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THE MINISTRY OF HEALTH
THE NATIONAL AGENCY FOR MEDICINES
AND MEDICAL DEVICES OF ROMANIA
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ACTIVITY REPORT

2022

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FOREWORD

"This is a time when the Agency, through its essential role in the Romanian healthcare system and at European level, together with the other national agencies, must ensure efficient management of medicinal products and medical devices on the Romanian market. Particularly in the context of the global crisis we are all experiencing, patients' right to access to appropriate medical treatment is mandatory, and healthcare institutions must assess the risks and find effective solutions as soon as possible. There are many things that need to be put back on a normal track, so that the institution regains its prestige and its specialists are valued once again", says Răzvan Mihai Prisada, the new president of the NAMMDR.

Răzvan-Mihai Prisada
President

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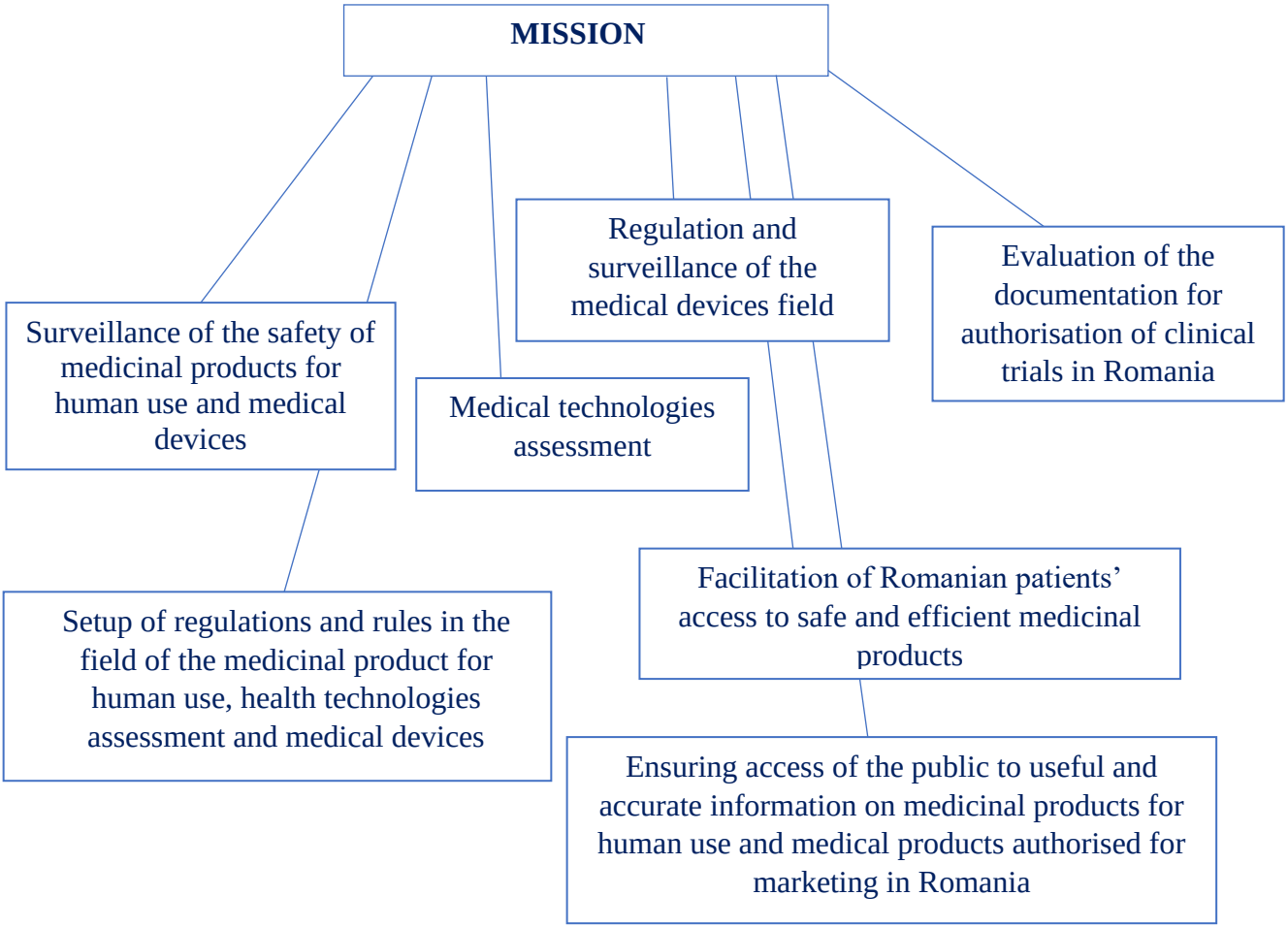
I.2. NAMMDR MISSION AND RESPONSIBILITIES

The National Agency for Medicines and Medical Devices of Romania is a public institution operating as a legal entity, a specialised body of the central public administration in the field of medicinal products for human use, medical devices and health technologies assessment, subordinated to the Ministry of Health, which operated in 2022 in accordance with the provisions of Law 134/2019 on reorganisation of the National Agency for Medicines and Medical Devices and amendment of further ruling provisions, as further amended and supplemented, and with the provisions of Order of the Minister of Health no. 857 of 22 March 2022 on approval of the Regulation on the organisation and operation of the National Agency for Medicines and Medical Devices of Romania.



I.3. THE CONTRIBUTION BROUGHT TO THE OBJECTIVES ASSUMED BY ROMANIA

Active participation in the meetings of the scientific committees and working groups of the European Medicines Agency (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.

For this purpose, in 2022, on the agency's website, www.anm.ro, special sections were created, such as: Clinical Trial Regulation / Informatic System for Clinical Trials, European Day of Information on Antibiotics - 2022, National Database of Medical Device Data.

Patients, patient associations, healthcare professionals, governmental and non-governmental organisations continued to request various information from the NAMMDR in 2022, according to Law 544/2001 on free access to public information, all of which have been resolved in compliance with the legislation in force. Also, the NAMMDR provided timely replies to all requests received on the e-mail address lipsamedicament@anm.ro.

The agency, as the basic institution of the Romanian healthcare system, participated through its specialists in debates and meetings with representatives of patient associations, professional societies and the medical industry, 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 or the media.

With regard to its legislative activity, in 2022, the NAMMDR amended and/or supplemented the legislation specific to the institution's activity through development and submission for approval to the Ministry of Health of draft regulatory documents needed in order to achieve the objectives in its field of activity

II. PUBLIC POLICIES

II.1. INFORMATION ON THE OUTCOMES OF THE IMPLEMENTATION OF THE INSTITUTIONAL STRATEGIC PLAN (PSI)

II.1.a. ACTIVITY OF THE SCIENTIFIC COUNCIL

The NAMMDR Scientific Council is established through Order of the Minister of Health, at the proposal of the NAMMDR President, and establishes the Agency's scientific policy.

In November 2022, after 4 years, the first meeting of the Scientific Council took place, with the following topics on its agenda:

- the election of the president of the NAMMDR Scientific Council according to Art. 11 paragraph (3) of Law no. 134/2019 on reorganisation of the National Agency for Medicines and Medical Devices and amendment of further ruling provisions;
- the presentation of the Regulation on the organisation and operation of the NAMMDR Scientific Council, approved according to Decision no. 1483/23.11.2022
- establishing priorities and working methods;

- proposing a calendar of the next Scientific Council meetings.

After casting the vote, DUMITRU LUPULIASA, Pharm., University Professor, PhD was appointed the President of the Scientific Council, whose members are as follows:

- RĂZVAN MIHAI PRISADA, Pharm. PhD
- ANCA DANA BUZOIANU, University Professor, PhD
- Ing. IOANA ȚENE, Engineer
- DOINA DRĂGĂNESCU, University Professor, PhD
- CAROLINA NEGREI, associate professor, PhD
- HĂNCIANU MONICA, University Professor, PhD
- ROXANA DONDERA, Senior Pharm.
- BIANCA GRIGORESCU, Senior lecturer, PhD
- EMANOIL CEAUȘU, University Professor, PhD
- CRISTIAN VLĂDESCU, University Professor, PhD

II.1.b. ACTIVITY OF THE ADMINISTRATION COUNCIL

In 2022, there were 7 meetings of the NAMMDR Administrative Council (AC), mainly focused on establishing appropriate administrative measures in order to apply the provisions of Law no. 134/2019, as further amended and supplemented, as follows:

1. **The AC meeting of 05.01.2022:**
   - Approval of the income and expenditure budget for January 2022 and the attached documents.

2. **The AC meeting of 13.01.2022:**
   - Approval of the income and expenditure budget accompanied by the list of investments for 2022, according to report no. 23453/29.12.2021 and the attached documents.
   - Approval of the Partnership Agreement between the NAMMDR and the "Carol Davila" University of Medicine and Pharmacy, Bucharest.

3. **The AC meeting of 27.01.2022:**
   - Approval of the Organization and Operation Regulation (ROF) of the National Agency for Medicines and Medical Devices of Romania, according to report no. 1509/26.01.2022 and the attached documents.

4. **The AC meeting of 30.06.2022:**
   - Approval of proposals for liquidation, according to report no. 10666/17.06.2022 and the attached documents;
   - Approval of proposals for fuel consumption rationing, according to report no. 10667/17.06.2022;
   - Approving the start of the procurement procedures for clearing, cleaning, transportation of plant mass and ploughing, related to the 22,000 sq m land in 145 Prelungirea Ghencea, Sector 6, Bucharest, according to report no. 10648/17.06.2022;

- Approval of the annual activity report of the NAMMDR for 2021 according to report no. 10943/22.06.2022;
- Approval of the financial statements of the NAMMDR (balance sheet and patrimonial result account) for the financial year 2021, according to report no. 10628/17.06.2022;
- Approval of the revenue and expenditure budget for 2022, amended according to the requests for transfer of credits between budget items according to report no. 10628/17.06.2022;
- Approval of tariff proposals for the activities carried out by the NAMMDR, according to report no. 11310/28.06.2022;
- Approval of the increase of the monthly rent ceiling for the 12 Territorial Units of Pharmaceutical inspection and/or control and supervision of the medicinal product market, as well as control through periodic verification of medical devices according to report no. 11010/23.06.2022.

5. **The AC meeting of 11.08.2022:**
   - Approval of the revenue and expenditure budget for 2022, amended according to the requests to transfer credits between budget items according to report no. 13446/29.07.2022;
   - Approval of the NAMMDR activity report for 2021 according to report no. 14295/10.08.2022;
   - Approval of the Partnership Agreement between the NAMMDR and the "Carol Davila" University of Medicine and Pharmacy, Bucharest;
   - Approval of the Partnership Agreement between the NAMMDR and the Faculty of Chemistry of the University of Bucharest;
   - Approval of the Cooperation Agreement between the NAMMDR and the "Romanian Medicines Serialisation Organisation" (OSMR).

6. **The AC meeting of 04.10.2022:**
   - Approval of the budget of revenues and expenses for 2022, amended based on requests to transfer credits between budget items and approval of the list of investments, according to report no. 17170/29.09.2022;
   - Approval of the NAMMDR job list for 2022 according to report no. 63060E/30.09.2022;

7. **The AC meeting of 04.10.2022:**
   - Approval of the revenue and expenditure budget for 2022, amended based on the transfer of credits between budget items, according to report no. 21187/25.11.2022 and the attached documents;
   - Approval of the income and expenditure budget for 2023 and the list of investments, according to report no. 21188/25.11.2022.

II.1.c. ACTIVITY OF NAMMDR COMMISSIONS

- **The Commission for Marketing Authorisation (CAPP)**

In 2022, 16 meetings were organised, during which a number of 577 medicinal products were discussed (495 – European procedures, 61 – National procedure, 21 – National procedure – Parallel import):

598 marketing authorisations (MAs) and Annexes 1, 2, 3, 4, 5 were issued for 598 medicinal products, of which 552 were related to the European procedures and 46 to the national procedure.

- **Commission for assessment and authorisation of medicinal products used for special needs**

132 authorisations were granted for medicinal products for special needs, in line with legal provisions.

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

In 2022, this Commission has completed:

- 15 assessment reports for the authorisation of 15 medicinal products used as last resort treatment;
- 9 assessment reports for renewal of authorisations of 9 medicinal products used as last resort treatment;
- 15 assessment reports for changes to the terms of authorisation of 15 medicinal products used as last resort treatment.

II.1.d. THE ACTIVITY OF SPECIFIC SCIENTIFIC AND TECHNICAL-ADMINISTRATIVE STRUCTURES

In 2022, 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.

AUTHORISATION THROUGH NATIONAL PROCEDURE

In 2022, 48 files were drawn up through the National Procedure, of which 32 authorisation requests and 16 authorisation renewal requests were validated.

Applications for authorisation	Applications for renewal	Applications for AIP variations	Applications for AIP authorisation	Export sheets
32	**16**	**100**	**53**	**376**

During 2022, 3573 works were received (MA transfer, design variations or modification and packaging inscription) and 4223 files were completed, the difference of 650 files meaning files registered between 2013 and 2021.

At the beginning of 2022, 305 files were outstanding, of which 158 authorisations and 147 renewals. In 2022, 40 of these files were authorised, 16 being authorisations and 24 renewals. At the end of 2022, 352 files were yet to be completed.

Considerable effort has been made to catch up on delays from previous years.

Status of applications received/resolved in 2022

No.	Type	Received in 2022	Solved in 2022 (including files registered between 2013-2022)
1.	Transfer APP	**19**	**61**
2.	Type I variations	**3247**	**3882**
3.	Type II variations	**129**	**128**
4.	Modification of packaging design and inscription	**178**	**152**
	Total: 1+2+3+4	**3573**	**4223**

AUTHORISATION THROUGH EUROPEAN PROCEDURES

6412 files were completed in 2022, as follows:

OVERALL REPORTING - 2022

Variations with RO-SMI: type IA/IA/G+IB/IB/G+II/WS	**5958**
Type P notifications in line with Article 61 (3) of Directive 2001/83/EC	**55**
National notifications in line with Order of the Minister of Health no.1205/2006	**150**
MA transfers in line with Order of the Minister of Health no. 1206/2006	**116**
Variations with RO-SMR: type IA/IA/G+IB/IB/G+II/WS	**133**
Overall total number of approvals per number of MAs (medicinal product strength)	**6412**

The activity of managing, validating and administering variation requests to MA terms through European procedures totalled 6,373 submitted variations, to which files registered during previous years were added.

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SITUATION OF CENTRALISED VARIATIONS FOR THE YEAR 2022 EUROPEAN PROCEDURES DIRECTORATE

SITUATION OF VARIATIONS OVER THE YEARS - complete package in various stages

YEAR of entry of the variation procedure (complete package*)	Total number of procedures entered (RO-SMR+RO-SMI)-various stages**/year	Total number of procedures approved – European stage -SMR/ CTS DATABASE	Total number of procedures approved – national stage - NAMMDR (from previous years as well)	Yearly backlog reported from previous years/procedures finished by the SMR (column 3-4)	Unfinished variation procedures on 01.01.2022 and from previous years reported for each year/ various stages** (NAMMDR INTERNAL DATABASE)	Unfinished variation procedures on 31.12.2022 and from previous years reported for each year/ various stages** (NAMMDR INTERNAL DATABASE)
2022	6494	6294	6412	not the case/recovery with a surplus of 118	Not applicable	5031
2021	7195	6849	5109	1740	4526	3122
2020	6631	6128	4624	1504	4020	1895
2019	7717	7198	4788	2410	2741	1019
2018	7179	6641	4250	2391	1234	150
				total 5536	302 (of 2016+2017)	11217
					12823	

Additional explanations:

11217 represents the number of variation procedures which includes the 5536 variations corresponding to the total annual backlog and from previous years, compared to procedures completed in the annual reference member state (SMR) annually, but also submissions in various stages as explained in **, and which cannot yet be approved in Romania, since they are not approved at European level, i.e. a number of 5681 variation procedures at the end of 2022.

12823 represents the number of variation procedures that includes the backlog from previous years as well as procedures in various stages at that time on 01.01.2022. It is visible from the difference between column 6 and column 7 that in 2022, 1606 more variations were handled, compared to the previous year 2021 (newly hired staff).

Clarification - the variation procedures can be approved at national level by the NAMMDR only after the completion of the procedure at European level and the receipt of the end of the procedure from the SMR -

THE REFERENCE MEMBER STATE WHICH LEADS THE PROCEDURE (column 3)

*full package=Payment form+cover letter+payment confirmation+documentation to evaluate the variation (these can enter in different years even with a one-year difference)

**in various stages of the procedure=these can be reported to the European procedure monitoring database -the CTS-Database:

not created in the CTS-in the submission/initiation phase

created in the CTS during the validation phase

created in the CTS in the deployment phase-started procedurally at European level

created in the CTS-unfinished SMR in suspension phase (with requests)

created in the CTS-unfinished SMR in suspension phase (requests were answered)

created in CTS-finished by the SMR in the European Stage-finished also in the CTS-APPROVAL MAY BE GRANTED LATER by the NAMMDR (DPE-SAPE-CVAV)- sent to the National Stage of approval of variation procedures

In the National Stage-with requests for translations/incomplete payments/clarifications/to be included in Renewal/other causes

OTHER ADDITIONAL SPECIFICATIONS FOR THE DATA PRESENTED

SMR=REFERENCE MEMBER STATE-leads the procedure from an administrative and evaluation viewpoint

SMI=INTERESTED MEMBER STATE-participates in the procedure and can invalidate/request additions due to the evaluation of the medicinal product documentation during the European stage

Note: In 2018, the submissions for MAH Transfers were 4 times the average of a normal year in the context of BREXIT.

In 2018, submissions for Type P Notifications were more than 10 times higher than the average of a regular year / National Notifications were 4 times higher than the average of a regular year in the context of SERIALIZATION - the anti-counterfeit directive.

In 2019, the submissions for MAH Transfers were 2 times the average of a regular year in the context of BREXIT/MAH amendment for the entire portfolio.

Variations with RO/SMR are procedures where we as an agency administer and evaluate the procedure, the complexity/responsibility of these procedures being much greater than those in which we are RO/SMI.

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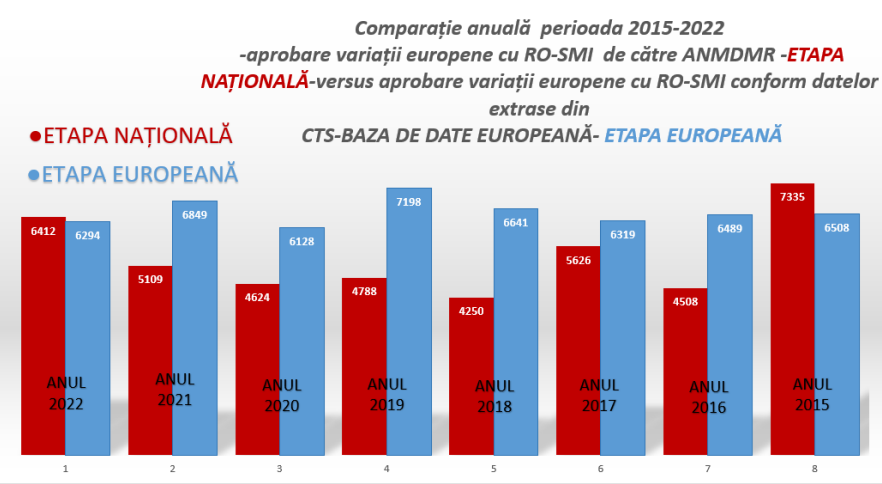
ANALIZA STATISTICĂ A DATELOR-ETAPA NAȚIONALĂ VERSUS ETAPA EUROPEANĂ



Statistical analysis of the data - national stage versus European stage
Annual comparison (2015-2022)
Approval of European variations with RO as interested member state in accordance with the data extracted from CTS – the European database – European stage
Red – national stage
Blue – European stage

HEALTH TECHNOLOGIES ASSESSMENT

In 2022, 124 new molecules from multiple treatment areas were evaluated. Among the evaluation reports completed by the DETM during 2022, there were:

- 87 reports were for new INNs or with extension of indication
- 37 reports were related to moving or adding population segments or treatment lines.

In 2022, the average duration for resolution of evaluation requests was 209 days (about 7 months), calculated between the date of registration of the request and the date of issuance of the decision, or for certain situations, the date of completion of the evaluation report.

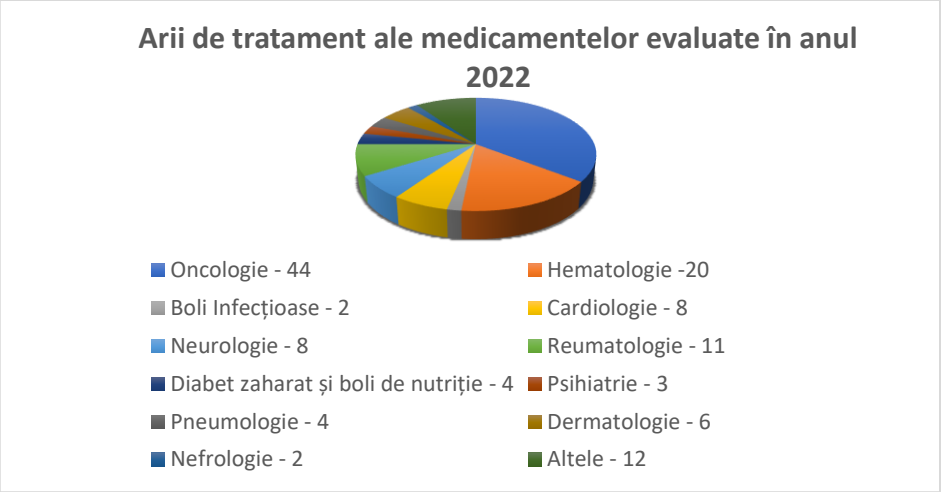
We hereby remind you that the evaluation period provided for in the updated Order of the Minister of Health no. 861/2014 is 90 working (not calendar) days. Only the date of submission of the application and the date of its completion are recorded into our database. The difference between the date of completion of an application and the date of its registration at the NAMMDR reflects the number of calendar days (it does NOT reflect the number of working days, as provided for in

the legislation). Therefore, the average duration of resolving the declared evaluation requests is less than 209 days.

In addition, the initiation of the evaluation of an application starts from the moment of submission of the complete documentation. Should the DETM consider that the submitted documentation is incomplete, it requests its completion, and the evaluation period is extended. Our database does not include data related to requests for completion of the documentation for all applications.

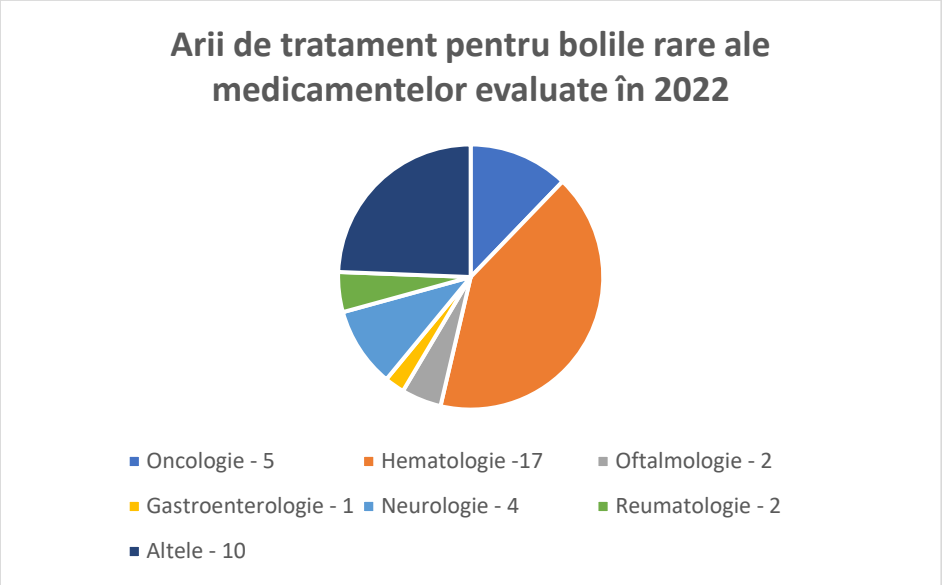
These situations cause a suspension of the application evaluation period between 1 and 3 months, according to DETM estimates.

Therefore, the DETM estimates that the actual deadline for evaluating applications for 2022 is approximately 5 months.



Treatment areas of the medicinal products evaluated in 2022
Oncology – 44
Infectious diseases – 2
Neurology – 8
Diabetes and nutritional diseases – 4
Pneumology – 4
Nephrology – 2
Haematology – 20
Cardiology – 8
Rheumatology – 11
Psychiatry – 3
Dermatology – 6
Other – 12

Of these, 41 new molecules were from treatment areas for rare disease medicinal products.



Treatment areas for the rare diseases linked to the medicinal products evaluated in 2022
Oncology – 5
Haematology – 17
Ophthalmology – 2
Gastroenterology – 1
Neurology – 4
Rheumatology – 2
Other - 10

Through reorganisation of the medical technology assessment process, started this year, the deadline for approving assessment files for new molecules has been reduced to less than half compared to the deadline of previous years.

ASSESSMENT AND AUTHORISATION OF CLINICAL TRIALS

Starting from 31 January 2022, the Clinical Trials Regulation (CTR) was implemented, which harmonizes the submission, evaluation and supervision of clinical trials at EU level.

The main aspect of the changes brought by the CTR is the new Clinical Trials Information System (CTIS), which is a single-entry point for clinical trial sponsors and regulatory authorities for submission and evaluation of data issued from clinical trials, which includes a public database, transparent and accessible to healthcare professionals, patients and the general public.

In 2022, 234 requests for evaluation and authorisation of clinical trials with medicinal products for human use were received (202 requests submitted in line with Directive 2001/20/EC and 32 requests submitted through CTIS in line with Regulation (EU) No. 536/2014), as follows:

Directive 2001/20/EC:

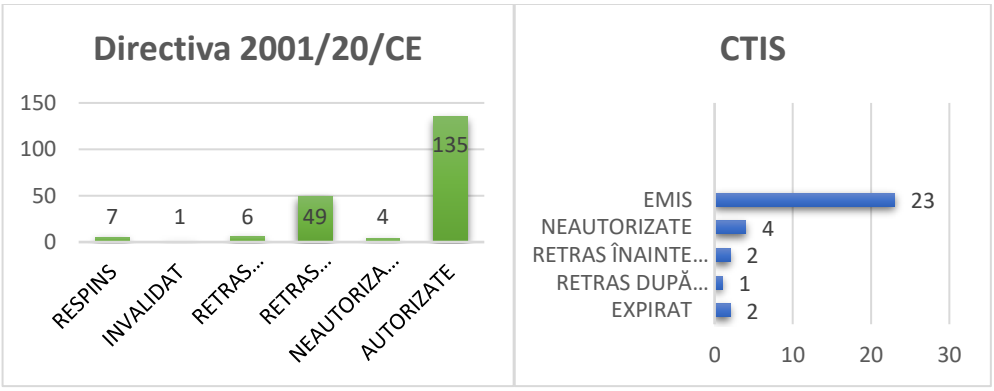
- 7 rejected (5 in 2022 and 2 in 2023) 1 invalidated
- 6 withdrawn after evaluation
- 49 withdrawn prior to evaluation

- 4 unauthorised
- 135 authorisations issued.

CTIS:

- 2 expired
- 2 withdrawn prior to evaluation
- 1 withdrawn after evaluation
- 4 unauthorised
- 23 authorisations issued.

These numbers are illustrated in the chart below:



Assessment and approval of amendments to approved clinical trials:

In 2022, the NAMMDR Clinical Trials Directorate received 776 applications (of which 774 submitted in line with Directive 2001/20/EC and 2 submitted through the CTIS in line with Regulation (EU) No. 536/2014) for evaluation and approval of substantial amendments;

1111 replies were issued (1109 approval notifications and 2 rejection notifications, including applications submitted in 2020 and 2021).

Assessment and approval of observational studies with human medicinal products:

- 22 requests were received;
- 48 replies were issued (16 initial approvals and 32 responses to amendments).

Authorisation of medical units conducting clinical studies:

- 35 requests for authorisation + 9 changes to initial authorisations (addition of workpoints or specialties);
- 35 authorisations issued (applications submitted in 2020 and 2021) and 9 changes approved.

11 meetings for evaluation of medical units were organised in order to conduct clinical studies (11 minutes were drawn in this respect).

Note: Starting from 23.03.2022, the authorisations of medical units shall be automatically extended until 31.01.2025 in line with Emergency Government Ordinance no. 29/23.03.2022.

Receiving and managing non-substantial amendments to approved clinical trials, various notifications, notifications containing requests for various information:

- 776 various notifications (first patient inclusion notification, study closure notifications, temporary interruptions, non-substantial amendments);
- 304 annual study reports;
- 41 non-interventional study notifications.

Management of tariff regularization notifications, when necessary:

- clinical trial tariff regularisations – 23;
- tariff adjustments amendments –12.

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: 420;
- PSURs: 309.

MANAGEMENT OF THE INDEX OF MEDICINAL PRODUCTS FOR HUMAN USE

In 2022, the Index of Medicinal Products Service carried out the following activities:

- Permanent update of the Index of medicinal products for human use – 1121 notifications for inclusion and 815 notifications for withdrawal;
- Management of notifications for enforcement of provisions of Articles 737, 738 of Law 95/2006 on healthcare reform - Title XVIII – "The medicinal product", regarding the SUNSET CLAUSE (withdrawal of the MA after 3 years if the medicinal product has not been marketed): 24 medicinal products;
- Permanent update of the electronic record "Medicinal product discontinuation notifications" on the NAMMDR website: 647 medicinal products.

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

In 2022, 42 Good Manufacturing Practice (GMP) certificates were issued for Romanian and foreign manufacturers, 102 manufacturing authorisations, including their annexes, 32 import authorisations including the amendment/update of import authorisation annexes and 2 Good Laboratory Practice (GLP) certificates.

150 requests for donations of medicinal products for human use were evaluated and approved.

Throughout 2022, the permanent update of the EudraGMDP database was ensured, by entering the information from the issued GMP authorisations/certificates.

In 2022, inspections were carried out for issuance of the Manufacturing Authorisation/GMP certificate including those for clinical investigation, authorisation inspections at the sites of

medicinal product importers, GMP compliance certification inspections at the sites of third country medicinal product manufacturers, GLP certification inspections /re-certification at bioequivalence centres (clinical unit and/or bioanalytical laboratory which performs bioequivalence studies), in order to check GLP compliance of these units.

5 agreements have been issued on registration as manufacturers/importers/distributors of active substances to be used as raw materials for medicinal products for human use.

The Yearly Sampling and Testing Plan on monitoring of medicinal product quality, containing 53 products proposed, based on the selection criteria, to be taken in 2022, was drafted;

All complaints received from pharmacies and hospitals at the address lipsmedicament@anm.ro were investigated, for which e-mail exchanges were carried out with wholesale distributors/MAH representatives/pharmacies.

In 2022, 252 rapid alerts received from other national authorities were managed through the European rapid alert system, whose subject was the quality noncompliances of some products (medicinal products, food supplements, personal care products).

Specific activities related to the serialization of medicinal products were carried out by drawing up 120 verification reports, in order to supervise the functioning of the repertoires and investigate potential incidents of falsification, by accessing the National Medicines Verification System.

PHARMACOVIGILANCE AND RISK MANAGEMENT

In 2022, the NAMMDR transmitted to the EMA Eudravigilance database, in electronic format, 396 serious adverse reactions and 1303 non-serious adverse reactions, received from patients and healthcare professionals.

The NAMMDR, as a pharmacovigilance and risk management activity, annually offers EFC (Continuing Pharmaceutical Education)/EMC (Continuing Medical Education) credits to healthcare professionals who report adverse reactions and sends, on a quarterly basis, information addresses regarding this aspect to the respective professional organisations (the Romanian College of Physicians/the Romanian College of Pharmacists). In 2022 the NAMMDR sent 230 such information letters to healthcare professionals. Through these efforts, the aim was to encourage healthcare professionals (physicians, pharmacists, nurses, midwives) to report suspected adverse reactions to medicinal products for human use.

In order to reduce the risks of medicinal products for human use and promptly inform healthcare professionals, 22 "Direct healthcare professionals communication" documents were approved and distributed by MAHs to professionals. The NAMMDR sent these to the National Health Insurance House, the Ministry of Health, the Romanian College of Physicians and the Romanian College of Pharmacists; they were published on the NAMMDR website.

Moreover, as an additional measure to minimize the risks of medicinal products for human use, the NAMMDR approved 61 requests for approval of educational materials, provided in the Risk Management Plan for the respective products. These are distributed by the MAHs to healthcare professionals and patients.

Placing safe medicinal products for human use on the market was ensured by evaluating the pharmacovigilance documentation and verifying the fulfilment of the pharmacovigilance requirements in line with the procedures for authorisation for placing medicinal products for human

use on the market, the procedures for marketing authorisation renewal (centralised procedures, European procedures, national procedures) and in line with the variations to the MA terms.

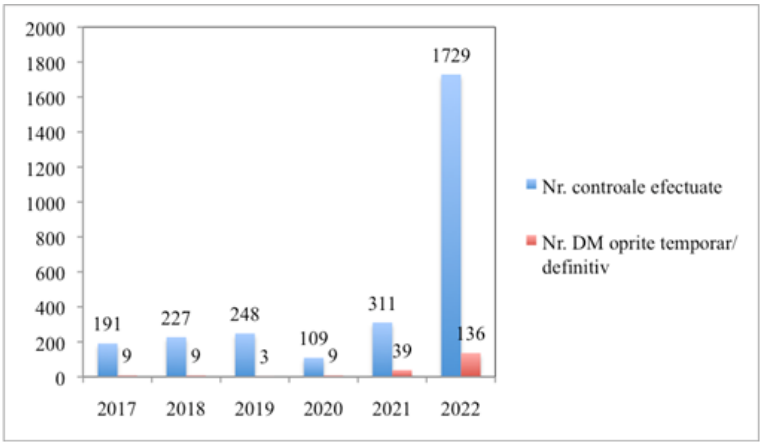
At European level, in the re-examination of the referral procedure in line with Article 31 of Directive 83/2001, initiated by Romania for medicinal products containing amfepramone, Romania was appointed in 2022 as Co-Rapporteur in the EMA Safety Committee (PRAC) and, in this capacity, Romania, through the NAMMDR-DFVMR, developed evaluation reports in the context of the re-examination procedure at European level.

Moreover, a single European procedure for the assessment of the Periodic Safety Update Report (RPAS) was completed, in which Romania was appointed as a reference member state (PSUSA Procedure - Periodic Safety Update Report Single Assessment).

THE GENERAL DIRECTORATE FOR MEDICAL DEVICES (DGDM)

In 2022, through the Market Surveillance Service (SSP) of the General Directorate of Medical Devices, 1729 control actions were carried out regarding the verification of the compliance of medical devices (MD) placed on the Romanian market as well as medical devices in use.
Among the economic operators subject to the controls carried out, there were manufacturers, importers, distributors, healthcare units, medical offices for aesthetic procedures, bioresonance/alternative medicine offices, clinics and pharmacies, medical optics units, retail stores.

The comparative situation of the controls carried out and noncompliant medical devices (DMs) - 2017-2022



Blue - Number of checks performed
Red – Number of medical devices temporarily/definitively turned off

Compared to previous years, the number of inspections performed has increased considerably, this being possible also due to the increase in the number of inspectors in 2022, as part of the strategy to make the institution's activity more efficient.

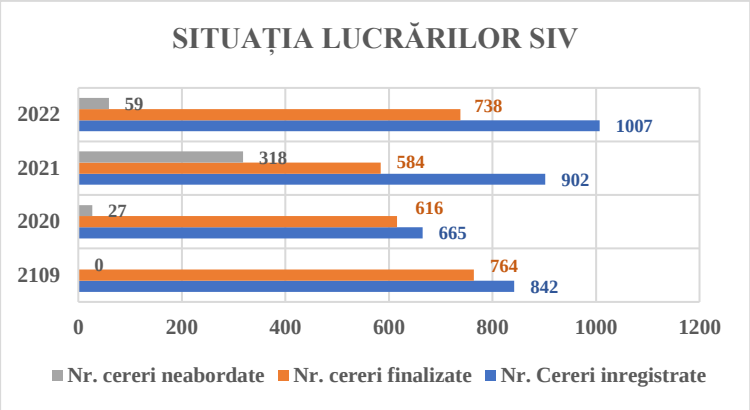
Another representative activity of the DGDM is the assessment of the competence and ability of economic operators to perform activities in the field of medical devices in order to issue an operation permit.

In 2022, 3175 files for approval of activities in the field of medical devices were evaluated.

The Technical-Laboratory Directorate is part of the DGDM and its activity consists of the technical verification of medical devices put into operation and in use through the Tests and Verifications Service (SIV) and the Nuclear Unit Service (SUN).

In 2022, 1007 checks of medical devices related to private healthcare units, public hospitals and county ambulance services were carried out throughout Romania.

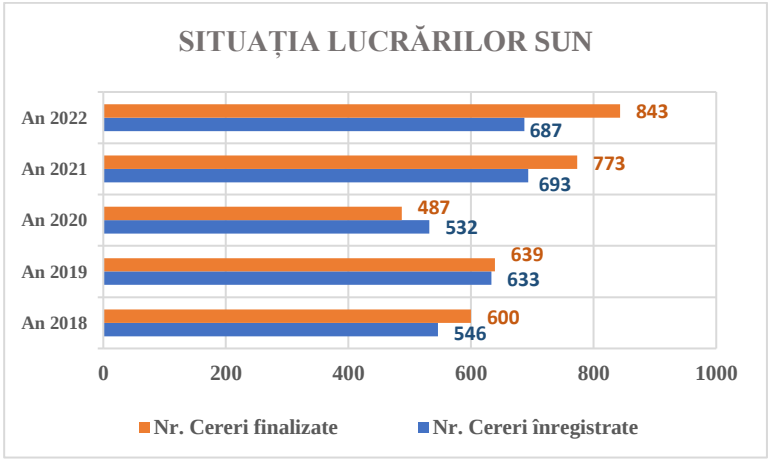
The tests and Verifications Service - 2022



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

Within the Nuclear Unit Service (SUN), in 2022, 687 requests for technical verification were registered and 843 were completed, the difference representing the recovery of outstanding files from previous years, bringing the activity up to date being one of the Agency's main objectives:

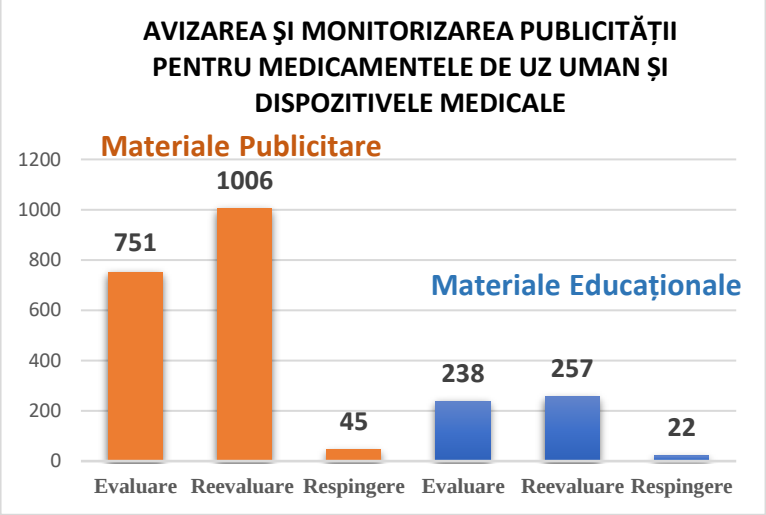
SIV ACTIVITY 2022 for the Nuclear Unit Service



SUN activity (per year):
Orange – Number of finished applications
Blue – Number of registered applications

APPROVAL AND MONITORING OF ADVERTISING FOR MEDICINAL PRODUCTS FOR HUMAN USE AND MEDICAL DEVICES

In 2022, 2319 advertising and educational materials in the field of human medicine and medical devices were registered at the Agency's Advertising service, of which 751 advertising materials were evaluated, 1006 re-evaluated and 45 rejected. Regarding educational materials, 238 materials were evaluated, 257 re-evaluated and 22 rejected, as seen in the chart below:



Orange – advertising materials

Blue – educational materials

Assessment-Reassessment – Rejection

COMMUNICATION AND PUBLIC RELATIONS

The NAMMDR communication activity ensures relations with all stakeholders: patients, patient associations, media, healthcare professionals, professional associations, pharmaceutical industry, national and international profile organisations.

In 2022, the NAMMDR responded promptly, on various topics of major interest for public health, to all requests received from other institutions as well.

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

The communication and public relations service (SCRP) continued to ensure an optimal degree of information and communication with all stakeholders, in accordance with the legal provisions, constantly aiming to optimize activities in the field of communication at national, institutional and network level, through:

- communication of the institution's strategic objectives and communication with stakeholders, 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 stakeholders;
- continuing to focus on a mainly proactive approach to communication, encouraging the transmission of a consistent, clear and correct message to stakeholders;
- granting maximum importance to the management of crisis situations in the healthcare field 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 collaborates closely (the EMA, etc.) was another objective of the SCRP through translation, validation of translated materials 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.

An important component of communication with stakeholders, 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 Medicines Serialisation Organisation (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.).

The Communications and Public Relations Service coordinated the MedSafetyWeek and Antimicrobial Resistance international communications campaigns, as well as the Clinical Trials Information System (CTIS) outreach campaign.

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

The SCRP contributed to the development of the Cooperation Agreement between the NAMMDR and the Romanian Organisation for Serialisation of Medicines (OSMR) and organized the "Operationalization of Real Word Evidence (RWE) in Romania and EU HTA implementation" Workshop.

The NAMMDR, through the SCRP, continues to monitor and manage the email address lipsmedicament@anm.ro, receiving notifications from patients, patients' relatives, hospitals, open circuit and hospital pharmacies, patient associations, pharmaceutical warehouses, medical societies, physicians, all of which were forwarded to the Agency's experts.

LOGISTICS, INFORMATION AND ELECTRONIC DATA MANAGEMENT

The NAMMDR Information and Communication Technology Service (STIC) continued in 2022 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 and collaborated with the EMA groups in order to digitize its activity in the context of European projects.

In 2022, in the context of legislative changes in the field of clinical studies, the STIC department created the Digital Platform for Submission of Clinical Trial Documentation.

INTERNAL AUDIT

In 2022, the Internal Audit Bureau performed assurance missions which involved an objective assessment of evidence performed by the audit team, in order to issue 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 levels of quality achieved in the fulfilment of responsibilities.

In 2022, according to the Annual Internal Public Audit Plan, 2 system audit missions were planned at NAMMDR level, as follows:

1. The Human Resources and Quality Management Directorate (DRUMC) - 31.08.2022 - 21.11.2022 - 17 measures (to be implemented) were identified;

2. The Legal Directorate for European Affairs and International Relations (DJAERI) - 18.10.2022 - 21.12.2022 - 11 measures (to be implemented) were identified.

According to the General Rules for performance of the internal public audit activity - approved through DECISION No. 1086 of 11 December 2013 *(2.4.5.2. The findings and recommendations of the internal auditors are forwarded to the audited entity/structure, and the observations or uncertainties are discussed with its managers during the internal public audit mission/2.4.5.3.)*

The internal public audit report is signed on each page by the internal auditors and on the last page by the supervisor/head of the internal public audit department, sent for approval to the head of the public entity which approved the mission, after which a copy is communicated to the audited entity/structure), the recommendations related to the audit reports drawn up by the BAI are not public and are addressed only to the heads of the audited structures and the president.

II.2. PRIORITIES FOR 2023

The Agency shall take into account in all its actions, in the wider context of the EU strategy in the pharmaceutical field until 2025 and the future European pharmaceutical policy, but also in the context of some potential challenges, which may arise from objective causes, at national or international level, from priority areas, as key factors for public health related activities.

Priority areas:

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

III. INSTITUTIONAL TRANSPARENCY

a. INCOMES:

The NAMMDR budget approved for 2022 was self-funded: 65,625 thousand lei.

a) Costs:

The final NAMMDR budget approved for 2022 consisted of 65,625 thousand lei, distributed as follows:

- Title 10 - Staff expenses: 57,087,000 lei.
- Title 20 - Expenses on goods and services: 5,176,000 lei.
- Title 59 - Amounts for disabled persons: 420,000 lei
- Title 70 - Capital expenses: 2,942,000 lei

b) NAMMDR budget execution:

Receipts: 89,340,991.02 lei

Budgetary expenses: 39,743.843.67 lei, of which:

- Title 10 - Staff expenses: 34,094,771.89 lei
- Title 20 - Expenses on goods and services: 3,480,690.70 lei
- Title 59 - Amounts for disabled persons: 322,187.00 lei
- Title 70 - Capital expenses: 2,173,528.47 lei
- Title 85- Payments made in previous years and recovered in the current year: -327,334.39 lei

At the end of 2022, the NAMMDR had a surplus of 49,924,481.74 lei.

All expenses were included in the approved budget for 2022, in compliance with the legal provisions regarding the economic-financial discipline.

b. PUBLIC PROCUREMENT INFORMATION

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 – 4 procedures.
- Open auction – 1 procedure.
- Simplified procedure – 5 procedures.
- Direct purchases – 420 procedures.

Of all the procurements carried out, the following were carried out through the electronic system during the reporting calendar year: open auction - 1 procedure, simplified procedure - 5 procedures, direct online purchases - 325 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 2022, no appeals were submitted to the public procurement procedures carried out by the NAMMDR and 4 procedures carried out by the Romanian Commodity Exchange, with the object of supplying natural gas, namely electricity supply for NAMMDR locations were cancelled or in the cancellation procedure.

Detailed information on public procurements carried out in 2022 is available online: https://www.anm.ro/informatii-de-interes-public/.

I.1. INFORMATION ABOUT LITIGATIONS IN WHICH THE INSTITUTION IS INVOLVED

As regards the litigations in which the NAMMDR was involved during the period of January - December 2022, there were 578 of them, which involved requests for summons, objections, written conclusions, requests for evidence, written notes, requests for legalization, notifications to

the courts regarding the pending cases, as well as the representation and defence of NAMMDR's interests before the courts.

In most of the definitively solved litigations, the solutions handed down by the courts were favourable to the NAMMDR.

c. ORGANISATIONAL CHART

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

INFORMATION ABOUT THE HUMAN RESOURCES MANAGEMENT

According to *Law 134/2019 on reorganisation of the National Agency for Medicines and Medical Devices and amendment of further ruling provisions, as further amended and supplemented,* the NAMMDR is led by a president and two vice-presidents, appointed in accordance with the law through Order of the Minister of Health.

The organisational structure is approved through Order of the Minister of Health, at the proposal of the NAMMDR president and with the approval of the administration board. The NAMMDR is structured on general directorates, departments, services, offices (bureaus) and compartments. Within the organisational structure, by decision of the NAMMDR president, laboratories, territorial units for inspection and/or control and supervision of the medicinal product market/supervision of the market of medical devices/in the use of medical devices, approval of activities in the field of medical devices can be organized, as well as control through periodic verification of medical devices, observing the maximum number of positions approved, namely 500 positions.
On 01.01.2022, there were 311 employees, 349 by the end of 2022, as follows:

- Number of approved positions: 500
- Number of positions occupied by 01.12.2022: 349
- Number of vacant positions by 01.12.2022: 151
- Average number of remunerated positions by 01.12.2022: 336

In 2022, 74 hires were made, as follows:

- 2 contractual management positions filled by competition, including the position of president;
- 1 contractual management position filled by secondment;
- 71 contract execution positions filled by competition;

In 2022, there were 41 terminations of activity, as follows:

- 1 contractual management position terminated on the date of cumulative fulfilment of the standard age conditions and the minimum contribution period for retirement;
- 1 contractual management position terminated by transfer upon request;

- 25 contractual execution positions terminated with the agreement of the parties;
- 1 contractual execution position terminated by transfer upon request;
- 8 executive contractual positions terminated on the date of cumulative fulfilment of the standard age conditions and the minimum contribution period for retirement;
- 2 executive contractual positions terminated at the end of the trial period;
- 2 executive contractual positions terminated on the expiry date of the individual employment contract concluded for a fixed period;
- 1 executive contractual position terminated by resignation.

Management positions exercised on a temporary basis in 2022:

- 33 contractual leadership positions exercised on a temporary basis;

Number of competitions organised in 2022:

8 competitions were organised in order to fill the vacant contract execution positions, of which:

 3 competitions for the occupation of 18 vacant contract execution positions of physicians (5 were filled);
 5 competitions for the occupation of 103 vacant contract execution positions (73 were filled).

The staff turnover rate in 2022 was 12.28%.

Information about salary rights and other rights of NAMMDR employees are available on the NAMMDR website - https://www.anm.ro/informatii-de-interes-public/situatia-drepturilor-salariale-si-alte-drepturi/.

IV. RELATIONSHIP WITH THE COMMUNITY

a. ACTIVITY REPORT DRAWN UP IN ACCORDANCE WITH LAW 544/2001, AS FURTHER AMENDED AND SUPPLEMENTED

During the reported period, 77 requests for information of public interest were registered, of which 24 from individuals and 53 from legal entities. The subject of the requests was 100% related to information on human medicinal products/medical devices.

In 2022, according to Law no. 544/2001 on free access to information of public interest by media representatives, 34 complaints were received electronically, which were solved in compliance with the legislation in force.

b. 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 solved during the next period.

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

With regard to the legislative activity, in 2022, the Legislation, Referrals, European Affairs and International Relations Service (SLSAERI) together with the NAMMDR specialised organisational structures, prepared the documentation (draft regulatory documents, substantiation notes, approval reports) for their promotion through the Ministry of Health and proposed amendments to the following draft regulatory documents:

1. The draft Order for the amendment and supplementation of the Annex to Order of the Minister of Health no. 1.032/2011 on approval of Norms concerning donations of medicinal products, medical supplies, medical devices, vaccines, sera and related supplies;

2. The proposal for amendment of the Draft Government Decision on amendment of Government Decision no. 144/2010 on the organisation and operation of the Ministry of Health;

3. The Government's draft emergency ordinance regarding the establishment of an institutional framework, as well as the necessary measures to ensure direct application of the provisions of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU;

4. The proposal for amendment of the Draft Law on the legal regime of the cannabis plant, of substances and preparations containing cannabis, used for medical purposes (PL-x no. 631/2019);

5. The proposal for amendment of the Draft Law on the approval of Government Ordinance no. 17/2021 for the amendment and supplementation of Law no. 134/2019 on reorganisation of the National Agency for Medicines and Medical Devices and amendment of further ruling provisions (L333/2021);

6. The draft Order regarding the control by periodic verification of in-use medical devices, the evaluation of the performances of second-hand medical devices put into operation and the release of the usage approval for medical devices from the endowment of means of intervention for pre-hospital emergency medical assistance;

7. The draft Order regarding the approval of the procedure for issuance of the free sale certificate of medical devices sent to the Ministry of Health through notification no. 66.625E of 25.11.2021;

8. The draft Order for the approval of Methodological Rules on clinical evaluation and clinical investigations with medical devices;

9. The draft Order regarding the approval of the methodological rules for the enforcement of the provisions of Art. 13 of Government Emergency Ordinance no. 46/2021 regarding the establishment of an institutional framework and necessary measures for 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, regarding the registration of custom-made devices introduced on the market under their own name by manufacturers based in Romania;

10. The draft Order on approval of the Methodological rules regarding advertising for medical devices;

11. The draft Order on approval of the Methodological rules regarding the assessment, designation and notification of medical device compliance assessment bodies, as well as regarding the monitoring of notified bodies;

12. The draft Order on approval of the Methodological rules regarding the introduction 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 compliance assessment procedures;

13. The draft Order on repeal of Order of the Minister of Health no. 373/2015 regarding the approval of the form with special regime of the minutes of ascertainment and application of contraventional sanctions regarding non-compliance with legal provisions regarding medical devices and related activities;

14. The draft Order on approval of the procedure regarding the manufacture and use of medical devices within healthcare institutions;

15. The draft Order on approval of the procedure regarding the grant of an out-of-scope notice for products which do not fall under the scope 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, sent to the Ministry of Health via address no. 52.469E/22.02.2022;

16. The proposal for amendment of the proposed law for the approval of Government Emergency 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 (PL-x no. 346/2021);

17. The proposal for amendment and supplementation of Order of the Minister of Health no. 1474/2021 on set up and operation of the group of experts responsible for technical standpoints on documents under EU debate, also ensuring representation in meetings of EU working entities;

18. The draft law amending and supplementing Law no. 286/2009 regarding the Criminal Code;

19. The draft Government emergency ordinance on establishing the institutional framework and measures for the implementation of Regulation (EU) no. 536/2014 of the European Parliament and of the Council of April 16, 2014 regarding interventional clinical trials with medicinal products for human use and repealing Directive 2001/20/EC;

20. The draft Order regarding the approval of the methodological norms for the application of the provisions of art. 3 (10), art. 4 (3) and art. 6 (2) of Government Emergency Ordinance no. 29/2022 regarding the establishment 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, as well as for amending some regulatory documents in the healthcare field;

21. The draft Order regarding the approval of the amount of tariffs for the activities carried out by the National Agency of Medicines and Medical Devices of Romania in the field of medical devices;

22. The proposal for amendment of the draft Government ordinance on amendment and supplementation of Law no. 95/2006 on healthcare reform;

23. The proposal for amendment of the Draft Law on approval of Government Ordinance no. 17/2021 on amendment and supplementation of Law 134/2019 on reorganisation of the National Agency for Medicines and Medical Devices and amendment of further ruling provisions (PL-x no. 484/2021);

24. The proposal for amendment of the Draft Government Ordinance on a single industrial license, co-initiated by the Ministry of Entrepreneurship and Tourism and the Competition Council;

25. The proposal for amendment of the Draft Government Decision on approval of the National Health Strategy 2022 – 2030 and the Action Plan for 2022 – 2030 in order to implement the National Health Strategy;

PRESIDENT,

The National Agency for Medicines and Medical Devices of Romania,

Răzvan Mihai Prisada

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THE NATIONAL AGENCY FOR MEDICINES
AND MEDICAL DEVICES OF ROMANIA
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***Annex to the NAMMDR 2022 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	Autorizare prin procedură descentralizată - 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 inspecţii de bună practică de distribuţie – 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 Sănătăţii
EMA	European Medicines Agency – Agenţia Europeană 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
PSUSA	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	Serviciul alertă rapidă, medicamente falsificate - The Rapid Alerts and Falsified Medicinal Products Service
SIBPD	Good Distribution Practice Inspection Service - Good Distribution Practice Inspection Service
SMC	Sistemul de management al Calității - Quality Management System
SMI	Stat membru interesat - 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
SRLM	întâlnire strategică pentru evaluare şi studiu - Strategic Review and Learning Meeting
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