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ACTIVITY REPORT OF THE NATIONAL AGENCY FOR MEDICINES AND MEDICAL DEVICES OF ROMANIA (NAMMDR)

2021

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I. ORGANISATIONAL PROFILE

I.1. FOREWORD OF THE PRESIDENT OF THE NATIONAL AGENCY FOR MEDICINES AND MEDICAL DEVICES OF ROMANIA (NAMMDR)

The National Agency for Medicines and Medical Devices of Romania, a strategic institution with a major role in facilitating Romanian patients' access to medicinal products and medical devices, continued in 2021 to respond to the challenges imposed by the pandemic context.

Greater attention was thus paid to all categories of patients, regardless of diagnosis, in compliance with the regulations in force regarding the provision of safe and effective medicinal products, as well as medical devices, for the benefit of the population.

As an institution responsible for ensuring compliance with European standards for medicinal products with a marketing authorisation, as well as for ensuring effectiveness and a certain degree of safety for medicinal products for human use, the NAMMDR has adapted its protocols and activity flows to address the demands imposed by the pandemic as soon as possible.

The dynamic epidemiological context generated by the pandemic required proactive communication with healthcare professionals, the media, patients, the general public and more, by facilitating applicants' access to information concerning medicinal products included in the protocols for the treatment of SARS-CoV- 2, vaccines authorised by the European Medicines Agency (EMA), adverse reactions, as well as devices used by healthcare professionals.

The agency organised working meetings to address issues raised by both patients and representatives of the pharmaceutical and medical device industry. The preparation of the institutional framework and the necessary measures for the implementation of Regulation (EU) no. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, through participation of NAMMDR representatives in the working group for elaboration of the framework for the application of Regulation (EU) no. 536/2014, at regular meetings with the representatives of the National Commission on Bioethics of Medicinal Products and Medical Devices and the Ministry of Health to prepare the implementation of this Regulation applicable from 31.01.2022 and the Clinical Trial Information System for clinical studies (CTIS) through which the sponsors can submit application dossiers in order to issue authorisations for interventional clinical trials in order to conduct interventional clinical trials in several EU member states. The draft regulatory document developed by the working group was adopted through Government Emergency Ordinance no. 29/2022.

Moreover, in order to ensure compliance with the obligation of Romania to adopt the necessary measures for application of Regulation (EU) 2017/745 of the European Parliament and of the Council

of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, to ensure the safeguard of patient health and safety, the NAMMDR developed a draft regulatory document for implementation of the Regulation, which was adopted by Government Emergency Ordinance no. 46/2021.

The experts of the Pharmacovigilance and Risk management Directorate (DFVMR) also had an important role in carrying on the management (monitoring and transmission), at national level, of undesirable post-vaccination adverse reactions (RAPI), received directly by the NAMMDR, according to the protocol in force.

Despite the challenges of 2021 and the priorities imposed by the pandemic, the NAMMDR has also made important progress in the field of Health Technology Assessment, by significantly reducing the time required for dossier assessment.

In order to solve the shortage of staff, the NAMMDR posted several jobs, in order to make the institution's activity more efficient.

2022 is a year full of challenges, but also of opportunities, in which we aim to give the Agency back the recognition it once enjoyed, positioning it, through the professional activity of its experts and efficient management, as an institution of strategic interest within the system of Romanian health.

Răzvan Mihai Prisada,
NAMMDR President since March 2022

I.2. NAMMDR MISSION AND RESPONSIBILITIES

The National Agency for Medicines and Medical Devices of Romania is a public institution operating as a legal entity, a specialized body of the central public administration in the field of medicinal products for human use, medical devices and assessment of medical technologies, subordinated to the Ministry of Health, which operated in 2021 in accordance with the provisions of Law no. 134/2019 on reorganisation of the National Agency for Medicines and Medical Devices and amendment of further ruling provisions and with the provisions of Order of the Minister of Health no. no. 1.522/2019 for the approval of the Regulation for the Organisation and Operation of the National Agency of Medicines and Medical Devices of Romania.

The NAMMDR mission is to help protect and promote public health by:

- Evaluation of the highest scientific competence of documentation for authorisation in view of marketing high quality, safe and effective medicinal products for human use;
- evaluation of the documentation for authorisation of clinical trials in Romania and of the units where those trials are conducted;
- medical technologies assessment, according to scientific criteria adopted through the legislation in force for inclusion/non-inclusion/maintenance/exclusion from the List (mentioned in the Annex to Government Decision no. 720 of 9 July 2008) 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 programmes;
- Surveillance of the safety of medicinal products for human use in therapeutic use by means of inspection and pharmacovigilance activities;
- Ensuring access for the pharmaceutical industry, patients and healthcare professionals to useful and accurate information on medicinal products for human use authorised for marketing in Romania;
- Setup of regulations and rules in the field of the medicinal product for human use, medical technologies assessment and medical devices, subject to the approval of the Minister of Health;
- Maintenance of a high level of performance and safety of medical devices in use by healthcare networks throughout the country, irrespective of ownership;

- Exigent assessment of technical – medical units dealing with medical devices, so that any type of stenting or fixing and maintenance services for medical devices can be performed at optimal quality and competence level;
- Issuing specific technical procedures in the field of medical devices;
- Ensuring institutional administrative effectiveness, efficiency and transparency of practices and procedures in use.

I.3. THE CONTRIBUTION BROUGHT TO THE GOVERNMENT'S OBJECTIVES AND TO THE OBJECTIVES ASSUMED BY ROMANIA

In 2021, the NAMMDR, in line with government policies and national strategies, implemented several measures in the healthcare field which aimed, among others: authorisation of essential medicinal products and medical devices; temporary prohibition, according to Order of the Minister of Health, of the distribution outside Romania of medicinal products, medical devices and sanitary materials needed for prevention and treatment of health issues associated with COVID-19; ongoing monitoring of adverse reactions following vaccination by encouraging the reporting of post-immunisation adverse reactions, in order to enable rapid identification of new medicinal product safety information.

The particular emphasis placed on the situation generated by the pandemic, on the facilitation of specific medication for COVID-19, have required a quick pace from the institution's specialists who, through common and efficiently managed effort, focused on the entire therapeutic area requested by Romanian patients, ensuring by issuing authorisations or assessment of some medicinal products, the specific treatment for various diagnostic categories (e.g. oncological, diabetes, cardiac).

Thus, in 2021, the NAMMDR issued 601 marketing authorisations (APP), of which 555 authorizations through European Procedure (EP), and 46 through National Procedure (NP). At the same time, in line with the specific legislation in force, 127 authorisations for special needs (ASNs) and 30 authorisations for parallel import (parallel import authorisations - PIAs) were issued. Also, in order to ensure the access of Romanian patients to innovative therapies, in 2021, 113 new molecules (international non-proprietary names – INNs) were approved which followed the procedural path in order to be included in the List of the Annex to Government Decision no. 720/2008 regarding compensated medicinal products.

Active participation in the meetings of the scientific committees and working groups of the EMA and other European bodies in the field of medicinal products and medical devices contributed to the immediate transposition, at national level, of the assimilated information, thus ensuring the general

public's real-time access to scientific information of vital interest, on the special sections of the NAMMDR website created for this purpose, such as: Important notifications - COVID-19 / Press releases; COVID-19 Clinical Trials Information; RO-Vaccinare (COVID-19 vaccination in Romania); Report an adverse reaction (related to COVID-19 vaccines); COVID-19 medication; COVID-19 tests.

Patients, patient associations, healthcare professionals, governmental and non-governmental organisations continued to request various information from the NAMMDR in 2021, according to Law no. 544/2001 on free access to public information, all of which have been resolved in compliance with the legislation in force. Also, 874 notifications were received on the e-mail address lipsamedicament@anm.ro, setup upon request of the Ministry of Health in February 2015, the NAMMDR providing timely replies to all requests.

The agency, as the basic institution of the Romanian healthcare system, participated through its specialists in debates and meetings with representatives of companies, patients, and professional societies, and the activity carried out for the benefit of Romanian patients was promoted on a permanent basis through interviews and articles published in specialised magazines.

In recent years, the NAMMDR has been increasingly involved in the testing of medicinal products authorized centrally or through European procedures, in standardisation studies of reference substances used in European laboratories.

With regard to its legislative activity, in 2021, the NAMMDR developed the draft regulatory documents needed in order to achieve the objectives in its field of activity, which were submitted for approval to the Ministry of Health, thus amending and/or supplementing the legislation specific to the institution's activity.

II. ACTIVITY OF THE NAMMDR SCIENTIFIC COUNCIL (SC)

In 2021, the NAMMDR communicated to the Ministry of Health proposals for amendment of Law no. 134/2019, namely for correction of the existing legislative inadvertence in the content of Article 11 paragraph (1). Thus, in August 2021, Law no. 134/2019 on reorganisation of the National Agency for Medicines and Medical Devices and amendment of further ruling provisions, was amended, and the aspects related to the constitution and training of the Scientific Council were clarified through amendment of Article 11 paragraph (1) and paragraph (2) of the mentioned law. In this context, in October 2021, the Order on setup of the Scientific Council was issued, however the changes in the management structure of the agency did not provide the opportunity for the Council to meet.

III. ACTIVITY OF THE ADMINISTRATION COUNCIL (AC)

In 2021, there were 5 meetings of the Administration Council of the NAMMDR, focused mainly on establishing appropriate administrative measures in order to apply the provisions of Law no. 134/2019, as further amended and supplemented.

IV. ACTIVITY OF NAMMDR COMMISSIONS

IV.1 NAMMDR Marketing authorisation commission

In 2021, 17 meetings were organised, during which a number of 588 applications for authorisation were discussed:

– 19 applications for marketing authorisation through national procedure;

– 19 applications for marketing authorisation through national procedure – parallel import;

– 548 applications for marketing authorisation through European procedures.

601 marketing authorisations (MAs) and Annexes 1, 2, 3, 4, 5 were issued, of which 555 were related to the European procedures and 46 to the national procedure.

IV.2 Commission for assessment and authorisation of medicinal products used for special needs

127 authorisations were granted for medicinal products for special needs.

IV.3 Commission for assessment and authorisation of the use of a medicinal product used in last-resort treatments

In 2021, the Commission for assessment and authorisation of the use of a medicinal product used in last-resort treatments has completed:

– 14 assessment reports for the authorisation of 14 medicinal products used as last resort treatment;

– 10 assessment reports for renewal of authorisations of 10 medicinal products used as last resort treatment;

– 9 assessment reports for changes to the terms of authorisation of 9 medicinal products used as last resort treatment.

V. ACTIVITY OF SPECIFIC SCIENTIFIC AND TECHNICAL-ADMINISTRATIVE STRUCTURES

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V.1 MARKETING AUTHORISATION AND RELATED ACTIVITIES

In 2021, the main activities of the Agency, mainly the assessment of the documentation submitted to the NAMMDR for marketing authorisation and marketing authorisation renewal, as well as post-authorisation surveillance of a medicinal product's safety, have been commendably performed, as imposed by high complexity standards, established through an increasingly severe European Union legislation in the field of the medicinal product for human use. These activities are specific to a competent authority in the field of the medicinal product, carried out in accordance with legal provisions on national procedure and European procedures (mutual recognition/decentralised/repeat-use mutual recognition procedure, centralised procedure).

In the past year, the specific activities carried out within the European Procedures Department (DPE) and the National Procedure Department (DPN) materialised in the release of Marketing Authorisations and Annexes 1, 2, 3, 4 and 5 - for 601 medicinal products of which 555 - European Procedures and 46 - National Procedure;

The following have been released:

- Authorisations for special needs for 127 medicinal products;
- Parallel import authorisations for 30 medicinal products;
- Authorisations for use of a medicinal product in last resort treatments:
  - Issuance of minutes for authorisations for use of a medicinal product in last resort treatments - 27 minutes;
  - Issuance of the authorisation for use of a medicinal product in last resort treatments – 14 authorisations;
  - Issuance of the renewal of the authorisation for use of a medicinal product in last resort treatments – 10 Renewals;
  - Issuance of changes to issued authorisations/renewals – 9 changes;
- 245 Certificates in Who format.

V.1.1 MARKETING AUTHORISATION THROUGH NATIONAL AND EUROPEAN PROCEDURES

A. **The National Procedure Administration Service (SAPN)**

Within the SAPN, the diversity of issues involves a variety of activities structured and presented as follows:

➢ Registration/Evaluation of applications for authorization/renewal specific to the National Procedure Administration Service:

– monitoring the registration into the SAPN database, examining the applications for authorisation/renewal of authorisation and checking the tariff form - 56

– monitoring the download of the CDs or CESPs on the Server, in created folders, of the documentation related to authorisation/renewal of authorisation applications – 56

– verification of the transmission of informative e-mails to the colleagues involved in the assessment of the documentation related to authorisation/renewal of authorisation - 56

– monitoring/receiving addresses after being signed, downloading them to the Server in the folder related to the „medicinal product" – 114

– verification of the download of the supplementary documentation on the romsys server for the files under evaluation submitted in view of authorisation/renewal of authorisation – 291

– signing and verifying notification addresses to assessors - 211

– signing and verifying addresses with post-marketing authorisation application – 99

– signing and verifying requests (from reports sent by assessors) – 238

– signing and verifying reports with requests to companies – 166

– monitoring and completion of the files submitted for authorisation/renewal of authorisation with documentation – 47

– verification and preparation of files for the Commission for Marketing Authorisation (CAPP) meeting – 19

– signing and verification by companies/petitioners upon request of hierarchical leaders – 132

– monitoring the downloading of documentation for Authorisations for Special Needs (ANS) – 156

– monitoring the downloading of documentation for waiver from labelling – 241

– distribution notifications, database management included – 107

– signing and verifying the replies sent to companies – 132

– checking/updating electronic databases with additions, notifications concerning medicinal product discontinuation;

– allocation for downloading received CDs or e-mails containing information about medicinal products under evaluation

– verification of the preparation of authorisations / renewal of authorisation files: 47 files (21 for authorisations – validated from 2018-2021, 26 for Renewals of authorisations – validated from 2020-2021)

– monitoring of the "ASMF" (Active Substance Master File) database, which includes the active substances for medicinal products authorised or submitted for authorisation/renewal of authorisation through national and European procedures

– daily distribution of all documents related to the active substance (ASMF) and registration of the documents submitted by the applicant within the Registry Service =1008

– taking over in order to manage the "Nitrosamine" database with the download of the documents (received from applicants) to the Server and inclusion of data related to nitrosamines in the Excel register = 290

– permanent update of the databases and files under evaluation.

Parallel import

➢ Verification and signing of applications for authorisation/variation specific to the National Procedure Administration Service:

– Monitoring of the registration into the SAPN database, examination of the applications for authorisation/variation and verification of the tariff form = 191

Verification and signing of the variations to the parallel import authorisation, with the preparation of the documents for approval of the request for variation to the AIP:

– Solved applications for variation (approval addresses) = 163

– Solved applications for variation (Annexes to approval addresses) = 163

– Changes to parallel import authorisations - AIP (following approval of variations) = 150

– Update of Annexes to AIP (PRO, RCP, AMB) = 150

– Preparation and technical editing of addresses for tariff regularisation to the DE – 6

– Preparation and technical editing of the list of documents = 49

– Verification and signing of export sheet requests: follow-up of e-mails sent to European agencies, containing sheets with information related to parallel export = 376

SAPN ACTIVITY - 2021								
Applications for authorisation		Applications for renewal		Applications for AIP variations		Applications for AIP authorisation		Export sheets
26		**31**		**155**		**24**		**376**
Validated	Requests	Validated	Requests	Approved	In progress	Approved	In progress	
21	**5**	**26**	**5**	**155**	**0**	**24**	**0**	

B. The National Procedure Assessment Service (SEPN)

The SEPN has 3 compartments: the quality compartment, the clinical efficiency and non-clinical safety compartment and the medicinal product information compartment.

Numerical quantification for the activities performed by the SEPN in 2021:

1. Authorisation of quality reports (initial reports) - 31
2. Completion reports -75
3. ASMF authorisation (initial report) - 15
4. ASMF authorisation (completion) - 2
5. Authorization of Clinical effectiveness / safety authorisation report (initial report)-26
6. Efficacy report / clinical safety authorisation (completion report)-6
7. Authorisation of non-clinical safety reports (initial report)-21
8. Authorisation of non-clinical safety reports (completion report)-13
9. Authorisation of Evaluation Reports - information from Annexes - 25
10. Verification/correction of authorisation annexes - 56
11. ASMF (initial report, Type II variation)-33
12. ASMF (completion)-13
13. ASMF (initial report - Type IB grouped variations)-10
14. ASMF (completion report - Type IB grouped variations)-0
15. Quality report – MA renewal (initial report)-50
16. Quality report – MA renewal (completion)-39
17. Assessment report – MA renewal (information from Annexes)-10
18. Verification/correction of MA renewal (Annexes)-140
19. Quality reports of bioequivalence study protocols (initial)-32
20. Quality reports of bioequivalence study protocols (completion)-11
21. Reports of clinical protocols of bioequivalence studies (initial)-17
22. Reports of clinical protocols of bioequivalence studies (completion)-0
23. Update of the bioequivalence study protocol databases - 34
24. Draft of notifications/issuance of approval of bioequivalence studies protocols -79
25. Assessment report – ANS (authorisation for special needs) - patient-75
26. Assessment report – ANS (authorisation for special needs) - commission-64
27. Notification for rejection/withdrawal-7
28. ANS extension report -19
29. Notification for approval/rejection of exemption from labelling -246
30. Minister of Health notifications - exemption from labelling - 4
31. Update of the database - exemption-240
32. Update of the database - supply-134
33. Request for authorisation conditions from the competent authority in order to issue AIP (parallel import authorisations) - 41

34. Reporting + issuance of AIP / annexes - 36
35. Tariff regulation -2
36. Assessment of variations-634
37. Checking Databases and Issuing Replies to Quick Alerts/ Quality Non-Compliance/GMP Suspension/CEP/Conditions for Authorisation of AIP-93
38. Replies to notifications related to petitions/other directorates-141

Applications solved by the SEPN in 2021

No.	Activity	Initial reports with requests	Positive initial reports	Reports completed with requests	Positive completed reports
1.	**Authorisation**				
	Quality reports	31	0	61	14
	ASMF reports	14	1	0	2
	Efficacy/clinical safety report	24	2	4	2
	Non-clinical safety report	15	6	10	3
	Evaluation of information from Annexes	0	25	0	0
	Verification/correction of renewal annexes	0	56	0	0
2.	**MA renewal**				
	Quality reports	25	25	17	22
	Evaluation of information from Annexes	10	0	0	0
	Verification/correction of renewal annexes	140	0	0	0
3.	**ASMF variations**				
	ASMF reports - Type II variations	20	13	12	1
	ASMF reports - Type IB grouped variations	0	10	0	0
4.	**Bioequivalence study protocols**				
	Quality assessment reports	14	8	1	10
	Clinical assessment reports	0	17	0	0
5.	**Authorization for the provision of medicinal products for special needs**				
	ANS assessment report - Patient	0	75	0	0
	ANS assessment report - Commission	0	64	0	0
	Notification of rejection/withdrawal	0	7	0	0
	ANS extension report	0	19	0	0
6.	**Labelling exemption**				

	Notification for approval/rejection	0	246	0	0
	MS notification	0	4	0	0
	Database update - exemption	0	240	0	0
	Database update - distribution	0	134	0	0
7.	**Parallel import authorisations**				
	Application for authorisation conditions - competent authority	0	41	0	0
	AIP report + issuance / Annexes	0	36	0	0
8.	**CIM variations**				
	Tariff regulation	0	2	0	0
	Variation assessment (no report) and issuance of notifications for approval	0	634	0	0
9.	**Other activities**				
	Checking the database and issuing a response to rapid alerts/quality non-compliance/suspension of GMP/CEP / AIP conditions for authorisation	0	93	0	0
	Replies to petitions/other directions	0	141	0	0
	Confirmation of the legal basis for administrative validation of applications for authorisation	0	48	0	0

Staff participation in EMA meetings:

– The Committee for Herbal Medicinal Products – HMPC,

– The Joint CHMP/CVMP Quality Working Party,

– The Joint CMD/ CHMP / CVMP / EMA /QWP/ EDQM working group on ASMF procedures,

– The Invented Name Review Group – NRG,

– The Homeopathic Medicinal Products Working Party – HMPWG,

–The Committee of Experts on the Classification of Medicines as Regards Their Supply – CD–P– PH/PHO;

–The EDQM: participation in the monthly meetings of the Competent National Authorities, participation in 2 official meetings of the European Pharmacopoeia Commission.

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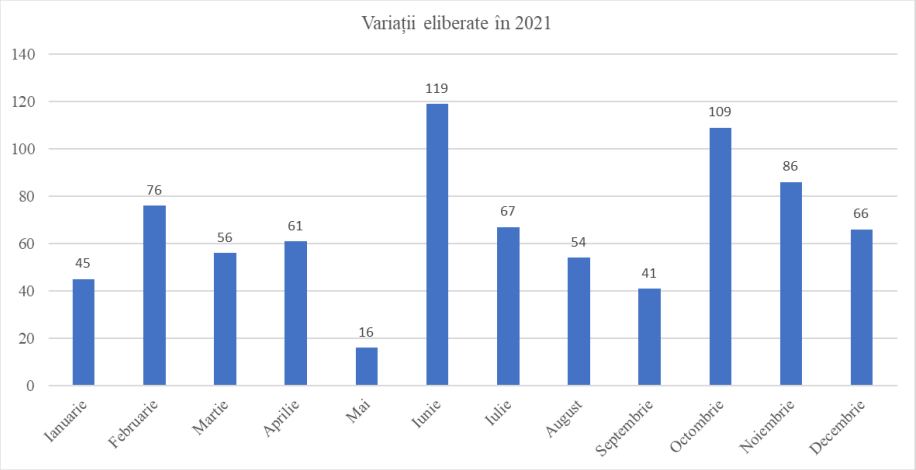
CIM variations

Situation of authorisations, renewals, variations – medicinal product	
Unapproved variations	
Unapproved variations (2021)	Approved variations (2021)
Authorisations	
Authorisation dossiers	100
Non-evaluated quality authorisation dossiers	35
Evaluated authorisation dossiers	65
Evaluated dossiers - finished	6
Evaluated dossiers with requests for authorisation	59
Renewals	
Renewal dossiers	143
Non-evaluated quality authorisation renewal dossiers	32
Evaluated renewal dossiers	111
Evaluated dossiers – renewal - finished	19
Evaluated dossiers with requests for renewal	92

CIM variations:

Unapproved variations					
Entry year	variations March 2022	variations January 2022	variations September 2021	variations May 2021	variations March 2021
2022	128	14	0	0	0
2021	784	790	647	440	189
2020	779	784	870	957	994
2019	459	463	539	588	608
2018	378	380	421	463	479
2006-2017	368	370	418	493	546
2013-2015	74	74	76	86	100
2011-2012	11	11	12	13	18
Total	2981	2886	2983	3040	2934

Variations issued in 2021 (per month):



C. Assessment – Authorisation, European Procedures Directorate

The European Procedures Directorate (DPE) is subordinated to the General Directorate for Evaluation and Authorisation and is an organisational structure of the National Agency for Medicines and Medical Devices of Romania. The Service for Administration of European Procedures (SAPE) and the Service for Assessment of European Procedures (SEPE) are subordinated to the European Procedures Directorate.

The European Procedures Directorate:

- The Service for Administration of European Procedures
  - The MRP DCP Administration Compartment
  - The Centralised Procedure Administration Compartment
  - The Compartment for validation/administration of variations
- The Service for Assessment of European Procedures
  - The Medicinal Product Quality Compartment
  - Non-clinical Safety and Efficacy Compartment
  - Medicinal Product Information Compartment
  - Centralised Procedure Assessment Compartment

The European Procedures Administration Service (SAPE)

The management, validation and administration of applications for authorisation/renewal of marketing authorisation through the European procedures with RO as a Concerned Member State (SMI) and RO as a Reference Member State (RMS) (decentralised, mutual recognition, repeat-use, repeat-use of the mutual recognition procedure):

1. Number of authorisation requests (letter of intent, payment form, documentation) related to the management activity:

Romania as a Concerned Member State (RO SMI):

- Applications for authorisation through decentralised procedure (DCP): 298
- Applications for authorisation through mutual recognition procedure (MRP): 5
- Applications for authorisation through repeat-use mutual recognition procedure (MRP-RU (E)): 43
- Applications for MA renewal (R): 304

Romania as a Reference Member State (RO SMR):

- Applications for authorisation through decentralised procedure (DCP): 3
- Applications for authorisation through mutual recognition procedure (MRP): 0
- Applications for authorisation through repeat-use mutual recognition procedure (MRP-RU (E)): 2
- Applications for MA renewal (R): 5

2. Saving the marketing authorisation/marketing authorisation renewal documentation on the Sever, at the location established by the European Procedures Department.

In accordance with the European legislation, the assessment/administrative verification of Module 1 within 14 calendar days of all applications for marketing authorisation/marketing authorisation renewal submitted through European procedures, verification of the authorisation fee and of the fee in accordance with the legal basis, the preparation of the validation reports in the validation stage, invalidation in CTS (Common Tracking System), setup of the invalidation requirements in English, informing SMR and applicants by e-mail about the reasons for invalidation, evaluation of replies received from applicants, uploading the respective documentation in electronic format on the NAMMDR server, preparation of validation files, validation in CTS, informing SMR and applicants by e-mail about the validation by Romania, in order to start the European procedures.

RO SMI :

- Applications for authorisation through decentralised procedure (DCP): 298

- Applications for authorisation through mutual recognition procedure (MRP): 4
- Applications for authorisation through repeat-use mutual recognition procedure (MRP-RU (E)): 64
- Applications for MA renewal (R): 280

RO SMR

- Applications for authorisation through decentralised procedure (DCP): 6
- Applications for authorisation through mutual recognition procedure (MRP): 0
- Applications for authorisation through repeat-use mutual recognition procedure (MRP-RU (E)): 2
- Applications for MA renewal (R): 4

3. Administration/coordination of European DCP/MRP/Renewal/Repeat-Use procedures with RO as SMI and SMR with permanent collaboration for clarifications requested by colleagues involved in the assessment of medicinal product documentation.

4. Follow-up and centralisation of the schedule for ongoing procedures / Transmission of the schedule with critical days for transmission of RO comments (with RO as SMI) and of RO reports (with RO as SMR).

5. Centralisation and transmission of comments/reports on the key days of ongoing procedures (verification of compliance with European/Romanian legislation in force, of the unitary character of comments for each procedure, of the correctness of the English language and their transmission by e-mail (to the SMR, SMI and applicant) in the format agreed by the CMDh.

RO SMI

- Comments for the decentralised procedure (DCP): 782
- Comments for the mutual recognition procedure (MRP): 18
- Comments for the MRP-Repeat-Use procedure (E): 66
- Comments for the MA renewal procedure (R): 286
- Comments for the ASMF Holder-Confidential Annex: 133

RO SMR (transmission of reports)

- Decentralised procedure (DCP): 2
- Mutual recognition procedure (MRP): 0
- MRP-Repeat-Use procedure (E): 1
- MA renewal procedure (R): 7

6. Letter of completion of the procedure (day 210/60/90/30, depending on the type of procedure), final assessment report, product information - RCP, leaflet, labelling agreed in the procedure - the files

for the issuance of the MA for the following number of medicinal products were prepared by the SMR (Reference Member State):

RO SMI

- For the decentralised procedure (DCP): 148
- For the mutual recognition procedure (MRP): 4
- For the MRP-Repeat-Use procedure (E): 35
- For MA renewal (R): 136

RO SMR (setup and transmission of the procedure's final documents to the SMI)

- decentralised procedure (DCP): 1
- mutual recognition procedure (MRP): 0
- MRP-Repeat-Use procedure (E): 0
- MA renewal (R): 7

7. Organisation of CAPP meetings and making the file available for the approval of the marketing authorisation:

In 2021, 17 meetings were organised at the NAMMDR headquarters and the following MA requests were approved after the positive opinion from the Marketing Authorisation Commission:

RO SMI

- Authorisation through the decentralised procedure (DCP): 233
- Authorisation through the mutual recognition procedure (MRP): 8
- Authorisation through the repeat-use mutual recognition procedure (MRP-Repeat-Use) (E) : 56
- MA renewal (R): 232

RO SMR

- decentralised procedure (DCP): 6
- mutual recognition procedure (MRP): 0
- MRP-Repeat-Use procedure (E): 0
- For MA renewal (R): 13

8. Coordination of the national phase of translation of medicinal product information (SPC, leaflet, labeling information) in view of issuance of the MA:

Total number of procedures: 559 (DC= 255 ; R= 244 ; E = 52 ; MR =8)*, of which:

- Ongoing:
  - For the decentralised procedure (DCP): 84
  - For the mutual recognition procedure (MRP): 2
  - For the MRP-Repeat-Use procedure (E): 12

- For MA renewal (R): 88

- Finished:
  - For the decentralised procedure (DCP): 171
  - For the mutual recognition procedure (MRP): 6
  - For the MRP-Repeat-Use procedure (E): 40
  - For MA renewal (R): 140
- Withdrawn/rejected:
  - For the decentralised procedure (DCP): 5 with a negative ending
  - For the mutual recognition procedure (MRP): 0
  - For the MRP-Repeat-Use procedure (E): 0
  - For MA renewal (R): 16
- Medicinal products for which translations have not been received from the applicant:
  - For the decentralised procedure (DCP): 13
  - For the mutual recognition procedure (MRP): 0
  - For the MRP-Repeat-Use procedure (E): 1
  - For MA renewal (R): 24

RO SMR

Total number of procedures: 19*, of which the following were finished:

- For the mutual recognition procedure (MRP): 0
- For the decentralised procedure (DCP): 6
- For the MRP-Repeat-Use procedure (E): 0
- For MA renewal (R): 13 (8 with MA+ 5 ongoing)

* Total number of procedures comprising one or several strengths, equivalent to one and to several marketing authorisation applications.

9. Update of the European CTS database, by entering the MA numbers issued by the NAMMDR for medicinal products authorised/renewed through European procedures:

- decentralised procedure (DCP): 209
- mutual recognition procedure (MRP): 7
- MRP-Repeat-Use procedure (E): 47
- MA renewal (R): 229

10. Management of European procedure information from EudraWebMail addresses in order to coordinate the entered, started, ongoing and completed procedures, as correctly as possible:

- ✓ ro-h-mrna (Romania's communication address for new MRP or DCP procedures with Romania as SMI or SMR).

- ✓ ro-h-mrve (Romania's communication address for MRP/DCP renewal with Romania as SMI or SMR).
- ✓ ro-h-cmd (information of the CMDh working group for the coordination of DC and MR procedures).
- ✓ MRP-DCP responses (communication address for applicants sending responses related to European procedures): 493 e-mails.
- ✓ MRP-DCP translation (address for communication in the national stage of the European procedures for transmission of final versions of the medicinal product information by applicants): 4459 e-mails.

The compartment for validation/ administration of variations (CVAV)

This Compartment deals with the management, validation, administration and approval at European and national level of applications for variation to the terms of the Marketing Authorisation (MA-APP) through the European procedures with RO as SMR/SMI (decentralised procedure, mutual recognition, repeat-use of the mutual recognition procedure (Repeat-Use)).
Activities (in numbers):

1. Management of variation applications and issuance of approval addresses for variation applications/notifications based on Order of the Minister of Health no. 1205/2006/type P notifications in accordance with Article 61 (3) of Directive 2001/83/EC/MA transfer in line with Order of the Minister of Health no. 1206/2006

RO as Reference Member State (SMR)

Variation type	**Number of variations submitted in 2021**	**Number of variations completed in 2021 (as well as from the previous year)**	**Observations**
Type IA variations/grouped variations	58	34 (2021) 25 (2020) 7 (2019)	2 in the national stage 1 discontinued 3 in the validation stage
Type IB variations/grouped variations	59	28 (2021) 29 (2020) 2 (2019)	2 in the European stage 2 in the national stage 9 in the validation stage

Type II variations/grouped variations	5	1 (2021) 10 (2020) 2 (2019)	4 ongoing
National notifications in line with Order of the Minister of Health no. 1205/2006	2	2 (2021) 1 (2020)	-
Type P Notifications in line with Article 61 (3) of Directive 2001/83/EC	1	0	1 ongoing
GRAND TOTAL	134	141	Started in 2021-144 variations (25 restarted upon request 57 IA/IA/G – of which 4 REJECTED 75 IB/IB/G - of which 2 REJECTED 18 II/II/G – of which 3 SUSPENDED + 2 RESTARTED)

RO as Interested Member State (SMI)

Variation Type	**Number of variations submitted in 2021**	**Number of variations submitted and discontinued in 2021**	**Number of variations completed in 2021 (as well as from the previous years)**
Type IA variations/grouped variations	2914	265	374 (2021) 762 (2020) 539 (2019) 288(2018) 172 (2017+B.V) Total number of Type IA variations = 2135
Type IB variations/grouped variations	2939	234	347 (2021) 748 (2020) 479 (2019) 264(2018) 159 (2017+B.V) Total number of Type IB variations =1997

Type II variations/grouped variations	767	66	68 (2021) 170 (2020) 139 (2019) 55 (2018) 29 (2017+B.V) Total variații II =461
National notifications in line with Order of the Minister of Health no. 1205/2006	131	1	149
Type P Notifications in line with Article 61 (3) of Directive 2001/83/EC	86	5	57
MA transfer in line with Order of the Minister of Health no. 1206/2006	224	2	169
GRAND TOTAL	7061	574	4968

2. Activity identification and quantification

Activity name	Total number performed by the CVAV
VALIDATION STAGE OF RO-SMI VARIATIONS - According to variation/procedure type:	
Preparation of addresses in view of payment regulation	220 addresses for 429 MAs
Handling/monitoring of medicinal products having an application for withdrawal/a withdrawn MA/an expired MA Management/monitoring of medicinal products with application for withdrawal/ withdrawn MA/expired MA	724 Variation discontinuation
Validation of Type IA/IA/G variations into the CTS	2349 per number of MAs+22
Validation of Type IB/IB/G variations into the CTS	2363 per number of MAs+7
Validation of Type II/II/G variations into the CTS	266+31 procedures for Type II variations / for 496 MAs+31
Validation of WS variations into the CTS	117 procedures /for 163 MAs

Validation of procedures in line with Article 61 (3) of Directive 2001/83/EC	19 procedures /for 19 MAs
National notifications – validation in line with Order of the Minister of Health no. 1205/2006	118 procedures – for 179 MAs
Validation of MA transfers in line with Order of the Minister of Health no. 1206/2006	120 procedures - for 210 MAs
Invalidation/applications for Type IA/IA/G variations	290
Invalidation/applications for Type IB/IB/G variations	343
Invalidation/applications for Type II/II/G+WS variations	14 procedures
Invalidation/applications – national notifications in line with Order of the Minister of Health no. 1205/2006	29 procedures
Invalidation/applications for MA transfers in line with Order of the Minister of Health no. 1206/2006	30 procedures
Distribution addresses drawn up by specialised services	180
Upload of the CESP/CD documentation on the server, in the „procedure" folder, including completions brought to the initial documentation (RO-SMR+RO-SMI)	6560 documents+supplementations
Setup/update of the work programme (periodic activity /depending on the start/restart of variations in the CTS) for RO-SMI variations	17
EUROPEAN VALIDATION STAGE OF RO-SMR VARIATIONS	
-validated procedures with RO-SMR: type IA, IB/IB/G, TYPE II/II/G introduced into the CTS database	92 procedures/ for 151 MAs
- invalidated procedures with RO-SMR: type IA, IB/IB/G, TYPE II/II/G with requests	37 procedures
-Distribution notifications sent to specialised services	92 notifications
-Assessor opinions sent on key days (Day 20/New Day 20/PVAR/FVAR)	48 opinions
NWG-Notification with grounds- Type IB variations	4 notifications
Total number of e-mails sent + letters of approval in English	89
Reports for assessment of administrative variations with RO-RMS	10

Handling/Administration – European stage - Total number of sent e-mails	439
Setup/update of the work calendar (periodic activity/depending on the start/restart of variations included in the CTS) for variations with RO-SMR	16 Calendars
RECEIPT OF CORRESPONDENCE on the given e-mail addresses and its upload on the server – daily activity of the CVAV	
ro-h.mrve-eudra.org	10696
var.responses@anm.ro	856
var.translations@anm.ro	773
STAGE OF NATIONAL APPROVAL OF VARIATIONS – Completion of the final report in tabulated form for Type IA/IA/G, IB/IB/G, II/II/G,WS variations, notified based on Article 61(3) of Directive 2001/83/EC/MA transfer – NATIONAL STAGE	
Final reports on CVAV- approval of variations	360
Final reports on MA transfer	120
Corrections made upon request of the applicant	15 notifications for approval of corrections for 29 variations
Draft of rejection notifications	2- for variations with RO-SMR
Urgent Requests (clinical variations included)	368 notifications
VARIATIONS INCLUDED IN THE MA RENEWAL PROCEDURE 1. Creation of a word file in the medicinal product procedure folder with the identification data from the NAMMDR Decision to issue the renewed MA 2. Checking the variation lists attached to the NAMMDR Decision to issue the renewed MA, which were approved at the same time as the reauthorisation and request to correct the lists (if applicable);	133 MA renewal procedures (240 MAs – strengths/pharmaceutical forms) = 133 Word files

3. Update of the Excel SAPE-CVAV-Records databases (daily activity) :

- Registration of entry of letters of intent and supporting documentation of variations
- Registration of payment confirmations + regularization addresses

- Registration of completions, replies of applicants (type IA, IB, II variations, MA transfer, notifications):

- *RO-SMI - according to the table centralisation*

Activity type / variation type	Type IA variations	Type IB variations	Type II variations	Notification - Article 61 (3) of Directive 2001/83/EC	National notification	MA transfer	Total
Payment intentions+forms	3049	3042	819	93	105	163	7271
Payment/regularization confirmations	2825	2918	691	91	111	169	6805
Support documentation	2914	2939	767	86	131	224	7061
Supplementation of documentation	570	1327	658	17	11	85	2668
Notifications for tariff regularisation	109	184	110	1	3	12	429
Requests for speed-up (*official address)	103	179	45	17	0	22	366
Notifications for approval (*per number of MAs)	2135	1997	461	57	149	169	4968

- *RO-SMR* according *to the centralization table*

Activity/variation type	Type IA variations	Type IB variations	Type II variations	Notification - Article 61 (3) of Directive 2001/83/EC	National notification	Total
Payment intentions+forms	67	60	6	1	2	136
Payment/regularization confirmations	62	56	5	1	2	126
Support documentation	58	59	5	1	2	125
Supplementation of documentation	10	12+6	9+5	0	0	31
Notifications for tariff regularisation	2	8	2	0	0	12
Requests for speed-up (*official address)	2	0	0	0	0	2
Notifications for approval (*per number of MAs)	66	59	13	0	3	141

GENERAL REPORTING OF APPROVALS ISSUED/DRAFTED IN 2021 BY THE SAPE-CVAV

Variations with RO-SMI: type IA/IA/G+IB/IB/G+II/WS	4593
Notifications in line with Article 61 (3) of Directive 2001/83/EC	57
National notifications in line with Order of the Minister of Health no.1205/2006	149
MA transfers in line with Order of the Minister of Health no. 1206/2006	169
Variations with RO-SMR: type IA/IA/G+IB/IB/G+II/WS	141
Overall total number of approvals per number of MAs (medicinal product strength)	5109

European procedure evaluation service (SEPE)

A. The Medicinal Product Quality Compartment

Specific activities performed:

a) Centralised procedure - Assessment of the quality documentation of medicines submitted for authorisation

Romania – as Rapporteur / Co-Rapporteur in centralised procedure – total number of reports: 18

- Issued reports: 4
- Completed/updated/finished reports: 14

Romania – opinions related to quality: 2

b) DCP/MRP/Repeat-Use/Renewal procedures - Assessment of the quality documentation for medicinal products submitted for marketing authorisation/marketing authorisation renewal

Romania - Reference Member State (SMR) - total number of reports: 27

- initial reports issued: 9
- total number of completed/updated/finished reports - during the intervening days: 18

c) Romania - Interested Member State (SMI) - total number of reports: 963

- Initial assessment reports (day 50/55/100): 379
- Intermediate assessment opinions (day 75, 85, 145, 195, 205): 550
- Conditions for authorisation: 263 procedures for 560 medicinal products

d) Variations - Assessment of the quality documentation of medicinal products

Romania - Reference Member State (SMR) - total number of reports: 130

API quality variations:
- Reports for type IA variations: 1
- Reports for type IB variations: 4

Finished product quality variations:
- Reports for type IA variations: 30
- Reports for type IB variations: 47
- Reports for type II variations: 10

Romania - Interested Member State (SMI) – variations: 38

e) Analysis of medicinal products included in the Annexes to European Commission (EC) Decisions and issuance of addresses for approval of the variations approved in the SMR:
- 20 EC Decisions
- 152 MAs

Variations for products included in the Annexes to EC Decisions: 55

Final reports and approval addresses/MA Amendments/Revised Annexes:
- Variations: 64
- MAs - 22
- Final reports –16
- approval addresses/MA Amendments/Revised Annexes: 16

f) Participation in meetings of the Medicinal Products Marketing Authorisation Commission: 17

Participation in working groups: the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human - CMDh, CHMP's Quality Working Party, the Name Review group, The Committee on Herbal Medicinal Products (HMPC), the Pharmaceutical Committee.

B. NON-CLINICAL SAFETY AND EFFICACY COMPARTMENT

Specific activities performed:

a) Centralised procedure - Evaluation of documentation related to non-clinical safety and efficacy and clinical safety of medicinal products submitted for authorisation: 5 procedures

b) DCP/MRP/Repeat-Use/MA renewal procedures - Evaluation of documentation related to non-clinical safety and efficacy and clinical safety of medicinal products submitted for authorisation /MA renewal

Romania - Reference Member State (SMR) - total number of reports:

- RO/H/200/001-003/DC: 1 Preliminary report on day 70, non-clinical and clinical, 1 Preliminary report on day 70, Overview, 1 Assessment report of the applicant's replies to SMR and SMI questions on day 120, 1 Preliminary report on day 70, Non-clinical and clinical, 1 Preliminary report on day 70, Overview, 1 Preliminary assessment report on day 40 of MA renewal procedures,
- 3 Final assessment reports on day 60 of the reauthorisation procedure,
- 15 Assessment reports of the Paediatric Investigation Plan on days 30, 60, 90 or 120 with RO as SMR

c) Romania - Interested Member State (SMI) - total number of reports: 945

- Initial assessment opinions (days 50/55/100): 379
- Intermediate assessment opinions (days 75, 85, 145, 195, 205): 539
- Types IB and II variations (days 55, 80): 27

d) Other:

- Assessment of clinical trial protocols: 16
- Documentation + response to validation of the European procedures legal basis: 126
- Last-resort treatment in line with Order of the Minister of Health no. 1018/2014:

Setup of the assessment reports and related documents (notification of the authorising company) for assessment reports for authorisation of medicinal products used as last-resort treatment: 14, assessment reports for renewal of authorisations of medicinal products used as last-resort treatment: 10, assessment reports for changes to the terms of marketing authorisations for medicinal products used as last-resort treatment: 9

- Activity of the Health Technologies Assessment Direction: preparation and participation in the HTA Appeals committee meeting – 2 meetings for resolution of appeals formulated to HTA assessment reports; participation in the negotiation of Cost-Volume Contracts - CNAS: 6 meetings for negotiation of cost-volume contracts,
- Assessment of special needs authorisation reports and opinions within special needs authorisation assessment commissions: 5
- Research regarding the effectiveness of medicinal products in the Covid-19 context,
- Participation in joint activities with the Ministry of Health in order to finish 2 legislative projects: application rules for Article 883 of Law 95/2006 and review of Order of the Ministry of Health no. 85/2013;

- Collaborations in order to issue replies to petitions/requests
- Non-clinical assessment
- Translation of post-authorisation commitments - ERA – European procedures
- Participation in PSUSA assessment – non-clinical comments.

Participation in committees and working groups: participation in teleconferences of the Non-clinical Working Party (NcWP); participation in the meeting of the Paediatric Committee (PDCO): 11 meetings + evaluation and support of the evaluation procedures of paediatric investigation plans (PIP), participation in the meeting of EMA's Committee for Orphan Medicinal Products (COMP).

C. MEDICINAL PRODUCT INFORMATION COMPARTMENT

DCP/MRP/Repeat use/MA Renewal Procedures - Evaluation of documentation regarding medicinal product information:
Romania - Reference Member State (SMR)

- Procedure evaluation reports (for each stage): 30 procedures x evaluation stages
- Assessment of clinical variations reports (for each stage): 25 procedures x assessment stages

Romania - Interested Member State (SMI)

- Initial assessment reports (day 50/100/55): 50
- Intermediate assessment reports (day 75, 85, 145, 195, 205): 50

DCP/MRP/Repeat use/MA renewal procedures - Elaboration of medical information in the national phase

- Verification and correction of the information necessary for the drafting of Annexes 1, 2, 3 to the Mas of medicinal products authorised through the European Procedure: 275
- Completion of Annexes 1, 2 and 3 in view of MA release: 275

Procedures: DCP/MRP/Repeat use/MA renewal/Variations/Notifications - Elaboration of medical information in the national phase

- Verification and correction of the information necessary for the drafting of Annexes 1, 2, 3 regarding the variations of medicinal products authorised through the European Procedure: 585
- Completion of Annexes 1, 2 and 3 to MAs for the variations of medicinal products authorised through European Procedure: 585

- Verification of the information submitted by the applicant regarding National Notifications/issuance of an opinion related to the appropriateness of notifications approval: 4

Centralised procedure:

- Evaluation of the documentation regarding the medicinal product information for medicinal products submitted for authorisation through the centralised procedure (Romania – Rapporteur/Co-rapporteur) - 5
- Verification from a medical and linguistic viewpoint of the translation into Romanian of the information on medicinal products authorised through the Centralised Procedure, after obtaining a positive opinion from the CHMP – 660
- Verification of the Romanian translation of information about the medicinal product (QRD Linguistic Review) signalled by the PRAC-12;
- Establishment of the information from the "Blue Border" for medicinal products authorised through the centralised procedure – 96.

Additional tasks: representation in the MA Commission for medicinal products authorised through European procedures/national procedure -12, representation in the MA Commission for medicinal products authorised through the special needs procedure - 62
Activities related to participation in the EMA scientific working groups: QRD, CAT, EDQM Working Group for Classification for Release of Medicines – 3

D. THE CENTRALISED PROCEDURE DEPARTMENT

Specific activities: evaluation of authorisation documentation/renewal of authorisation/variations for medicinal products through centralised procedure

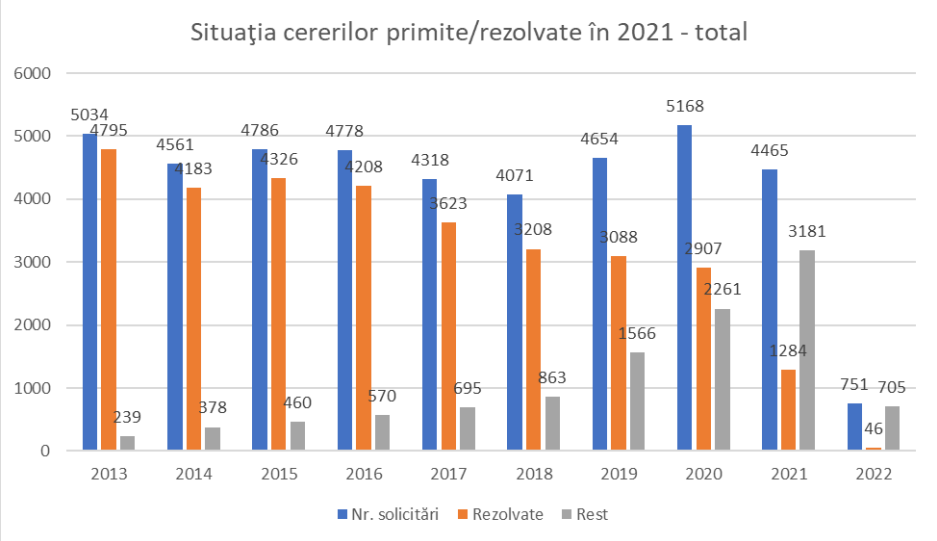
V.1.2 ASSESSMENT OF VARIATIONS TO MARKETING AUTHORISATION (MA) TERMS

Status of applications received/resolved in 2021:

THE MINISTRY OF HEALTH
THE NATIONAL AGENCY FOR MEDICINES
AND MEDICAL DEVICES OF ROMANIA
48 Av. Sănătescu, sector 1, 011478 Bucharest
Telephone: +4021-317.11.15
Fax: +4021-316.34.97
www.anm.ro

Entry year	1			2D			MD			Transfer		
	Number of requests	Solved	Remaining	Number of requests	Solved	Remaining	Number of requests	Solved	Remaining	Number of requests	Solved	Remaining
2013	4572	4346	226	183	170	13	197	197	-	82	82	-
2014	4201	3842	359	142	123	19	139	139	-	79	79	-
2015	4393	3982	411	207	166	41	125	117	8	61	61	-
2016	4393	3869	524	188	159	29	117	100	17	80	80	-
2017	3828	3186	642	159	121	38	150	135	15	181	181	-
2018	3557	2762	795	115	67	48	267	247	20	132	132	-
2019	4295	2824	1471	124	74	50	126	81	45	109	109	-
2020	4681	2619	2062	219	107	112	196	109	87	72	72	-
2021	4015	1082	2933	148	25	123	141	65	76	161	112	49
2022	687	45	642	31	1	30	26	-	26	7	-	7
Total	38622	28557	10065	1516	1013	503	1484	1190	294	964	908	56

Situation of applications received/solved in 2021:
Blue – number of requests
Orange – solved
Grey - remaining



Issuance of rectification documents to the marketing authorisation, as a result of the approval of the transfer of the marketing authorisation, type I, II variations, received during 2013-2021: 415 MA amendments, 1517 Annexes to MA.

V.1.3 HEALTH TECHNOLOGIES ASSESSMENT

In 2021, 150 files were evaluated for inclusion 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 programmes.

Of these, 113 were new INNs or extensions of indication and 37 files for moving/adding population segments or lines of treatment.

Among the evaluated medicinal products, 48 were oncological (for hepatocellular carcinoma, skin carcinoma, multiple myeloma, diffuse large B-cell lymphoma, chronic lymphocytic leukaemia, bronchopulmonary neoplasm, breast cancer, etc.), 9 for the treatment of type 2 diabetes, 4 medicinal products for the treatment of haemophilia, 2 for the treatment of spinal muscular atrophy. A significant number of medicinal products addressed unmet medical needs, for which there was no therapeutic alternative in Romania, until the entry into force of Government Decision no. 720/2008.

In 2021, the following updates of Government Decision no. 720/2008 and of the order of the Minister of Health related to therapeutic protocols took place:

1. Government Decision no. 537/2021 on amendment and supplementation of the Annex to Government Decision no. 720/2008 on approval 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

2. Government Decision no. 796/2021 on amendment and supplementation of the Annex to Government Decision no. 720/2008 on approval 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.

Therapeutic protocols regarding the prescription of medicinal products provided in the List of medicinal products, approved by Government Decision no. 720/2008, were updated as follows:

1. Order no. 14/69/2021 on amendment and supplementation of Annex 1 la Order of the Minister of Public Health and of the President of the National Health Insurance House no. 1.301/500/2008 on approval of the therapeutic protocols on prescription of medicinal products related to International Non-proprietary Names mentioned 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, approved through Government Decision no. 720/2008.

2. Order no. 140/127/2021 on amendment and supplementation of Annex 1 to Order of the Minister of Public Health and of the President of the National Health Insurance House no. 1.301/500/2008 on approval of the therapeutic protocols on prescription of medicinal products related to International Non-proprietary Names mentioned 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, approved through Government Decision no. 720/2008.

3. Order no. 564/499/2021 on approval of the therapeutic protocols on prescription of medicinal products related to International Non-proprietary Names mentioned in 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, approved through Government Decision no. 720/2008, and of the Methodological Norms on their implementation.

4. Order no. 1098/647/2021 on amendment and supplementation of Annexes 1 and 2 to Order of the Minister of Health and of the president of the National Health Insurance House no. 564/499/2021 on approval of the therapeutic protocols on prescription of medicinal products related to International Non-proprietary Names mentioned in 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, approved through Government Decision no. 720/2008, and of the Methodological Norms on their implementation.

5. Order no. 1667/813/2021 on amendment and supplementation of Annexes 1 and 2 to Order of the Minister of Health and of the president of the National Health Insurance House no. 564/499/2021 on approval of the therapeutic protocols on prescription of medicinal products related to International Non-proprietary Names mentioned in 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, approved through Government Decision no. 720/2008, and of the Methodological Norms on their implementation.

V.1.4 MONITORING AND CONTROL OF ADVERTISING FOR MEDICINAL PRODUCTS FOR HUMAN USE

The Advertising Service is subordinated to the Vice-President with responsibilities regarding scientific activities. In 2021, the following activities were carried out:

- advertising:
  - Evaluation of advertising materials, followed by approval: 633
  - Reapproval of advertising materials: 1047
  - Forms for rejection of advertising materials: 18
  - Evaluation and approval of educational materials: 259
  - Reapproval of educational materials: 218
  - Forms for rejection of educational materials: 8
  - Record of notifications regarding the participation of the MAH in medical events.
- sponsorship:
  - the centralisation of the declaration forms of sponsorship activities carried out by manufacturers, MAHs or their representatives in Romania, as well as by wholesale and retail distributors of medicinal products for healthcare professionals, professional organisations, patient organisations and any other type of organisation carrying out activities relating to human health, medical or pharmaceutical assistance – 109;
  - the centralisation of sponsorship activity declaration forms by beneficiaries of sponsorship activities, physicians, nurses, professional organisations, patient organisations and any other type of organisations carrying out activities related to human health, medical or pharmaceutical assistance - 4913.

V.1.5 MANAGEMENT OF THE INDEX OF MEDICINAL PRODUCTS FOR HUMAN USE

The diversity of the activities caried out by the Index of Medicinal Products Service involves a variety of activities structured and presented as follows:

- Index:

a. Handling of the index of Medicinal Products for Human Use. Inclusion into the „Index" database of medicinal products authorised through national/European/centralised/ANS procedures:
   - Marketing authorisation/marketing authorisation renewal (authorised through national/European/centralised/ANS procedures (for those that notify the actual placing on the Romanian market) – information about the Marketing Authorisation (MA) – the following were entered: trade name, MAH, person responsible for batch release, packaging materials, etc; -1121 medicinal products + history update
   - correspondence with the SEA in order to clarify/resolve inconsistencies between the MA and Annexes in the case of new MAs:- permanent activity (over 235 medicinal products)

- Maintenance of the database of medicinal products authorised for marketing: constantly updating the Index of medicinal products for human use by verifying and operating, based on the documentation received from the involved services, the resolved applications for authorisation/renewal of Marketing Authorisations, of variations/ amendments to MA terms, of termination/expiration of MA variations/expiration/termination, of medicinal products "with right of circulation".
    - variations to MAs approved through all procedures: national / European / centralised (information on changes to the approved Marketing Authorisation: trade name, MAH, person responsible for batch release, packaging materials, etc. were specified) - 1361 medicinal products + history update;
    - operation into the Index and Registry database of the MAs whose validity has ceased:
    - Expired MAs (for those MAs for which the applicant has not submitted the intention to initiate a renewal procedure) - 21 medicinal products;
    - introduction of renewal positions in the Index (correlation with the Registry) - 327 medicinal products;
    - introduction in the Index of medicinal products for human use of the data for extension of the validity of ANS (authorisations for medicinal products for special needs) - 10 medicinal products;
    - MA termination decisions:
        - termination of the validity of a national MA when a MA is issued for the same medicinal product through a European procedure - 162 medicinal products;
        - termination of the validity of a valid MA - 460 medicinal products
        - termination of the validity of an MA under SUNSET CLAUSE - 24 medicinal products;
    - decisions for MA suspension – 12 medicinal products
    - decisions to lift the suspension – 1 medicinal product
    - decisions for ANS termination – 5 medicinal products

b. Replies sent to the Directorate for Economy and Public Procurement for solving the situations regarding the "tariff for setup and update of the Index of medicinal products for human use": 73

c. Registration in the "AIP Index" application (upon request) of medicinal products authorised through national procedure for issuance of AIPs (parallel import authorisations) and update of the section "Parallel import authorisations for which CIM/xls was requested" - 15 medicinal products.

- Sunset Clause:

a. Management of notifications for enforcement of provisions of Article 737, 738 of Law 95/2006 on healthcare reform - Title XVIII – "The medicinal product";

– assessment and management of information for compliance with the legal provisions in force regarding the "SUNSET CLAUSE" on marketing (involves MA withdrawal after 3 years if the medicinal product hasn't been marketed), drafting replies to requests for exemption from these provisions; drafting the addresses to the MAH informing on failure to meet the legal requirements and enforcement of the termination clause of the MA validity;

- notifications of temporary and permanent discontinuation of marketing - 456 medicinal products
- notifications of resumption of marketing – 191 medicinal products
- marketing notifications - 2202 medicinal products
- requests for exemption from the Sunset clause – 75 medicinal products
- exemptions granted by e-mail – 57 medicinal products
- notifications of withdrawal of MAs/MA renewal procedure – 815 medicinal products

– permanent update of "Notifications on medicinal product discontinuations" on the NAMMDR website – 647 medicinal products

– verification in the Index of medicinal products for human use of therapeutic alternatives (MAs) with the same INN, pharmaceutical form and strength as the medicinal products notified as temporarily or permanently discontinued by sending e-mails to all MAHs involved whenever the information is amended – 1125 INNs

b. Providing information on the following situations: marketing, non-marketing, temporary discontinuation of marketing, permanent discontinuation of marketing, resumption of marketing to the NAMMDR Communication and Public Relations Service in order to respond to complaints received from patients/hospitals/pharmacies at lipsamedicament@anm.ro, including those redirected from http://medicamentelipsa.ms.ro/ - 377 replies sent by e-mail;

c. Monthly preparation of Annexes to the Ministry of Health in the context of the NAMMDR obligations established through Ordinance no. 8/2018 - 12 addresses + 54 Annexes

d. Setup and technical drafting of decisions for discontinuation / suspension or lifting of suspension of MAs - 378 decisions (659 medicinal products) accompanied by 3 Annexes each (CNAS + MS + MAH / applicant).

V.2 ASSESSMENT AND AUTHORISATION OF CLINICAL TRIALS

The Clinical Studies Directorate (DSC) is directly subordinated to the NAMMDR vice-president with attributions regarding specific scientific activities in the field of human medicinal products and medical devices or to the NAMMDR President.

DSC representatives participated in:

– The HMA Clinical Trial Facilitation Group (CTFG);

– The Working Group of EMA and Member States for the Clinical Trial Information System (CTIS), provided by the Clinical Trials Regulation;

– The group of experts of the European Commission on clinical trials;

– The European Medicines Agency's (EMA) committee for Advanced therapies.

Activities performed:

– assessment and authorisation of clinical trials with medicinal products for human use: 140 requests for assessment and authorization of clinical trials with medicinal products for human use received, of which: 4 withdrawn before assessment, 2 withdrawn after assessment; 101 authorisations were issued (including applications submitted in 2019 and 2020) and there were 2 notifications of rejection;

– assessment and approval of amendments to approved clinical trials: 752 requests for evaluation and approval of important amendments received; 747 response notifications issued (746 - approval and 1 - rejection, both submitted in 2019, 2020 and 2021).

– assessment and approval of observational studies with human medicinal products: 21 applications received, 9 responses issued (5 initial approvals, 2 withdrawals, 4 responses to amendments).

– authorisation of medical units conducting clinical studies: 196 requests for authorisation + 16 changes to initial authorisations (adding work points or specialties); 200 authorisations issued (applications submitted in 2020 and 2021) and 21 amendments approved, 14 files evaluated with requests, 1 application withdrawn after evaluation. 21 medical unit evaluation meetings were organised in order to conduct clinical trials.

– The DSC has permanently participated in the VHP procedure (Voluntary Harmonised Procedure): 21 VHP procedures for evaluation of initial clinical studies (1 as Reference Member State, 20 as Interested Member State); 74 VHP procedures for evaluating important amendments (3 as Reference Member State, 71 as Interested Member State).

– receipt and management of non-important amendments for approved clinical studies, various notifications, addresses with requests for various information: 790 various notifications (notification

of first patient inclusion, trial closure notifications, temporary interruptions, non-important amendments), 399 yearly study reports, 13 notifications for non-interventional studies.

– management of tariff regularisation notifications, when necessary: clinical trial tariff regularisations – 24; tariff adjustments amendments – 29.

– management of adverse reaction reports, serious and non-serious, from spontaneous reporting and non-interventional clinical trials, on paper and/or electronic format: Periodic safety reports: RAGNS: 424, DSURs: 327.

Specific processes:
- authorization of clinical trials with medicinal products for human use;
- approval of important amendments of clinical trials with medicinal products for human use;
- authorization of non-interventional trials with medicinal products for human use;
- evaluation and authorization of Medical Units for conduct of clinical trials with medicinal products for human use.

Other activities:

– participation through 2 appointed assessors in the assessment of the documentation submitted in support of the Applications for approval for last resort treatment: 18 assessment reports for the authorisation of 11 medicinal products as last resort treatment; participated in the discussion of 5 evaluation reports for renewal of the authorisations for 11 medicinal products as last resort treatment, 28 assessment reports for changes to the authorisations of medicinal products authorised as last resort treatments;

– managing and/or uploading the XML files of assessed clinical trial applications in the EudraCT European database for clinical trials and completing the information related to the authorisation status and the issuance of an ethical opinion;

– participation in the development and review of regulations regarding the authorisation of clinical trials: providing a viewpoint regarding the proposal for a Regulation of the European Parliament and of the Council on cooperation in safety assessment; participation in the elaboration of proposals for normative acts for setup of a national framework for implementation of the European Regulation for interventional clinical trials by organizing and participating in the meetings of the Working Group established by the WHO;

– participation in meetings of committees and working groups dealing with human medicinal products from the European Commission, EMA, European Council, Council of Europe, HMA-CTFG, CTFG expert group, CAT, PDCO or from the working groups for combined therapies, in vitro diagnosis with relevance to clinical investigations: CTFG - 6 meetings; for CTIS: 4 meetings of the

Working Group of the Member States with EMA, trainings and meetings in view of training in the Sandbox (training environment) in order to use the CTIS, to establish the country pattern and user profiles (user personas), training as a Master Trainer and participation in the meetings organised by EMA for the finalisation of training materials for use of the CTIS, for training on the techniques of disseminating the training materials as well as in the organized testing sessions; participation in the meetings for performance of the project for the European Grant on the CT CURE common action within the EU4Health project;

– participation, through representatives appointed by the NAMMDR management, to the commissions within the NAMMDR, to the meetings of various working groups of public authorities and institutions, as well as of other competent European bodies related to the human medicinal product, medical technologies and medical devices: meetings of the Commission for Assessment and Authorisation of Medical Units in order to conduct clinical trials (3 members from the DSC participate in this commission): 20, meetings of the Commission for Authorisation of last resort treatments: 50;

– preparation of documents required in order to submit for archiving the documentation submitted for approval of clinical trials and all documents subsequent to approval;

– professional training of staff by participation in training courses organised through the EU NTC platform, participation in training organised by the EMA (related to the use of the CTIS), participation in national and international scientific events related to the medicinal product for human use, depending on their specialty.

V.3 INSPECTION ACTIVITY FOR SUPERVISION AND QUALITY CONTROL OF MEDICINAL PRODUCTS FOR HUMAN USE IN THE PROCESS OF MANUFACTURE, IMPORT, WHOLESALE/RETAIL DISTRIBUTION AND RELATED ACTIVITIES

a) Directorate for the administration of DGIF processes (DAPDGIF) until 26.10.2021, modified according to Order of the Minister of Health no. 2.318/27.10.2021 in the DGIF Process Management Office (BAPDGIF)

In 2021, the following activities were carried out:

– registration and management of 3232 inputs and 3231 outputs regarding requests distributed/resolved within the DGIF, including records of Payment Orders for UTIs (rents, telephone calls, utilities);

– verification of the documents submitted by applicants for conduct of GMP, bioequivalence, BPLA inspections, verification of the Standard Unit File (DSU), verification of the documentation submitted in order to update the Annexes to manufacturing/import authorisations, including the

preparation of correspondence needed in order to complete the documentation (as required) –90 (Annexes + assessment);

– setup and issuance of certificates/authorisations: GMP certificates (for Romanian and foreign manufacturers): 31, manufacturing authorisations, including their annexes: 31; import authorisations: 13;

- amendment/update of import authorisation Annexes: 21;
- GLP certificates: 1;
- authorisations for independent control units: 0;
- update of the EudraGMDP database: entering information from issued GMP authorisations/certificates: permanent;

– creating and managing the file of each inspected unit, respectively of each unit which requested updates of the Annexes to the Manufacturing/Import Authorisations and GMP certificates: 90;

– administration of databases related to the codification of inspections, the list of authorised/certified manufacturing units, authorised importers, qualified persons: permanent;

- issuance of tariff addresses to DEAP (inspection tariffs and tariffs for updating the Annexes to the manufacturing authorisations for medicinal product manufacturers and importers;
- checking the documentation submitted by applicants in order to issue the certificate attesting the status of "qualified person", correspondence with those persons in order to complete the documentation, drafting documents for charging the service and tracking the payment of these fees: 39;
- preparation and issuance of qualified person certificates: 20;
- issuing the agreement regarding registration as manufacturers/importers/distributors of active substances to be used as raw materials for medicinal products for human use: 4.
- organising the meetings of the Inspection Commission - BPF, BPD, BPL, BPLA, BPSC, pharmacovigilance in order to present the inspection reports of the DGIF: 0;
- drawing up the yearly DGIF programme of activities, including Annexes (yearly inspection programmes);
- ensuring, through the designated person (property manager), the supply and administration of the fixed assets and consumables necessary for DGIF: permanent.

b) The Directorate for Good Manufacturing Practice Inspection, Laboratory, Analytical Laboratory, Clinical Trial and Pharmacovigilance (DIBPFLLASCFV)

In 2021, the following activities were carried out:

–GMP inspections for issuance of the Manufacturing Authorisation/GMP certificate, including for clinical investigation products: 34;

– authorisation inspections at the sites of medicinal product importers: 15;
– GMP compliance certification inspections at the sites of medicinal product manufacturers from third countries: 3;
– Good Laboratory Practice (GLP) inspections for certification/re-certification at bioequivalence centres (clinical unit and/or bioanalytical laboratory conducting bioequivalence studies): 3;
– unannounced inspections: 1 to verify GLP compliance of a bioanalytical laboratory;
– the application of legal sanctions for medicinal product manufacturers/importers, following non-compliance with the provisions of the GMP guideline: 3;
– evaluation of requests for supply of samples for authorised medicines: 19;
– issuance of an agreement regarding the provision of free medical samples: 19;
– evaluation of the reports regarding the situation of the samples distributed to healthcare professionals, sent by the MAH at the end of the validity of the supply agreements: upon request;
– evaluation of the documentation submitted in support of the application for approval of donations of medicinal products for human use, drafting of donation notices and related Annexes: 145; (except for a request for which the donor waived because the patient has deceased): 145;
– Rejection of the request for a donation notice on grounds of noncompliance with Order of the Minister of Health no. 1032/2011: 7;
– verification of the documentation for approval of export declarations to third countries and approval of export declarations: 940 requests for 5621 export declarations;
– the rejection of the approval of export declarations and entrance into force of Military Ordinances, Order of the Minister of Health no. 428/2020 and Order of the Minister of Health no. 672/2020 suspending the distribution outside Romania of medicinal products included in the CANAMED (Order of the Minister of Health no. 428/2020), and of medicinal products covered by the Protocol for treatment of the SARS-Cov-2 virus infection, approved through Order of the Minister of Health no. 487/2020, and of medicinal products at increased risk of discontinuation for chronic pathologies in the context of the SARS-Cov-2 virus pandemic, as stipulated in the Annex to Order of the Minister of Health no. 672/2020: 14.
– participation, through representatives appointed by the NAMMDR, in meetings of the EMA working groups in the field of BPF, BPL, BPSC and FV inspections: GCPIWG – 1 meeting, PhVIWG – 1 meeting.

c) The Good Distribution Practice Inspection Service (SIBPD) of the DIBPFLLASCFV, until 26.10.2021, whose name was changed, in line with Order of the Minister of Health no.

2.318/27.10.2021, to the Directorate for Good Distribution Practice Inspection (DIBPD), subordinated to the General Director of the DGIF

– In 2021, the following activities were carried out:

– registration and management of distributed/solved documents: 8537 entries and 1304 exits;

– assessment of requests for BPD inspections: 135;

– issuing addresses with requests for supplementations to the submitted documentation: 58;

– issuance of tariff addresses to the DEAP: 117;

– carrying out GDP authorisation/recertification inspections: 109 (10 in 2019, 55 in 2020 and 44 in 2021);

– performance of unexpected inspections at the sites of wholesale distributors: 1;

– drawing up lists of deficiencies:109;

– issuing addresses with requests for additions to the plan of corrective/preventive measures: 2;

– preparation of final BPD inspection reports: 107 (of which 0 negative);

– issuance of Wholesale Distribution Authorisations: 45;

– issuance of Certificates of compliance with Good Distribution Practice (GDP): 107;

– introduction into the EudraGMDP and into the internal database (Microsoft Access) of the issued GDP authorisations and certificates: on a permanent basis;

– assessment of applications for update/amendment of wholesale distribution authorisations (amendment of Annexes): 182;

– issuance of updated authorisations/annexes: 133;

– application of contravention sanctions for wholesale distributors, following noncompliance with the provisions of the GDP guideline on purchase and transport of medicinal products, noncompliance with the public service obligation, improper implementation of the Quality Management System created, noncompliance with prices approved through Order of the Minister of Health: 22;

– 54 complaints received from pharmacies and hospitals on lipsamedicament@anm.ro, for which electronic correspondence was carried out with wholesale distributors/MAH representatives/pharmacies, were investigated.

– checking the stocks of medicinal products and processing the information from daily reports (SER), in order to formulate the replies to the interested institutions and to the complaints received on the email address lipsamedicament@anm.ro and on the website of the Ministry of Health (www.medicamentelipsa.ro) and communication of the information to the SACR in order to draft the replies to the complainant: on a daily basis;

−processing (recording, centralisation) of information from monthly reports submitted by wholesale distributors/manufacturers/importers in accordance with Order of the Minister of Health no. 502/2013 and Order of the Minister of Health no. 1295/2015: 3355;

−registration of reports on imported medicinal products in line with Order of the Minister of Health no. 1295/2015: 320;

−processing (registration, centralisation, verification, posting on the NAMMDR website) of intra-community delivery notifications sent to the NAMMDR by wholesale distributors in line with Order of the Minister of Health no. 269/2017: 3541 (for 121073 products);

−Rejection of notifications of intra-community supply of medicinal products covered by the Protocol for the treatment of the SARS-Cov-2 virus infection, approved through Order of the Minister of Health no. 487/2020, and of medicinal products at high risk of discontinuation for chronic pathologies in the context of the SARS-Cov-2 pandemic, as provided in the annex to Order of the Minister of Health no. 672/2020: 58;

−collaboration with the National Vaccination Coordination Committee and other state authorities for preparation of the COVID-19 vaccination campaign, regarding the reception, storage and transport of vaccines;

d) The Directorate for Quality Supervision of Medicinal Products and Territorial Units (DSCMUT) – until 26.10.2021, namely the Directorate for Quality Supervision of Medicinal Products, Alerts and Territorial Units (DSCMAUT), in line with Order of the Minister of Health no. 2.318/27.10.2021

This Directorate has 12 subordinated territorial inspection units (UTI), without legal personality, located in the following cities: Iasi, Bacău, Galati, Piteşti, Satu Mare, Cluj, Oradea, Deva, Tg. Mureş, Timişoara, Craiova and Constanţa, as well as the Falsified Medicinal Products Alerts Bureau (BAMF). The following activities took place in 2021:

−elaboration of the Yearly Sampling and Testing Plan on monitoring of medicinal product quality, containing 29 products;

−sampling of samples taken from the 2021 plan (CF inspection code) and transmission to the DCCM for laboratory analysis: 17 (the remaining 12 were not found in the distribution network);

−receiving the results of laboratory analyses: 2 analysed samples were declared appropriate, and 15 are being analysed;

−the sampling of medicinal products within the programme coordinated by the EMA/EDQM for the supervision of centrally authorised products, which are tested by laboratories (OMCL) of other EU competent authorities; sampling is done from distribution units and is sent by parcel service to the EDQM headquarters in Strasbourg, France: 7 (the results were compliant);

– the sampling of medicinal products within the programme coordinated by the EDQM for surveillance of medicinal products (MSS study), the testing of which is carried out by the DCCM: 2 (under analysis);

– elaboration of the thematic Plan of surveillance inspections;

– carrying out (thematic) inspections to monitor the quality of medicinal products in the distribution network (warehouses, community pharmacies, hospital pharmacies, local offices, medicinal product stores), including surveillance inspections of pharmacy activity (activity added as a result of the entry into force of Order of the Minister of Health no. 444/2019): 542;

– enforcement of contravention sanctions for pharmacies and medicinal product stores, following noncompliance with provisions of the Pharmacy Law no. 266/2008: 9;

– resolving notifications regarding possible quality non-compliances of medicinal products for human use received from patients or healthcare professionals: 4 (3 ranking without consequences and 1 in progress);

– recall from the market of medicinal products with quality non-compliances: 28;

– coordination of the activity of Territorial Inspection Units (UTI) related to medicinal product quality surveillance by quarterly reporting the activity;

– updating the DSCMAUT database (the situation of inspections carried out to solve the thematic plan, the situation of medicinal products sampled within the yearly sampling and testing plan/upon request of the EDQM/of imported medicinal products for supply in case of special needs, the situation of medicinal products sampled in order to solve quality complaints);

– elaboration of the quarterly situation of medicinal products withdrawn due to quality non-compliances detected through the inspection activity, which is published in the agency's informative materials and on the NAMMDR website: 4;

e) The Rapid Alerts and Falsified Medicinal Products Service (SARMF), part of the DIBPFLLASCFV until 26.10.2021, whose name was changed according to Order of the Ministry of Health no. 2.318/27.10.2021 to the Falsified Medicinal Products Alerts Bureau (BAMF) within the Directorate for Quality Supervision of Medicinal Products, Alerts and Territorial Units (DSCMAUT)

The following activities were performed in 2021:

– rapid alerts received from other national authorities, through the European rapid alert system, dealing with quality non-compliances of some products (medicinal products, food supplements, care products, etc.): 271

- ✓ 18 targeted batches of medicinal products distributed in Romania for some of which the withdrawal from the market was initiated;
- ✓ 26 targeted medicinal products authorised but not marketed in Romania;

✓ 227 targeted medicinal products unauthorised for marketing in Romania and other products which are not medicinal products (dietary supplements, care products, etc.);

- rapid alerts received from the EMA, through the European rapid alert system, dealing with quality non-compliances of centrally authorised medicinal products: 18;
- information received from the EDQM, through the European rapid alert system, which were subject to suspension/withdrawal/restoration of CEP certificates: 18;
- rapid alerts received from other national authorities, through the European rapid alert system, dealing with declarations of non-compliance with GMP or suspension/withdrawal/restoration of GMP certificates: 62;
- rapid alerts received from other national authorities, through the European rapid alert system, dealing with declarations of non-compliance with GDP or suspension/withdrawal/restorations of GDP certificates: 11;

– rapid alerts received from other national authorities, through the European rapid alert system or WGEO, dealing with cases of medicinal product theft: 14; Of these: 7 concerned medicinal products also authorised in Romania, and 7 concerned medicinal products not authorised to be placed on the market in Romania and other products which are not medicinal products (food supplements);

–rapid alerts received from other national authorities, through the European rapid alert system or WGEO, dealing with suspected/confirmed cases of falsification of medicinal products: 95; Of these: 27 concerned medicines also authorised in Romania, 2 products not authorised but marketed in Romania (containing sildenafil, lidocaine) and 66 concerned medicinal products not authorized to be placed on the market in Romania and other products which are not medicinal products (food supplements, medical devices); in some of these cases, customs authorities and criminal investigation and prosecution bodies were informed about fraud or counterfeit medicinal products, by the Directorate for Legal, European Affairs and International Relations: 4 (Fenistil, medicinal products seized from the market, Testoviron Depot, Lidocaine);

– managing the notifications received on the e-mail address contrafacere@anm.ro:1 (aggressive internet advertising for Friocard);

-participation in the 29th meeting of the Working Enforcer Officers (WGEO) working group organised by the HMA on 02.06.2021 (video conference);

-Participation in the plenary sessions of the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH/CMED), minimizing the risks for the public health represented by the falsification of human medicinal products and similar threats, organised by the EDQM on 18-10.05.2021 and 19-20.1021 (video conference): Transmission of cases from Romania, draft of report and transmission to the Ministry of Health.

In 2021, specific activities related to the serialisation of medicines were carried out:

- access to the SNVM for the purpose of supervising the functioning of the repertoires and investigating potential falsification incidents, to check the traceability of unique identifiers, upon request of other authorities, the OSMR, fellow inspectors, MAHs: 143 reports;
- communication with the OSMR and end users of the SNVM in various specific cases related to the serialization of medicinal products;
- drawing up and transmitting responses to the requests submitted by the OSMR;
- receipt of the alerts generated by the SNVM via the e-mail address alertosmranm@anm.ro (to which level 5 alerts generated in the SNVM are transmitted): about 1 million;
- Receiving monthly reports related to SNVM alerts from the OSMR: 12 reports;
- Participation in online meetings organised by the OSMR for software providers: 6 sessions;
- posting an announcement on the NAMMDR website intended for end users of the National Medicinal Product Verification System (SNVM) regarding the obligation to scan and decommission serialised medicinal products and the penalties for non-compliance;
- participation in the meetings of the Expert Group regarding the Delegated Act regarding the safety features printed on the packaging of medicinal products for human use (EGSF) organised by the European Commission, the General Directorate for Health and Food Safety, by video conference: drawing up a negotiation mandate and report and transmission to the Ministry of Health: the 32nd meeting on 01.09.2021 and the 33rd meeting on 16.11.2021;
- drawing up and sending to the OSMR notifications regarding the suspension/withdrawal of a manufacturing or wholesale distribution authorisation, according to Article 21 (4) of Order of the Minister of Health no. 1473/2018: 2 notifications.

V.4 PHARMACOVIGILANCE AND RISK MANAGEMENT

The Pharmacovigilance and Risk Management Directorate (DFVMR) is a structure within the General Directorate for Authorisation Assessment (DGEA), subordinated to the Vice-President with duties regarding specific scientific activities.

Activities performed in 2021:

1. Monitoring the safety of medicinal products for human use in the therapeutic circuit by:

a. Management of reports of suspected adverse reactions to medicinal products for human use from spontaneous reporting in Romania (Article 836 of Law 95/2006).

– electronic transmission of serious adverse reaction reports received by the NAMMDR from patients and healthcare professionals into EMA's Eudravigilance database. The NAMMDR received 1840 reports of suspected serious adverse reactions, all of which were submitted to EMA's Eudravigilance database.

– electronic transmission to the EMA Eudravigilance database of non-serious adverse reaction reports received by the NAMMDR from patients and healthcare professionals. The NAMMDR received 20,101 reports of non-serious adverse reactions to medicinal products, vaccines included.

– Transmission to the CNSCBT (National Surveillance Centre and Control of Communicable Diseases) within the INSP (National Institute of Public Health) of undesirable post-vaccination adverse reactions (RAPI), directly received by the NAMMDR, in line with the protocol in force - 18,119 RAPIs transmitted.

– letters informing healthcare professionals who reported adverse reactions, regarding the number of EFC (Continuing Pharmaceutical Education)/ EMC (Continuing Medical Education) credits obtained (addresses and e-mails) - 813

– quarterly information addresses sent to professional organisations (the Romanian College of Physicians/Romanian College of Pharmacists) regarding the transmission of adverse reactions spontaneously reported in Romania and validated by the NAMMDR, in order to grant EMC / EFC credits (Continuing Medical/ Pharmaceutical Education) - 3 notifications sent to the CMR and 3 to the CFR.

– management of adverse reactions received by the NAMMDR from all sources - 21,941 reports of suspected serious and non-serious adverse reactions.

b. Periodic evaluation of the safety profile of medicinal products authorised in Romania and in the European Union, in order to determine whether any new risks, changes in known risks or changes in the Benefit/Risk balance of medicinal products have appeared:

– PSUSA procedure (Periodic Safety Update Report Single Assessment) – Evaluation of the periodically updated safety report in the single European assessment procedure, in which Romania was appointed Reference Member State (Ro - SMR) – 6 PSUSA procedures

– Referral procedure under Article 31 of Directive 83/2001, initiated by France for medicinal products containing etifoxine, in which RO was appointed Co-Rapp in the CHMP - Development of assessment reports in the procedure regarding safety aspects.

– Initiation of a referral procedure under Article 31 of Directive 2001/83/EC for medicinal products containing amfepramone, used in the treatment of obesity.

c. Detection and management of safety signals for medicinal products authorised in Romania, including safety signals for active substances allocated to Romania according to the European principle of work sharing, in order to determine if new risks have appeared, if known risks have changed and if they have an impact on the benefit/risk balance for 40 active substances or combinations of active substances.

2. The marketing of safe, effective and quality medicinal products for human use by:

a. The marketing authorisation process for medicinal products for human use - evaluation of pharmacovigilance documentation.

– Marketing authorization procedure within the centralised procedure - Comment reports on evaluation of the pharmacovigilance documentation (summary of the pharmacovigilance system - Module 1.8.1, Risk Management Plan - Module 1.8.2) within the Centralized Procedure in which Romania is appointed as Rapporteur /Co-rapporteur – 4 procedures

– Marketing authorisation procedure within European procedures - assessment reports of pharmacovigilance documentation (summary of the pharmacovigilance system - Module 1.8.1, Risk Management Plan - Module 1.8.2) within the DC (decentralized)/ MRP (mutual recognition Procedure)/ Repeat-Use procedure, with Romania as Reference Member State (RO - SMR) - 1 procedure

– Marketing authorisation procedure within European procedures - Comment reports on the evaluation of pharmacovigilance documentation (summary of the pharmacovigilance system - Module 1.8.1, Risk Management Plan - Module 1.8.2) within the DC Procedure (decentralised)/ MRP (mutual recognition procedure)/ Repeat-Use procedure, with Romania as interested member state (Ro - SMI) - 275 comment reports

– Establishment/verification/translation of Conditions for authorisation specific to Pharmacovigilance – through European procedure – 26

- Marketing authorisation procedure - Verification of pharmacovigilance documentation submitted by applicants for administrative validation in the National Procedure - 23

- Marketing authorisation procedure through the national procedure - assessment reports of the documentation (summary of the pharmacovigilance system - Module 1.8.1, Risk Management Plan - Module 1.8.2) in the National Procedure - 10 assessment reports

– Marketing authorisation procedure for authorisation of medicinal products for special needs (ANS) - Verification of documentation submitted by applicants for authorisation of medicinal products for special needs - 145 checks for ANS

– Marketing authorisation procedure for authorisation of medicines used in last-resort treatments - Verification of pharmacovigilance documentation submitted by applicants for authorisation of medicinal products used in last-resort treatments - 15 checks for authorisation of medicinal products used in last-resort treatments.

b. Marketing authorisation renewal for authorised medicinal products – meeting the pharmacovigilance requirements and evaluating the pharmacovigilance documentation.

– Marketing authorisation renewal in European procedures (RO - SMR) - Assessment reports of the pharmacovigilance documentation (summary of the pharmacovigilance system - Module 1.8.1, Risk Management Plan - Module 1.8.2, Addendum to clinical overview - Module 2.5) in European procedures with Romania as Reference Member State (RO - SMR) – 4 procedures

– Marketing authorisation renewal in European procedures (RO - SMI) - Comment reports on assessment of the pharmacovigilance documentation (summary of the pharmacovigilance system - Module 1.8.1, Risk Management Plan - Module 1.8.2, Addendum to clinical overview - Module 2.5) in European procedures with Romania as interested member state (RO - SMI) - 185 comment reports

– Marketing authorisation renewal procedure - Verification of pharmacovigilance documentation submitted by applicants for administrative validation in the National Procedure - 21

– The procedure for marketing authorisation renewal in the national procedure - Assessment reports of the pharmacovigilance documentation (summary of the pharmacovigilance system - Module 1.8.1, Risk Management Plan - Module 1.8.2, Addendum to clinical overview - Module 2.5 / RPAS - Updated Periodic Safety Report - Module 5) in the National Procedure - 17 assessment reports

c. Assessment and approval of changes to the terms of the Marketing Authorisation - Risk Management Plan.

– Variations submitted by the MAH for medicinal products authorised through European Procedures with RO as SMR - Evaluation of pharmacovigilance documentation submitted through type IA, IB and II variations for medicinal products authorised through the European procedure (summary of the pharmacovigilance system - Module 1.8.1, Management Plan of Risk - Module 1.8.2) – 1 assessment report with RO - SMR.

– Variations submitted by the MAH for medicinal products authorised through European Procedures in which RO is SMI - Evaluation of pharmacovigilance documentation submitted through type IA, IB and II variations for medicinal products authorised through European procedures (summary of the pharmacovigilance system - Module 1.8.1, Risk Management Plan - Module 1.8.2) – 84 reports with RO-SMI according to the calendars for carrying out the procedures received from the Department for Validation of Administration of Variations.

– Variations submitted by the MAH for medicinal products authorised through national procedure - Evaluation of pharmacovigilance documentation in type IA, IB and II variations for medicinal products authorised through national procedure - 41 approved variations

3. Reducing the risks associated with the use of medicinal products for human use by taking appropriate safety measures and regulatory actions by:

a. Approval of additional risk minimisation measures provided for in the Risk Management Plan for medicinal products for human use.

– Evaluation and approval of educational materials contained in the Risk Management Plan for medicinal products authorised according to Article 127a of DIRECTIVE 2001/83/EC as further amended - 55 completed files.

b. Monitoring the results of risk minimisation measures provided for in the risk management plan as well as the conditions mentioned in the MA.

– Follow-up and verification of the implementation of EC decisions

4. Ensuring an urgent exchange of information between the Competent Authorities and the EMA by transmitting information in the rapid alert system, as well as non-urgent information.

– Responses to non-urgent requests (NUIs) or rapid alerts to requests for information received from the EMA or other authorities in EU Member States regarding information on certain medicinal products or classes of medicinal products – 11 responses.

5. Promptly informing the public and interested parties about safety issues of medicinal products for human use.

– Approval of Direct Healthcare Professional Communications (CDPDS) related to medicinal product safety issues – 25

– EMA press releases: translation/translation verification – 29 press releases

– Updating the information available on the NAMMDR website in the sections corresponding to pharmacovigilance/Reporting of adverse reactions to COVID-19 vaccines, elaboration of documents regarding the adverse reaction reporting, available to the public.

– Elaboration and submission of replies to internal requests/petitions received from the Directorate for Legal, European Affairs and International Relations and/or the Service for Communication and Public Relations - approx. 100 petitions

6. Educating stakeholders on safety, efficacy and quality reporting

– Development and presentation of the paper "Monitoring the safety profile of COVID-19 vaccines and the importance of adverse reaction reporting in order to safeguard public health", at the National Pharmacy Conference (online participation)

– The NAMMDR participated in the yearly social media campaign aiming to promote awareness of the importance of reporting suspected adverse reactions to medicinal products - https://www.anm.ro/medsafetyweek/ - Organised between 1-7 November 2021, the sixth yearly "social media" campaign #MedSafetyWeek, whose main theme was the increase in the number of reports of suspected side effects following vaccination. This campaign aimed to encourage reporting of suspected adverse reactions to COVID-19 vaccines by healthcare professionals, national immunisation programme staff, as well as patients, caregivers and their families.

– The method of reporting and encouraging the reporting by vaccinated persons/patients of suspected adverse reactions to COVID-19 vaccines and other medicinal products were presented by NAMMDR representatives during the meeting with the representatives of several patient associations in Romania.

– The NAMMDR-DFVMR has made available an electronic reporting system and reporting sheets for adverse reactions post-immunisation to COVID-19 vaccines, to healthcare professionals and patients.

– Update of the NAMMDR official website, www.anm.ro, the COVID-19 Vaccination section, with relevant information regarding: the use of the European platform adrreports.eu, various guidelines containing questions and answers related to the reporting of adverse reactions to COVID-19 vaccines, information brochures etc.

7. The NAMMDR contribution to relevant European activities through active participation in scientific committees and expert groups of relevant European bodies.

- Participation of appointed members in the monthly meetings of the Pharmacovigilance Risk Assessment Committee (PRAC) of the EMA.

- Participation of appointed members in the monthly meetings through the online system organised by PRAC – ORGAM Teleconference.

V.5 MEDICINAL PRODUCT QUALITY CONTROL

The Medicinal Product Quality Evaluation and Control Directorate (DECCM) has the status of an Official Medicines Control Laboratory (OMCL), an active member with full rights within the European network of official European control laboratories (GEON), under the coordination of the European Directorate for the Quality of Medicines & Healthcare (EDQM).

DECCM represents a unique structure in Romania, with the role of supporting the competent authority through independent testing of the quality of medicinal products. The NAMMDR OMCL has been officially audited and certified (Certificate No. EDQM/MJA-137 issued on 20 Sept. 2018) by the EDQM, the World Health Organisation (WHO) and the EMA.

In recent years, DECCM has been increasingly involved in the testing of medicinal products authorised centrally and through European procedures, in standardisation studies of reference substances used in European laboratories and interlaboratory studies. The results obtained were appreciated by European institutions, and the testing activities were remunerated according to the contracts with EDQM/EMA. Romania is represented in the yearly meetings of the European OMCLs in all organised sections: vaccines, blood-derived medicinal products and synthetic medicinal products. Expert staff from the DECCM are part of assessment teams for applications for marketing authorisation through the EMA centralised procedure, as well as in international audit teams as EDQM and WHO auditors/experts/specialist consultants.

Similar to other European OMCLs, the DECCM carries out (since 2003) both control and evaluation activities. Since 2017, DECCM has been involved in the evaluation of quality documentation for biological medicinal products submitted through the EMA centralised procedure, as co-rapporteurs/peer reviewers.

From the DECCM perspective, in 2021, the testing activities within the European procedure for the official batch release by the control authority (OCABR) could be carried out within the time provided by the European OCABR procedure (60 days).

The evaluation of OCABR documents in the case of the COVID-19 vaccine batches, released by other OMCLs in the EU, was carried out with the highest priority, in order to ensure the availability of COVID-19 vaccines as soon as possible.

The main categories of activities carried out by the DECCM in 2021 consisted of laboratory control and evaluation of the documentation submitted for marketing authorisation (MA)/renewal of the MA/approval of Type I/II variations to the terms of the MA/approval of applications for conduct of clinical trials:

1. Laboratory control - laboratory testing addresses synthetic, biological and radiopharmaceutical medicinal products, covering the following testing types:

a. laboratory control of biological medicinal products for human use submitted for testing with a view to the official batch release (OCABR);

For 1 batch of a biological medicinal product (vaccine) tested, the quality parameters were analysed, the summary of the batches protocol was evaluated and the official batch release certificate (OCABR certificate) was issued. Also, for this medicinal product, the trend analysis was performed for the potency parameter.

b. laboratory analyses for medicinal products included in the National Market Surveillance Program (in collaboration with the DGIF, the DPN);

In 2021, 25 batches of medicinal products included in the DGIF sampling plan were analysed within the DECCM; all fell within the approved quality criteria.

c. laboratory analyses for medicinal products authorised by the procedure for special needs: 1 batch of biological medicinal products;

d. laboratory analyses for medicinal products claimed from the territory by healthcare units, by natural or legal persons, in collaboration with the DGIF: 2 batches of claimed medicinal products;

e. as in previous years, the DECCM continued its collaboration with European institutions in the field of medicinal product quality control, by participating in the following types of studies coordinated by the EDQM:

- laboratory proficiency testing studies (PTS) – mandatory participation to demonstrate proficiency in testing. The DECCM participated through its laboratories in the following 2 PTS studies, and the outcomes of the participation were very good:

PTS 217: Relative Density, assay. The test consisted in determining the relative density of 2 samples, according to PhEur 2.2.5 and the methodologies described in the EDQM protocol.

PTS 218: Assay - Liquid Chromatography – the test consisted in determining the content of a sample by HPLC (high performance liquid chromatography), according to the analytical procedure described in the EDQM protocol.

- standardisation studies of chemical/biological reference substances (CRS/ BRP), which consist of conducting studies in parallel, based on well-established protocols, by a small number of laboratories, selected by the EDQM from the proposals submitted on a voluntary basis by laboratories within the OMCL network, aiming at the dosage of some reference substances later used as standard reference substances in the monographs of the European Pharmacopoeia.

The CRS 5 Study - the determinations consisted of the standardisation of the reference substance, according to the EDQM protocol, by comparative testing in two independent batches of HPLC determinations of the impurity profile.

- testing samples of medicinal products authorised for introduction on the market by the EMA through the centralised procedure;

As far as CAP 2021/06 is concerned, in 2021, the stages of documentation and correspondence with EDQM representatives regarding testing were completed, medicinal product samples and the reference standards necessary for testing were received only partially, due to objective reasons. The procedure is still ongoing.

f. For the characterisation of medicinal products tested by the DECCM in 2021, 92 distinct analyses were carried out according to the techniques described in the European Pharmacopoeia, in the pharmaceutical files of manufacturers or in the analytical protocols sent by the EDQM.

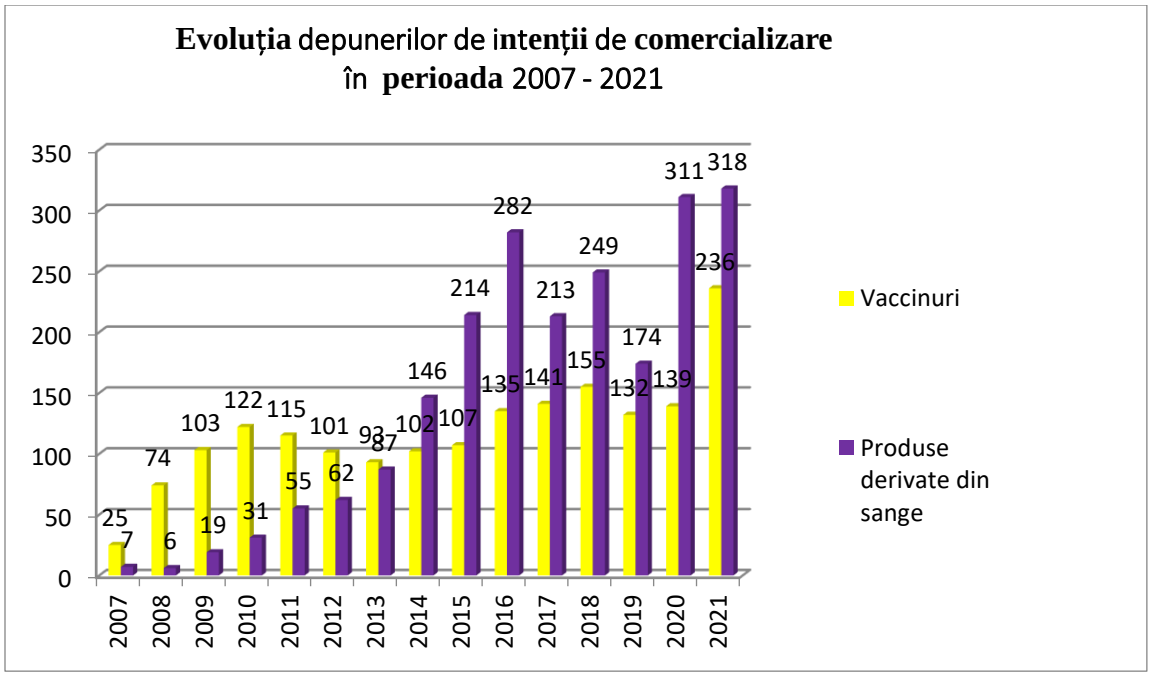
g. In 2021, the DECCM issued 25 certificates of analysis and 1 certificate of official release of the vaccine batches.

h. Approval of biological medicinal products for which official batch release has been carried out by a control authority in an EU member state:

As part of this activity, documents were received from the distribution companies regarding the marketing intention for 554 batches of authorised biological products marketed in Romania (236 batches of vaccines; 318 batches of blood-derived products). 355 commercialisation agreement notifications were issued for the 554 commercialisation intentions entered in the NAMMDR for the biological medicinal products under the scope of the OCABR.

In 2021, at the same time as the start of COVID-19 vaccination, 118 commercialisation intentions for vaccines authorised centrally by the EMA were evaluated in the DECCM as a priority. For these, 115 marketing agreements were issued with maximum priority.

The evolution of submissions of commercialisation intentions (2007-2001):
Yellow – vaccines
Purple – Blood-derived products



2. Evaluation of the quality documentation submitted:

a. Within the DECCM, for the national procedure, the activity of validating applications for (type IB and type II) variations to MA terms is carried out for biological medicinal products.

During 2021, this activity mainly consisted of:

- 83 validations of type IB and type II variation applications;
- 5 invalidations of type IB and type II variation applications.

b. Evaluations of quality documentation - national procedure

→ For biological medicinal products submitted for authorisation/renewal of the marketing authorisation:

8 reports were developed, of which 4 reports with requests for supplementation of the documentation and 4 reports with a proposal for approval of the MA renewal. Also, upon request of the National Procedure Evaluation Service within the National Procedure Department, the information regarding the method of verification of microbiological parameters (sterility, endotoxins, etc.) was evaluated for 6 medicinal products in the authorisation procedure, through national procedure.

→ Within the DECCM, the supporting documentation for (type IA/IB/II) variations / design changes / MA transfer, submitted through the national procedure for biological medicinal products, was also evaluated:

For Type IA and IB variations/Design changes/MA transfer/Braille imprinting, 225 addresses/annexes to the applicant (the addresses accompanied by Annexes with requests were sent in electronic format) were issued after evaluation of the documentation:

- 38 addresses with proposal for approval for simple type IB variations;
- 13 addresses with proposal for approval for type IB grouped variations;
- 3 annexes with request for completion for simple type IB variations;
- 29 addresses with proposal for approval for simple type IB variations - worksharing procedure;
- 38 addresses with proposal for approval for grouped type IB variations - worksharing procedure;
- 65 addresses with proposal for approval for simple Type IA variations;
- 19 addresses with proposal for approval for Type IA grouped variations;
- 4 addresses with proposal for approval for design changes;
- 1 request for design changes;
- 15 addresses with proposal for approval for MA transfer.

For type II variations (simple and grouped), 91 evaluation reports were issued after the evaluation of the documentation:

- 8 reports with proposal for approval/with a request for completion of simple type II variations;
- 3 reports with requests for simple type II variations;
- 16 reports with proposal for approval for type II variations;
- 23 reports with proposal for approval for simple type II variations - worksharing procedure;
- 41 reports with proposal for approval for type II grouped variations - worksharing procedure;

Upon request of the Variations Service/DPN, the evaluation of the supporting documentation of some requests for variations related to the quality of synthetic medicinal products was carried out: 2 evaluation requests;

c. Evaluation of quality documentation – European procedure;

In 2021, the evaluation of the quality documentation for biological medicinal products for which an application for authorisation was submitted through the mutual recognition procedure, but also through the decentralised procedure, was continued, followed by the delivery of assessment reports in accordance with the stipulated deadlines, as follows:

→ Mutual recognition procedure (MRP) and/or decentralised procedure (DCP)

Quality assessment reports for medicinal products under authorisation/renewal through the mutual recognition procedure/decentralised procedure were developed and drafted, with the issuance of 7 reports with a proposal for MA renewal, 9 reports with a request for supplementation and 3 reports with proposal for authorisation and conditions for authorisation.

→ Centralised procedure

The DECCM assessors participated in centralised procedures coordinated by the EMA, as co-rapporteurs for:

- 2 biosimilar medicinal products (monoclonal antibodies)
- 1 ASMF for synthetic medicinal products

→ Within the DECCM, the supporting documentation for variations submitted through the European procedure were also evaluated, for which 76 annexes for type IB variations and 54 evaluation reports and the corresponding Annexes for type II variations were developed. For all the approved variations, the final tabular reports for the variations approved by the SMR are issued as well.

→ Within the DECCM, the supporting documentation was evaluated and the quality assessment reports of the ASMF documentation submitted through the European procedure were developed as follows:

- 5 reports for variations with Romania as Reference Member State
- 163 ASMF documentation evaluation reports for variations with Romania as Interested Member State
- 105 ASMF documentation evaluation reports for medicinal products submitted through the European procedure
- 26 reports supplementing the ASMF documentation for medicinal products submitted through the European procedure

d. Evaluation of the quality documentation submitted in order to approve applications for conducting clinical trials:

In 2021, the quality documentation submitted in support of the request for authorisation to conduct clinical trials was also evaluated within the DECCM. Quality assessment reports were developed for active substances included in investigational medicinal products (approval of clinical trial protocols): 20 reports.

e. Amendment of the terms of marketing authorisations for biological medicinal products for human use.

As regards the amendment of the terms of marketing authorisations for biological medicinal products for human use, as a result of the approval of some type I or II variations or as a result of some editorial corrections, during 2021, 53 changes to the MA were made in the DECCM.

f. Evaluation of the quality documentation submitted for approval of applications for authorisation through the special needs procedure, of applications for exemption from labelling in Romanian, of applications for authorisation for use in last-resort treatments.

In 2021, the DECCM also evaluated the quality documentation submitted in support of authorization applications through the special needs procedure, applications for exemption from labelling in Romanian, requests for authorisation for use in last-resort treatments for biological medicinal products.

V.6 MEDICAL DEVICES

1. The Medical Devices Regulation and Market Surveillance Directorate (DRSP)

The Medical Devices Market Regulation and Surveillance Directorate (DRSP) carries out its activities as the national market surveillance authority, through the Medical Devices Market Surveillance Service, and as competent authority in the field of medical devices, through the Regulatory Service.

The DRSP is structured in 2 different services, as follows: the Regulation Service (SR) and the Medical Devices Market Surveillance Service (SSP).

Both services are in a coordination/collaboration relationship with the other medical device departments, namely the Technical Laboratories Department (DTL) and the Approval Department (DA).

According to the approved organisational chart, the DRSP is subordinated to the General Directorate for Medical Devices (DGDM).

Activities performed:

According to the NAMMDR ROF, the Regulatory Service has the following main duties:

a) Internally (within the NAMMDR):

– evaluates the compliance with the legal provisions of the submitted files and registers the medical devices placed on the market, the domestic manufacturers, authorised representatives, importers and distributors of medical devices, in line with the regulations in force.

Thus, the following were issued:

- ✓ 692 (from certificate no. 10314 to 11006) medical devices introduced on the market by responsible economic operators (domestic producers, authorised representatives residing in Romania);
- ✓ 7 (from certificate no. 8643 to 8649) medical devices put into operation by responsible economic operators (all aforementioned types);
- ✓ 60 medical devices placed on the market in accordance with the MDR (from certificate no. 1 to 60).

– creates and updates the national database in accordance with the provisions of national legislation transposing European directives and regulations - permanently.

– authorises the conduct of clinical investigations with medical devices based on the approval of the NAMMDR president and according to the result of the evaluation of the files related to the requests made in this regard by the sponsors of the investigations.

In 2021, the following were assessed:

- ✓ 2 dossiers for clinical investigations with CE marked devices;
- ✓ 12 final/yearly reports;
- ✓ 1 substantial amendment;
- ✓ 1 non-substantial amendment;
- ✓ 1 file registered for grant of authorisation;
- ✓ 1 authorisation was issued;
- ✓ information and clarifications were provided for 17 requests, most of them related to the national legal provisions for the application of the MDR for clinical investigations.

The voluntary registration, started in 2020, of economic operators in the EUDAMED continued in 2021, an operation managed by the DRSP, with registration requests being validated through the EUDAMED. 81 producers, 13 authorised representatives and 249 importers were validated (as NAMMDR-LAA).

The records from the European database of medical devices (Eudamed 2) were viewed, in order to check the compliance and validity of the documents from the files registered at the NAMMDR - permanently.

– carries out documentation, implementation, research and development activities in its field of activity - permanently.

– issuance of customs notices, notifications and registration certificates for medical devices, upon request and in accordance with the specific legal provisions in force: 25 approvals for donation, 35 denials; 2 notifications for clarification and request for additions related to the release of denials - elaboration of responses (addresses, e-mails to clients and various e-mails) for requests of information and clarification of some legal aspects (of which 7 in English).

–2800 medical device registration (F3 notifications) were closed. As a result of the suspension, starting from June 11, 2021 of the registration of medical devices notified through the F3 forms, determined by the repeal of Order of the Ministry of Health no. 1009/2016 regarding the registration of medical devices into the national database (except for the provisions of Art. 4 b), Art. 5, Art. 7(1)-(3), Art. 8, Art. 12, Art. 13, of Annex 1 and Annex 4), according to Art. 33 of Emergency Government Ordinance no. 46 / 2021, there are still 1,277 F3 notifications to be classified.

b) At national level (in relation to Romanian authorities / bodies):

– In 2021, Emergency Ordinance no. 46/2021 was drafted, regarding the establishment of the institutional framework and measures for implementation of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 regarding medical devices, amending Directive 2001/83/EC, Regulation (EC) no. 178/2002 and Regulation (EC) no. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

– Elaborates methodological norms regarding the organisation and operation of the medical devices sector and submits them to the approval of the Minister of Health. In this respect, drafts of the methodological norms for the application of the provisions of Art. 3, 6, 10, 12, 13, 16 of Emergency Government Ordinance no. 46/2021 were developed and proposed for approval in 2021:

 draft Order of the Minister of Health for the application of Art. 13 of Emergency Government Ordinance 46/2021 (custom devices);

 draft Order of the Minister of Health regarding the placement of medical devices on the market and the registration of economic operators in the Eudamed as well as in the national database and derogation from compliance assessment procedures;

 draft Order of the Minister of Health regarding the approval of the procedure regarding the manufacture and use of medical devices within healthcare institutions;

✓ draft Order of the Minister of Health regarding the approval of the procedure for issuing denials for products which do not fall within the scope of the MDR;

✓ draft Order of the Minister of Health regarding the approval of the procedure for issuing the free sale certificate for medical devices;

✓ draft Order of the Minister of Health on approval of the Methodological Norms regarding clinical evaluation procedures and clinical investigation with medical devices;

✓ draft Order of the Minister of Health on amendment and supplementation of Order of the Minister of Health no. 1.202/2017 regarding the establishment, organisation and operation of specialised commissions and subcommissions of the Ministry of Health.

✓ Elaboration of draft Order of the Minister of Health on approval of the Methodological norms regarding the reporting of suspected serious incidents in relation to medical devices - in accordance with the provisions of Art. 87 of Regulation (EU) 2017/745 and Art. 9 of Emergency Ordinance no. 46 of 9 June 2021 (completed in 2021 by the publication in the Official Gazette of the Order of the Minister of Health No. 2882/2021 regarding the method of reporting suspected serious incidents related to medical devices).

✓ Elaboration of the draft Order of the Minister of Health on approval of the Methodological norms regarding the assessment, designation and notification of medical device compliance assessment bodies and the monitoring of notified bodies - in accordance with the provisions of Art. 42 of Regulation (EU) 2017/745 and 26 (6) of EMERGENCY ORDINANCE no. 46 of 9 June 2021.

✓ Repeal of Order of the Minister of Health no. 373/2015 regarding the approval of the form with special regime of the minute related to the findings and application of legal sanctions regarding non-compliance with the legal provisions for medical devices and related activities.

✓ Proposal for amendment of the legislation – Emergency Government Ordinance no. 46/2021 regarding the establishment of the institutional framework and measures for the implementation of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, of Regulation (EC) no. 178/2002 and Regulation (EC) no. 1.223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

✓ Proposal for amendments to the legislation - Law 95/2006 on healthcare reform, republished - Title XX.

– elaborates the lists including the Romanian standards adopting the European standards harmonised with the European directives in the field of medical devices and submits them for approval to the Minister of Health: collaborated with the ASRO in order to translate some standards in 2021; participation as NAMMDR experts in a virtual meeting of CT 374 organized by the ASRO and management of documents received in electronic form (via e-mail) from the ISO CASCO - approximately 150;

c) At international level:

– Participation in meetings and working groups in the field of medical devices at European Union level:

Participation in meetings of working groups: MDCG (Medical Device Coordination Group) WG: MD + IVD, Standards, NBO, MD + IVD, EUDAMED, UDI, ANNEX XVI, Clinical Investigation, International Matters, Borderline & Classification, Nomenclature, Regulatory Committee on medical devices-oct. 2021, Working Party on Pharmaceuticals and Medical Devices;

- ✓ participation in working groups of the EU Council for Medicinal Products and Medical Devices - discussions in the field of medical devices, the preparation of points of view in relation to the proposals for community legislative acts and the themes of the working groups at EU level in the field of medical devices, of the mandates of representation for the Ministry of Health or the Romanian Representation at the European Commission, the verification of translations into Romanian of documents issued by the EU Council and/or the European Commission, in the field of medical devices;
- ✓ participation in a meeting of the competent authorities in the field (CAMD) on issuance of free sale certificates;
- ✓ transmission to the European Commission of the documents related to requested updates regarding the NAMMDR experts nominated in the working groups.

- ✓ online participation in the teleconferences of the Competent Authorities for Medical Devices (CAMD), held between 07-08/06/2021 by the Competent Authority of Portugal, as the Member State having held the EU Council presidency during the first semester of 2021; 05-06/10/2021 by the Competent Authority of Slovenia, as the Member State having held the EU Council presidency during the second semester of 2021.
- ✓ online participation in the CAMD – Operational Working Group teleconference (14.10.2021).
- ✓ online participation in the following specific COVID-19 meetings:
- ✓ IVD Corona call (21/01/2021; 25/02/2021; 25/03/2021; 09/04/2021 (workshop on Common Specifications); 29/04/2021; 03/06/2021; 07/10/ 2021;
- ✓ transmission to the COM of the supporting address of the chairman of the IVD working group in order to complete the implementation acts and all the necessary steps in the immediate vicinity of the date of implementation of the IVDR.
- ✓ online market surveillance participation in the Joint Inspection Group in view of establishing a common EU-wide approach to inspections carried out in the field of medical devices (Part I - 20/05/2021 and Part II - 21/10/2021).
- ✓ online participation in the international conference «Legislation in the field of MD in the current European and international context», in the International Scientific Conference «Applications of Chemistry in Nanosciences and Biomaterials Engineering», UPB Bucharest, 25.06.2021.

– Elaboration from a technical viewpoint of Romania's position and mandate of representation concerning the proposals of community legislative acts and the themes of working groups at EU level, in the field of medical devices, and their transmission to the Ministry of Health.

- verification of the RO version of the proposed Regulation amending Regulation 746/2017/EU.
- ensures administrative cooperation with the competent authorities of EU member states regarding the provision of services in the field of medical devices, through the Ministry of Health and the information system of the internal market - IMI, established by the European Commission - permanently.

–records and evaluates information on reported incidents and proposed corrective actions in relation to medical devices and implements the vigilance procedure according to the harmonised legislation in force:

- manufacturer incident reports (MIR) – from at least 35 producers;
- field safety corrective action (FSCA) reports – from at least 39 manufacturers;
- competent authority reports (NCAR) + field safety notices (FSN) – from at least 36 manufacturers.

Information requests were made to 2 Competent Authorities (Bulgaria, Germany), 9 Notified Bodies, 6 authorised representatives in the EU and 1 manufacturer.

Correspondence with the Competent Authorities regarding sanctioned non-compliant products (COEF): COEF evaluation for information – a minimum of 134; COEF evaluation for response and response formulation – 18; initiation of COEF RO – 12.
Information on falsified CE Certificates of Compliance detected on the EU market was analysed, while informing the other departments and creating notifications posted on the NAMMDR website - 28.
Information on suspended / withdrawn / refused EC Compliance Certificates was analysed, having informed the other departments (as the case may be) – 81.
In line with Art. 8(3) of 93/42/EEC and 98/79/EC and Art. 7 (3) of 90/385/EEC we are in a permanent exchange of information with the other authorities of member states, regarding product compliance. We actively participate in the meetings of the COEN (Compliance and Enforcement Group), MDCG - Market Surveillance, Joint Inspection Group.

The Market Surveillance Service controls whether medical devices meet the requirements of the applicable technical regulations and whether economic operators act according to their obligations. As part of the market surveillance activity, the following stages are carried out:

a) monitoring of medical devices introduced on the market and/or put into operation as well as those exposed at fairs, exhibitions, demonstrations and the like;

b) establishing the measures to be taken by economic operators, as the case may be, in order to meet the compliance of the products;

c) tracking the way of applying the established measures.

The staff of the market surveillance service carried out control actions aimed at checking compliance with European and national legislation related to medical devices (including IVDs and active implantable medical devices).

In 2021, the SP service (with headquarters in Bucharest) organised and carried out 311 thematic control actions regarding the check of compliance of medical devices placed on the Romanian market (registration, notification, compliance with the requirements in accordance with the provisions of HG 54/2009, HG55/2009, HG798/ 2003, GEO 46/2021) and in-use medical devices, in compliance with the legislation in force (ensured by economic agents) - Law 95/2006: 183 importers and distributors, 7 manufacturers, 65 medical optics units, 9 healthcare units, 41 clinics and pharmacies, 6 retail stores. Of the 311 controls: 104 reactive controls and 207 proactive controls.
In 2021, 110 fines and 4 warnings were applied at the main headquarters in Bucharest, for which minutes were drawn up in order to determine and apply the legal sanctions.
For the 364 notifications/complaints received for resolution within the market surveillance service, viewpoints, objections, addresses were drawn up and sent to the NAMMDR DJAERI in order to verify the reply and send it to petitioners within the legal term.
Viewpoints were sent to other state authorities: Customs - 25, Prosecutor's Office - 7, ANPC - 21, DSP - 8, Police - 9, Town Halls - 4, Court - 5, Infocons Civic Associations - 7.

As part of the market surveillance activity, 39 types of medical devices were temporarily/definitely stopped from being sold/used.

Within the Iasi ICU, in 2021 (07.01.2021-12.31.2021), 75 control minutes were concluded at commercial companies and medical units, following checks carried out in the territory; deviations from the applicable legislation were found and 15 legal sanctions were applied.

In 2021, within the Craiova ICU (09.08.2021-12.31.2021), 55 control minutes were concluded at commercial companies and medical units, following the checks carried out, of which 45 in Bucharest and 10 in the territory. Minutes of infringements were drawn up for 20 of the controlled companies.

In 2021 (07.01.2021-12.31.2021), within the Timișoara ICU, 80 control minutes were concluded at commercial companies and medical units, following the checks carried out (39 in Bucharest and 41 in the territory). Minutes of infringements were drawn up for 21 of the controlled companies. Following the hiring of staff, the number of controls increased from 109 in 2020 (2 inspectors) to 311 in 2021.

Between 12.10.2021 – 28.10.2021, NAMMDR representatives were members of the commission regarding the procedure for procurement of equipment such as: rapid tests for SARS-COV2 detection from nasopharyngeal swab and saliva samples, organised by the National Office for Centralised Procurement, at the request of the DSU.

Warnings regarding non-compliant medical devices placed on the EU market were posted on the NAMMDR website – 28 notifications regarding falsified EC Compliance Certificates detected on the EU market.

Activity report - status of controls carried out within the Market Surveillance Service in 2021

Performed controls	All controls - 311 - reactive controls - 104 - proactive controls - 207
Theme of performed controls	Verification of compliance with specific regulations in the field of medical devices
Legal basis:	- Law 95/2006 on healthcare reform, republished, as amended; - GOVERNMENT DECISION NO. 306/2011 regarding some measures of market surveillance of products covered by EU legislation and their marketing conditions; - GOVERNMENT DECISION NO. 798/2003 regarding the establishment of the conditions for placement on the market and use of in vitro diagnosis medical devices;

	- Emergency Government Ordinance no. 46/2021 on establishing the institutional framework and measures for the implementation of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, of Regulation (EC) no. 178/2002 and Regulation (EC) no. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC; - Order of the Minister of Health no. 566/2020 on approval of the Methodological norms for enforcement of Title XX of Law 95/2006 on healthcare reform, regarding the approval of activities in the field of medical devices; - Order of the Minister of Health no. 308/2015 on the control through periodic verification of medical devices put into operation and in use
Potential subjects of controls:	- Romanian manufacturers of medical devices; - importers of medical devices; - distributors of medical devices; - units ensuring installation and maintenance of medical devices; - state and private health facilities; - medical offices for aesthetic procedures; - bioresonance/alternative medicine offices (According to the provisions of Article 15 of Emergency Government Ordinance no. 46/2021).
Economic operators subject to the controls performed:	- manufacturers - **7** - importers - 82 - distributors - 101 - healthcare units - 9 - medical offices for aesthetic procedures - 6 - bioresonance/alternative medicine offices - 2 - clinics and pharmacies - 33 - medical optics units - 65 - retail stores - 6
Observed deviations:	- carrying out unauthorised activities in the field of medical devices;

	- non-compliance with the conditions for approval; - minor or major non-compliance of imported/distributed medical devices; - non-compliance with the conditions of use of medical devices; - failure to ensure the checks, established by law, of the medical devices in use; - failure to provide maintenance services for medical devices, with approved units, in accordance with legal provisions.	
Sanctions/measures taken:	- legal sanction; - prohibition of distribution/marketing and recall of non-compliant medical devices; - withdrawal and prohibition of use of non-compliant medical devices; - banning advertising for non-compliant products.	
Legal sanctions with a fine, applied to economic operators	Contravention fines -109 - manufacturers - 2 - importers - 26 - distributors - 81	
The amount of contravention fines applied:	- producers - 10 000 RON - importers - 181 000 RON - distributors - 309 000 RON - hospital units - 20 000 RON Total: 520.0000 RON	
Warnings:	- importers - 4 - distributors - 10	
Notifications/complaints addressed to the NAMMDR/DGDM/SSP	364	Solved
Requests from state bodies / civic associations:	Customs - 25 The Public Prosecutor's Office - 7 ANPC - 21 DSP - 8	Solved

	Police - 9 City halls - 4 Courts - 5 Infocons Civic associations - 7	
Withdrawal of non-compliant medical devices: Prohibition of advertising:	- latex examination gloves, powdered; - nitrile examination gloves; - high flow therapy oxygenation set; - Allergan prefilled syringes; - vacutainer needles; - nasal aspirators for children; - various types of non-contact thermometers; - different types of pulse oximeters, marketed on information community platforms; - compresses, plasters - various types; - face masks - ”Children’s protective mask”; - face masks - ”Disposable kid’s mask”; - for Aquafilling – from the service platforms of the information society. Temporarily/permanently discontinued from marketing/use - 39 types of medical devices.	

Please see below the activity of the SSP in previous years.

	2017	**2018**	**2019**	**2020**	**2021**
Number of controls performed	191	227	248	109	311
Number of medical devices temporarily/definitely decommissioned	9	9	3	9	39

2. The Technical Laboratories Department (DTL)

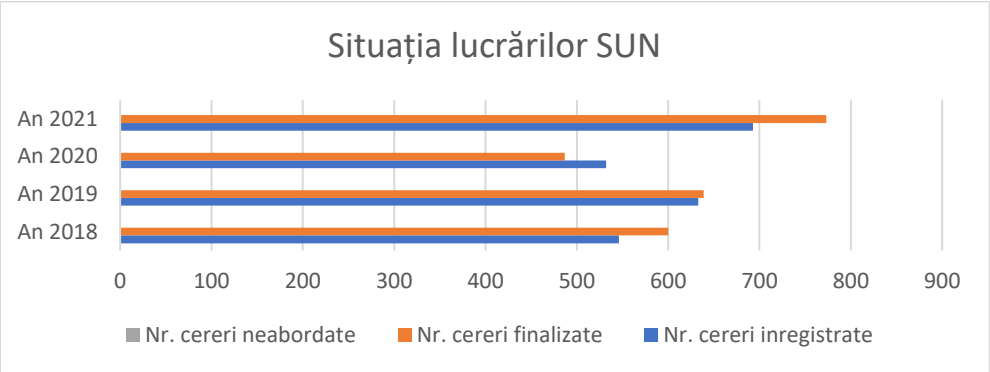
Within the General Directorate for Medical Devices, the Technical-Laboratories Directorate operates through two services: the Tests and Verifications Service and the Nuclear Unit Service.

The main activity of the Technical-Laboratories Directorate is the technical verification of in-use medical devices put into operation. Checks are carried out upon request from the healthcare units. This activity is carried out for widely distributed medical devices with high degree of risk (according to Order of the Minister of Health no.308/2015) and for second-hand ones (according to Article 931 of Law 95/2006 with further amendments and completions), to all users of medical devices, both in the public and in the private sector, and is completed by issuing a periodic check bulletin or usage notice. The bulletins and notices issued for healthcare facilities are similarly requested by health insurance houses in order to conclude the contract for medical services.

A test report is drawn up for each checked medical device, which is kept in the work file and sent to the beneficiary, for a fee, together with the periodic check report/use notice. For non-compliant medical devices, a negative test report is issued, prohibiting their use until the non-compliances are resolved and the periodical verification bulletin or the usage approval is obtained. This type of report is sent to the user of the medical device instead of the verification report or notice of use.

The Nuclear unit service

1	Applications registered in 2021	693
2	Applications completed in 2021	773 (104 closed)
3	BVP + AU issued in 2021	706
4	RI issued for medical devices with radiation generators in 2021	463
5	RI issued for radiation protection equipment in 2021	1349



SUN activity (per year):
Grey - unaddressed applications
Orange – Number of finished applications
Blue – Number of recorded applications

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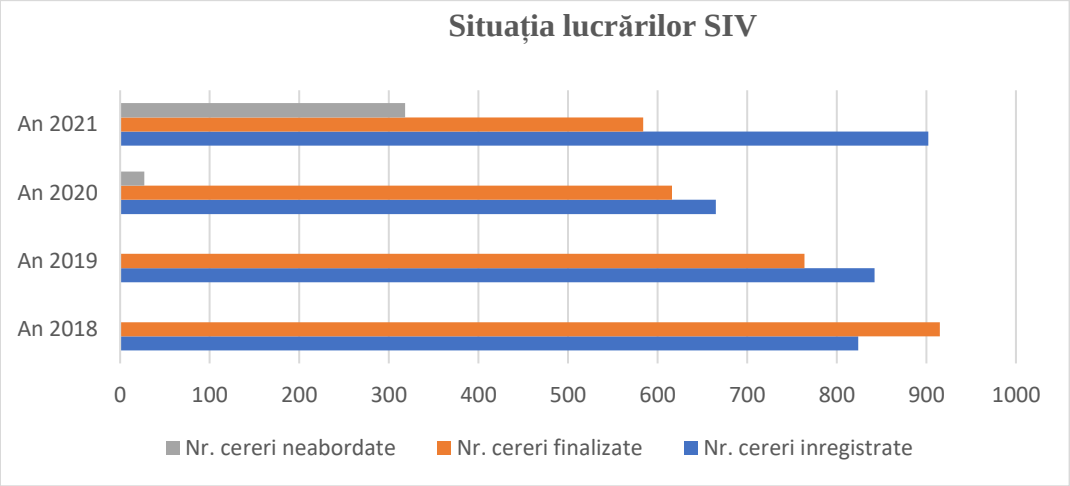
The Tests and Verifications Service

No.	Key-indicators	Total
1	Applications registered in 2021	902, of which 318 not addressed
2	Applications completed in 2021	584
3	BVP issued in 2021	1622
4	AU issued in 2021	139
5	RI issued for medical devices in 2021	3936



SIV activity (per year):
Grey - unaddressed applications
Orange – Number of finished applications
Blue – Number of recorded applications

Trips were made to private healthcare units, public hospitals and county ambulance services. For large hospitals, several trips were necessary; during a delegation, it was possible to check 30-60 devices / week.

3. The Approval Directorate (DA)

The activity of the Approval Directorate took place in 2021 according to Order no. 566/2020 on approval of the Methodological Norms for the application of title XX of Law 95/2006 on healthcare

reform, regarding the approval of activities in the field of medical devices, issued by the Minister of Health on 04.03.2020 and according to procedure PO-DGDM/DA/01, Version: 01, Edition of: 06.2020.

The marketing and service activities in the field of medical devices subject to approval control were:

a) import of medical devices;
b) distribution of medical devices;
c) installation and/or maintenance of medical devices.

The centralised situation of requests for the last six years is presented as follows:

Year	**Number of registered requests**	**Average number of works/month**	**Average number of works/employee/month**	**Number of hired assessors**
2016	395	33	4	8
2017	1049	87	10.8	8
2018	2223	185	20.5	9
2019	1817	151. 4	16.8	9
2020	2986	248.8	24.8	10
2021	3538	294.83	29.48	10 *

*An average number of assessors was used, since throughout the year some inspectors worked temporarily and some were hired during the last period of the year.

In 2020 and 2021, the number of requests increased considerably, given the COVID-19 pandemic and the great need for medical devices: oxygen concentrators, pulse oximeters, surgical masks, coveralls, gowns, rapid tests to determine the presence of the COVID-19 virus, etc. The pressure on operators is very high, all operators requesting the rapid issuance of Notices/Annexes to Notices, given the fact that they need the documents for customs and/or participation in auctions for purchase of sanitary protection materials.

In 2021, 324 works registered in 2020 were completed, as follows: 76 operating approvals, 161 approval annexes, 35 renewals and 52 classifications. Of the 3538 papers assigned in 2021, 2585 were completed and 268 were overlooked. At the end of 2021, there were 644 works left to be carried out in 2022. Economic operators request by e-mail information about the approval process, information about legislation, etc. A high number of requests for information are received from healthcare facilities and other public institutions which make purchases of medical devices and ask for clarification on applicable legal requirements. In 2021, more than 1000 requests for information received both by electronic mail and in written format were solved.

The employees of the Approval Directorate participated in the committees for auctions and assessment of the files submitted to the auctions organised by the Ministry of Health, ONAC.

V.7 COMMUNICATION AND PUBLIC RELATIONS

The Communication and Public Relations Service (SCRP) is directly subordinated to the vice-president of the NAMMDR with attributions regarding technical-administrative activities which support the specific scientific activities.

Through the communication activity it carried out, the SCRP ensures relations with all interested parties: patients, patient associations, media, healthcare professionals, professional associations, pharmaceutical industry, national and international profile organisations.

In 2021, the SCRP contributed to the implementation of the institution's organisational and communication strategies and, through the head of structure, actively participated in the working group of the Government of Romania regarding the implementation of the government communication strategy.

The SCRP proceeded to implement the general standard for displaying information of public interest on the NAMMDR website (management agenda, 2021 Activity Report, newsletters).

Direct communication with journalists, as well as with patients, orienting and focusing communication on the exposed issue and implicitly identifying solutions for each individual case contributed to strengthening the image and trust of the general public in the institution's activity.

The NAMMDR responded promptly to all requests received from other institutions which requested the Agency's viewpoint on various topics of major interest for public health.

The Communication and public relations service participated, together with other professional structures, in the management of issues related to the proper functioning of the NAMMDR in the national and international network of competent authorities in the field of medicinal products and medical devices.

Given the current dynamic epidemiological context generated by the COVID-19 pandemic, a proactive communication with healthcare professionals, the media, patients, the general public and more was required, SCRP's activity particularly focusing on facilitating applicants' access to information about medicinal products included in protocols for the treatment of the SARS-CoV-2 virus infection, vaccines authorised by the European Medicines Agency (EMA), side effects, and about the tests and masks used by healthcare professionals for COVID-19 testing.

In order for the general public to be permanently informed and to facilitate access to scientific information of vital interest in this pandemic context, special sections have been created on the NAMMDR website.

The SCRP continued to ensure good information and communication with all interested parties, in accordance with the legal provisions, constantly aiming to optimize activities in the field of communication both at institutional and national level and within the network through:

- communication of the institution's strategic objectives and communication with interested parties, especially in crisis situations;
- using an effective and collaborative communication method;
- building and maintaining the trust of the civil society as a whole in the activity carried out, by strengthening the institution's reputation and authority in front of the interested parties;
- continuing to focus on a predominantly proactive approach to communication, encouraging the transmission of a consistent, clear and correct message to interested parties;
- giving maximum importance to the management of crisis situations in the field of health through prompt, consistent and effective communication to the general public.

The rapid and efficient communication of all information received from the European institutions with which the NAMMDR closely collaborates (EMA, etc.) was another objective of the SCRP through translation, validation with NAMMDR experts and posting all notifications of public interest on the NAMMDR website.

The promotion of the Agency as a basic institution of the Romanian healthcare system was also achieved through constant participation of its representatives in conferences, debates and meetings organised by third parties, on topics that fall under the competence of the NAMMDR. This promotion was also achieved by facilitating the publication of interviews and articles in specialised magazines.

An important component of communication with interested parties, showing the Agency's openness for constant and transparent communication, for the benefit of Romanian patients, was carried out through permanent meetings with representatives of companies and professional societies (the Romanian Organisation for Serialisation of Medicines (OSMR), the Romanian Generic Medicines Association and the Association of Romanian Medicines Manufacturers - APMGR, the Romanian Association of International Medicines Manufacturers - ARPIM, the Romanian College of Physicians, etc.), of other institutions in the healthcare field and more (the Parliament of Romania, Department for the Relation with Romanians Abroad, the National Authority of Quality Management in Health (ANMCS) etc.).

In 2021, the SCRP actively participated in the Working Group of Communications Professionals (WGCP) of the EMA, in weekly meetings and all other meetings, press conferences or international conferences (organised under the Portuguese Presidency, etc.), dealing with the communication of the authority during the pandemic.

The SCRP has permanently sent lines-to-take, received from the EMA, to the interested structures within the NAMMDR, but also to the The

Romanian National Coordinating Committee for COVID-19 Vaccination (CNCAV) or the Ministry of Health.

At the same time, the SCRP coordinated the international communication campaigns occasioned by the MedSafetyWeek or the Antimicrobial Resistance.

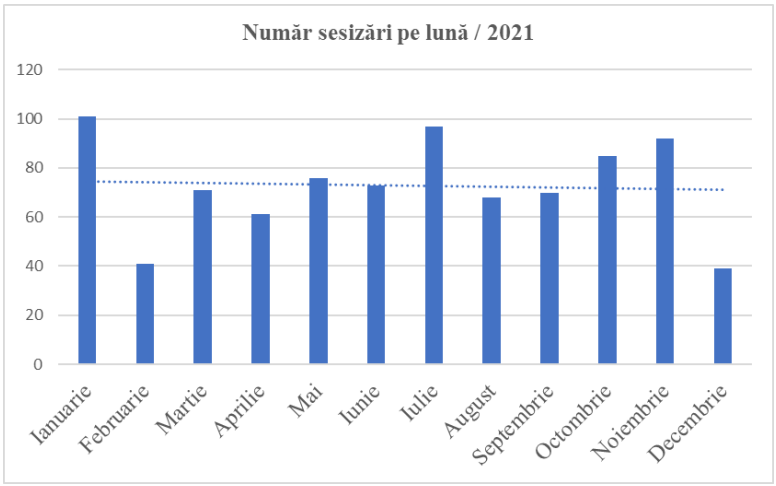
The SCRP ensured correspondence with the Heads of Medicines Agencies (HMA) - EMA and the Management Board (MB) - EMA.

Moreover, throughout this period, SCRP's main objective was the facilitation of the communication process to the general public and the mass media, by promptly replying to the requests received both through social media (the NAMMDR Facebook and Linkedin webpage), as well as by e-mail/telephone.

The SCRP continues to monitor and manage the email address lipsmedicament@anm.ro, established upon request of the Ministry of Health in February 2015. Thus, in 2021, 874 notifications were received from patients, patients' relatives, hospitals, open circuit and hospital pharmacies, patient associations, pharmaceutical warehouses, medical societies, physicians, all of which were resolved quickly.

The monthly situation is as follows:

Number of findings per month in 2021:



The SCRP continued the activity of monitoring, documenting and formulating replies to notifications forwarded from the e-mail address of the Ministry of Health, noreply@medicamentelipsa.ro, dealing with notifications posted on the platform http://medicamentelipsa.ms.ro/ (in parallel with the lipsmedicament@anm.ro e-mail address, the Ministry of Health developed and put into practice, in September 2016, another means of signalling the lack of medicinal products from the market, namely by posting notifications on the Ministry of

Health platform http://medicamentelipsa.ms.ro/) . Therefore, between March and December 2021, 480 out of a total number of 874 notifications were automatically forwarded by the Ministry of Health to the lipsmedicament@anm.ro address (since the end of October 2020 - the Ministry of Health platform stopped working and became operational from March 2021).

In 2021, as in previous years, in support of effective internal and external, prompt and quality communication, the SCRP also carried out other activities, such as:

- participation in internal and external communication, namely taking positions, communication with print media and TV, relations with other relevant institutions in Romania and outside the country;
- daily monitoring of the mass media (TV press, print media and online media) in the healthcare field, as well as the administration of the NAMMDR Facebook page;
- organising a working meeting with patient associations and several discussions with the patients on various topics;
- preparing/verifying/broadcasting to the mass media the official press releases and opinions of the NAMMDR management, as well as posting them on the institution's website;
- managing and participating in NAMMDR audiences alongside other structures;
- elaborating and managing minutes of internal and external meetings or working groups (82 minutes);
- approving information on the website and social media;
- editing press releases and other materials (informative brochures) received from specialised departments;
- revision of the List of NAMMDR employees assigned as representatives or alternates in the Management Board, Scientific Committees and Working Groups of the European Medicines Agency (EMA), the Heads of Medicines Agencies, the European Directorate for the Quality of Medicines & HealthCare (EDQM), the European Council, the Council of the European Union, The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) and the European Commission and other working groups of the European Union and international institutions – 12 major revisions;
- monitoring and updating the NAMMDR database on the Server-romsys, regarding Decisions of the European Commission (EC) and consensus agreements of the Coordination groups for Mutual-recognition and Decentralised Procedures – human (CMDh), regarding medicinal products authorised in Romania, with a view to their implementation by the NAMMDR employees appointed in this respect, 22 decisions;
- managing and periodically updating the "INFO - Pharmacopoeia Service" database accessible on Server-Romsys, as well as setup of electronic and written records of European Commission Decisions;

- the translation from English of 124 press releases of the European Medicines Agency, as well as posting them (in Romanian and English) on the NAMMDR website;

- elaboration of 4 NAMMDR Newsletters, their translation into English and posting them on the NAMMDR website;

- verification/translation of documents requested by internal departments of the NAMMDR – 50 documents (including Orders of the Minister of Health and their Annexes);

- preparation of monthly statements according to Law 95/2006 on healthcare reform, republished, with further amendments and supplementations, which were sent to the Medicinal Products Index Service;

– drawing up and permanently updating a database for internal use containing 54 complaints received from pharmacists and the manner of their resolution by the Pharmaceutical Inspection Directorate, in line with Order of the Minister of Health no. 269/2017 on mandatory provision of medicinal product adequate and undisrupted stocks;

– preparation of the Centralizer related to intra-community delivery notifications sent to the NAMMDR according to Order of the Minister of Health no. 672/2020 and Order of the Minister of Health 740/2021 (weekly);

- 104 replies to notifications received from patients regarding the lack of medicinal products on the market;
- managing/posting the 2020 NAMMDR activity report: requesting and managing replies received from specialised structures, termination of the Agency's activity report.

V.8 LOGISTICS, INFORMATION AND ELECTRONIC DATA MANAGEMENT

The NAMMDR Information and Communication Technology Service (STIC), structured into two departments (IT&C project development office, infrastructure and technical support and Design department, websites), continued in 2021 to ensure, in optimal conditions, the communication with the EMA and to ensure a real-time exchange of information between the Agency and its external collaborators (MAHs, distributors, healthcare professionals, patients, organisations and associations).

In order to respond to these diverse and complex tasks, the profile service acted in the following areas:

– relationship with the European Medicines Agency (EMA) (issuing replies to various information technology questionnaires upon request of the EMA and working groups; managing the database together with the Agency's experts and updating their information through the application provided by the EMA, administration of the Learning Management System portal; managing the database with the Agency's experts assigned to the EMA working groups; managing the database with

"IRIS Competent Authority Users" experts within the EMA Account Management Portal with the role of local administrator; ensuring the Agency's connection to the Common Repository (Centralized Procedure Submissions) database; ensuring the Agency's connection to the Common European Submission Portal (C.E.S.P.) database; participation in IT Directors working groups according to nominations during the year; participation in E.U.T.C.T working groups according to nominations during the year;

– Other activities: development of the programme for online reporting of post-vaccination adverse reactions; development of programmes/applications for internal use; updating programmes/applications for internal use; installation of specific applications for carrying out the activity within the NAMMDR (the European Pharmacopoeia, the United States Pharmacopoeia, etc.); ensuring the publication of sponsorship declarations (sponsors) in 2021on the NAMMDR website; facilitating access to the PhEur, USP, CTS, etc.; updating the WEB application for submission of beneficiaries' declarations of sponsorships in 2021; updating some series of forms on the NAMMDR website; updating the SSL digital certificates of the adverse reaction reporting portal; implementation and updating of SSL digital certificates for NAMMDR domains; intermediation for the creation of access accounts to the CTS service, according to the reports; communicating with the CTS helpdesk service in order to report malfunctions in the provision of the service; administration of the Index, Registry and Variations databases; elaboration of reports from the databases upon request of the management or collaborating institutions (weekly or upon request); updating the automatic periodic update system for posting the Index of Medicinal Products on the website; updating the automatic periodic update system for posting the Index of Medical Devices on the website; daily download of documentation submitted in electronic format via the CESP; configuring and optimizing the manner of network working for the NAMMDR staff; implementation and updating of the Quality Assurance IT system - Standard Info required by the Human Resources and Quality Management Department - Quality Assurance, Ethics and Integrity Department.

- administration, configuration and repairs of local equipment, by monitoring EudraNet connectivity (EudraCT, EudraLink, EudraMail, EudraPharm, EudraVigilance, CTS, Citryx, EPITT);

- software and hardware interventions, as well as maintenance of the NAMMDR website (www.anm.ro) and other software applications.

V.9 LEGAL ISSUES, EUROPEAN AFFAIRS AND INTERNATIONAL RELATIONS

The Directorate for Legal, European Affairs and International Relations carried out its activity in 2021 according to the provisions of Article 34 of the Regulation on the organisation and operation of

the National Agency for Medicines and Medical Devices of Romania, approved by Order of the Minister of Health no. 1522/2019 through the two structures: the General Legal Assistance, Debt Tracking and Administrative Litigation Service (SAJGUDCA) and the Legislation, Notifications, European Affairs and International Relations Service.

In 2021, 1,857 documents were registered at the General Legal Assistance, Debt Tracking and Administrative Litigation Service (SAJGUDCA).

The activity of the General Legal Assistance, Debt Tracking and Administrative Litigation Service (SAJGUDCA) consists mainly of providing consultancy in the field of general legal assistance, namely the legality approval of contracts and administrative documents drawn up by the NAMMDR specialised structures, carrying out legal steps for debt recovery, drawing up documents and representation and defence of NAMMDR's interests before courts, criminal investigation and prosecution bodies, bodies with jurisdictional powers and permanent arbitration institutions.

Regarding the litigations involving the NAMMDR between January and December 2021, there were 440 litigations (16 settled definitively, 333 pending, 91 suspended); in the pending litigations, summonses, responses, written conclusions, requests for evidence, written notes, appeals and appeals, requests for legalisation, notifications to the courts were drawn up; similarly, representing and defending the interests of the NAMMDR before the courts was ensured by legal advisers. In most litigations, the solutions handed down by the courts were favourable to the NAMMDR.

Also, any request addressed by the courts, by other institutions with administrative-jurisdictional activity, by investigative and criminal investigation bodies, in connection with the communication of some information or documents, was promptly answered, including in the cases where the NAMMDR did not have the status of stakeholder.

In 2021, the General Legal Assistance, Debt Tracking and Administrative Litigation Service responded to 73 addresses sent by research and criminal prosecution bodies.

In 2021, the Legislation, Referrals, European Affairs and International Relations Service participated in the meetings organised by the Council of the European Union and prepared, together with the specialized organisational structures within the NAMMDR, the instructions and mandates for representation and negotiation in the field of medicinal products for human use, the assessment of medical technologies and medical devices for the regulations regarding:

- The proposal for a Regulation of the European Parliament and of the Council on assessment of medical technologies in the healthcare field, amending Directive 2011/24/EU;

- The Proposal for a Regulation of the European Parliament and of the Council on strengthening the role of the European Medicines Agency in terms of preparedness for crisis situations in the field of medicinal products and medical devices and their management (EMA Proposal);

- The CONS Draft Conclusions regarding access to medicinal products and medical devices for a stronger and more resilient EU;

- The Proposal for a Regulation of the European Parliament and of the Council for the framework of measures for ensuring the supply of relevant medical countermeasures during a crisis in the event of a public health emergency at EU level (Council Regulation on a framework of measures for ensuring the supply of crisis-relevant medicinal countermeasures in the event of a public health emergency at Union level – HERA regulation proposal);

- The Pharmaceutical Committee, Standing Committee on Medicinal Products for Human Use, Regulatory Committee for Medical Devices, Expert Group on Delegated Act on Safety Features.

The Legislation, referrals, European affairs and international relations Service ensured representation at the Working Group for legislation (EMACOLEX – European Medicines Agencies Cooperation on Legal and Legislative Issues) and the Working Group for the application of legislation/combating falsification of medicinal products (Working Group of Enforcement Officers) – HMA (Heads of Medicines Agencies), organised in 2021 by the Presidency of Portugal and Slovenia of the Council of the European Union.

In applying the attributions in the field of European affairs and international relations, the Legislation, Referrals, European Affairs and International Relations Service permanently monitored the correspondence received from the Ministry of Health and the Romanian Representation in Brussels and formulated the replies within the requested deadlines.

As regards the draft of regulatory acts, the Legislation, Referrals, European Affairs and International Relations Service actively participated and collaborated in the drafting of regulatory acts initiated by the organisational structures within the NAMMDR and were sent for approval to the Ministry of Health.

In 2022, the Legislation, Referrals, European Affairs and International Relations Service resolved a number of: 794 petitions, 96 requests for information of public interest and 243 external addresses, with the support of specialised organisational structures in the institution or, as the case may be, forwarded to the authorities and public institutions with competences and attributions in resolving them, within the legal term from the date of registration, depending on the type of the request.

V.10 QUALITY MANAGEMENT

The Quality Assurance and Registry Service (SACR) is an organisational structure subordinated to the Human Resources and Quality Management Directorate, whose main field of activity is establishing, documenting, implementing, maintaining and continuously improving the effectiveness of the quality management system (QMS) at NAMMDR level.

The Registry and Archive Compartment and the Quality Assurance, Ethics and Integrity Compartment are subordinated to the SACR.

For this purpose, the SACR collaborates with all other organisational structures as well as with the quality assurance managers appointed within the organisational structures of the NAMMDR.
Activities carried out (with quantitative assessment):

Specific processes:

a) Coordination of the SACR activity:

In 2021, the activity within the service was coordinated in the following main directions:

- Staff coordination in the performance of current activities, in line with the job description;
- Coordination of the activities carried out:
  - their processing with the aim of implementing the SCIM; reupdating the operational procedures according to the legislative changes made;
  - monitoring the functionality of the circuits and the information flows necessary in order to supervise and carry out the activities within the DRUMC; proactive management approach in carrying out these activities.
  - proactive approach through permanent concern of the leaders of the services subordinated to the department, as well as of the head of the department, for monitoring compliance with the deadlines for finishing the works carried out in the structure.

All activities in 2021 within the DRUMC were carried out:

• in fulfilling the direction's specific objectives;

• with the aim of achieving performance indicators.

b) SMC coordination at NAMMDR level

Through the attributions defined in the ROF, specific to quality management at the level of the entire organisation, the SACR coordinates the design, documentation, implementation, maintenance, improvement and continuous reporting of the Quality Management System in the NAMMDR in line with the requirements of SR EN ISO 9001:2008 and, in addition, in line with the requirements of SR EN ISO/CEI 17025:2005 for NAMMDR laboratories.

In this respect, the SACR implements the Policy in the field of quality and the objectives related to quality at NAMMDR level (document published on the NAMMDR website at the address https://www.anm.ro/_/STRATEGII/Politica%20referitoare%20la%20calitatea.pdf).

In 2021, specialist assistance was provided to the persons responsible for quality assurance from the organisational structures of the NAMMDR, in order to comply with quality management requirements, through the methodological coordination of their activities in the field of the SMC.

Maintained the "Quality Management System" (SMC) section on the intranet server with the support of the Information Technology and Communications Service (STIC).

c) Internal quality audit

In line with Decision no. 606/27.05.2021, starting from the date of the decision, an expert ranked "IA" within the General Directorate of Pharmaceutical Inspection, the Rapid Alert Service, falsified medicines and a specialist referent ranked "IA" from the Human Resources and Quality Management Directorate, the Quality Assurance Service, the Quality Assurance, Ethics and Integrity Department were appointed to audit the quality management system within the Pharmacovigilance and Risk Management Directorate, during August 1, 2019 – July 31, 2021.

d) Complaints

In line with the System Procedure in force, Handling customer complaints, Code: PS-07/06, Version: 01, Edition of: 05.2018, the SACR has responsibilities in the process of handling complaints received at NAMMDR level from customers/interested parties, through transfer of proposed actions at the level of the various organisational structures in the system of SMC actions and the follow-up of the implementation of the proposed actions.

Since an issue with QMS or operational activities (error, omission, misconduct, deviations from policies/ rules/ PS/ PO/ IL etc.) is usually identified following a complaint, the SACR transfers any corrective or improvement action established as a result of handling a complaint in the SMC action system.

In 2021, no complaints were received regarding the activity of the SACR or other NAMMDR structures which would determine the transfer of corrective or improvement actions established as a result of handling a complaint in the SMC action system.

e) Analysis performed by the management

The analysis carried out by the management of the SMC is carried out simultaneously with the analysis of the professional activity. Thus, at the SACR level, an annual activity report is drawn up, a document disseminated to the DRUMC and to the Communication and Public Relations Service (SCRP) to be used in the preparation of the NAMMDR Activity Report.

f) External documents

External documents relevant to the SACR activity and the implementation of SMC at NAMMDR level, such as guidelines of some organisations/authorities (ISO, WHO, EMA, EDQM, etc.) and publications (books, etc.) are kept under control within the SACR.

g) Quality documents

In 2021, the NAMMDR Quality Manual (MC) developed in 2018 remains in force, together with the "Policy in the field of quality and quality objectives in the NAMMD", as Annexes to the quality

manual. They are made known to all staff by being posted on the NAMMDR intranet server; the Quality Policy and objectives were similarly posted on the NAMMDR website in order to ensure the information of all interested parties.

h) Documented procedures

In order to ensure a unitary and coherent system of documentation of all procedures at the level of the entire organisation, the NAMMDR management maintained and supported the integration of the two systems - SMC (quality management system) and SCIM (internal managerial control system) - by developing a single pattern of procedure (PS-09/01-Management of procedures, in force).

The process of keeping under control (elaboration, revision, modification, distribution) of the system and operational procedures was integrated into the activity of the Technical Secretariat of the SCIM Monitoring Commission provided by the staff of the SACR. Thus, the following activities were carried out:

- the allocation of codes to system procedures and the coordination of the allocation of codes to operational procedures within all NAMMDR organisational structures;
- analysing the documented procedures, from the point of view of compliance with the minimum structure provided for in the model presented in SGG Order no. 600/2018, supplemented with the requirements of NAMMDR's own procedure regarding the management of procedures, the version in force (13-PO/2021);
- keeping the original copies of the system procedures (37 PS at the end of 2021);
- withdrawal of cancelled versions of PS and archiving them in order to prevent the unintended use of expired procedure versions;
- keeping up-to-date the record of all PS and PO within the NAMMDR.

At the level of NAMMDR organisational structures, the review/update of procedures continued for the transposition of all procedures into the new unitary format, the achievement of this objective was affected by a number of internal and external factors, such as:

A. Amendment of Law No. 134 of 12 July 2019 on reorganisation of the National Agency for Medicines and Medical Devices and amendment of further ruling provisions through Ordinance no. 17 of August 30, 2021 for the amendment and completion of Law no. 134/2019 on reorganisation of the National Agency for Medicines and Medical Devices and amendment of further ruling provisions;

B. Issuance of Order of the Minister of Health no. 2318/27.10.2021, published in the Official Gazette no. 1080/11.11.2021, whereby:

a. The new organisational structure of the National Agency for Medicines and Medical Devices of Romania is approved, according to the Annex which is integral part of the Order;
b. Order of the Minister of Health no. 1412 of 13 September 2019 on approval of the organisational structure of the National Agency for Medicines and Medical Devices of Romania, published in the Official Gazette of Romania, Part I, no. 764 of 20 September 2019, is repealed.

C. The steps taken to the Ministry of Health, through notifications 59274E/21.07.2021 and 59274E/02.11.2021, requesting the amendment of the Regulation on organisation and operation of the NAMMDR;
The Order of the Minister of Health on approval of the proposal to amend the NAMMDR Organisation and Operation Regulation and its publication in the Official Gazette was not issued until the end of 2021.

The SACR-CACEI staff participated in:
- the elaboration/transposition according to the new pattern, for analysis, of 3 operational procedures (OP) of the DETM;
- the elaboration/transposition according to the new pattern, in order to be forwarded to the DEAP, of 5 operational procedures (OP);
- the elaboration/transposition according to the new pattern of 10 operational procedures (OP) for the DRUMC/SPS/;
- the elaboration/transposition according to the new pattern of 6 operational procedures (PO) for the DRUMC/SACR/CRA;
- elaboration/transposition according to the new pattern of 1 operational procedure (PO) for the DGDM / Approval Directorate/;

i) Records/documented information:

In 2021, the process of keeping under control the records/documented information in the SACR was maintained and significantly improved by moving from written records to electronic records (Excel records).

Within the Registry and Archive Department, many activities were carried out regarding the receipt, registration, distribution and archiving of documents/records received/sent at NAMMDR level.

The activity carried out within the NAMMDR Archive:

- Documents re-archived in the NAMMDR site of General Atanasie Demostene Street, Bucharest: 1495 files;

• Documents re-archived at the NAMMDR site of Episcop Radu Street, Bucharest: 360 files;
• Collection of documents from the DPN (variations): 3077 brochures, 1427 CDs, 1515 CESP, 54 volumes; including 26 delivery and receipt minutes;
• Collection of documents from the Authorization and Evaluation Service / DGEA: 954 volumes included in 3 delivery and receipt minutes;
• Collection of documents from the Advertising Service: 287 volumes including 4 minutes;
• Collection of documents from the DFVMR: 151 volumes and 341 CDs included in 4 delivery and receipt minutes;
• Collection of documents from the SPNA: 4012 files, 507 brochures, 1387 CDs, 10 volumes; 8 minutes;
• Collection of documents from SAPE – CVAV: 805 volumes; 14 minutes;
• Documents circulated between the Archive Department and the other NAMMDR organisational structures (in order to evaluate the documentation related to medicinal products): 64 files, 26 copies, 5 ASMF, 2 legal files, 5 CDs;
• Files received from departments as a result of evaluation: 93 files.

Activity of the NAMMDR Registry:

Activities	Number of documents
Record of documents into the Internal Registry Database – A	24290 doc.
Record of economic documents into the Registry Database - A (cancellations, regularisations)	100 doc.
Record of documents into the Registry Database - B;	18540 doc.
Introduction of documents submitted by the applicants and the reply addresses sent to them (exits) into the Registry A and B electronic databases;	daily
Sending e-mails to customers in order to confirm payment in the NAMMDR account and solving requests received from customers	300 e-mails
Sending e-mails to clients in order to confirm the registration number of documents entered in the NAMMDR on the registratura@anm.ro platform	Approx. 1300 e-mails/month
E-mail notifications sent to applicants regarding correspondence or for submission of additional documents;	daily

Sending correspondence information e-mails to medical centres with ongoing clinical trials	151 e-mails
Sending payment confirmation e-mails for clinical trials and national variations to applicants	2278 e-mails
Coupling the documentation for clinical studies, national variations, authorisation / reauthorisation - national procedure with the letter of intent, payment form and payment confirmation	2806
Entering into the Interactive database the information on the medicinal products presented by the applicants in order to authorise/reauthorise the MA through national procedure, MRP, DCP	699
Operation and maintenance of the database of the IT Logistics and Electronic Data Management Department	daily
E-mail notification of applicants on correspondence or submission of additional documents	daily
Sorting mail into envelopes intended for each applicant and handing over to couriers, according to the AWB	daily
Stamping and preparation of correspondence folders	daily
Printing the e-mail and registering the documents submitted by representatives to the Registry by: fax, e-mail, post, CESP or in person to the NAMMDR	daily
Summarizing the content of the documents in order to be fitted into the appropriate category	daily
Checking the history for the existence of other documents referring to the same issue and identifying the number and registration date of the first registered document, for connection	daily
If a non-compliance is noticed (an incorrectly used form, missing procedure number, wrong entry in the form, lack of signature), the sender is notified (verbally or via e-mail) about the need for correct submission of the documents	daily
Daily preparation of the internal delivery register	daily
Distributes the entry documents to the NAMMDR structures, highlighting their circulation within the NAMMDR on the basis of prior registration in the Internal Delivery Register	daily
Receipt of all exit documents sent by the secretariat approved by signature by the NAMMDR President	daily

Registration of output documents into the database/electronic register located on the NAMMDR data server.	daily
Separation of the original copy of exit documents, distribution of exit documents (internal copy) to the respective NAMMDR structure, distribution of output documents (external copy) into folders or envelopes (intended for applicants) and their release based on the signature of the persons authorised to pick up or on the basis of an AWB	daily
Sending information/clarification e-mails to customers who do not have representation in Romania	daily
Download of the ASMF documentation from the CESP platform or from CD on the NAMMDR data server	daily
Receipt of documents sent by post, verification and entry into the 2009-2021 electronic work register, allocation of a related connection number or a new number, as appropriate	daily

j) Activity related to standardisation

In 2021, at the SACR level, the record of all standards within the NAMMDR is kept up-to-date.

k) Training related to quality:

Through its attributions, the SACR carries out/participates in quality management training for SACR staff and, upon request, for staff from other NAMMDR organisational structures. In 2021, a person from the CACEI participated in an online training programme related to "Ethics and Institutional Integrity".

l) External audits/assessments

Through its attributions, the SACR participates in activities related to external audits carried out by professional/certification bodies in different organisational structures of the NAMMDR.

In 2021, there were no external audits, but the non-compliances and recommendations following the external audits carried out in previous years were maintained within the system of SMC actions.

m) Participation in external professional activities

By the specifics of the activity, as a result of the nomination by the NAMMDR President, the Head of the SACR represents the SACR/NAMMDR in activities related to quality management (working groups, meetings of authorities or other organisations, regulatory/certification/accreditation bodies, exchanges of experience, scientific events, symposia, etc.), organised outside the NAMMDR.

n) Risk management

At the SACR level, the specific activities of the risk management process were carried out, under the coordination of the SCIM Monitoring Commission, in line with OSGG 600/2018.

o) Implementation of the SCIM

At SACR level, the SCIM implementation stage was evaluated through completion of the self-assessment questionnaire, according to OSGG 600/2018.

p) The technical secretariat of the SCIM Monitoring Commission

The SACR ensures the duties of the Technical Secretariat of the SCIM Monitoring Commission (CM) established in line with OSGG 600/2018, according to the decision of the NAMMDR president regarding the establishment of the SCIM Monitoring Commission and the commission's ROF.

Activities performed:

- updating the Decision on the establishment of the Monitoring Commission, following the vacancies, with the support of the DRUMC-SPS;

- preparation of supporting documents, organisation and elaboration of the minutes of committee meetings;

- keeping under control the system procedures (PS) and operational procedures (PO) by allocating PS codes, as well as coordinating the allocation of PO codes within all organisational structures of the NAMMDR;

- analysing the documented procedures from the point of view of compliance with the minimum structure provided for as shown in OSGG no. 600/2018, supplemented with the requirements of NAMMDR's own system procedure (PS-09/01-Management of procedures), in force;

- dissemination of the current versions of the PS;

- keeping up-to-date the records of all PSs and POs within the NAMMDR;

- centralisation of the self-assessment questionnaires of the implementation stage for internal managerial control standards completed by each structure in the NAMMDR organisational chart in order to prepare the synthetic situation of self-assessment results, elaborated in line with Annex 4.2 to the code approved through OSGG 600/2018 and the centralising situation regarding the stage of implementation and development of the internal managerial control system on 31 December, elaborated in line with Annex 3 to the Code approved through OSGG 600/2018;

- preparation of the Report on the internal managerial control system on 31 December, elaborated in line with Annex no. 4.3 to the Instructions in OSGG 600/2018 and the transmission to the Ministry of Health, upon request, together with the centralising situation regarding the implementation and development stage of the internal managerial control system on 31 December, developed according to Annex 3 to the Code approved through OSGG 600/2018.

q) Internal public audit

In 2021, no internal public audit was carried out at the SACR by the Internal Audit Bureau (BAI).

Other activities:

The coordination (orientation, organisation, planning, management and control) of the entire activity of the SACR had the objective of ensuring efficiency of the activities through a good use of human and material resources and was achieved by planning the activities, tracking their achievement.

Documents specific to the SACR activity (notifications, reports, situations, etc.) were drawn up/approved, in relation to other NAMMDR structures:

- in relation to the DRUMC-SPS:

- Declarations of interests, commitments of confidentiality, commitments of compliance with the Code of Conduct, Activity reports for the SACR staff;

Quality management system:

In the particular case of the SACR, since the specific processes defined by the ROF refer to the SMC of the NAMMDR, the details of these activities were shown above, in the SPECIFIC PROCESSES section.

The SMC implemented at NAMMDR level and, implicitly, in each of the directions/organisational structures is compliant with the SR EN ISO 9001 standard for all activities and on the SR EN ISO/CEI 17025 standard in the field of laboratory activities, the process-based approach being implemented for all activities.

Operational management at the level of organisational structures and top management are involved in quality management activities. The NAMMDR staff knows and respects the specific requirements of the SMC, is familiar with the quality documentation and implements the procedures within the current activity.

V.11 ACTIVITY RELATED TO ECONOMIC ISSUES AND PUBLIC PROCUREMENT

The Directorate for Economy and Public Procurement is directly subordinated to the NAMMDR president and is made up of:

- The Financial accounting and budget service;

- The Public procurement and protocol office.

Within the Financial accounting and budget service, the activity consists mainly in substantiating and implementing the budget project, issuing invoices to collect the revenues provided for in the approved revenue and expenditure budget, managing the approved budget with payments carried out within the stipulated limits, as well as transferring budget credits in accordance with the needs of the institution.

The provisions for classification of the requested amounts by categories of budgetary expenditures were observed, with their detailing by titles, articles and paragraphs; the documentation related to the 3 phases of the budgetary execution of expenditures, namely the commitment, liquidation and ordering of expenses, were correctly registered in the "ALOP" computer system.

In 2021, the approved budget, as well as all subsequent changes made in line with the corrections approved by the chief credit ordinator, as well as all budgetary and legal commitments approved within the institution, were entered into the Forexebug IT system.

Within the Financial Budget Accounting Service, in 2021, the following duties and responsibilities were fulfilled:

a) the yearly drafting of the expenditure budget project, the list of investments based on the data presented by the organisational structures and their submission for approval to the management board and for approval to the chief credit accountant - 3;

b) organisation of accounting according to legal provisions and ensuring correct and timely registrations - 25,943;

c) tracking and ensuring the uniform enforcement of national legal provisions regarding the management of allocated funds;

d) ensuring budget planning in order to ensure the necessary funds for the optimal performance of of activities;

e) ensuring the financing of current and capital expenses within the limits of the approved budget (tariff invoicing services for services requested, authorisation/renewal of marketing authorisations for human medicinal products, variations, control certificates, advertising materials, inspections, clinical studies, rents, regularisations, cancelled invoices based on the addresses received from the specialised structures, issuance of external invoices for services to be paid in foreign currency (marketing authorisation/MA renewal for human medicinal products, inspections, variations, clinical studies, advertising materials, etc.) – 20,019;

f) preparation of individual/global budget commitments – 3,243;

g) drawing up proposals for allocating an expense - 3,436;

h) preparation of the payment order form for institution-specific acquisitions and salary rights - 3,547;

i) drawing up payment orders for the payment of wages and expenses related to goods and services – 3,101;

j) tracking 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 - 18,762;

k) verification of documents justifying expenses in terms of form, content and compliance with the financial-accounting legislation of the operations - 751 statements;

l) registration of receipts according to the statement - 14,099;

m) registration of payments according to the statement – 5,025;

n) preparing the centralized, quarterly and yearly financial statements, other financial reports and statements and submitting them for approval to the NAMMDR president in order to forward them to the competent/requesting institutions: MFP, MS, control and audit bodies, etc. – 4,673;

o) monitoring the allocation of expenses on budget items, as well as in accordance with the quarterly and yearly distribution provided by the NAMMDR budget;

p) recording the results of the inventory;

q) drawing up and updating the standard operating procedures specific to the department and collaborating in order to develop common procedures with other organisational structures.

Within the Department of Economics and Public Procurement, the Bureau of Public Procurement and Protocol, the 2021 activity consisted mainly in the elaboration, modification and updating of the "Yearly Programme of Public Procurement - 2021" at the level of the institution based on the requirements specified in the purchase requisitions, drawn up by NAMMDR departments, the elaboration of the "Yearly Public Procurement Programme - year 2022" project, the procurement of goods/products/services/work/investments through the procedures provided by the legislation in force.

In 2021, the following duties and responsibilities were fulfilled:

a) the elaboration, amendment and updating of the "Yearly Programme of public procurement - year 2021" at the level of the institution based on the requirements specified in purchase requisitions, prepared by NAMMDR directorates - 3 departments;

b) the centralisation of the yearly purchase requisitions for PAAP 2022 drawn up and sent by NAMMDR directorates - 95;

c) elaboration of the "Yearly Public Procurement Programme - year 2022" project;

d) querying the SEAP electronic catalogue of products/services/works upon request of NAMMDR structures;

e) drawing up and finalising the public procurement files, through the public procurement procedures provided by the legislation in force - 10;

f) making direct offline and online purchases from the SEAP Electronic Catalogue - 362;

g) conducting and finishing the procedures for public procurement contract award (elaboration of supporting documents, award documentation related to public procurement procedures);

h) drawing up legal commitments related to public procurement - contracts for public procurement of products/services/works and firm offers - 341;

i) fulfilling the advertising obligations (publication of the initiation of purchases by direct purchase from the SEAP electronic catalogue, award notices, advertising notifications, market consultation notifications, participation notifications, etc.) - 211;

j) drawing up and publishing ascertaining documents in SEAP upon completion of public procurement contracts - 24;

k) prospecting the market and consulting the SEAP/SICAP catalogue in order to determine the estimated value and make purchases;

l) collaboration with all organisational structures within the NAMMDR depending on the specifics and complexity of the object of the purchase and collaboration with external suppliers regarding the requested purchases.

m) drawing up and updating the standard operating procedures specific to the department and collaborating to develop common ones with other organisational structures.

The details of the NAMMDR Budget are detailed in Chapter IV – INSTITUTIONAL TRANSPARENCY, Subchapter 1, and information on Public Procurement is detailed in the same chapter, Subchapter 2.

V.12 GENERAL ADMINISTRATION

In 2021, the Directorate for General Administration and External Financial Assistance fulfilled its specific duties as provided for in the ROF and in each employee's specific job description.
Administrative activities:

- organisation and provision of support services (secretariat, car transport of goods and people, courier, telephone communication, cleaning, security, prevention of emergency situations) required for a good performance of the activity within the institution;
- NAMMDR infrastructure maintenance (maintenance of buildings and installations);
- Ensuring cleanliness in: offices, bathrooms, internal stairs, entrance, (ground floor), internal courtyards, parking - permanently in the head office and the workplace in the N. Titulescu Boulevard, no. 48;
- carrying out handling and transport activities of NAMMDR goods;
- ensuring the car transport of goods and people;
- car park monitoring: RCA insurance; ITP; road tax and car revisions and repairs;
- monitoring the execution of the works carried out on the basis of public procurement contracts and their reception;
- monitoring the execution of the works carried out under own direction and their reception (painting, electrical and sanitary installation repairs);
- drawing up the documents required for carrying out the department's activity (consumption and transfer vouchers; security service schedule at NAMMDR level);

- drawing up and follow-up of utility contracts for UTIs (rent + utilities);
- drawing up and updating the department's specific operational and system procedures;
- prepared consumption statements per work point (gas, electricity, water and sewer) from the locations: Av. Sanatescu Street; Demostene Street; N. Titulescu Street; Episcopul Radu Street;
- granting inventory numbers;
- completing the register of inventory numbers;
- creating the documents regarding the designation of persons in charge on PSI line;
- updating DAG procedures;
- evaluation of energy consumption for all locations belonging to the NAMMDR in order to conclude a new electricity supply contract for 2021;
- assessment of natural gas consumption for the Demostene location, the Titulescu location and the NAMMDR headquarters with a view to concluding a new contract for supply of NATURAL GAS for 2021;
- approving invoices by granting the "good for payment" visa for utility and service invoices: natural gas, electricity, fixed telephony, elevator;
- the development of "Warning" posters on the PSI and Guard line according to Law 307 of 2006 and Law 333 of 2003;
- security activity, courier activity, activity at the Ilfoveni Farm, maintenance and repair activity.

V.13 INTERNAL AUDIT

The Internal Audit Bureau (BAI) is part of the organisational structure of the National Agency for Medicines and Medical Devices of Romania.

In 2021, the Internal Audit Bureau performed assurance missions that involved an objective assessment of evidence by the audit team, in order to formulate opinions or conclusions concerning the audited structures and activities.

The objectives of the internal public audit activity were aimed at evaluating and improving the risk management, control and governance processes, as well as the quality levels achieved in the fulfilment of responsibilities, with the aim of providing reasonable assurance that these are operational and enable the achievement of the objectives and the proposed goals, and with the aim of making recommendations for optimizing the functioning of the activities of the audited structures in terms of efficiency and effectiveness.

The audit team also considered the allocation of audit resources in an appropriate manner, to the audits with significant risks, in order to optimize NAMMDR activities, and saving resources based on risk analysis was a priority.

The evaluation of the efficacy and effectiveness of the internal managerial control system was carried out based on the results of the risk assessment and concerned the operations regarding:

– The reliability and integrity of operational information.

– The effectiveness and efficiency of the processes/activities/operations specific to the audited structures.

– Safeguarding the heritage.

– Application of laws, regulations and procedures.

The purpose of the internal public audit missions was to examine the responsibilities assumed by the management of the audited structures and the executive staff regarding the organisation and implementation of activities and the fulfilment of obligations, in an efficient and effective manner.
4 assurance missions were carried out in 2021.
The findings following the internal public audit missions carried out according to the yearly internal public audit plan established for 2021 were recorded in the Internal Public Audit Reports drawn up for each mission, bearing the signature of the members of the audit team and the NAMMDR management.
Following the findings of the internal public audit missions carried out in 2021, 162 recommendations (proposed measures) were made.

V.14 ACTIVITY OF THE SERVICE FOR PREVENTION AND PROTECTION

In 2021, the Prevention and Protection Service carried out the following types of activities: the identification of hazards and evaluation of risks through elaboration of occupational risk exposure sheets; development of training topics in the field of safety and health at work; elaboration and planning of the periodic safety and health at work training for the year; elaboration of the occupational health and safety policy; the development of personal instructions on the training of workers in the field of SSM and personal SSM instructions for serious and imminent danger of injury and high and specific risk areas; carrying out general introductory training for employment; making records of jobs which require skill testing and/or psychological control and the medical control of categories of workers, performed by the occupational physician; establishing the need for individual protective equipment for the NAMMDR staff and drawing up a report on the need for this purchase; knowledge testing and verification of compliance of all workers with the prevention and protection measures in the field of occupational safety and health; taking over and managing skills sheets issued following occupational medicine control; ensuring relational interfaces regarding the provision of data related to prevention

and protection, requested by various institutions (ITM, DSP); highlighting high and specific risk areas; establishing the areas which require occupational health and safety signage; procedures regarding the expertise of workplaces and determination of damages; procedures regarding the acquisition of occupational medicine services; ensuring maternity protection at the workplace (reports sent to the ITM, occupational medicine).

V.15 MONITORING AND REPORTING

The Monitoring and Reporting Bureau (BMR) is directly subordinated to the NAMMDR president and is led by a head of bureau.

During 2021, the monitoring and reporting activity carried out at BMR level was based on professional collaboration with all NAMMDR organisational structures, in order to fulfil the duties established by the Agency's president.

Starting with 03.08.2021, the BMR took over the management of the Secretariat database.

Documents registered in the Secretariat database between 03.08.2021 and 31.12.2021: 1,845 IDs.

- Actions carried out within the Secretariat app:
- Papers with overdue status, without response (2): Checked: approximately 2,080 records (papers); Changing the status in the database as a result of their resolution: 1,300 records (papers);
- Papers with due status, without response: Checked: about 350 records (papers); Changing the status in the database as a result of their resolution: 70 records (papers).
    - The BMR identified in the Secretariat application the papers with expired resolution deadlines and sent addresses to the heads of organisational structures regarding the obligation to comply with legal resolution deadlines: 49 notifications.
    - On 31 December 2021, the status of the papers registered in the Secretariat application was:
- Total number of records (03/04/2021 – 12/31/2020): 3,339 IDs, of which:
- Status 1 – Within the deadline, without response: 1
- Status 2 - Deadline exceeded, without response: 243
- Status 3 - With response given within the deadline: 1,496
- Status 4 - With delayed response: 338
- Status 5 – Undetermined (court orders, court communications): 1,261
    - Addresses were sent to the leaders of the organisational structures in order to request information on the activity carried out: 2 reports: - The status of works

on 12.07.2021 and on 12.11.2021, detailing the relevant activities carried out by NAMMDR structures.

- Prepared 2 reports containing the responses received from NAMMDR organisational structures: in July 2021 and November 2021.

VI. PRIORITIES ENVISAGED FOR 2022

In the wider context of the EU pharmaceutical strategy until 2025 and the future European pharmaceutical policy, the Agency will take into account in all its actions its priority areas, as key drivers for public health activities. The priority areas will be:

1. Availability and accessibility of medicinal products – increasing the level of predictability;
2. Challenges related to supply chain;
3. Antimicrobial resistance and other emerging health threats;
4. Improving human resources and optimizing available resources;
5. Increasing collaboration and involvement with stakeholders, international partners and decision-makers and adequate preparation for implementation of the new European legislation;
6. Orientation towards strategic projects in order to ensure long-term financial sustainability of the Agency;
7. Building trust in regulatory decisions through continuous and transparent communication.

VII. INSTITUTIONAL TRANSPARENCY

VII.1 THE INSTITUTION'S BUDGET

a) Incomes:

The NAMMDR budget approved for 2021 was self-funded: 63,331 thousand lei. The NAMMDR did not request and receive subsidies from the state budget.

b) Costs

The final NAMMDR budget approved for 2021 consisted of 63,331 thousand lei, distributed as follows:

- Title 10 - Staff expenses: 54,259 thousand lei.
- Title 20 - Expenses on goods and services: 4,803 thousand lei.
- Title 59 - Amounts for disabled persons: 420 thousand lei
- Title 70 - Capital expenses: 3,849 thousand lei

c) NAMMDR budget execution:

Receipts: 95.207.553,27 lei

Budgetary expenses: 35,276.987.25 lei, of which:

- Title 10 – Staff expenses: 29,477 thousand lei
- Title 20 - Expenses on goods and services: 2,576 thousand lei
- Title 59 - Amounts for disabled persons: 267 thousand lei
- Title 70 - Capital expenses: 3,207 thousand lei

At the end of 2021, the NAMMDR had a surplus of 59,930,566.02 lei.

From the budget execution for 2021, it appears that the total amount of budget expenses represents 56.10% of the approved budget, of which: the value of staff expenses represents 54.33% of the approved budget for this category; the amount of expenses on goods and services represents 53.67% of the approved budget for this category; the amount of capital expenses represents 83.32% of the approved budget for this category.

All expenses were included in the approved budget for 2021, in compliance with the legal provisions regarding the economic-financial discipline.

VII.2 INFORMATION RELATED TO THE PUBLIC PROCUREMENT PROCESS

64 public procurement contracts for goods/products/services/works/investments were concluded.

362 offline and online direct purchases were made from the SEAP e-Catalogue.

Number of procurement processes per category:

- Negotiation without publishing an add – 3 procedures.
- Open auction – 2 procedures.
- Simplified procedure – 4 procedures.
- Direct purchases – 362 procedures.

Of all the procurements carried out, the following were carried out through the electronic system during the reporting calendar year: open auction - 2 procedures, simplified procedure - 4 procedures, direct online purchases - 193 direct purchases of products/services/works.

The average duration of a public procurement process by procurement category:

- Open auction: 90 calendar days from the date of submission of documentation in the SEAP
- Simplified procedure: 60 calendar days from the date of submission of documentation in the SEAP
- Negotiation without publication of an announcement: 30 calendar days from the date of transmission of the invitation
- Direct purchase of products/services/works: 7 days from the date of approval of the report

In 2021, no appeals were submitted to the public procurement procedures carried out by the NAMMDR and no public procurement procedure was cancelled.

Detailed information on public procurements carried out in 2021 is available online: https://www.anm.ro/informatii-de-interes-public/.

VII.3 INFORMATION ABOUT THE LITIGATIONS IN WHICH THE INSTITUTION IS INVOLVED

In 2021, the number of litigations in which the institution was a party has continuously increased, compared to 2020, when 262 litigations were pending; as regards the scope and object of the file, they concerned most branches of law, as follows:

440 litigations, of which:

- files settled definitively: 16
  - the obligation to solve: 6
  - presidential ordinance: 9
  - claims (litigations with professionals): 1
- pending files: 333
  - the obligation to solve: 155
  - annulment of administrative document: 5
  - legal complaint: 3
  - insolvency: 3
  - presidential ordinance: 106
  - claims (litigations with professionals): 11
  - occupational litigation: 1
  - enforcement appeal: 1
  - tort liability action: 1
  - refusal to grant rights/request resolution: 15
  - declaration of nullity of legal document/claims: 24
  - communication of information of public interest (in line with Law 544/2001): 1

- annulment appeal: 2
- obligation to issue an administrative act: 3
- legal complaint: 1

➢ suspended files: 91
- the obligation to solve: 21
- annulment of administrative document: 1
- claims (litigations with professionals): 1
- patrimonial liability action: 1
- declaration of nullity of legal act/claims: 63
- presidential ordinance: 3

VII.4 ORGANISATIONAL CHART

The detailed NAMMDR organisational chart is available online: https://www.anm.ro/despre-institutie/structura-organizatorica/.

VII.5 INFORMATION ABOUT THE HUMAN RESOURCES MANAGEMENT

The Human Resources and Quality Management Directorate carries out its activity in accordance with the provisions of Art. 33, Order no. 1522 of 9 October 2019 on approval of the Regulation on the organisation and operation of the National Agency for Medicines and Medical Devices of Romania (NAMMDR), the Human Resources and Quality Management Directorate is directly subordinated to the NAMMDR vice-president with attributions regarding the technical-administrative activities supporting the specifically scientific activities and is led by a manager.

The activity of the Staff-Payroll Service is detailed below, referring to payroll within the Human Resources and Quality Management Directorate; the activity of the Quality Assurance and Registry Service within the same Directorate was detailed in chapter II.14 – Quality management activity.

The mission, as well as the objectives that had to be achieved during the reporting period regarding the NAMMDR Staff-Payroll Service:

The mission: development, implementation, monitoring and evaluation of the strategy regarding the modernization of human resources management and staff management within the NAMMDR.

In order to carry out its activity effectively, the NAMMDR relies on the knowledge, skills, experience and motivation of its employees. The professional training of employees and the development of employees are crucial for creating the appropriate working environment which leads to the achievement of high levels of quality and professionalism.

The Human Resources and Quality Management Directorate / Staff-Payroll Service develops policies and procedures regarding human resources for implementation of ongoing development activities and intensification of the learning process.

General objectives:

- Management of the professional files of the NAMMDR staff;
- Employment of staff who will provide, depending on the needs of the institution, the appropriate combination of technical skills and the potential to develop their knowledge and the corresponding personal assets, for the support and future development of the institution.
- Ensuring an effective and well-organized professional training system that meets the professional development requirements of the NAMMDR staff, offering training opportunities corresponding to the training needs of both the organisation and each of its employees.
- Ensuring an operational system for evaluating the professional performance of staff that identifies and encourages good performance and at the same time detects inadequate performance in order to adopt appropriate corrective measures.
- Effective management of professional career development, supporting the NAMMDR in the process of motivating and maintaining the staff.
- Ensuring the promotion in ranks of the NAMMDR staff;
- Implementation of the legal provisions regarding the establishment of wage rights for the NAMMDR staff.

No.	Specific objectives	Activities	Actions* *If required
1.	Continuous updating of the payroll computer system.	The correct and on-time preparation of the Wage Statements for the basic activity.	monthly
2.	Record of collective sheets of attendance and annual leave, medical leave, etc.	The correct and on-time preparation of the Wage Statements for the basic activity.	monthly

3.	Record of CIM suspension periods (parental leave, leave without pay for scholarships, personal reasons).	The correct and on-time preparation of the Wage Statements for the basic activity.	permanently
4.	Declaration 112	Correct preparation of declarations related to taxes and wage contributions, within the legal term.	monthly
5.	Organisation of contests for filling vacant/temporarily vacant positions.	Preparation of documents related to contests at NAMMDR level.	permanently
6.	Ranking of the new employee.	Employment of staff.	permanently
7.	Staff files.	Management of staff files.	permanently
8.	Establishing the duties of employees through a correct and complete preparation of job descriptions.	Management of staff files.	permanently
9.	Compatibility between professional competence and duties.	Management of staff files.	permanently
10.	The retirement file.	Staff retirement.	upon request, according to the deadline
11.	Elaboration of statistical situations/informative data.	Preparation of statistical reports for the MS, ANAF, INSSE.	permanently
12.	The job title list for NAMMDR structures	Management of the job title list at NAMMDR level.	permanently

Staff activities:

a) The NAMMDR Job Title List (2021) was prepared, containing all changes, additions, documentation/correspondence with the Ministry of Health regarding: the request for modification/ approval of the job title list, the transformation of some structures and jobs, the modification of the NAMMDR Regulation for Organisation and Operation, approved through Order no. 1522 of 9 October 2019, published in the Official Gazette of Romania, Part I, no. 841 bis of 16 October 2019.

b) 602 Decisions were drawn up regarding the appointment, release/termination, suspension, promotion, secondment, reassignment, transfer, relocation and modification of the service/work reports for NAMMDR staff;

c) Activities performed in order to carry out the measures ordered by the Decision of the Romanian Court of Accounts - Department V no. 5/V/14.04.2017 and Conclusion no. 64/30.VI.2017 of the Romanian Court of Accounts – Department V;

d) Considering the fact-finding report regarding the control action carried out at the National Agency for Medicines and Medical Devices of Romania (NAMMDR), registered at the Prime Minister's Control Body with no. 2615/13.05.2021, the viewpoint of the DRUMC was communicated regarding the aspects found by the control team, concerning the activity of the structure, as well as the documents supporting it;

e) Relevant facts about the Internal Audit Bureau: internal information was sent to the management regarding the situation in which the NAMMDR does not have a functional Internal Audit Bureau; response notification no. 61592C-14. 09.2021 to the Ministry of Health, following notification no. BAPI899/06.12.2021 and registered at the NAMMDR with no. 67156/07.12.2021 considering the preparation of the Annual Report on the internal public audit activity of the National Agency for Medicines and Medical Devices of Romania (NAMMDR) for year 2021, according to which the NAMMDR does not have a functional Internal Audit Bureau.

f) Ensuring human resources within NAMMDR structures

As regards this main objective of the activity of the Human Resources and Quality Management Directorate, in 2021, a continuous analysis of the institution's human resources needs was carried out, in accordance with the organisation's long-term objectives and efficiency. In this respect, the possibility of ensuring the structures within the institution with qualified specialised staff, the maintenance and efficient use of the existing staff were taken into account. In connection with this aspect, of maximum importance for the smooth running of the institution's activity, it must be highlighted that in 2021, the competition for vacant jobs continued, the DRUMC drawing up the necessary documentation in order to start the procedure for filling vacant jobs through competition, for hiring staff following a competition/examination/secondment and for staff promotion as well.

Following approval of the NAMMDR management, contests were organised in order to fill the vacant contract execution and management jobs, for an indefinite period, and file selection regarding the occupation of the vacant jobs for a fixed period, during the state of alert, as follows:

– Jobs removed in accordance with the provisions of Art. 9 of Order of the Ministry of Health no. 1839/30.10.2020 regarding the amendment of Order of the Ministry of Health no. 905/26.05.2020 based on Art. 11 of Law 55/2020, for a determined period (February - March 2021);

A competition was organized to fill vacant jobs without competition, for a fixed period, within the NAMMDR, in line with Art. 9 of Order of the Minister of Health no. 1839/30.10.2020 regarding

the amendment of Order of the Ministry of Health no. 905/26.05.2020 on approval of the Methodology regarding the occupation, without competition, of vacant or temporarily vacant jobs within the Ministry of Health and its subordinated units and units coordinated and under the authority of the Ministry of Health, including public execution and management jobs, for a determined period, in the context of the establishment of the state of alert on the Romanian territory, in line with Article 11 of Law no. 55/2020 regarding some measures to prevent and combat the effects of the COVID-19 pandemic, "Appointment within the units subordinated or under the coordination of the Ministry of Health is made by administrative act of the head of the institution or the employing unit, subject to the maximum number of jobs approved by the chief credit ordinator through the job title list, and ceases in no more than 30 days following termination of the state of alert, according to the provisions of Art. 11 of Law 55/2020 regarding some measures to prevent and combat the effects of the COVID-19 pandemic, with further amendments and supplementations".

	Enrolled candidates	Candidates rejected following file selection	Candidates admitted following file selection	Candidates rejected after interview	Candidates hired after interview
Total	73	33	40	17	23

– Vacancies or temporarily vacant jobs for an indefinite period will be filled by competition in 2021:

- Jobs open to public competition in accordance with the provisions of GOVERNMENT DECISION no. 286/2011 on approval of the Framework Regulation regarding the establishment of the general principles for filling a vacant or temporarily vacant job corresponding to contractual functions and the criteria for promotion to immediately higher professional ranks or steps of contractual staff in the budgetary sector paid from public funds, with further amendments and supplementations, and with Law no. 33/2021 on approval of Government Emergency Ordinance no. 183/2020 regarding the competitions to fill vacant positions within some institutions of the law system, as well as within the Court of Accounts, during the state of alert;

Total number of jobs	118
Total number of candidates	198
Candidates rejected following the selection of files	32
Candidates admitted following the selection of files	166

Absentees (written test)	24
Rejected following written test	38
Admitted following written test	104
Absentees (interview)	5
Candidates rejected following the interview	3
Admitted following interview (admission score)	96
Hired	76 (+2 who have resigned)

- Positions open to public competition in accordance with the provisions of Order of the Minister of Health no. 869/2015 on approval of the methodologies regarding the organisation and conduct of competitions for the jobs of physician, dentist, pharmacist, biologist, biochemist and chemist in public healthcare units, as well as the jobs of head of department, head of laboratory and head of department in healthcare units without beds, respectively of the job of chief pharmacist in public healthcare units with beds, with further amendments and supplementations;

Considering the provisions of Article I of EMERGENCY ORDINANCE No. 103 of 22 September 2021 regarding some measures at public administration level: "By derogation from the provisions of art. 27 para. (3) from Law no. 55/2020 regarding some measures to prevent and combat the effects of the COVID-19 pandemic, with further amendments and supplementations, for vacant and temporarily vacant positions and positions, other than those provided for in art. II from Law no. 203/2020 for the amendment and completion of Law no. 55/2020 regarding some measures to prevent and combat the effects of the COVID-19 pandemic, contests can be organized and held under the law, until December 31, 2021, with the inclusion of commitment credits and budgetary credits approved in the budget for 2021 ".

– Positions open to public competition in accordance with the provisions of Order of the Minister of Health no. 869/2015 on approval of the methodologies regarding the organisation and conduct of competitions for the jobs of physician, dentist, pharmacist, biologist, biochemist and chemist in public healthcare units:

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Total number of vacant jobs	7
Registered candidates	6
Registered candidates (no response was received to the addresses sent for the constitution of the commissions)	1
Candidates rejected following file selection	1
Candidates admitted following file selection	4
Absentees (written test)	1
Admitted following written test	3
Admitted following interview	3
Hired	3

– Total jobs made available in accordance with the provisions of GOVERNMENT DECISION NO. no. 286/2011 with further amendments and supplementations and Government Emergency Ordinance no. 103/2021 regarding some measures at public administration level:

In accordance with the provisions of GOVERNMENT DECISION no. 286/2011 on approval of the Framework Regulation regarding the establishment of the general principles for filling a vacant or temporarily vacant job corresponding to contractual functions and the criteria for promotion to immediately higher professional ranks or steps of contractual staff in the budgetary sector paid from public funds, with further amendments and supplementations,

Considering the provisions of Article I of EMERGENCY ORDINANCE No. 103 of 22 September 2021 regarding some measures at public administration level: "By derogation from the provisions of Art. 27 (3) from Law 55/2020 regarding some measures to prevent and combat the effects of the COVID-19 pandemic, with further amendments and supplementations, for vacant and temporarily vacant positions, other than those provided for in Art. II of Law 203/2020 for amendment and supplementation of Law 55/2020 regarding some measures to prevent and combat the effects of the COVID-19 pandemic, contests can be organised and held in accordance with the law, until 31 December 2021, with the inclusion of commitment credits and budgetary credits approved in the budget for 2021".

Total number of vacant jobs in accordance with the provisions of GOVERNMENT DECISION no. 286/2011 with further amendments and supplementations, and Government Emergency Ordinance no. 103/2021 regarding some measures at the public administration level:

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Total number of jobs	43
Enrolled candidates	65
Candidates rejected following file selection	6
Candidates admitted following file selection	59
Absentees (written test)	6
Rejected following the written test	11
Admitted following written test	42
Absentees (interview)	4
Rejected following the interview	0
Admitted following interview with admission score	38
Hired	25

Management positions - competition (2021):

Total number of jobs	9
Enrolled candidates	15
Candidates rejected following file selection	2
Candidates admitted following file selection	13
Absentees (written test)	2
Rejected following the written test	2
Admitted following written test	9
Absentees (interview)	0
Rejected following the interview	0
Admitted following interview with admission score	9
Hired	9

– Management jobs made available in 2021 by the Ministry of Health (staff file management – the Staff-payroll Service):

Considering the provisions of Order of the Minister of Health no. 1480 of 30.09.2019 on approval of the Methodology regarding the organisation of the competition for the jobs of president and vice-president of the National Agency for Medicines and Medical Devices in Romania, the Ministry of Health organised a competition to fill the following vacant management jobs within the National Agency for Medicines and Medical Devices of Romania:

- Vice-president for specific scientific activities in the field of medicinal products for human use and medical devices:
-

Enrolled	Employed
5	1

- Vice-president for technical-administrative activities supporting specific scientific activities:

Enrolled	Employed
5	1

g) Decisions were drawn up for establishing/increasing the amount of basic gross monthly wages, as well as certificates regarding the completion of accumulated service of employees after 01.01.2011:

- Notifications/addresses (the Wages Compartment, CPP, manager/head of service): 665;
- Elaboration of reports (risk premium, report of appointments/dismissals/delegations/teleworking, etc.): 170;
- Calculation of accumulated service and in the specialty, required for: employment, promotion, retirement as well as for the preparation of certificates requested by employees or upon request of managers: 150;
- Decisions issued by the DRUMC - 602;

h) Decisions on the appointment and dismissal of committee members were drawn up - 132;

i) Reports were drawn up and submitted for approval for: contest publications in newspapers and the Official Gazette, part III - 37;

h) The professional files of employees were drawn up:

- Individual employment contracts and additional documents for contractual staff within the institution were drawn up and monitored according to the law;
- 81 contracts have been submitted and submitted for approval for the candidates admitted to the competition for the occupation of contract executive positions and management positions;

- Management of the general record register of employees in electronic format (REVISAL): recording changes to individual employment contracts of NAMMDR employees in the REVISAL program, sending them to the ITM Bucharest: various corrections: 1200;
- Preparation of documentation for the individual employment contract: 81
- Preparation of the documentation for the secondment to the NAMMDR: 1
- Liquidation notes: 79

i) Management of all the declarations of interests of the NAMMDR staff, as well as the wealth declarations of the staff with management positions and executive functions within the NAMMDR, of the members of the Management Board and their submission to the National Integrity Agency, as well as their display on the institution's website;

- 69 declarations of wealth and 68 declarations of interests of employees with positions of responsibility were registered, submitted and posted on the NAMMDR website;

j) The IT processes regarding the Wages application within the Softech programme have been upgraded, according to the legislation in force;

k) Statistical statements (annual, semi-annual and quarterly) submitted to the Ministry of Health, the National Institute of Statistics and the Directorate of Public Health, Treasury, ANAF were drawn up;

Replies to requests/clarifications from the Ministry of Health, as well as from the Public Health Directorate - 58.

• 1 SAN+CAP 15 Statistics research for 2020;
• 1 INSSE S3 Statistics research - staff expenses and payments for 2020;
- 12 researches - INSSE S1 2020 Statistics, staff expenses;
- 4 researches - INSSE LV (quarterly – 2020) statistics - staff categories situation;
- 12 notifications sent to the Ministry of Health – SMSS no. 374/2020 regarding staff expenses related to the month of January for establishing the percentage of raises in 2021 for the NAMMDR;
- 12 notifications sent to the Ministry of Health, requests for similar positions in 2021;
- 12 Declarations in 2021;
- 24 addresses and CM centralizers in 2021 - CASMB;
- 12 declarations in 2021;

The following were drawn up and sent as requested by the Payroll Department:

- 12 payment centralizers regarding SALARY LIQUIDATION - 2021 (payrolls, medical leaves, centralizers, slips and other documents for salary liquidation);
- 7 salary rectification situations in 2021 (payrolls, medical leaves, centralizers, slips and documents for salary liquidation);
- 380 communications with salary changes sent to the staff department;
- 26 liquidation notes for calculation of employees - termination of CIM - in 2021;

l) The necessary documentation was drawn up regarding the approval of leave: rest, unpaid, medical - 2446;

m) Labour logs, as well as their verification, were requested monthly;

- Monthly labour logs and highlighting of hours worked during 2021 - 948.

n) Income certificates, for health and other certificates required by the employed staff were drawn up / issued, as well as copies of work books, copies of extracts with the accumulated service, issuance of salary certificates -120.

o) Notices were sent to the DEAP with salary changes, employment and CIM terminations, invoice payment reports - 59;

p) The records of individual professional performance evaluation sheets of the employed staff and of the job descriptions prepared by the responsible persons, according to law, were monitored - 216;

q) Archiving of registered documents, specific to human resources (documents according to the personnel file) - permanent;

r) Requests and notifications addressed to the human resources department were followed up and answered, within the term provided by law;

s) The management of the job descriptions and individual professional performance evaluation sheets for the NAMMDR staff and the provision of assistance and advice to the structures for the elaboration of these documents were monitored;

Declarations of interests 2021	268
GDPR declarations	268
Confidentiality commitments 2021	268
Assessment 2020	184
Activity report 2020	187
Individual job descriptions 2021	257
Basic job descriptions 2021	108
Training programmes 2021	9

t) 3325 requests were registered, drawn up and sent (holiday requests, certificate requests, overtime recovery requests, increment and seniority certificate requests);

– 399 certificates were issued to NAMMDR employees (related to: physician, CAR, income, employee, bank, high school, nursery school, expired card, kindergarten, seniority, seconded, mothers, unemployment);

- 342 income certificates were issued in 2021;

- 18 certificates were issued to former employees (NMA, ICSMCF, OTDM);

Other specific activities of the NAMMDR Staff and Payroll Service:

- Consultancy regarding the application of legislation specific to the Staff and Payroll Service duties;

- Participation in competition commissions and appeals commissions for competitions organized to fill vacant positions;

- Permanent monitoring of the emergence/modification/repeal of normative acts (laws, ordinances, decisions, orders, regulations, etc.) specific to human resources and payroll activities (labour legislation, payroll, etc.) and making sure that these are implemented within the NAMMDR;
- Informing the top management about the new occurrences or changes in legislative acts in the field of labour legislation, payroll;
- Organisation of the annual assessment process of the professional performance of NAMMDR employees;
- Record of professional training of NAMMDR employees;
- Ensuring a confidential system of granting monetary rights, as well as a system of job promotion;
- Ensuring the confidentiality of all documents and information managed by DRUMC employees;
- Ensuring the controlled access of the persons appointed by the top management to the documents and information regarding human resources and staff wages;
- Ensuring the administration of the databases, by the responsible persons, in accordance with the decisions of the NAMMDR president;
- Representation of the NAMMDR in relations with various institutions on issues related to human resources, payroll and contributions to the general consolidated budget of the state;
- Representation of the NAMMDR in its subordinate relations with the Ministry of Health, in specific issues related to human resources and payroll;
- Preparation of any papers provided by the labour and payroll legislation.

VIII. RELATIONSHIP WITH THE COMMUNITY

VIII.1 ACTIVITY REPORT DRAWN UP IN ACCORDANCE WITH LAW NO. 544/2001, AS FURTHER AMENDED AND SUPPLEMENTED

During the reported period, 165 requests for information of public interest were registered: 128 from physical persons and 37 from legal persons. The subject of the requests was 100% related to the way of fulfilling the duties of the public institution.

In 2021, in line with Law no. 544/2001 regarding free access to information of public interest from media representatives, 67 notifications were received electronically, and were resolved in compliance with the legislation in force.

VIII.2 INFORMATION ON ATTRACTING RESOURCES FROM THE COMMUNITY

Attracting experts to occupy the currently available job title list is one of the Agency's priorities. The need to supplement the human resource with staff prepared to respond to specific national and European challenges, in terms of amendments of legislation, will be resolved following the next period.

IX. LEGISLATION - INFORMATION ON DRAFT REGULATORY DOCUMENTS INITIATED BY THE INSTITUTION

With regard to the legislative activity, in 2021, the Legislation, Referrals, European Affairs and International Relations Service (SLSAERI) together with the NAMMDR specialised organisational structures, prepared the documentation (draft normative acts, substantiation notes, approval reports) for their promotion through the Ministry of Health and proposed changes to the following draft normative acts:

I) Draft laws/Government Ordinance/Emergency Government Ordinance/Government Decision: 5

1) The draft of Emergency Government Ordinance on establishing the institutional framework and measures for the implementation of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, which has become The Emergency Government ordinance no. 46/2021, published in the Official Gazette no. 588 of 11 June 2021, ensuring the legal framework required for application of the provisions of Regulation (EU) 2017/745 and the rules applicable to medical devices are aligned with the new European legislative framework.

2) The draft of Emergency Government Ordinance for amendment and supplementation of Law 134/2019 on reorganisation of the National Agency for Medicines and Medical Devices and amendment of further ruling provisions, which has become Government Ordinance no. 17/2021, published in the Official Gazette no. 916 of 24 September 2021.

3) The draft of Emergency Government Ordinance for amendment and supplementation of Law 95/2006 on healthcare reform and amendment of further ruling provisions in the healthcare field, which has become Government Ordinance no. 18/2021 for amendment and supplementation of Law 95/2006 on healthcare reform and amendment of further ruling provisions in the healthcare field, as well as for repeal of Art. 4 of Law 584/2002 of 29 October 2002 on Measures to Prevent the Spread of HIV and to Protect Persons infected with HIV or Suffering from AIDS in Romania, published in the Official Gazette no. 834 of 31 August 2021.

4) The draft of Law for amendment and supplementation of Law 286/2009 on the Criminal code, forwarded to the Ministry of Health through notification no. 58486E/06.07.2021 registered at the Ministry of Health with no. IM/2708/22.06.2021 din 06.07.2021, which was returned through notification no. 58468E/23.12.2021, registered at the Ministry of Health with no. P1911/27.12.2021 Proposing the amendment of Art. 357 of the Criminal Code for the purpose of signing and ratifying the Medicrime Convention.

The Council of Europe Convention on the Counterfeiting of Medical Products and Similar Crimes involving threats to public health (Medicrime Convention) is the first international criminal law legislative instrument which legally sanctions criminal acts related to the counterfeiting, manufacturing and supply of medical products marketed without authorisation or without complying with safety standards, which not only provides criminal sanctions, but also measures to prevent and protect the victims. Medical products are defined in Art. 4 a) of the Convention, as "medicinal products and medical devices".

In line with the provisions of the Medicrime Convention, signatory parties shall take the necessary legislative measures, as well as other measures, in order to ensure that representatives of health, customs, police and other competent authorities exchange information and cooperate, in accordance with the national legislative framework to effectively prevent and combat the counterfeiting of medical products and similar crimes threatening public health.

In relation to the mentioned, the current provisions of Law no. 286/2009 on the Criminal Code, with further amendments and supplementations are insufficient, and shall be supplemented with other provisions in order to meet all the requirements of the Medicrime Convention.

5) The draft for an Emergency Government Ordinance regarding the establishment of the institutional framework and the necessary measures to ensure the direct application of the provisions of Regulation (EU) no. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, as well as for the amendment of some regulatory acts, which has become Emergency Government Ordinance no. 29/2022, published in the Official Gazette no. 283 of March 24, 2022, ensuring the legal framework required for application of the provisions of Regulation (EU) no. 536/2014, and the rules applicable to interventional clinical trials are aligned with the new European legislative framework.

II. Order of the Minister drafts: 13

1) The draft Order on amendment of Order of the Minister of Public Health no. 895/2006 on approval of the Regulations regarding marketing authorization and supervision of medicinal products for human use and for repeal of Order of the Minister of Public Health no. 1.203/2006 on approval of the National Medicines Agency procedure for cancellation of marketing authorisation applications for medicinal products for human use, which has become Order of the Minister of Health no. 551/2021, published in the Official Gazette no. 1.226 of 17 May 2021, regulating the

measures for streamlining the evaluation process of authorisation request and renewal of marketing authorisations submitted through national procedure.

2) The draft Order on the manner of reporting suspected serious incidents related to medical devices, which has become Order of the Minister of Health no. 2882/2021 on the manner of reporting suspected serious incidents related to medical devices, published in the Official Gazette no. 1.226 of 24 December 2021, regulating aspects related to the procedure for reporting suspected serious incidents related to medical devices.

3) The draft Order on approval of the amount of tariffs for the activities performed by the National Agency for Medicines and Medical Devices of Romania, in decisional transparency on the website of the Ministry of Health from 29.09.2021. The draft Order was sent for approval in line with NAMMDR Administration Council Decisions no. 4/25.03.2021 and no. 5/05.07.2021, through notification no. 60634E/05.08.2021 registered at the Ministry of Health with no. Reg2/18753/06.08.2021.

4) The draft Order for amendment of Order of the Minister of Health no. 118/10.02.2017 on setup of a commission for resolution of appeals against decisions for assessment of health technologies, of documentation to be submitted by applicants, methodological means used in the assessment for 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, sent to the Ministry of Health through notification no. 61030E/13.08.2021 registered at the Ministry of Health with no. P1169/16.08.2021, proposing the regulation of the Commission's procedure for resolution of appeals following the findings of the Report of the Control Body of the Prime Minister no. 4259/15.07.2021, registered with the National Agency for Medicines and Medical Devices of Romania with no. 60162/27.07.2021, regarding compliance with the legal provisions regarding the establishment and achievement of incomes, as well as regarding some expenses at entity level.

5) The draft Order on setup of a working group for elaboration of the methodology for medical technologies assessment on 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, as well as the means for appeal thereof, in order to meet the result indicators which are the basis of loan withdrawals according to the Loan Agreement between Romania and the International Bank for Reconstruction and Development, signed in New York on 23 September 2019, amended and updated through the Letter of amendment signed between Romania and the International Bank for Reconstruction and Development in Bucharest on 31 July 2020 and 26 August 2020, ratified by the Romanian Parliament through Law nr. 1/2021,

forwarded through NAMMDR notification no. 51880/22.06.2021, registered at the Ministry of Health with no. 2157/23.06.2021.

6) The draft Order for amendment and supplementation of Order of the Minister of Health no. 904/2006 on approval of the Norms relating to the implementation of good clinical practice rules in the conduct of clinical trials conducted with medicines for human use, forwarded through notification no. 60229E/28.07.2021 registered at the Ministry of Health with no. P1062/29.07.2021 and resent through notification no. 60229E/10.08.2021 registered at the Ministry of Health with no. P1145/11.08.2021 and notification no. 60229E/06.09.2021 registered at the Ministry of Health with no. P1251.4/07.09.2021, available on the website of the Ministry of Health in decisional transparency starting from 08.09.2021.

7) The draft Order on approval of the Methodological norms for the application of the provisions of Article 13 din The Emergency Government ordinance no. 46/2021 on establishing the institutional framework and measures for the implementation of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, forwarded through notification no. 59837E/19.07.2021, registered at the Ministry of Health with no. P990/20.07.2021, pending approval.

8) The draft Order on approval of the Methodological norms regarding the placement of medical devices on the market and the registration of economic operators into the European Database of Medical Devices (Eudamed), as well as into the national database and exemption from conformity assessment procedures and of the exemption from compliance assessment procedures, forwarded through notification no. 63724E/13.10.2021, registered at the Ministry of Health with no. Reg1/24050/13.10.2021, pending approval.

9) The draft Order on approval of the regarding the assessment, designation, notification and monitoring of medical device compliance assessment bodies, forwarded through notification no. 60423E/02.08.2021 registered at the Ministry of Health with no. P1105/03.08.2021, pending approval.

10) The draft Order on approval of the Methodological means regarding advertising for medical devices, forwarded through notification no. 66156E/18.11.2021 registered at the Ministry of Health with no. P1642/19.11.2021, pending approval.

11) The draft Order on approval of the Methodological means regarding clinical evaluation and clinical investigations with medical devices, forwarded through notification no. 66301E din 22.11.2021 registered at the Ministry of Health with no. P 1664 din 23.11.2021, pending approval.

12) The draft Order regarding the approval of the procedure for issuing the free sale certificate for medical devices, forwarded through notification no. 66625E din 25.11.2021, registered at the Ministry of Health with no. 1/27610 din 26.11.2021, in decisional transparency starting with 07.03.2022.

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13) The draft Order regarding the approval of the procedure for taking over and destroying the confiscated medicinal products for human use, sent via the NAMMDR notification address no. 43437E/04.12.2019, registered at the Ministry of Health with no. 68050/04.12.2019, which was returned through NAMMDR notification no. 43437E;51534E/29.03.2021, registered at the Ministry of Health with no. Reg1/8374/30.03.2021 and notification no. 51534E/22.06.2021, registered at the Ministry of Health with no. R1/8374/2021 of 23.06.2021, developed in line with the provisions of Article 1 paragraph (4) and of Article 5 paragraph (2) a) from Government Ordinance no. 14/2007 for the regulation of the manner and conditions for capitalisation of goods entered, according to the law, into the private property of the state and those of Articles 42-43 of the Annex to Government Decision no. 731/2007 regarding the approval of the Methodological Norms for the application of Government Ordinance no. 14/2007 on regulation of the manner and conditions of capitalisation of the goods entered, in line with the law, into the private property of the state, republished, as amended.

PRESIDENT,

The National Agency for Medicines and Medical Devices of Romania,

Răzvan Mihai Prisada

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Annex to the NAMMDR 2021 activity report

List of acronyms used in the report

Acronym	Meaning
AIP	Autorizație pentru Import Paralel - Parallel Import Authorisation
ANMDMR	National Agency for Medicines and Medical Devices of Romania – National Agency for Medicines and Medical Devices of Romania
ANS	Autorizație pentru Nevoi Speciale - Authorisation for Special Needs
API	Autorizație pentru Import - Import Authorisation
APP	Autorizație de Punere pe Piață - Marketing Authorisation
AR/ NUI	Sistemul de Alertă Rapidă / Informații non-urgente - Rapid Alert System / Non-urgent Information
BAPDGIF	Birou administrarea proceselor DGIF – Bureau for administration of DGIF processes
BAMF	Birou Alerte Medicamente Falsificate - Falsified Medicinal Products Alerts Bureau
BPD	Bună Practică de Distribuție - Good Distribution Practice
BPF	Bună Practică de Fabricație - Good Manufacturing Practice
CA	Consiliul de Administrație - Administration Council
CaNaMed	Catalogul Național al Prețurilor Medicamentelor de uz uman - National Catalogue of the Prices of Medicinal Products Authorised for Marketing in Romania
[1]CAP	Medicamente autorizate prin procedură centralizată - Centrally Authorised Products
CAPP	Comisia de Autorizare pe Punere pe Piață - Commission for Marketing Authorisation
CAT	Comitetul pentru terapii avansate - Committee for Advanced Therapies
CESP	Common European Submission Portal
CFR	Colegiul Farmaciștilor din România - Romanian College of Pharmacists
CMR	Colegiul Medicilor din România - Romanian College of Physicians
CNAS	Casa Naţională de Asigurări de Sănătate - National Health Insurance House
CNCAV	Comitetului Național de Coordonare a Activităților privind Vaccinarea împotriva COVID-19 - National Committee for COVID-19 vaccination activities
CNSCBT	Centrul Național de Supraveghere și Control al Bolilor Transmisibile - The National Centre for Surveillance and Control of Communicable Diseases

COEN	Grupul pentru Conformitate şi Aplicare - Compliance and Enforcement Group
CRS	Substanţe chimice de referinţă - Chemical Reference Substances
DA	Direcția Avizare – Directorate for Endorsement
DAPP	Deținătorul Autorizației de Punere pe Piață - Marketing Authorisation Holder (MAH)
DAPDGIF	Birou administrarea proceselor DGIF – Directorate for administration of DGIF processes
DCCM	Direcția Control Calitatea Medicamentelor – Medicinal Product Quality Control Directorate
DCI	Denumire Comună Internațională - International Non-Proprietary Name (INN)
DCP	Authorisation through Decentralised Procedure
DETM	Direcția Evaluare Tehnologii Medicale - Directorate for Health Technologies Assessment
DFVMR	Direcția farmacovigilență și managementul riscului - Pharmacovigilance and Risk Management Directorate
DGDM	Direcția Generală Dispozitive Medicale – The General Directorate for Medical Devices
DGEA	Direcția Generală Evaluare Autorizare - General directorate for evaluation and authorisation
DGIF	Direcția Generală Inspecție Farmaceutică – General Directorate for Pharmaceutical Inspection
DIBPD	Direcția inspecții de bună practică de distribuție – Directorate for Good Distribution Practice Inspection
DIBPFLLASCFV	Direcția inspecție de bună practică de fabricație, de laborator, de laborator analitic, în studiul clinic și de farmacovigilență - The Directorate for Good Manufacturing Practice Inspection, Laboratory, Analytical Laboratory, Clinical Trial and Pharmacovigilance (DIBPFLLASCFV)
DPE	Direcția Proceduri Europene - European Procedures Directorate
DPN	Direcția Proceduri Naționale - National Procedure Directorate
DRUMC	Direcția Resurse Umane și Managementul Calității - Directorate for Human Resources and Quality Management
DRSP	Direcția Reglementare și Supraveghere Piață - Medical Devices Regulation and Market Surveillance Directorate
DSCMUT	Direcţia supravegherea calităţii medicamentelor şi unităţi teritoriale – Directorate for Surveillance and Alerts of Medicinal Products and Territorial Units
DSCMAUT	Direcţia supravegherea calităţii medicamentelor, alerte şi unităţi teritoriale - Directorate for Quality Supervision of Medicinal Products, Alerts and Territorial Units

DSU	Dosarul Standard al Unității - Unit Master File
DTL	Direcția Tehnic Laboratoare – Technical Laboratories Department
EDQM	European Directorate for the Quality of Medicines - Directoratul European pentru Calitatea Medicamentului şi Ingrijirea Sãnãtăţii
EMA	European Medicines Agency – Agenţia Europeanã a Medicamentului
EMF /EFC	Educație Medicală / Farmaceutică continua - Continuing Medical/Pharmaceutical Education
Eudra GMDP	Baza de date Eudra GMDP - European Inspections Database operated by EMA
GMP	Good Manufacturing Practice - buna practică de fabricaţie
GDP	Good Distribution Practice - buna practică de distribuţie
HMA	Heads of Medicines Agencies - Șefii Agențiilor Medicamentului
IGPR	Inspectoratul General al Poliției Române - General Inspectorate of Romanian Police
INSP	Institutul Național de Sănătate Publică - National Institute of Public Health
MRP	Autorizare prin Procedura de Recunoaștere Mutuală - Authorisation through mutual recognition procedure
MRP-RU	Autorizare prin Procedura de Recunoaștere Mutuală cu Utilizare Repetată – Authorisation through Mutual Recognition Procedure-Repeat Use
MSS	Market Surveillance Study - Studiu supraveghere piață
OCABR	Eliberarea oficială a seriilor de medicamente biologice - Official Control Authority Batch Release
OMS	Ordinul Ministrului Sănătății - Order of the Minister of Health
OSMR	Organizația de Serializare a Medicamentelor din România - The Romanian Organisation for Serialisation of Medicinal Products
OUG	Ordonanță de Urgență - Emergency Ordinance
PO	Proceduri operaționale - Operational Procedures
PRAC	Pharmacovigilance Risk Assessment Committee - Comitetul pentru evaluarea riscurilor în materie de farmacovigilenţă
PS	Proceduri de system – System Procedures
PSURSA	Evaluări unice ale rapoartelor periodice actualizate privind siguranța - Periodic Safety Update Report Single Assessments
PTS	Proficiency Testing Study - studii de testare a competenţei laboratoarelor
PTS	Proficiency Testing Scheme - Schemele de testare a competenţei laboratoarelor
RA	Reacții Adverse – Adverse Reactions
RAPI	Reacții Adverse Post-vaccinale Indezirabile - Undesirable Post-vaccination Adverse Reactions
RMS	Stat membru de referinţă - Reference Member State

RPAS	Raport Periodic actualizat privind Siguranța - Periodic Safety Update Report (PSUR)
SACR	Serviciul asigurarea calității și registratură – Quality Assurance and Registry Service
SARMF	The Rapid Alerts and Falsified Medicinal Products Service - Serviciul alertă rapidă, medicamente falsificate
SIBPD	Good Distribution Practice Inspection Service - Good Distribution Practice Inspection Service
SMC	Sistemul de management al Calității - Quality Management System
SMI	Interested Member State - Concerned Member State
SNVM	Sistemul Național de Verificare a Medicamentelor - National Medicinal Product Verification System
SPPSSM	Serviciul de Prevenire și Protecție în Domeniul Securității și Sănătății în Muncă - the service for prevention and protection of occupational safety and health
SAPE	Serviciul administrare proceduri europene – The Service for Administration of European Procedures
SEPE	Serviciul evaluare proceduri europene - The Service for Assessment of European Procedures
SRLM	Strategic Review and Learning Meeting - întâlnire strategică pentru evaluare și studiu
UTI	Unităţi Teritoriale de Inspecție – Territorial Inspection Units
VHP	procedura VHP pentru evaluarea armonizată a cererilor de studii clinice – Voluntary Harmonisation Procedure
WGEO	Grupul de lucru pentru aplicarea legislaţiei/combaterea falsificării medicamentelor – Working Group of Enforcement Officers