natural or legal persons, who request ANMDMR to issue an approval or an annex to the approval for provision of

activities in the field of medical devices, in accordance with the legislation in force;

2. supervising the activity of economic operators who have obtained ANMDMR's approval for the provision of activities in the field of medical devices, in accordance with the legislation in force;

3. issuing operating opinions and their annexes for economic operators who provide activities in the field of medical devices;

4. carrying out any other activities by delegation of powers from the Ministry of Health, according to the law;

5. developing and updating the database of approved economic operators;

6. participating in the technical committees of the Romanian Standard Association (ASRO) in the development and adoption of standards applicable in its field of activity;

7. participating in updating the tariffs for services provided by the directorate;

8. participation, through representatives nominated by the ANMDMR management, in the committees within the ANMDMR, in the meetings of various working groups of public authorities and institutions, as well as other European bodies competent in the field of medical devices;

9. ensuring professional training of personnel through internal/external training, participation in advanced training and specialisation courses, experience exchanges, participation in national and international scientific events in the field of medical devices;

10. providing, within the legal term, responses to the notices of the Ministry of Health, other public authorities and institutions, to petitions, as well as to requests for information of public interest, through the authorised organisational structure;

11. participates in the development and revision of legislation in its field of activity;

12. professional collaboration with all organisational structures of the ANMDMR;

13. fulfils any other duties established by the ANMDMR management.

Art. 32 - The Advertising Service is directly subordinated to the Vice-President of the ANMDMR with responsibilities regarding specific scientific activities in the field of medicinal products for human use and medical devices, is led by a head of service and has the following duties:

1. evaluation of advertising materials, approval, formulation of requests for modification or non-approval of advertising materials in the field of medicinal products for human use and medical devices, as appropriate;

2. evaluation of educational materials, approval, formulation of requests for modification or non-approval of educational materials in the field of medicinal products for human use and medical devices, as appropriate;

3. physical and electronic archiving of advertising materials and solved educational materials;

4. records of notifications regarding participation of marketing authorisation holders (MAHs) in medical events;

5. centralisation of forms for declaring sponsorship activities carried out by manufacturers, MAHs or their representatives in Romania, as well as wholesale and retail distributors of medicinal products for healthcare professionals, professional organisations, patient organisations and any other type of organisations carrying out activities related to human health, medical or pharmaceutical care, medical devices;

6. centralisation of the forms for declaring sponsorship activities carried out by manufacturers, MAHs or their representatives in Romania, as well as wholesale and retail distributors of medicinal products and medical devices for healthcare professionals, professional organisations, patient organisations and any other type of organisations carrying out activities related to human health, medical or pharmaceutical care in the field of medicinal products for human use, as well as in the field of medical devices;

7. centralisation of the forms for declaring sponsorship activity by beneficiaries of sponsorship activities, physicians, nurses, professional organisations, patient organisations and any other type of organisations performing activities related to human health, medical or pharmaceutical assistance in the field of medicinal products for human use, as well as in the field of medical devices;

8. participation, through representatives nominated by the ANMDMR management, in committees within the ANMDMR, in meetings of various working groups of public authorities and institutions, as well as in meetings of other European bodies competent in the field of medical devices;

9. ensuring professional training of personnel through internal/external training, participation in advanced training and specialisation courses, experience exchanges, participation in national and international scientific events in the field of medical devices;

10. providing, within the legal term, responses to the notices of the Ministry of Health, other public authorities and institutions, to petitions, as well as to requests for information of public interest, through the authorised organisational structure;

11. participates in the development and revision of legislation in its field of activity;

12. professional collaboration with all organisational structures of the ANMDMR;

13. fulfils any other duties established by the ANMDMR management.

Art. 33 - The Scientific Advice Bureau is directly subordinated to the Vice-President of the ANMDMR with responsibilities regarding specific scientific

activities in the field of medicinal products for human use and medical devices, is led by a head of service and has the following duties:

1. provides scientific consultancy services in the field of medicinal products for human use and medical devices regarding:

- submission of applications and related documentation for: authorisation of medicinal products through national procedure, mutual recognition procedure and decentralised procedure; authorisation of manufacturing and wholesale distribution units of medicinal products for human use and approval of units with marketing activities and provision of services in the field of medical devices;
- post-authorisation procedures for medicinal products for human use (variations)/approval of medical devices;
- registration of medical devices;
- pharmacovigilance;
- advertising and sponsorship;
- good practices of: manufacturing, distribution, laboratory, analytical laboratory, clinical trial and pharmacovigilance;
- submission of applications and related documentation for authorisation of medical units to conduct clinical /clinical investigations/bioequivalence trials and the authorisation of clinical trials, bioequivalence studies and clinical investigations;
- submission of requests regarding the assessment of medical technologies of medicinal products for human use, high-performance medical devices and equipment.

2. participation in updating the tariffs for the activities provided by the service;

3. participation, through representatives designated by the ANMDMR management, in the committees within the ANMDMR, in the meetings of various working groups of public authorities and institutions, as well as of other European bodies competent in the field of medical devices;

4. ensuring professional training of personnel through internal/external training, participation in advanced training and specialisation courses, experience exchanges, participation in national and international scientific events in the field of medical devices;

5. professional collaboration with all organisational structures of the ANMDMR;

6. fulfils any other duties established by the ANMDMR management.

Art. 34 - The Directorate for Human Resources and Quality Management is directly subordinated to the vice-president of the ANMDMR with responsibilities regarding technical-administrative activities, supporting specific scientific activities, is led by a director, has in its service the Quality Assurance and Registry Service, with the Compartment for Quality Assurance, Ethics and Integrity and the Registry and Archive Compartment in its service and

the Staff - Payroll Service with the Staff Compartment and the Payroll Compartment in its service, and has the following duties:

1. permanently monitors the emergence/amendment/repeal of regulatory provisions (laws, ordinances, decisions, orders, regulations, etc.) specific to human resources and payroll activities (labour legislation, payroll, etc.) and ensures their implementation within the ANMDMR;
2. informing top management about new emergences or amendments to legislative provisions in the field of labour legislation, payroll;
3. developing the annual training program, annual work plan, annual activity report for all organisational structures within the ANMDMR;
4. organising the annual evaluation of professional performances of ANMDMR employees;
5. keeping records of professional training of ANMDMR employees;
6. keeping records of personnel at the organisational level;
7. keeping records of documents issued within the DRUMC;
8. management of the general record of employees in electronic format (REVISAL);
9. ensuring the preparation and submission for approval of the ANMDMR President of the documentation relating to the modification of the organisational structure of the number of positions, the staff lists;
10. preparing the staff list according to the organisational structure;
11. preparing and submitting for approval the ANMDMR President of draft regulations on the organisation and operation of the ANMDMR, the internal regulations and the code of conduct and their updating;
12. ensuring the employment of personnel, upon hiring or promotion, according to the position list;
13. ensuring a confidential system for granting monetary rights, as well as a system for promotion in positions;
14. preparing, updating and recording all certificates specific to the human resources activity;
15. recording labour logs (time sheets) and calculating salary rights of ANMDMR employees, respecting the deadlines for salary payment;
16. preparing payrolls, salary flyers, centralizers, initial/rectifying monthly single declarations regarding employee and employer contributions and other specific situations regarding salary rights of ANMDMR employees;
17. implementing the annual evaluation system of professional performances of ANMDMR employees and establishing all salary rights resulting from the obtained scores;
18. preparing the necessary documentation for application of the legislation in force regarding professional training courses and ensuring the participation of ANMDMR employees in professional training courses;

19. electronic record of training carried out by ANMDMR employees, as well as their professional activities;
20. management of all declarations of interests of ANMDMR staff, as well as, where appropriate, wealth declarations of staff holding management and executive positions, as appropriate, within the ANMDMR, of members of the Board of Directors and the Scientific Council and their submission to the National Integrity Agency, as well as posting them on the institution's website;
21. ensuring the confidentiality of all documents and information managed by employees within the DRUMC;
22. ensuring controlled access of persons designated by the top management to documents and information regarding human resources and personnel payroll;
23. ensuring database administration, through responsible persons, in accordance with the decisions of the ANMDMR President;
24. preparing the documentation required for organising exams and competitions for filling vacant positions within the ANMDMR and for promoting ANMDMR employees;
25. preparing decisions regarding the sanctioning of ANMDMR personnel based on the report of the hierarchical superiors of the persons proposed for sanctioning with a written reprimand/warning and submitting them for approval to the ANMDMR President;
26. draws up decisions regarding the sanctioning of ANMDMR personnel based on the report of the disciplinary committee and submits them for approval to the ANMDMR president;
27. monitors the preparation and updating of job descriptions of ANMDMR personnel by heads of organisational structures and ensures their filing, dated/signed;
28. ensuring a staff motivation system (basic salaries, bonuses, meal vouchers, vacation vouchers, training, promotions, etc.);
29. keeping records of documents issued by the ANMDMR management or by other organisational structures, archiving them and transmitting them for communication to the persons who are to carry them out;
30. keeping records of employee declarations regarding additional tax deductions;
31. establishing the basic salary upon hiring, promotion, return to work and modification of the work norm;
32. keeping records of garnishments;
33. calculating salary rights of employees (basic salaries, management allowances, merit salaries, bonuses, overtime pay, vacation or sick leave allowances, increases, etc.) according to the legal provisions in force and in compliance with the deadlines for payment of salaries;
34. drawing up and keeping records of documentation regarding salary cards;

35. representing the ANMDMR in relations with various institutions on issues of human resources, payroll and contributions to the general consolidated state budget;
36. representing the ANMDMR in subordination relations with the Ministry of Health, on issues specific to human resources and payroll;
37. performing any other works provided for by labour and payroll legislation;
38. managing databases regarding the records of quality documents developed in the DRUMC;
39. promoting the concept of integrity through specific training and education activities;
40. identifying, in collaboration with the persons responsible for integrity in the public health system, fraud and corruption situations in the ANMDMR, based on received notifications;
41. collaborating with representatives of the institutions authorised to identify and combat fraud and corruption;
42. ensuring implementation of the strategies and objectives related to quality management declared by the ANMDMR management;
43. coordinating the design, documentation, implementation, maintenance, improvement and reporting of the Quality Management System, in accordance with the requirements of the ISO 9001:2015 standard and with the objectives established by the ANMDMR management;
44. promoting the Quality Management System according to the requirements of the ISO 9001:2015 standard at ANMDMR level, in order to provide compliant services by the personnel involved;
45. collaborating with all ANMDMR structures in order to continuously improve the quality management system;
46. providing specific advice to ANMDMR personnel on quality management issues;
47. assisting and responding to all requests from the ANMDMR management in the field of quality management;
48. permanently reporting to the ANMDMR management on the operation of the Quality Management System and makes proposals for its improvement;
49. representing the ANMDMR in external relations in the field of quality management;
50. coordinating and monitoring the preparation, revision, controlled distribution, maintenance of revisions of the Quality Manual, system procedures, operational procedures, general instructions, work instructions specific to each activity, structure, as well as other specific documents for quality assurance;
51. updating all quality assurance documents, depending on the dynamics of the organisational and functional structure and specific requirements;
52. initiating and monitoring corrective and preventive actions for development and improvement of the quality management system;

53. initiating and participating in the annual analysis of the Quality Management System, carried out by the ANMDMR management;
54. ensuring the continuous improvement of knowledge, skills and values within the framework of continuous professional training;
55. developing the Annual Quality Training Programme and organizing internal training;
56. keeping records of the training of management, execution personnel and internal auditors for improvement of the quality management system;
57. preparing and analysing the Annual Quality Management Plan;
58. making proposals for improving the Quality Management System documents;
59. ensuring the implementation and maintenance of the quality management system's compliance with the specific requirements of the ISO 9001:2015 standard;
60. implementing quality assurance and service evaluation tools;
61. participating in the primary analysis of possible non-compliances, non-compliant services and complaints for their validation or invalidation and establishing the manners of handling non-compliances;
62. collaborating with the staff from all ANMDMR structures in order to continuously improve the quality management system;
63. participating in quality audits performed by representatives of certification bodies;
64. transmitting, for implementation, the proposed changes following the audit in the quality management documents;
65. coordinating analyses carried out by management on the effectiveness of the quality management system and the manner of finalising corrective actions resulting from internal and external audits;
66. monitoring the implementation of corrective actions and solutions resulting from non-compliance reports and corrective actions, as well as from audit reports;
67. carrying out the necessary activities to certify the compliance of the Quality Management System with the requirements established by ISO 9001:2015;
68. preparing specific documents and participating in the management analysis on the functioning, effectiveness and efficiency of the Quality Management System;
69. systematically centralizing the information received through questionnaires, regarding the assessment of citizen/patient satisfaction, and identifying effective manners of monitoring their satisfaction;
70. preparing the annual analysis and assessment of the degree of satisfaction of citizens/patients and submits them to the ANMDMR management for proposing and taking measures to improve the degree of satisfaction;
71. ensuring and respecting the confidentiality of data, information and documents used in accordance with the legal rules regarding the secrecy and confidentiality of data and information;

72. preparing, updating and internally disseminating the list of retention and archiving periods for documents and records;
73. ensuring both physical and electronic archiving of documents in the field of activity, according to the regulatory documents in force;
74. performing other duties entrusted by the ANMDMR management, in the field of competence, under the conditions and in compliance with the legal framework in force;
75. ensures the technical secretariat of the committee for monitoring the internal managerial control system, under the conditions described in the committee's organisation and operation regulations;
76. performs specific registry and archive activities according to internal procedures approved by the ANMDMR management;
77. providing, within the legal term, responses to the notices of the Ministry of Health, other public authorities and institutions, to petitions, as well as to requests for information of public interest, through the authorised organisational structure;
78. participation, through representatives nominated by the ANMDMR management, in committees within the ANMDMR, in meetings of various working groups of public authorities and institutions, as well as in meetings of other European bodies competent in the field of medicinal product for human use and medical devices;
79. ensuring professional training of personnel through internal/external training, participation in advanced training and specialisation courses, experience exchanges, participation in national and international scientific events in the field of the medicinal product for human use and medical devices;
80. professional collaboration with all organisational structures of the ANMDMR;
81. fulfils any other duties established by the ANMDMR management.

Art. 35 - The Directorate for Legal, European Affairs and International Relations is directly subordinated to the vice-president of the ANMDMR with responsibilities regarding technical-administrative activities, supporting specific scientific activities, is led by a director, has in its service the Service for General Legal Assistance, Debt Tracking and Administrative Litigation and the Service for Legislation, Referrals, European Affairs and International Relations and has the following duties:
1. informing the president of the ANMDMR, as well as all heads of organisational structures regarding the emergence, modification, supplementation of regulatory documents applicable to the entire activity of the institution;
2. filing legal actions, representing and defending the interests of the ANMDMR before courts, criminal investigation and prosecution bodies, bodies with jurisdictional powers, permanent arbitration institutions, as well as in relations with other bodies, legal entities and individuals, based on the authorisation given by the management of the ANMDMR;

3. preparing responses and communicating documents requested by courts, criminal investigation and prosecution bodies and other bodies with jurisdictional activity;
4. initiating actions before courts to recover receivables, starting the forced execution procedure, insolvency procedures and judicial liquidation of debtors, based on the situation transmitted by the Directorate for Economy and Public Procurement, and carrying out legal steps to finalize them;
5. informing customs authorities and criminal investigation and prosecution bodies regarding fraud or counterfeit/stolen medicinal products at the request of the General Directorate for Pharmaceutical Inspection and communicating information and documents requested by customs authorities and criminal investigation and prosecution bodies;
6. drafting and formulating any other procedural documents in which the ANMDMR is involved;
7. ensuring the representation and support of the interests of ANMDMR in non-contentious procedures, before any natural or legal persons, including public authorities or institutions, as well as in the mediation procedure;
8. collaborating with customs authorities and criminal investigation and prosecution bodies, regarding fraud or counterfeit/stolen medicinal products;
9. approving the legality of contracts drawn up by specialised structures of the ANMDMR, according to their competences;
10. approving the legality of administrative acts of an individual and/or collective nature issued by the ANMDMR;
11. approving, in terms of compliance with legal provisions and legislative technique, draft regulatory documents initiated by the organisational structures within the ANMDMR and submitting them for approval to the Ministry of Health;
12. participation and collaboration in the development of draft regulatory documents initiated by the organisational structures within the ANMDMR and submission for approval to the Ministry of Health;
13. participation and collaboration with the organisational structures within the ANMDMR in the modification, supplementation or repeal of regulatory documents which are no longer in accordance with the field of medicinal products for human use, health technologies assessment and medical devices;
14. contribution, together with the structures within the ANMDMR, to the harmonisation of Romanian legislation in the field of medicinal products for human use, health technologies assessment and medical devices with the legislation of the European Union;
15. analysing the legislation in force in the field of medicinal products for human use, medical technologies assessment and medical devices and contributing, together with the initiating organisational structures within the ANMDMR, to the formulation of proposals for the harmonisation of legislation;

16. coordinating the steps regarding the creation of the legal framework for direct application of community regulations in the field of medicinal products for human use, medical technologies assessment and medical devices;
17. providing advice to the ANMDMR management and organisational structures on legal issues in which the ANMDMR is involved;
18. formulating responses to petitions, notifications, memoranda, requests, information of public interest, etc. addressed to the ANMDMR by other public authorities/institutions, as well as by other individuals and legal entities, based on the viewpoints formulated by other organisational structures;
19. ensuring and coordinating the activities of the ANMDMR in the field of international relations and European affairs:
20. ensuring active promotion of the ANMDMR image and the visibility of the ANMDMR activity outside the territory of Romania, by intensifying and expanding bilateral and multilateral cooperation relations in the field of medicinal products for human use, health technologies assessment and medical devices and relations with international organisations and initiates, negotiates and participates in the conclusion of national and international cooperation agreements and documents, within the limits of the ANMDMR competences, under the coordination of the ANMDMR management;
21. proposing, together with the other organisational structures of the ANMDMR, in the specific field of activity, measures for development of collaborative relations with EU institutions, similar organisations in Member States and other states, international organisations;
22. ensuring administrative cooperation with competent authorities in the Member States of the European Union, regarding the provision of services in the field of medicinal products for human use and medical devices, through the Ministry of Health and the Internal Market Information System - IMI, established by the European Commission;
23. participation in the implementation of national/European/international projects and programmes and the development of the organisational strategy, by establishing the strategic objectives and guidelines of the institution's activity in the context of the legislative framework in force, for a three/five-year period, with the possibility of updating, depending on the general legislative framework and the legislation in ANMDMR’s field of activity;
24. monitoring the correspondence received from the Permanent Representation of Romania to the EU, the European Commission and other European and international institutions and bodies in the field of medicinal products for human use, medical technologies assessment and medical devices, the Ministry of Health, preparing responses to the requests received, in collaboration with the organisational structures within the ANMDMR and forwarding to nominated ANMDMR experts, the received communications regarding the meetings and working groups of the European Union and international institutions;

25. preparing the decisions of the ANMDMR President related to the trips of experts within the ANMDMR responsible for developing the viewpoints on the documents under debate, to the working groups of the European Union and international institutions;
26. managing and monitoring the participation of the ANMDMR experts designated to the working groups and periodically updating the List of ANMDMR employees designated by the ANMDMR President as holders or substitutes to the working groups of the European Union and international institutions, posting it on the ANMDMR website;
27. preparing, together with experts from specialised technical departments of the ANMDMR, the instructions and mandates/general negotiating mandates in the field of medicinal products for human use, medical technologies assessment and medical devices for European regulations, strategies and policies (at EU level or in relation to candidate states, acceding and non-EU member states), under promotion/negotiation regardless of the level of representation and correlating them with the positions adopted by other member states, and communicating them to the Ministry of Health;
28. participation, through representatives nominated by the ANMDMR management, in committees within the ANMDMR, in meetings of various working groups of public authorities and institutions, as well as in meetings of other European bodies competent in the field of medicinal products for human use, health technologies assessment and medical devices;
29. ensuring professional training of personnel through internal/external training, participation in advanced training and specialisation courses, experience exchanges, participation in national and international scientific events in the field of medicinal products for human use, health technologies assessment and medical devices;
30. professional collaboration with all organisational structures of the ANMDMR;
31. fulfils any other legal duties established by the ANMDMR management.

Art. 36 - The Communication and Public Relations Service is directly subordinated to the Vice-President of the ANMDMR with responsibilities regarding technical-administrative activities which support specific scientific activities, is led by a head of service, has in its service the Bureau for Communication with the Press, Stakeholders and Social Media, and the Translations Compartment, and has the following duties:
1. developing the communication strategy, by establishing the objectives of the institution's internal and external communication activity for a three/five-year period, with the possibility of updating, according to the general legislative framework and the legislation in the field of activity of the ANMDMR;
2. initiating, negotiating and concluding cooperation agreements and documents with central and local public administration institutions, professional

organisations, as well as with other organisations in the health field and interested parties, at national level, within the limits of ANMDMR's competences;
3. preparing and posting the annual activity report of the ANMDMR on the ANMDMR website;
4. ensuring internal and external communication, respectively ensuring proactive and reactive communication with the media, other specialised institutions in Romania or abroad and various other interested parties, preparing and distributing official press releases and position statements to the media, etc., through:
a) collaborating with all ANMDMR structures to ensure transparency in the agency's activity, in the sense of ensuring public accessibility/availability, respectively passive transparency and by ensuring reactive information upon request;
b) ensuring free access to information of public interest, in accordance with the legal provisions in force in the field, ex officio and/or upon request, for media representatives or for any person interested in communication issues in the field of activity of the ANMDMR;
c) informing media representatives and/or other applicants within the deadlines provided for by regulations in force, if the requested information is already communicated ex officio, also indicating the location where the requested information can be found;
d) informing the applicant, within the deadlines provided by the regulations in force, if the requested information is identified as being exempt from free access;
e) collaborating with all ANMDMR structures to collect and systematise the information requested by the media/other interested parties according to point b), on aspects related to communication in order to develop and draft the requested response;
f) drafting/verifying and disseminating to the media the official press releases and positions of the ANMDMR;
g) drafting and editing the minutes of meetings organised by the agency management with various external partners;
h) drafting and editing the minutes of operational meetings of the agency's management with the heads of various ANMDMR structures;
5. ensuring the scientific secretariat activity of the Scientific Council (SC) of the ANMDMR and, respectively, the preparation of SC meetings through collaboration of the organisational structures, by:
a) centralising and verifying the draft decisions of the SC;
b) organising SC meetings and drawing up the SC agenda;
c) sending the agenda and documents in electronic version/ on paper to the SC members;
d) managing the electronic versions of the decisions of the Scientific Council (HCS), from draft phase to publication (in the Official Gazette of Romania, Part I, in the case of Orders of the Minister of Health approving HCS of a regulatory nature, as well as on the ANMDMR website, under the headings "Legislation",

"Newsletters" and, as the case may be, "Specific Legislation", in the case of HCS of a non-regulatory nature, posted on the website immediately after approval in the SC meeting) in the directories dedicated to Scientific Council meetings;
e) keeping a record of the contact details of SC members and sending the list of members proposed to be part of the SC, in order to issue the Order of the Minister of Health establishing the SC, to the Ministry of Health;
f) drawing up the minutes of Scientific Council meetings.
6. ensures information on medicinal products for human use;
7. participation in the creation of an interface between the ANMDMR and stakeholders, through:
a) updating and improving the information contained on the ANMDMR website, in collaboration with other structures;
b) drafting the ANMDMR quarterly Newsletters, in Romanian and English, and posting them on the ANMDMR website;
c) drafting the (bilingual) ANMDMR Annual Activity Report and posting it on the ANMDMR website, respectively preparing the necessary documents for publication in the Official Gazette of Romania, Part III (after approval through decision of the ANMDMR Administration Council);
d) updating the ANMDMR Facebook page on a permanent basis;
e) monitoring complaints received at lipasmedicament@anm.ro and those forwarded from the dedicated website of the Ministry of Health http://medicamentilipsa.ms.ro/ and formulating, as appropriate, replies based on data owned by the ANMDMR or requested from the MAH/wholesale distributors;
f) organizing meetings with patient associations on topics of interest to them;
g) monitoring and coordinating the participation of ANMDMR representatives in scientific events of professional associations (medical societies, College of Pharmacists, College of Physicians, etc.), of the pharmaceutical industry, patient associations, etc.;
h) coordinating the organization of meetings with media representatives to address information of public interest in the field of ANMDMR's profile;
8. ensuring the secretariat activity of the commission for the management of crisis situations determined by issues related to the quality, safety and/or efficacy of medicines, according to the regulation of organization and functioning of the Commission, by drawing up and editing the minutes of the meetings;
9. participating in updating and improving the information contained on the ANMDMR intranet website, in collaboration with the other structures;
10. ensuring translation/verification of translation/consultancy on the translation into/from English, by:
a) ensuring the translation/verification of the translation of European directives, regulations and guidelines in the field of medicinal products for human use, medical devices and medical technologies assessment;

b) ensuring verification of the translation of the summary of product characteristics (SPC) and the package leaflet;
c) ensuring correspondence and consultancy for communication in English with European bodies;
d) ensuring translation into English of the ANMDMR Newsletter, the ANMDMR Annual Activity Report and other reports and documents requested by external partners;
e) developing the English version of the ANMDMR website;
11. publishing on the ANMDMR website the summary of public assessment reports submitted by the organisational structures;
12. organising working meetings and scientific events in the field of medicinal products for human use, medical devices and medical technologies assessment;
13. organizing the reception/sending of delegations, according to protocol rules, as well as the reception and accompanying the delegation from abroad, regarding activities in the field of medicinal products for human use, medical devices and medical technologies assessment;
14. providing, within the legal term, responses to the notices of the Ministry of Health, other public authorities and institutions, to petitions, as well as to requests for information of public interest, other than those provided for in Art. 35 point 4 letter b), through the authorised organisational structure;
15. participation with scientific papers, at the request of the ANMDMR management, in scientific events organised in Romania by various bodies in the pharmaceutical and medical field;
16. participation, through representatives nominated by the ANMDMR management, in committees within the ANMDMR, in meetings of various working groups of public authorities and institutions, as well as in meetings of other European bodies competent in the field of medicinal product for human use and medical devices;
17. ensuring professional training of personnel through internal/external training, participation in advanced training and specialisation courses, experience exchanges, participation in national and international scientific events in the field of the medicinal product for human use and medical devices;
18. professional collaboration with all organisational structures of the ANMDMR;
19. fulfils any other duties established by the ANMDMR management.

Art. 37 - The Directorate for Economy and Public Procurement is directly subordinated to the vice-president of the ANMDMR with responsibilities regarding technical-administrative activities, supporting specific scientific activities, is led by a director, has in its service the Budget, Finance and Accounting Service and the Bureau for Public Procurement and Protocol, and has the following duties:
1. organising accounting in line with legal provisions and ensuring a correct and timely execution of records;

2. timely preparing financial and accounting reports, in line with legal provisions;
3. verifying the supporting documents which form the basis of accounting records;
4. ensuring compliance with the legislation regarding collection and payment operations;
5. preparing and updating the calculation methodology for the tariffs related to the activities carried out by the ANMDMR and submitting it to the approval of the ANMDMR management;
6. centralising tariffs prepared according to the calculation methodology and proposed by the organisational structures within the ANMDMR, to be charged for the services provided by the ANMDMR and submitting them for approval to the Administration Council;
7. preparing the annual draft expenditure budget, the list of investments based on the data presented by the organisational structures and submitting them for approval to the chief credit ordinator;
8. drafting and updating standard operating procedures specific to the department and collaborating in view of drafting common procedures with other organisational structures;
9. proposing the necessary measures for avoiding uneconomic and inappropriate expenses;
10. verifying the application by all organisational structures of the legal provisions in force regarding the commitment, liquidation, authorisation and payment of expenses of public institutions;
11. drafting the individual budget commitment/proposal to commit an expense for the commitment of occasional expenses related to the organisational structure;
12. drafting the payment authorisation form for occasional purchases specific to the organisational structure;
13. verifying the financial and accounting documents attached to the payment authorisations, including the invoices which must bear the "Payment voucher" visa;
14. participating in organising the information system of the ANMDMR by entering and processing financial and accounting documents;
15. verifying and ensuring the execution of payments within the limits of approved budget credits;
16. verifying the documents received from organisational structures and third parties, from the viewpoint of compliance with financial and accounting legislation, timeliness, efficiency and economy, which represent the basis for making payments that commit the ANMDMR;
17. monitoring the classification of expenses by budget items, as well as in accordance with the quarterly and annual distribution provided for by the ANMDMR budget;
18. ensuring the administration of databases, through responsible persons, in accordance with the decisions of the president;

19. preparing estimates of expenses for trips abroad;
20. issuing invoices for the services requested and to be paid in lei (authorization/renewal of marketing authorisations for human use medicinal products, variations, control certificates, advertising materials, inspections, clinical trials, rents, etc.);
21. issuing invoices for requested services, which are to be paid in lei (marketing authorisation/renewal of marketing authorisations for medicinal products for human use, variations, control certificates, advertising materials, inspections, clinical trials, rents, regularizations, cancellations, etc.), based on the notices received from specialised organisational structures;
22. following up on the collection of invoices issued in lei and foreign currency and subsequently confirming the existing payment to the professional organisational structures in order to perform the services;
23. keeping records of invoices;
24. entering tariffs in the payment forms submitted by service providers;
25. performing other administrative activities;
26. developing/revising the specific standard operating procedures (PSO) to the activities they carry out, participating in the implementation, maintenance and improvement of the service quality management system;
27. archiving documents;
28. keeping records of receipts and payments in foreign currency;
29. granting advances for travel and household expenses;
30. checking the supporting documents for expenses in terms of form, content and compliance with financial and accounting legislation of the operations and drawing up payment/collection orders to the cashier for the differences which are to be paid/collected;
31. ensuring that payments are made within the limits of the approved budget credits, according to the "Payment Order" form;
32. checking the cash register and the annexed documents;
33. cash receipts and payments (in lei and foreign currency);
34. ensuring that cash receipts and payments are carried out correctly and in accordance with legal provisions;
35. preparing the cash register;
36. cash deposits and withdrawals in/from the Treasury and the BCR;
37. keeping records of documents (BCF) regarding the entry and fuel consumption;
38. keeping records and using special regime forms (cash register, receipts, checks);
39. preparing accounting notes based on documentation received from all organisational structures, including territorial units;
40. keeping records of customers, suppliers, creditors, debtors, other values;
41. preparing the monthly trial balance of synthetic and analytical account sheets, journal, general ledger;

42. keeping records of expenses of organisational structures;

43. drawing up the payment order form for occasional purchases specific to the organisational structure;

44. checking documents (invoices) relating to the administrative activity and the existence of the "Payment voucher" visa;

45. recording the results of the inventory;

46. providing data for the calculation of fees by organisational structures;

47. elaborating the draft of the Annual Public Procurement Programme and the Annex regarding direct purchases, based on the requisition of products, services and works, communicated by the ANMDMR organisational structures through the requisition reports developed, in the last quarter of the current year, regarding the requisitions for the following year;

48. finalises the annual public procurement programme, after approving the revenue and expenditure budget;

49. makes subsequent changes or additions to the annual procurement programme, when the situation requires it, with the approval of the head of the institution and of the Economic and Public Procurement Directorate, according to the purchase requisitions drawn up by ANMDMR structures;

50. organises and completes the public procurement process for products, services and works, according to the legislation in force;

51. fulfils the obligations regarding advertising, as they are provided for in the public procurement legislation;

52. ensures development of the market consultation process, part of the public procurement process, initiating the procurement, by publishing the announcement related to the market consultation in the SEAP/SICAP;

53. publishes advertising announcements in the SEAP/SICAP, in order to award direct purchases;

54. estimating the value of the acquisition and the public procurement contract, matching it with the CPV code;

55. choosing the procedure for awarding public procurement contracts in accordance with legal provisions;

56. consulting the electronic catalogue of products/services/works in order to identify the bidders who have published the products/services/works which meet the needs of the contracting authority;

57. carrying out direct purchases (including from the SICAP Catalogue) based on the reports/substantiation notes prepared by the ANMDMR structures and approved by the ANMDMR management;

58. publishing in the SICAP the invitation for participation/participation notice/award notice for the public procurement procedure depending on the chosen procedure, according to the thresholds established by the public procurement legislation;

59. develops or, as the case may be, coordinates the activity of developing the award documentation and the contracting strategy, in the case of organising

public procurement procedures, based on the needs and specifications submitted by the specialised structures;

60. ensures the information and publication activity for preparation and organization of public procurement procedures (open auction, simplified procedure, etc.), their object, deadlines, as well as other information which will build compliance with the principles underlying the award of public procurement contracts;

61. monitors and ensures compliance with legal provisions when carrying out procedures regarding the confidentiality of documents received from bidders/candidates;

62. proposes the structure of evaluation committees;

63. ensures the application and completion of the award procedures, based on the minutes and reports of the procedures drawn up by evaluation committees, by concluding public procurement contracts;

64. ensures the establishment and preservation of the procurement file, a public document;

65. prepares and transmits the ascertaining documents to economic operators and institutions which regulate public procurement;

66. prepares any other works provided for by the financial-accounting legislation and by the public procurement legislation;

67. takes the necessary steps for accommodation, medical insurance and purchase of airline tickets for internal and external routes necessary for performance of the activities in which the institution is involved, as well as for the travel of the institution's staff, according to legal provisions in force;

68. duties related to performance of logistics and protocol activities (supply of goods and services) necessary for performance of the ANMDMR activity;

69. providing, within the legal term, responses to the notices of the Ministry of Health, other public authorities and institutions, to petitions, as well as to requests for information of public interest, through the authorised organisational structure;

70. participation, through representatives nominated by the ANMDMR management, in committees within the ANMDMR, in meetings of various working groups of public authorities and institutions, as well as in meetings of other European bodies competent in the field of economy and public procurement;

71. ensuring professional training of personnel through internal/external training, participation in advanced training and specialisation courses, experience exchanges, participation in national and international scientific events in the field of economy and public procurement;

72. professional collaboration with all organisational structures of the ANMDMR;

73. fulfils any other duties established by the ANMDMR management.

Art. 38 - The Directorate for General Administration and External Financial Assistance is directly subordinated to the vice-president of the ANMDMR with responsibilities regarding technical-administrative activities, supporting specific scientific activities, is led by a director, has in its service the Administrative and Heritage Compartment, and has the following duties:
1. maintenance of the ANMDMR infrastructure, which includes: buildings, workspaces and associated utilities, as well as certain equipment necessary for the processes carried out within the institution;
2. organising and ensuring support services (courier, telephone communication, cleaning, security) necessary for the activities carried out within the organisation;
3. ensuring organisation of security activities in the ANMDMR;
4. ensuring organisation of cleaning activities in the ANMDMR;
5. ensuring performance of current repair works;
6. determining the need for repair, maintenance, construction materials, etc. for the work carried out with own personnel;
7. ensuring vehicle transport for the organisation;
8. ensuring vehicle fleet maintenance;
9. drawing up route sheets, daily activity sheets (FAZ), etc.;
10. monitoring compliance with standard fuel consumption;
11. monitoring the validity of permits for pressure vessels;
12. ensuring the procurement of services for mandatory metrological verifications;
13. maintaining and preserving the ANMDMR heritage;
14. managing and keeping up to date the records of the ANMDMR heritage (constructions and land), according to legal provisions in force;
15. requesting and analysing property and cadastre documents for the assets administered by the ANMDMR and taking steps to register the properties in the land registry;
16. initiates draft Government decisions on updating the situation and identification data of real estate assets which are part of the state's public domain and which are administered by the ANMDMR;
17. prepares approval reports for the ANMDMR President regarding the legal action by the Directorate for Legal, European Affairs and International Relations in order to establish/re-establish the Romanian state's ownership right over their real estate assets that are in the state's public domain and under the administration of ANMDMR, as well as to clarify their legal situation;
18. monitors and updates Annex No. 15 to Government Decision No. 1,705/2006 on the approval of the centralized inventory of assets in the state's public domain, with subsequent amendments and completions or the legislation in force;
19. completing the necessary forms in order to make payments to ANMDMR suppliers;
20. qualitative and quantitative reception of purchased products, services and works;

21. drawing up and monitoring the implementation of space rental contracts for territorial inspection units (UTI) and utility contracts;
22. drawing up global budget commitment forms, individual budget commitments, expenditure commitment proposals and payment orders in order to make payments related to ongoing or completed contracts/procurements;
23. centralising and managing the operational records of fixed assets, inventory items, and other goods within the ANMDMR;
24. releasing purchased products to internal customers, namely the requesting organisational structures within the ANMDMR;
25. maintaining and updating the warehouse database, regarding existing material stocks, in written and electronic form;
26. updating the authorisations needed to carry out activities within the ANMDMR;
27. coordinates projects financed from external reimbursable or non-reimbursable funds;
28. identifies financial assistance programmes granted by the European Union;
29. collaborates with managing authorities and intermediate bodies which coordinate and ensure financial assistance from non-reimbursable funds;
30. identifies financing sources, develops project proposals and requests approval of financial services regarding external credits;
31. undertakes the steps required by the programming exercise, in order to ensure the eligibility of the proposed projects;
32. prepares documents subsequent to the approval of project proposals;
33. supervises the fulfilment by service providers and product suppliers of the obligations assumed under the contracts for the projects;
34. plans and is responsible for organising the activities approved by the projects, under optimal conditions;
35. prepares periodic reporting documents on the status of project implementation, project monitoring and assessment reports, according to procedures;
36. ensures the exchange of information related to the technical aspects of project implementation with partners;
37. ensures liaison with other beneficiary institutions and participates in inter-institutional meetings on issues of common interest for externally financed projects;
38. ensures participation in meetings related to the financial assistance activity for externally financed projects, organised at the level of the ANMDMR management;
39. develops budget proposals for projects with non-reimbursable external financing, proposals for distribution of sums, on a quarterly basis, related to budgetary projects and proposals for the opening of budgetary credits;

40. prepares documents regarding the commitment, liquidation and ordering of expenses strictly related to the activities provided for in the calendar of projects under implementation;
41. monitors the implementation of loan agreements and repayable financial assistance agreements, from beginning to completion of the financed projects and the full repayment of the contracted loans;
42. requests the Economic and Public Procurement Department to include in the ANMDMR budget the sums allocated to co-financing of projects financed from non-reimbursable funds;
43. coordinates the integrated project management in line with the provisions of the financing agreement, aiming to achieve the project objectives with maximum diligence and efficiency;
44. providing, within the legal term, responses to the notices of the Ministry of Health, other public authorities and institutions, to petitions, as well as to requests for information of public interest, through the authorised organisational structure;
45. participation, through representatives nominated by the ANMDMR management, in committees within the ANMDMR, in meetings of various working groups of public authorities and institutions;
46. ensuring professional training of personnel through internal/external training, participation in advanced training and specialisation courses, experience exchanges;
47. professional collaboration with all organisational structures of the ANMDMR;
48. fulfils any other duties established by the ANMDMR management.

Art. 39 - The Information and Communication Technology Service is directly subordinated to the Vice-President of the ANMDMR with responsibilities regarding technical-administrative activities which support specific scientific activities, is led by a head of service, has in its service the Bureau for Development of Information and Communication Technology projects, infrastructure and technical support and the Design and Webpages Compartment and has the following duties:
1. ensuring IT activities within the ANMDMR;
2. developing IT projects at ANMDMR level;
3. developing software and applications at ANMDMR level;
4. managing servers and the ANMDMR network;
5. designing and managing databases;
6. maintaining and updating ANMDMR's internet/intranet webpages;
7. providing hardware and software service for computing equipment in the ANMDMR network;
8. ensuring software service for peripherals in the ANMDMR network;
9. ensuring antivirus and anti-spam protection of the ANMDMR computer network;
10. ensuring the maintenance of ANMDMR in the EudraNet and CTS networks;

11. ensuring connectivity to the Common Repository database (centralised procedures);
12. ensuring connectivity to the CESP (Common European Submission Platform) database;
13. administration/updating of the database with the experts designated in relation to EMA - Experts Database;
14. administration/updating of the EU Network Training Centre - Learning Management System platform, having the role of local administrator;
15. administration/updating of the "IRIS Competent Authority Users" within the EMA Account Management Portal, having the role of local administrator;
16. ensuring the activities of taking over and posting of sponsorship declarations, according to the legal provisions in force;
17. informing and guiding ANMDMR personnel in order to make appropriate use of the provided IT equipment;
18. participation, through representatives nominated by the ANMDMR management, in committees within the ANMDMR, in meetings of various working groups of public authorities and institutions, as well as in meetings of other European bodies competent in the field of the information and communication technologies;
19. ensuring professional training of personnel through internal/external training, participation in advanced training and specialisation courses, experience exchanges, participation in national and international scientific events in the field of the information and communication technologies;
20. professional collaboration with all organisational structures of the ANMDMR;
21. fulfils any other duties established by the ANMDMR management.

Art. 40 - The Compartment for Critical National Infrastructures is directly subordinated to the Vice-President of the ANMDMR with responsibilities regarding technical-administrative activities which support specific scientific activities, is led by the Vice-President and has the following duties:

1. represents the point of contact of the owner/operator/administrator of national/European critical infrastructure in relation to the responsible public authority (Ministry of Health), with the Critical Infrastructure Protection Coordination Centre, as well as other structures with which it has an interdependent relationship, for issues related to critical infrastructures security;
2. develops and/or updates the risk analysis and identifies vulnerable points regarding the national/European critical infrastructure under its responsibility or proposes the initiation of steps, under the terms of the law, for designation of a certified natural/legal person to perform these activities;
3. develops threat scenarios for national/European critical infrastructure under its responsibility;

4. is responsible for periodically updating the documents developed at the level of the specialised structure of the owner/operator/administrator of the national/European critical infrastructure;

5. is responsible for updating the database related to the national communication mechanism in the field of critical infrastructure protection, regarding the risks, threats and vulnerabilities identified for the national/European critical infrastructure under its responsibility;

6. ensures permanent monitoring of the evolution of the situation regarding risks, threats and vulnerabilities to the national/European critical infrastructure under its responsibility;

7. dynamically informs the responsible public authorities and other interdependent structures on the evolution of risks, threats and vulnerabilities to the national/European critical infrastructure;

8. proposes immediate measures in the event of risks to the national/European critical infrastructure under its responsibility;

9. participates, at the request of the responsible public authority, in the process of establishing critical criteria and thresholds for the national/European critical infrastructure under its responsibility;

10. is responsible for the evaluation, testing and, where appropriate, update and revision of the PSO, within the deadlines established by the legislation in force;

11. organises and manages the specific exercises and activities on the occasion of testing the PSO or equivalent documents;

12. ensures the preparation and submission to the responsible public authority, for approval, of the PSO developed at the level of the specialised structure of the owner/operator/administrator of the national/European critical infrastructure;

13. plans and ensures, in accordance with the law, the participation of subordinate personnel in specialised training activities;

14. ensures preparation/transmission of classified documents related to the national/European critical infrastructure in the area of responsibility, ensuring compliance with legal provisions regarding access to classified documents;

15. permanently monitors the fulfilment of the obligations provided for by the national legislation in the field.;

16. develops and submits to the approval of the President of the ANMDMR the internal rules regarding the protection of classified information, according to the law;

17. ensures the preparation of the Programme for prevention of the leakage of classified information, as well as the Security Plan;

18. coordinates the protection of classified information, in all its components;

19. ensures the relationship with the Romanian Intelligence Service, the National Registry Office for Classified Information (ORNISS) and the Security

Structure of the Ministry of Health for implementation within the institution of measures related to classified information, according to the law;
20. ensures, through the designated Head of the Security Structure of the ANMDMR, the counselling of the ANMDMR President, in relation to all aspects regarding the field of classified information;

21. ensures monitoring of the activity of applying the rules for protection of classified information and the manner of their compliance at ANMDMR level;

22. ensures preservation and organises the records of security certificates and authorisations for access to classified information;

23. permanently updates the records of security certificates and authorisations for access to classified information;

24. submits to the President of the ANMDMR proposals regarding the establishment of objectives, sectors and places of particular importance for the protection of classified information within the sphere of responsibility and, as appropriate, requests support of competent institutions;

25. develops the Specific Plan for training of personnel requiring access to classified information;

26. ensures the necessary measures for recording and preserving classified information;

27. draws up the minutes related to destruction of classified information and, subsequently, ensures their physical destruction;

28. ensures, through the personnel authorised in this regard, the delivery-reception of classified correspondence, between the institution and the specialised unit of the Romanian Intelligence Service;

29. ensures the annual inventory of classified documents and, according to it, proposes measures accordingly, in line with the law;

30. draws up and updates the lists of positions and persons requiring access to information classified as State Secret and Service Secret;

31. makes available to the persons for whom the issuance of the security certificate/authorisation for access to classified information is requested, the standard forms corresponding to the level to which they are to have access, and prepares the requests according to the provisions of Government Decision no. 585/2002 on approval of the National Standards for the protection of classified information in Romania, as further amended, and sends them, together with the standard forms, to the institutions authorised to carry out the checks in view of approval of issuance of the security certificate/the authorisation for access to classified information;

32. keeps records of the holders of security certificates and authorisations for access to classified information;

33. participation, through representatives nominated by the ANMDMR management, in committees within the ANMDMR, in meetings of various working groups of public authorities and institutions, as well as in meetings of other European bodies competent in the field of classified information;

34. ensuring professional training of personnel through internal/external training, participation in advanced training and specialisation courses, experience exchanges, participation in national and international scientific events in the field of classified information;

35. professional collaboration with all organisational structures of the ANMDMR;

36. fulfils any other duties established by the ANMDMR management.

Art. 41 - The Prevention and Protection Compartment is directly subordinated to the Vice-President of the ANMDMR with responsibilities regarding technical-administrative activities which support specific scientific activities, is led by the Vice-President and has the following duties:

1. identifying hazards and assessing risks for each component of the work system, namely the performer, work task, work tools/work equipment and the work environment at workplaces/work stations;

2. developing and updating the prevention and protection plan;

3. developing its own instructions for supplementing and/or applying occupational health and safety regulations, taking into account the particularities of the activities and the unit/enterprise, as well as the workplaces/work stations;

4. proposing the duties and responsibilities related to occupational health and safety of the employees, corresponding to their jobs, which are mentioned in the job description, with the approval of the employer;

5. verifying the knowledge and application by all employees of the measures provided for in the prevention and protection plan, as well as the duties and responsibilities given to them, in the field of occupational health and safety, established by the job description;

6. drawing up the necessary technical documentation for informing and training employees in the field of occupational health and safety;

7. developing the topic for all training phases, establishing the appropriate periodicity for each workplace, ensuring the information and training of employees in the field of occupational health and safety and verifying the knowledge and application by employees of the information received;

8. developing the training-testing programme within the enterprise and/or unit;

9. ensuring the preparation of the action plan in case of serious and imminent danger, according to the Occupational Health and Safety Law;

10. highlighting the high and specific risk areas provided for in the Methodological Rules for application of the provisions of the occupational safety and health law;

11. establishing the areas requiring the signalling of occupational safety and health issues, establishing the signalling type required and its location, according to legal provisions;

12. highlighting the professions provided for by specific legislation for which an authorisation for performance is required;

13. highlighting the work positions which require additional medical examinations;

14. highlighting the jobs that, upon recommendation of the occupational physician, require aptitude testing and/or periodic psychological control;

15. informing the employer, in writing, of the deficiencies found during the checks carried out at the workplace and proposing prevention and protection measures;

16. drawing up the reports and/or lists provided for by the Rules issued in application of Law on Occupational Safety and Health No. 319/2006, as further amended and supplemented, including those relating to asbestos, vibrations, noise and temporary and mobile construction sites;

17. identifying work equipment and ensuring that periodic checks and, where appropriate, periodic tests of work equipment are carried out by competent persons, in accordance with the provisions on the minimum safety and health requirements for use of work equipment by employees;

18. identifying individual protective equipment required for the work positions in the unit and drawing up the necessary equipment for equipping employees with individual protective equipment, in line with the provisions on the minimum safety and health requirements for use of individual protective equipment by employees at the workplace;

19. monitoring the maintenance, handling and adequate storage of the individual protective equipment and their replacement within the established deadlines, as well as in other situations provided for by the rules in force;

20. participating in the investigation of events according to the competences provided for in the Methodological Rules for the application of the provisions of the Law on Occupational Safety and Health No. 319/2006, as subsequently amended and supplemented;

21. drawing up records according to the competences provided for in the Methodological Rules for the application of the provisions of the Law on Occupational Safety and Health No. 319/2006, as further amended and supplemented;

22. preparing reports on work accidents suffered by employees in the enterprise and/or unit, in line with the provisions of the Law on Occupational Safety and Health No. 319/2006, as further amended and supplemented;

23. monitoring the implementation of measures ordered by labour inspectors, during inspection visits and investigation of events;

24. collaborating with employees and/or employees' representatives, the occupational physician, in order to coordinate prevention and protection measures;

25. collaboration with appointed employees/internal structures and/or competent external authorities, in the event that several employers carry out their activity in the same workplace;

26. monitoring the update of the protection and prevention plan;

27. proposing sanctions and incentives for employees, based on fulfilment of duties in the field of occupational safety and health;

28. proposing clauses regarding occupational safety and health when concluding service contracts with other employers, including those concluded with foreign employers;

29. coordinates the activity in the field of emergency situations;

30. participates in the development and implementation of the fire protection concept at the level of ANMDMR;

31. controls the implementation of fire protection and civil protection rules;

32. guides and controls the activity of fire protection and civil protection;

33. participates in training sessions planned and organised by the ANMDMR;

34. draws up PSI provisions;

35. monitors the implementation of measures following fire prevention controls and inspections;

36. controls the application of legal provisions for fire protection and civil protection within the ANMDMR;

37. prepares the documents necessary for carrying out exercises in the field of emergency situations, participates in and keeps records of them;

38. proposes the conclusion of protocols on the line of emergency situations;

39. executes the duties provided for in the laws, regulations and instructions in force in the field of occupational safety and health, emergency situations - PSI and emergency situations - civil protection;

40. participation, through representatives nominated by the ANMDMR management, in committees within the ANMDMR, in meetings of various working groups of public authorities and institutions, as well as in meetings of other European bodies competent in the field of occupational health and safety, emergency situations - PSI and emergency situations - civil protection;

41. ensuring professional training of personnel through internal/external training, participation in advanced training and specialisation courses, experience exchanges;

42. professional collaboration with all organisational structures of the ANMDMR;

43. fulfils any other duties established by the ANMDMR management.

CHAPTER V
Funding

Art. 42 - (1) ANMDMR funding is from its personal revenues as resulting from the collection of the fees established in line with the legislation in force, and a subsidy granted from the state budget.

(2) In line with the provisions of Art. 17 paragraph (2) first sentence of Law no. 134/2019, as further amended and supplemented, the ANMDMR charges fees for the activities carried out according to the conferred attributions. Revenues obtained from tariffs collected in relation to conduct of its specific activities represent the ANMDMR's personal revenues.

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

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

Cap. VI
Final provisions

Art. 43 - The provisions of this Regulation are supplemented with any other legal provisions regarding the organisation and operation of the ANMDMR, as well as its attributions.

Art. 44 - The heads of the structures of the ANMDMR are obliged to ensure that subordinate personnel are aware of and understand this Regulation.

Art. 45 - The ANMDMR personnel is obliged to perform other tasks related to their job duties, according to the regulations in force, this Regulation and the job description of each employee.