THE MINISTRY OF HEALTH
THE NATIONAL AGENCY FOR MEDICINES
AND MEDICAL DEVICES OF ROMANIA
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YEARLY ACTIVITY REPORT
2024

THE MINISTRY OF HEALTH
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FOREWORD

" For the National Agency for Medicines and Medical Devices of Romania, 2024 was a year of consolidation and progress as well.

A year in which we continued our commitment made two years ago, to protect public health through rigorous surveillance and regulation of medicinal products and medical devices.

In a constantly changing context, we have managed to promptly respond to challenges and adapt to the new legislative and technological requirements.

We have taken important steps towards digitization, streamlining internal processes and strengthening international collaboration, particularly with European institutions. We have focused on transparency, professionalism and openness towards all those involved in the healthcare system.

Together, we will continue to develop a modern, responsible agency connected to the real needs of patients and professionals in the field."

Răzvan-Mihai Prisada

President

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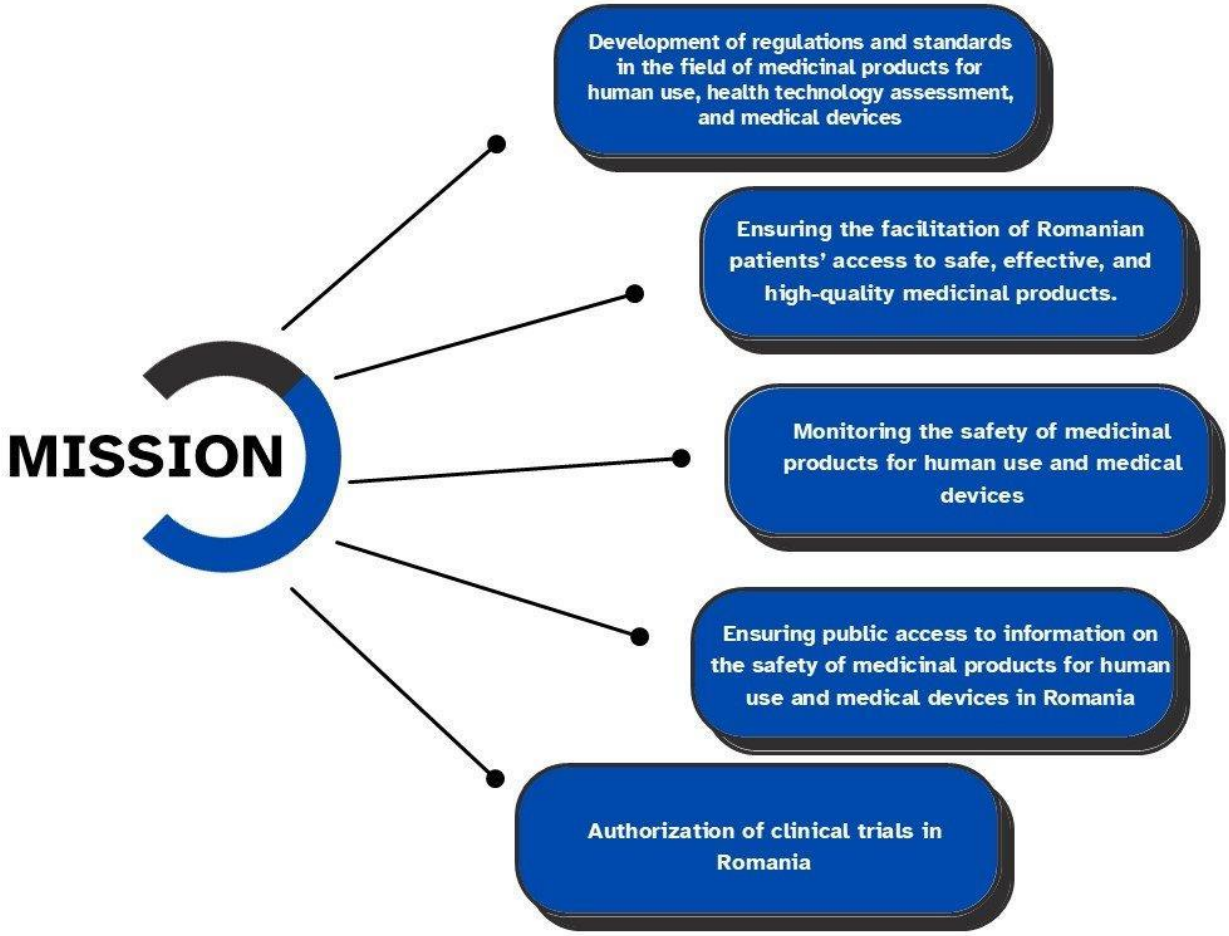
SECTION I – ORGANISATIONAL PROFILE

I.1. 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 2024 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.



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I.2. THE CONTRIBUTION BROUGHT TO THE OBJECTIVES ASSUMED BY ROMANIA

In 2024, the National Agency for Medicines and Medical Devices of Romania contributed to achieving the strategic objectives assumed by Romania in the field of public health, by exercising its role as competent authority in the regulation and control of medicinal products for human use and medical devices.

The Agency's activity focused on facilitating patients' access to essential treatments, strengthening the safety and quality of medicinal products for human use and medical devices, as well as supporting national efforts to digitize and modernize public services for the benefit of the Romanian patient.

At the same time, the NAMMDR continued the harmonisation of the national regulatory framework with the European Union legislation, actively contributing to the initiatives and working groups coordinated by the European Medicines Agency (EMA) and other European bodies. Through these steps, the NAMMDR has consolidated Romania's position as an active partner in the European regulatory system, thus supporting national objectives regarding administrative efficiency, public health protection and increasing the quality of services in the field of medicinal products and medical devices.

Regulation

Safety

European harmonisation

Access to treatments

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SECTION II - PUBLIC POLICIES

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

II.1.a. ACTIVITY OF THE ADMINISTRATION COUNCIL

In 2024, there were 6 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 1.02.2024:
   - Approval of the income and expenditure budget on 31.12.2023;
   - Approval of the budget for 2024 for the JAMS 2.0 project "Reinforced market surveillance of medical devices and in vitro medical devices" of the European EU4H Framework Programme;
   - Approval of the budget for 2024 for the IncreaseNET project "Supporting the increased capacity and competence building of the EU medicines regulatory network";
   - Approval of the proposals for indexed tariffs according to the provisions of Art. 3 of Order of the Minister of Health no. 3467/2022;
2. The AC meeting of 26.03.2024:
   - Approval of the financing of ineligible expenses provided for in the project "Modernisation of the electronic system for reporting medicinal product stocks - Component 7 - Digital transformation. 13.2. Digitization of institutions with responsibilities in the healthcare field subordinated to the Ministry of Health;
   - Approval of the income and expenditure budget for 2024;
   - Approval of the budget for 2024 for the EU4H – 2021 – JA – 11 project;
   - Approval of the financing of the expenses provided for in the "Coordination and Harmonisation of the Existing Systems against Shortage of Medicine – European Network cod CHESSMEN" project.
3. The AC meeting of 27.06.2024:
   - Approval of the organisational structure of the NAMMDR;
   - Approval of the NAMMDR job list;
   - Approval of the income and expenditure budget for 2024;
   - Approval of the execution of the income and expenditure budget on 31.03.2024.

4. The AC meeting of 17.07.2024:
   - Approval of the income and expenditure budget for 2024;
   - Approval of the execution of the income and expenditure budget on 30.06.2024;
5. The AC meeting of 11.10.2024:
   - Approval of the execution of the income and expenditure budget on 30.06.2024;
   - Approval of the income and expenditure budget for 2024;
   - Approval of the NAMMDR activity report;
   - CHESSMEN project expense approval.
6. The AC meeting of 19.12.2024:
   - Approval of the execution of the income and expenditure budget for year 2025- 1/12;
   - Approval of the NAMMDR Regulation for the organisation and operation;
   - Approval of the NAMMDR job list;
   - Approval of the NAMMDR – OSMR collaboration protocol.

II.1.b. ACTIVITY OF NAMMDR COMMISSIONS

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

In 2024, 8 meetings were organised, during which a number of 606 medicinal products were discussed (562 – European procedures, 44 – National procedure, 73 – National procedure – Parallel import);

Marketing authorisations (MAs) and Annexes 1, 2, 3, 4 and 5 were issued for 396 medicinal products, of which 31 were related to the European procedures and 71 to the national procedure – parallel import authorisations.

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

- 155 authorisations were granted for medicinal products for special needs (ANS), in line with legal provisions.

Commission for marketing authorisation of medicinal products needed on grounds of public health

- 6 marketing authorisations for medicinal products needed on grounds of public health were issued.

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

- 27 authorisations for use of medicinal products used as last resort treatment;
- 14 renewals of authorisations of medicinal products used as last resort treatment;

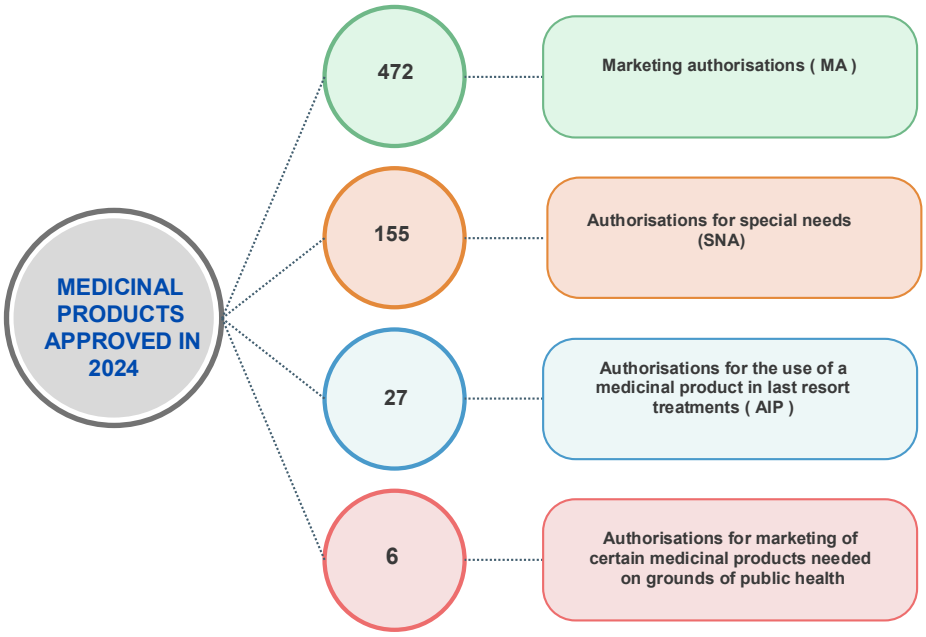
- 10 changes to the terms of authorisations of medicinal products used as last resort treatment.

Issuance of pharmaceutical product certificates

- 246 pharmaceutical product certificates in WHO format were issued.

Commission for the authorisation of medical units for conducting phase I/bioequivalence clinical trials

- 3 authorisations were issued for medical units, authorising them to conduct phase I/bioequivalence clinical trials



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

In 2024, the NAMMDR performed activities such as: the assessment of the documentation submitted for marketing authorisation (MA) and marketing authorisation renewal, post-authorisation surveillance of a medicinal product's safety, authorisation of clinical trials, market surveillance, informing the public about medicinal products and medical devices. The NAMMDR activity was carried out in accordance with the standards, having a high degree of complexity, established by EU legislation, which is increasingly rigorous in the field of medicinal products for human use.

AUTHORISATION THROUGH NATIONAL PROCEDURE

In 2024, 97 files were drawn up through the National Procedure, of which 41 applications for authorisation and 45 authorisations for renewal were validated, 74 parallel import authorisations (PIA) (of which 73 medicinal products were granted a PIA, and 1 was discontinued upon applicant request), 66 applications for PIA variations.

STATUS OF AUTHORISATIONS THROUGH NATIONAL PROCEDURE – 2024							
Marketing Authorisation Applications		**Applications for Renewal**		**Applications for variation to parallel import authorisations**		**Applications for parallel import authorisations**	
41		**45**		**66**		**74**	
VALIDATED	**REQUESTS**	**VALIDATED**	**REQUESTS**	**APPROVED**	**PENDING**	**APPROVED**	**DISCONTINUED**
41	**4**	**45**	**7**	**66**	**1**	**73**	**1**

During 2024, 3433 files were received (MA transfer, design variations or modification and packaging inscription) and 4029 files were completed, the remaining 596 being files registered between 2015 and 2022.

Status of applications (MA transfer, variations or design modification and packaging imprinting) received/resolved in 2023

No.	Type	Received in 2023	Solved in 2024 (including files registered between 2015-2023)
1.	MA transfer	**51**	**62**
2.	Type I variations	**3592**	**3544**
3.	Type II variations	**133**	**144**
4.	Modification of packaging design and imprinting	**116**	**124**
	Total 1+2+3+4	**3892**	**3874**

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 between 2015-2023

No.	Document type	Total number
1.	Amendment to MA terms	**338**
2.	Annexes to MA	**1574**

In 2024, through the national procedure assessment service, the NAMMDR undertook the following activities to evaluate the safety, quality and efficacy of medicinal products:

- 44 validations of clinical efficacy and non-clinical safety module for medicinal products submitted for authorisation
- 27 Quality reports - authorisation (initial report)
- 35 Efficacy/clinical safety reports - authorisation (initial report)
- 5 Efficacy/clinical safety reports - authorisation (report for supplementation)
- 21 Non-clinical safety reports - authorisation (initial report)
- 15 Non-clinical safety reports - authorisation (report for supplementation)
- 10 Quality reports of bioequivalence study protocols (initial)

- 13 Quality reports of bioequivalence study protocols (initial)
- 74 Assessment reports – ANS (authorisation for special needs) - patient
- 52 Assessment reports – ANS (authorisation for special needs) - commission
- 3 Reports for medicinal products on grounds of public health

AUTHORISATION THROUGH EUROPEAN PROCEDURES

6177 requests sent to the institution were completed in 2024, as follows:

OVERALL REPORTING FOR ISSUED/ELABORATED APPROVALS – 2024

(01.01.2024-31.12.2024)

Variations with RO-SMI: type IA/IA/G	**3003**
Variations with RO-SMI: type IB/IB/G+WS	**2163**
Variations with RO-SMI: type II/II/G+WS	**585**
Type P notifications in line with Article 61 (3) of Directive 2001/83/EC	**37**
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	**163**
Variations with RO-SMR: type IA/IA/G+IB/IB/G+II/WS	**77**
Overall total number of approvals per number of MAs (medicinal product strength)	**6177**

RO as interested member state (SMI):

- 290 authorisations through decentralised procedure (DCP)
- 8 authorisations through mutual recognition procedure (MRP)
- 46 authorisations through repeat-use mutual recognition procedure - MRP-Repeat-Use (E)
- 213 MA renewals

RO as reference member state (SMR):

- 2 MA renewals (R)
- Coordination of the national phase of medicinal product information translation (SmPC, leaflet, labelling information) in view of issuance of a MA:

In 2024, the European Procedures Directorate performed 488 procedures (DC= 312; R= 205; E =52; MR = 8)*, of which:

- Pending:
  - 104 for the decentralised procedure (DCP)
  - 1 for the mutual recognition procedure (MRP)
  - 18 for the MRP-Repeat-Use procedure (E)
  - 82 for MA renewals (R)
- Finished:
  - 189 for the decentralised procedure (DCP)
  - 7 for the mutual recognition procedure (MRP)
  - 30 for the MRP-Repeat-Use procedure (E)
  - 113 for MA renewals (R)

- Withdrawn/rejected:
  - 1 rejected and 7 withdrawn for the decentralised procedure (DCP)
  - 1 for a MA renewal (R)

- Medicinal products for which applicants have not submitted translations:
  - 11 for the decentralised procedure (DCP)
  - 4 for the MRP-Repeat-Use procedure (E)
  - 10 for MA renewals (R)

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

- 231 - decentralised procedure (DCP)
- 7 – mutual recognition procedure (MRP)
- 36 - Repeat-Use mutual recognition procedure (E)
- 162 – MA renewals (R)

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

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RO as Reference member state (SMR) – overall status - Submissions versus approvals

Variations	Number of variations **submitted in 2024** (full set*) Per strength= number of MAs	Number of variations **finished in 2024** (from previous years as well)** Per strength= number of MAs	**Notes**
Type IA variations/groups of variations	**37**	**14 (2024)** **20 (2023)** **1 (2022)** **Total 35**	**4 pending - European stage**
Type IB variations/groups of variations	**50**	**17 (2024)** **18 (2023)** **1 (2022)** **Total 36**	**4 pending - European stage**
Type II variations/groups of variations	**5** **1*** **4***	**5 (2023)** **Total 5**	**1* (2024) pending – European stage/suspended**
National notifications in line with Order of the Minister of Health no. 1205/2006	**1**	**1**	**-**
Type P notifications - Art. 61 (3) of Directive 2001/83/EC	**0**	**0**	**Not submitted in 2024**
OVERALL TOTAL	**93**	**77**	**9** **pending - various stages**

Note: full set*: complete submissions with Letter of Intent, Payment Form, Payment to the Economic Department, documentation supporting the variation/transfer/notification) ** all variations submitted in full set in 2024 have been completed.

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RO as an Interested Member State (SMI)- overall status - Submissions versus approvals

Variation type	Number of variations submitted in 2024 (full set*/ databases from previous years 2022+2021)	Finished approved variations (corrective documents included) in 2024 (including previous years)
Variations/groups of Type IA variations	**2817** (2773 +44* (*intention in 2023 and documentation in 2024)	Total number of finished variations IA=3003
Variations/groups of Type IB variations	**2217** (2088 +129* (*intention in 2023 and documentation in 2024)	Total number of finished variations IB =2163
Variations/groups of Type II variations	**509** (491 +18* (*intention in 2023 and documentation in 2024)	Total number of finished variations II =585
National notifications in line with Order of the Minister of Health no. 1205/2006	115	Total number of finished notifications NN=149
Type P notifications - Art. 61 (3) of Directive 2001/83/EC	69	Total number of finished P notifications =37
MA transfer in line with Order of the Minister of Health no. 1205/2006	86	Total number of finished MA transfers = 163 (including previous years)

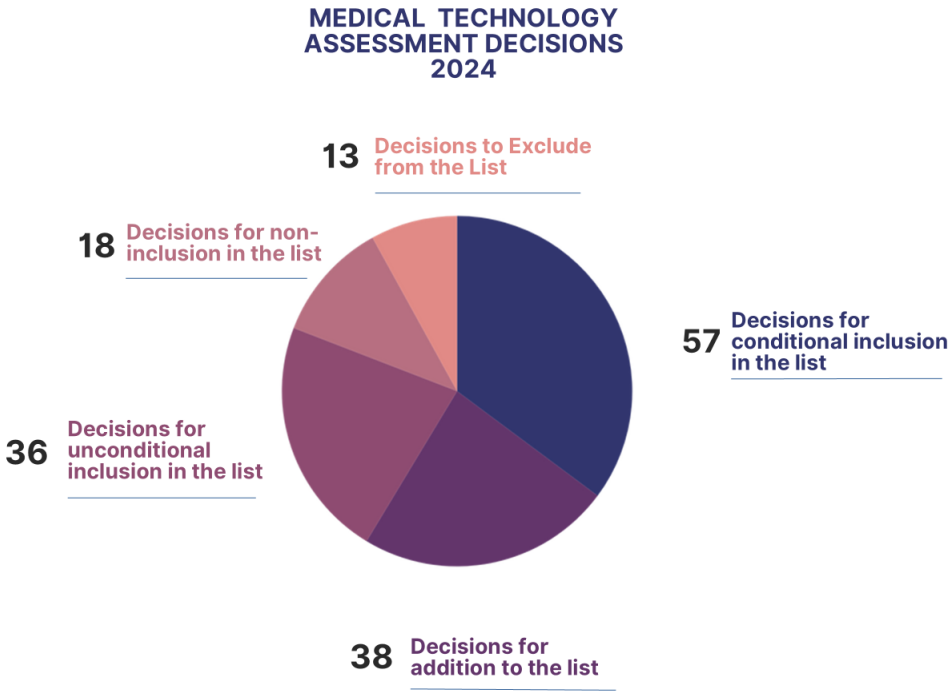
Note: full set*: complete submissions with Letter of Intent, Payment Form, Payment to the Economic Department, documentation supporting the variation/transfer/notification) ** - Phases: submission, pending, suspended, completed SMR, national stage, sent to the assessor, with requests, sent upon renewal)

HEALTH TECHNOLOGIES ASSESSMENT

In 2024, through the Directorate for Medical Technologies Assessment (DETM), renamed the Health Technologies Assessment Service (SETS), in line with Order no. 3994 of 25 July 2024 on approval of the organisational structure of the National Agency for Medicines and Medical Devices of Romania, the Agency completed a number of 143 evaluation reports, in accordance with the provisions of Order of the Minister of Health no. 861/2014 on approval of criteria and methodology 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, as well as the means for appeal thereof, as further amended and supplemented (the List).

Following the evaluations carried out by the DETM (renamed SETS) in 2024, the following decisions were issued:

- 36 decisions for unconditional inclusions in the List, of which 8 were related to the therapeutic area of oncology, 6 to the therapeutic area of haematology, 3 to the therapeutic area of cardiology, 4 to the therapeutic area of metabolic diseases, 2 to the therapeutic area of neurology, 3 to the therapeutic area gastroenterology, 2 to the therapeutic area of allergology, 2 to the therapeutic area of infectious diseases, 1 to the therapeutic area of psychiatry, 2 to the therapeutic area of nephrology, 1 to the therapeutic area of pneumology and 2 to the therapeutic area of endocrinology;
- 57 decisions for conditional inclusion in the List, of which 25 were related to the therapeutic area of oncology, 7 to the therapeutic area of neurology, 6 to the therapeutic area of rheumatology, 1 to the therapeutic area of allergology, 1 to the therapeutic area of infectious diseases, 4 to the therapeutic area of cardiology, 3 targeted the therapeutic area of dermatology, 2 targeted the therapeutic area of gastroenterology, 2 targeted the therapeutic area of nephrology, 1 decision was related to the therapeutic area of pneumology and 1 decision was related to the therapeutic area of psychiatry;
- 13 Decisions for non-inclusion in the List;
- 38 Decisions to add a new strength, pharmaceutical form or population group;
- 18 Decision for addition to the List.



Of the 143 finished reports, 97 files were submitted in 2024, 45 in 2023, 1 in 2021, incomplete at the time of submission, whose deadline for evaluation had been suspended.

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, as further amended and supplemented was updated twice in 2024, as a result of the related evaluation reports and was materialised in Decision no. 397 of 23 April 2024 and Decision no. 1262 of 9 September 2024.

Order of the Minister of Health and of the President of the National Health Insurance House no. 564/499/2021 on approval of therapeutic protocols for prescription of medicinal products with International Non-proprietary Names specified in the List of International Non-proprietary Names of on-prescription medicinal products as provided to insurants, irrespective of personal contribution, in the frame of the health insurance system, as well as of International Non-proprietary Names of medicinal products provided in national health insurance programs, as approved through Government Decision no. 720/2008, and of the methodological norms on their implementation, as further amended and supplemented, was updated 7 times in 2024, as follows:

1. Order of the Minister of Health no. 1386 of 8 March 2024 and of the National Health Insurance House no. 292 of 8 March 2024;
2. Order of the Minister of Health no. 2402 of 24 April 2024 and of the National Health Insurance House no. 523 of 24 April 2024;
3. Order of the Minister of Health no. 2497 of 09 May 2024 and of the National Health Insurance House no. 560 of 09 May 2024;
4. Order of the Minister of Health no. 2890 of 29 May 2024 and of the National Health Insurance House no. 648 of 29 May 2024;
5. Order of the Minister of Health no. 4396 of 29 August 2024 and of the National Health Insurance House no. 1355 of 29 august 2024;
6. Order of the Minister of Health no.5594 of 15 November 2024 and of the National Health Insurance House no. 1861 of 15 November 2024;
7. Order of the Minister of Health no. 6328 of 30 December 2024 and of the National Health Insurance House no. 2192 of 30 December 2024;

MEDICINAL PRODUCT QUALITY ASSESSMENT AND CONTROL

The Directorate for medicinal product quality assessment and control (DECCM) has the status of an Official Medicines Control Laboratory (OMCL), full active member of the General European OMCL Network (GEON), coordinated by the European Directorate for the Quality of Medicines & HealthCare (EDQM). The DECCM represents a unique structure in Romania, with the role of supporting the competent authority through independent testing of the quality of medicinal products.

In 2024, the DECCM was involved in the testing of nationally authorised medicinal products, within the Sampling Plan, in the OCABR procedure, as well as in the testing of medicinal products authorised through European procedures and in interlaboratory studies.

In 2024, testing activities within the European procedure for Official Control Authority Batch Release (OCABR) for the hepatitis B vaccine were successfully completed in accordance with the deadline provided by the European OCABR procedure (60 days).
In 2024, the NAMMDR represented Romania in the yearly meeting of European OMCLs, hosted by the Medicines Agency of North Macedonia, in sections dedicated to vaccines, blood-derived medicinal products and synthetic medicinal products.
As regards laboratory control, the following types of testing were performed in 2024:

- 1 laboratory control of domestic/imported biological medicinal products (batch by batch) (in case there is no OCABR certificate), for 1 batch of vaccine for human use in order to release the batch for which 7 quality parameters were tested, was carried out, the summary of batch protocol was evaluated and 2 records for the summary of batch protocol were elaborated; Also, the comparative

analysis of the tendency data obtained by the manufacturer for the critical parameters to the results obtained within the testing control laboratories, as well as 2 analysis certificates and 1 OCABR certificate, were performed;

** Within the Official Control Authority Batch Release (OCABR) of blood-derived vaccines/derivatives, physical-chemical, serological, immunochemical, cellular, pharmacological and microbiological cultures are performed; moreover, the analysis of the tendency of laboratory results is performed.*

- 494 marketing intentions for biological medicinal products assessed for OCABR purpose and 396 commercial agreements issued by the NAMMDR;
- Issuance of 114 quality parameters of laboratory analyses for medicinal products included in the National Market Surveillance Programme (in collaboration with the DGIF, the DPN and the DPE) and 20 certificates of analysis for medicinal products included in the DGIF yearly sampling plan;
- Participation in 4 studies for assessment of laboratory performance (Proficiency Testing Studies - PTS) and in 2 Inter-laboratory comparisons (ILC) studies:

1. UV-visible spectrophotometry (Ph. Eur. 2.2.25) - PTS245;
2. Loss on drying (Ph. Eur. 2.5.32) - PTS247;
3. Liquid chromatography (Ph. Eur. 2.2.29, RP C-8, UV detection)- PTS248;
4. Dissolution and Mass uniformity (Ph. Eur. 2.9.3, basket apparatus, UV detection, and Ph. Eur. 2.9.5)- PTS249;
5. Inter-laboratory Comparison Test for Extractable volume (2.9.17 Ph Eur.) – ILC;
6. Inter-laboratory Comparison Test for Particulate contamination - visible particles, (Ph. Eur. 2.9.20);

All participations were completed with very good results.

- 2 Chemical/Biological Reference Substances (CRS/BRP) standardisation studies, whose results were appreciated by the organiser (the EDQM);
- 1 Laboratory analysis on the quality of a medicinal product centrally authorised for marketing by EMA (through centralized procedure) (coordinated by the EDQM);

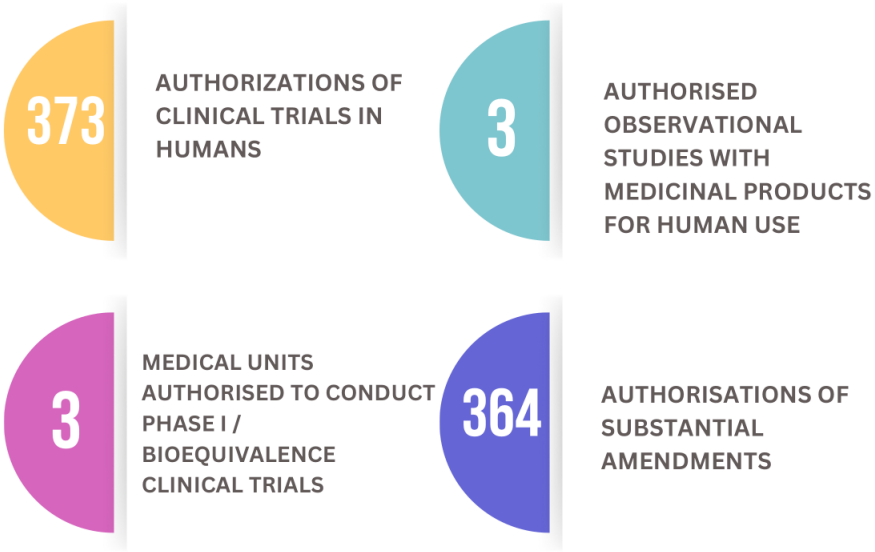
As regards the evaluation activity, the DECCM carried out the evaluation of the quality documentation, as follows:

- 13 reports for assessment of marketing authorisation for all biological medicinal products submitted through the national procedure and European procedures;
- 14 marketing authorisation/marketing authorisation renewal for biological medicinal products submitted through the centralised procedure;
- 4 renewals of MA for all biological medicinal products submitted through the national procedure and European procedures;
- 156 notices/notices for completion sent to applicants for IA and IB variations for all biological medicinal products submitted through national procedure;

- 66 reports for evaluating approval/completion notices to applicants for type II variations submitted through national procedure;
- 12 notices/notices for completion to applicants for IA and IB variations for all biological medicinal products submitted through national procedure;
- 11 approval/completion notices to applicants for approval requests for the proposed MA transfer for biological medicinal products submitted through national procedure;
- 125 annexes for type IB variations, submitted through mutual recognition/decentralised procedure and 72 type II variations submitted through mutual recognition/decentralised procedure;
- 90 reports for assessment of synthetic medicinal products submitted through mutual recognition /decentralised procedure;
- 8 assessments of quality variations for active substances of synthetic medicinal products (radiopharmaceuticals included);
- 10 reports for assessment of quality documentation for biological medicinal products, submitted within other procedures such as the authorisation for special needs (ANS), 5 assessment reports for the quality documentation for compassionate use and 100 reports for exemptions, for biological medicinal products;
- 14 reports for assessment of the quality documentation submitted in order to authorise clinical trials submitted through national procedure/VHP for investigational medicinal products of biological origin;
- 4 requests for assessment of the quality documentation submitted for reporting quality defects, for biological medicinal products.

ASSESSMENT AND AUTHORISATION OF CLINICAL TRIALS

In 2024, 414 requests for assessment and authorisation of clinical trials with medicinal products for human use were received. Of these, 11 were withdrawal requests, 182 were transition requests and 2 were additional Member State requests with Romania being the Reference Member State (SMR).
374 response notices were issued, namely 373 authorisations and 1 rejection.



The NAMMDR, through the DSC, carried out 46 assessment procedures for clinical trials with Romania as Reference Member State.

In 2024, 16 procedures for assessment of requests for clinical bioequivalence studies (BE) were evaluated by the National Procedure Directorate and administered by the DSC.

Concerning the evaluation and approval of substantial amendments (MS) in clinical trials, in 2024, 546 MS applications were submitted and 364 authorisations for substantial amendments were submitted at the NAMMDR.

The NAMMDR has conducted 29 assessment procedures for substantial changes to clinical trials with Romania – SMR.

In 2024, the NAMMDR also received 182 applications for important amendments for trials approved in line with Law 249/2022, of which 178 were approved.

The assessment of the safety of investigational medicinal products was carried out in 2024, together with the other Member States, in work-sharing regime, Romania being designated a Member State responsible for safety assessment (safety assessment member state - SAMS) for 49 active substances.

12 assessment reports for annual safety reports (ASR) were drawn up and the NAMMDR participated in 261 procedures for assessment annual safety reports (ASR) which involved Romania.

Regarding the evaluation and approval of observational studies with medicinal products for human use, 14 applications were received and 3 authorisations were issued.

6 applications for authorisation of medical units for carrying out phase I clinical trials/ bioequivalence trials were received and 3 authorisations were issued.
The DSC has received and managed non-important amendments for approved clinical trials, various notifications and notices with requests for various information, such as:

- 1003 various notifications (first patient inclusion notification, study closure notifications, temporary discontinuations, non-substantial amendments);
- 197 yearly study reports;
- 16 notifications for non-interventional studies.

During 2024, DSC managed 2 addresses to regularise the tariff for clinical trials and 5 regular tariffs.
The DSC participated, through 2 specialists appointed to carry out the evaluation of the documentation submitted in support of applications for approval of last-resort treatments, and in 2024 it prepared:

- 27 evaluation reports for the authorisation of medicinal products, as last-resort treatment;
- 14 evaluation reports for the renewal of medicinal product authorisations, as last-resort treatment;
- 10 evaluation reports for changes to the authorisations of medicinal products authorised as last-resort treatments;
- 36 opinions and minutes.

THE INDEX OF MEDICINAL PRODUCTS SERVICE

The NAMMDR, through its Index of Medicinal Products Service (SN), integrates information from related departments and synthesizes it in the form of a database available on the agency's website under the "Index" section. Managing this database involves including newly authorised medicinal products and permanently updating information for already authorised ones.

In 2024, information regarding medicinal products for human use was updated in the database of the "Index" section (https://nomenclator.anm.ro/medicamente), as follows:

- Newly issued marketing authorisations for 349 medicinal products;
- Renewed marketing authorisations for 217 medicinal products;
- 165 authorisations for medicinal products for special needs;
- 7 authorisations on grounds of public health;
- 6918 variations;
- Marketing authorisations which have expired or have been discontinued by decisions for discontinuation from marketing for 286 medicinal products.

As regards the "Discontinuations" section on the NAMMDR website, the following information was updated during 2024:

- Notifications of temporary and permanent interruption of marketing for 606 medicinal products;
- Notifications of resumption of marketing for 287 medicinal products;
- Notifications of marketing for 1690 medicinal products;
- Sending 100 completed questionnaires to SPOC WP/EMA concerning the availability of medicinal products on the Romanian market;
- Permanent updating of the electronic record on the Agency's website https://www.anm.ro/medicamente-de-uz-uman/autorizare-medicamente/notificari-discontinuitate-medicamente/ for 825 medicinal products.

In 2024, there were 71 requests for exemption from the Sunset clause, from which the NAMMDR approved exemptions for 58 medicinal products.

GENERAL DIRECTORATE FOR PHARMACEUTICAL INSPECTION

As regards supervision of good manufacturing practice for medicinal products, including investigational medicinal products, the following actions were carried out in 2024:

- 72 inspections for authorisation, respectively certification of good manufacturing practice (GMP) for the manufacturing activities related to medicinal products for human use, including investigational medicinal products;
- 13 inspections for GMP certification at the sites of manufacturers of medicinal products, investigational medicinal products and active substances from third countries;
- 4 pharmacovigilance inspections at the sites of marketing authorisation holders or their partners;
- 1 unannounced inspection regarding the activity of units in the field of Good Clinical Practices (BPSC) for solving a complaint, requested by the Clinical Trials Directorate following an adverse reaction report submitted to the NAMMDR by a relative of a patient participating in a clinical trial.

The NAMMDR participated in joint GCP inspections with other European or international authorities: bioequivalence studies at the Institutia Medico Sanitara Publica Clinical Investigation Center in Spain, at the Clinical Hospital of the Ministry of Health, Labor and Social Protection in Chisinau, Republic of Moldova and at a bioanalytical laboratory (Pharmaserv International S.R.L.) in Bucharest. The also participated in 2024 in the implementation of the inspection programme by EMA, in relation to products authorised through the centralised procedure.

Following the inspections carried out in 2024, the following were issued by the NAMMDR:

- 271 authorisations for manufacturing/import (AFI);
- 104 certificates attesting to the compliance with the good manufacturing practice (GMP) were issued.
- 1 certificate attesting to the compliance with the good laboratory practice (GLP) was issued.
- 13 certificates attesting the qualified person status and maintenance of the database of certificates issued to qualified persons;
- 18 granted permissions for registration of manufacturers and importers of active substances used as raw materials for medicinal products.

In the case of two inspections, violations of the legal provisions in the field of good manufacturing practice were found and appropriate sanctions were applied, in line with the legislation in force.
In 2024, 6 manufacturing authorisations/certificates regarding compliance with the good manufacturing practice were suspended/withdrawn (5 upon applicant's request and 1 certificate following the issuance of a GMP non-compliance declaration).
All information contained by manufacturing/import authorisations and issued GMP certificates as well as in the statements regarding non-compliance with GMP are entered into the European database of EudraGMDP inspections.

In 2024 as well, the following have been updated on the Agency's website (www.anm.ro), on a permanent basis:
the list of authorised Romanian manufacturers of medicinal products and active pharmaceutical ingredients, the list of units authorised for medicinal product import, the list of certified manufacturers of medicinal products and active pharmaceutical ingredients from third countries and the list of GLP certified laboratories.
As regards the supervision of the quality of medicinal products, the NAMMDR performed the following activities:

- 97 inspections for authorisation, namely for certification of the Good Distribution Practice (GDP) of wholesale distribution units;
- 1 GDP inspection for verification of the activity of wholesale distributors of active substances used as raw materials for medicinal products for human use;
- 6 unannounced inspections in connection with the investigation of self/notices regarding the activity of pharmaceutical units in the GDP field;

The NAMMDR has issued 214 authorisations for distribution and 128 GDP certificates, 3 agreements regarding the registration of importers and distributors of active substances used as raw materials for medicinal products.

During 2024, following the inspections of wholesale distribution units carried out by the NAMDMR, 27 violations of legal provisions in the GDP field were found and appropriate sanctions were applied, according to the legislation in force.

16 wholesale distribution authorisations/certificates regarding compliance with the Good Distribution Practice (13 upon applicant's request and 3 following the issuance of the GDP declaration of non-compliance) were suspended/withdrawn.

All information contained by wholesale distribution authorisations and GDP certificates issued by the Agency, as well as the information from the declarations for non-compliance with the GDP is entered into the EudraGMP.

The list of authorized wholesale distribution units is permanently published and updated on the NAMMDR website.

The NAMMDR has permanently analysed the data from the notifications regarding intra-community deliveries and the reports transmitted by wholesale distributors and from the monitoring of the medicinal product market in order to comply with the public service obligation and to apply the specific legislation.

As regards the supervision of the quality of medicinal products, alerts and territorial units, in 2024, the NAMMDR carried out the following activities:

- 18 medicinal products supervised by drawing up the annual Sampling and Testing Plan and testing the quality of the medicinal product;
- 96 solved reports of marketing authorisation holders or medicinal product manufacturers, regarding suspected quality non-compliances of medicinal products;
- 823 thematic inspections for supervision of the quality of medicinal products in the distribution network (pharmaceutical units) and of the activity of the pharmaceutical units;
- 17 unexpected inspections for solving some (self) notifications regarding the activity of pharmaceutical units;
- 20 inspections for sampling of medicinal product samples, active substance samples, raw materials, including excipients, inner and outer packaging materials used in the manufacturing of medicinal products, intermediate products or finished bulk products, for testing within the annual sampling and testing plan;
- 3 inspections for sampling of medicinal products, at the request of the EDQM, within the framework of the market surveillance activity of medicinal products at European level, for the European MSS Programme (EDQM), and for the Year Sampling and Testing Programme of centrally authorised medicinal products (CAP Sampling & Testing Programme);

Following the aforementioned inspections, 65 violations of the legal provisions in the field of medicinal products and/or the activity of pharmaceutical units were found and appropriate sanctions were applied, according to the legislation in force. These violations are posted on the Agency's website, as a list of units sanctioned by the NAMMDR.

Moreover, in 2024, the NAMMDR arranged 5 withdrawals of medicinal products with non-compliances and 21 withdrawals initiated by manufacturers or authorisation holders. All medicinal products withdrawn from the market in 2024 were published on a quarterly basis on the NAMMDR website, in the list of medicinal product batches withdrawn from the market, in Newsletter section.

The NAMMDR issued a rapid alert for warning through the Rapid Alert Systems (RAN, PIC/S, WHO rapid.alert@anm.ro) and managed 492 rapid alerts and non-urgent information about suspected quality non-compliances in authorised medicinal products, as well as cases of falsified or stolen medicinal products.

The NAMMDR issued 5 quality non-compliances to prevent medicinal products suspected of health hazards to patients.

The NAMMDR managed:

- 4397 notifications on intra-community deliveries sent by wholesale distributors on raportarenotificari@anm.ro;
- 80 reports sent by importers on raportareimporturi@anm.ro;
- 3600 monthly reports were submitted on raportaremedicamente@anm.ro by authorised wholesale distributors/importers/manufacturers regarding medicinal product traceability throughout the entire chain.

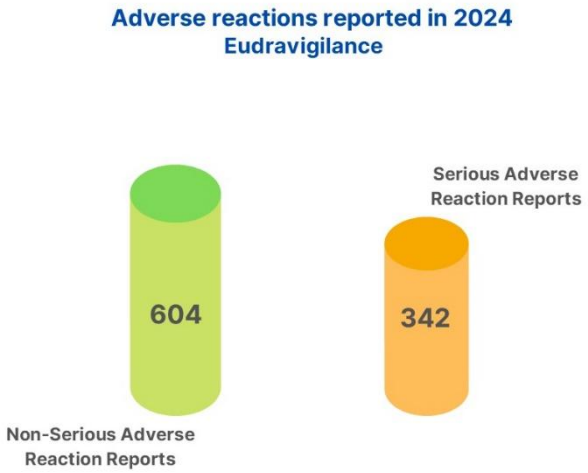
The list of notifications regarding intra-community deliveries received from wholesale distributors has been permanently posted and updated on the NAMMDR website.

In 2014, 274377 alert messages were received on the Agency's e-mail address, alertaosmranm@anm.ro, strongly suspected of counterfeit, identified in level 5 alerts generated by the National Medicinal Product Verification System (SNVM).

PHARMACOVIGILANCE AND RISK MANAGEMENT

In 2024, the NAMMDR received and managed a total number of 840 adverse reactions spontaneously reported by patients and healthcare professionals from Romania and post-immunisation adverse reactions (RAPI) received from the National Institute of Public Health (INSP) through the National

Center for Surveillance and Control of Communicable Diseases (CNSCBT), according to the protocol in force.
In 2024, the NAMMDR transmitted to the EMA Eudravigilance database, in electronic format, 342 serious adverse reactions and 604 non-serious adverse reactions, received from patients and healthcare professionals (from the INSP-CNSCBT as well), reported from Romania.



In 2024, 4 information notices were prepared and sent quarterly to the Romanian College of Physicians (CMR) and to the Romanian College of Pharmacists (CFR) and 245 notification addresses were sent to physicians in the healthcare network, regarding adverse reactions validated by the NAMMDR, within the framework of the National Continuing Medical Education Programme, for crediting.
3532 adverse reaction reports submitted by marketing authorisation holders (MAHs)/sponsors were managed in the EudraVigilance database.
Periodic safety update reports (PSURs) were assessed, requested in line with the European single assessment procedures (Periodic Safety Update Report Single Assessment - PSUSA, for which Romania was nominated as the reference Member State (SMR) for a single European procedure for the assessment of the periodic safety update report (PSUSA procedure).

38 report checks (eRMR) were carried out on the safety signal detection activity for active substances/combinations of active substances for which Romania is a Member State responsible for monitoring in the safety signal management activity and for substances for which safety concerns are identified at national level.

As regards the marketing of safe, effective and quality medicinal products for human use through marketing authorisation procedures for medicinal products for human use, the Pharmacovigilance and Risk Management Directorate checked the specific documentation and submitted requests/comments, where necessary, for:

- 2 procedures for evaluation of the pharmacovigilance documentation for the marketing authorisation of medicinal products through a centralised procedure in which Romania is the rapporteur/co-rapporteur;
- 2 procedures for evaluation of the pharmacovigilance documentation for the marketing authorisation of medicinal products through European procedures (DCP/ MRP/ Repeat-Use), in which Romania is the reference member state (RO - SMR);
- evaluation of pharmacovigilance documentation for the marketing authorisation of medicinal products through European procedures (DCP/ MRP/ Repeat-Use), in which Romania is an interested member state (RO - SMI);
- 45 checks of pharmacovigilance documentation submitted by applicants for administrative validation in the national marketing authorisation procedure;
- 122 evaluations of pharmacovigilance documentation for the purpose of marketing authorisation of medicinal products through the national authorisation procedure;
- 22 reports establishing/verifying/translating specific pharmacovigilance authorisation conditions – in the European/national procedure;
- 150 checks of the authorisation procedure for medicinal products for special needs (ANS)
- 5 documentation checks for the granting of marketing authorisations for medicinal products needed on grounds of public health;
- 27 checks for authorisation and 14 checks for renewal of authorisations through the authorisation procedure for medicinal products used in last resort treatments.

Regarding the marketing of safe, effective and quality human medicinal products through marketing authorisation renewal procedures, the assessment of the pharmacovigilance documentation consisted of:

- 7 procedures for evaluation of the pharmacovigilance documentation for MA renewal through European procedures in which Romania is an interested/reference member state (RO – SMI/SMR) - according to the procedure schedules received from the European Procedures Directorate;
- Verification of the pharmacovigilance documentation submitted by applicants for administrative validation in the national MA renewal procedure – 44 validations;
- Evaluation of the pharmacovigilance documentation for the renewal of the MA through the national procedure – 57 reports;
- Evaluation of the pharmacovigilance documentation in procedures for variation to the terms of the marketing authorisations of medicinal products authorised through European procedures

(DCP/MRP/E) with RO-SMI - according to the procedure schedules received from the Variation validation and administration compartment of the DPE;

- 2 procedures for evaluation of the pharmacovigilance documentation in procedures for variation to the terms of the marketing authorisations of medicinal products authorised through European procedures (DCP/MRP/E) with RO-SMR;
- 12 procedures for evaluation of the pharmacovigilance documentation in shared (work-sharing=WS) procedure for variation to the terms of the marketing authorisations of medicinal products authorised through the national procedure;
- 32 procedures for evaluation of the pharmacovigilance documentation in the national procedure for variation to the terms of the marketing authorisations of medicinal products authorised through the national procedure;

Concerning the reduction of risks associated with the use of medicinal products for human use by taking appropriate measures and regulatory actions regarding safety, 80 requests were assessed and approved in relation to educational materials for healthcare professionals and patients proposed as additional risk minimisation measures in the risk management plan.

The NAMMDR ensured the urgent exchange of information between the Competent Authorities and the EMA by transmitting information in the rapid alert system and non-urgent information, drafting 13 responses to requests for information related to certain medicinal products or classes of medicinal products, received from other member states.

In 2024, the NAMMDR, through the Pharmacovigilance and Risk Management Directorate, assessed, approved and published 19 direct healthcare professional communications (DHPC) regarding medicinal product safety issues, on the Agency's website. It also sent information letters regarding direct healthcare professional communications to the National Health Insurance House, the Ministry of Health, the Romanian College of Physicians and the Romanian College of Pharmacists.

THE GENERAL DIRECTORATE FOR MEDICAL DEVICES (DGDM)

The NAMMDR, through its Market Surveillance Directorate (DRSP), evaluates the documents for compliance of medical devices and issues certificates or information related to registration.

The national database of medical devices was updated in 2024, as shown in the table below:

Registered devices	2024	Total
Registered in line with the MDR	517	1465
Registered in line with the MDD	37	5413

In 2024, 79 validations of companies (manufacturers, manufacturers of systems and procedure packages, authorised representatives and importers) with declared headquarters in Romania were introduced into the EUDAMED European database, as follows:

- 20 manufacturers
- 6 authorised representatives
- 53 importers

The following were issued:

- 28 waivers from language requirements by the DRSP.
- 31 out-of-scope notices for products in borderline cases, for which it is unclear whether they fall within the scope of the MDR or the IVDR;
- 3 customs notices in special situations (for the purpose of technical evaluation, clinical investigation and/or performance evaluation for certification, devices imported as samples for fairs, exhibitions or other promotional events);
- 50 free sale certificates;
- 31 donation notices.

As regards the conduct of clinical investigations with medical devices and clinical studies assessing the performance of in vitro diagnostic devices, the following documents were issued in 2024:

- 1 authorisation for clinical investigation with active implantable medical devices, class III, IIb invasive, IIa invasive medical devices and similar devices specified in Annex XVI to the MDR;
- 1 validation of application for clinical investigation with non-invasive class IIa, non-invasive IIb medical devices and similar devices specified in Annex XVI to the MDR;
- 1 validation of application for clinical investigation with class I medical devices and similar devices specified in Annex XVI to the MDR;
- 12 approvals of substantial and technical amendments for approved clinical investigations with medical devices and similar devices specified in Annex XVI to the MDR and of substantial amendments to clinical trials assessing the performance of IVDs;
- 6 approvals of administrative amendments for approved clinical investigations with medical devices and similar devices specified in Annex XVI to the MDR and non-substantial amendments to clinical trials assessing the performance of IVDs;
- 9 authorisations for assessment of performance of IVDs, self-testing and IVDR classes C and D

Type of activity	Number of issued documents
Registrations in the national database - information and registration certificates in the national database of medical devices, IVDs of manufacturers and authorised representatives Custom-made medical devices registration certificates	107 7
Free sale certificates	50
Customs approvals	3
Out-of-scope notices	31
Issuance of authorisations for clinical investigation with active implantable medical devices, class III, IIb invasive, IIa invasive medical devices and similar devices specified in Annex XVI to the MDR	1
Issuance of validation applications for clinical investigation with non-invasive class IIa, non-invasive IIb medical devices and similar devices from Annex XVI to the MDR	1
Validation of applications for clinical investigation with class I medical devices and similar devices specified in Annex XVI to the MDR	1
Substantial and technical amendments to approved clinical investigations with medical devices and similar devices specified in Annex XVI to the MDR and substantial amendments to clinical trials assessing the performance of IVDs	12
Approvals of administrative amendments for approved clinical investigations with medical devices and similar devices specified in Annex XVI to the MDR and non-substantial amendments to clinical trials assessing the performance of IVDs	6
Issuance of authorisations for assessment of performance of IVDs, for self-testing and IVDR classes C and D	9
Authorisation of performance studies for companion diagnostic devices using only residual samples [art. 58 (2) of the IVDR]	4

Confirmations of PMCF (MDR) notifications and PMPF (IVDR) notifications	6
Validations into the EUDAMED	79

- 4 authorisations for performance studies for companion diagnostic devices using only leftover samples;
- 6 PMCF notification confirmations (MDR)

The NAMMDR participated in clinical investigations, performance assessment studies and studies with medical devices used in combination with medicinal products or multinational companion devices (IVDs used in combination with medicinal products) to increase the quality of clinical outcomes, according to regulations. SR CIC members are surveying the results of the conducted COMBINE study.
Information notices were also issued in response to frequent requests for information concerning national legal provisions for the application of the MDR to clinical investigations and the IVDR to clinical performance studies.

In 2024, 3 decisions were also issued to classify borderline products in the medical device category, at the request of manufacturers or authorised representatives.

As the competent authority in the field of medical devices, the NAMMDR was accepted as a beneficiary in the JAMS 2.0 project (101127889), "Reinforced market surveillance of medical devices and in vitro medical devices" of the European EU4H Framework Programme, a project coordinated by the French National Agency for Medicines and Health Products Safety (ANSM), which will run for a 36-month period, and confirmed its participation in this project by signing the grant agreement and the consortium agreement.

In 2024, the NAMMDR, through the market surveillance service, carried out control actions at the premises of 1422 units, checking the compliance of medical devices made available on the Romanian market as well as of medical devices in use by professional users.
Following controls, 592 economic operators were sanctioned. 496 warnings and 245 legal fines were applied for a total amount of 1,265,000 lei. 169 types of non-compliant medical devices were identified (1,208,414 items).

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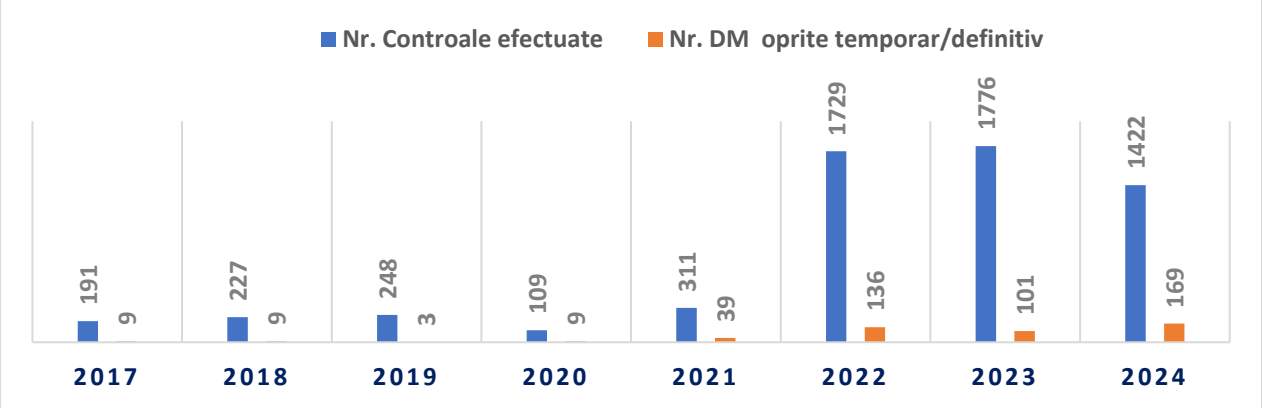
The comparative situation of the controls carried out and noncompliant medical devices (DMs) - 2017-2024



Number of controls performed
Number of medical devices temporarily/definitively turned off

Year	2017	2018	2019	2020	2021	2022	2023	2024
Number of checks performed	191	227	248	109	311	1729	1776	1422
Number of medical devices temporarily/definitively turned off	9	9	3	9	39	136	101	169

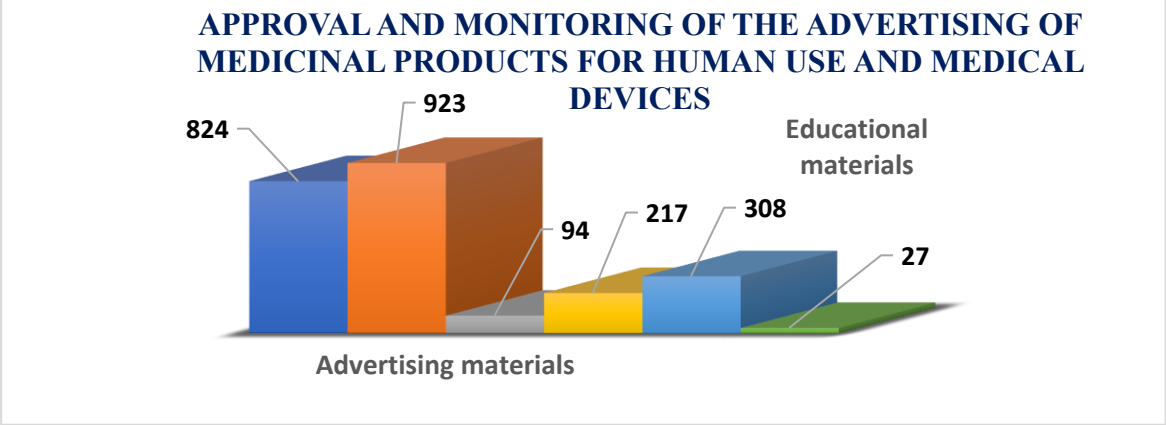
Following the controls carried out in 2024, 28 types of devices were identified, totalling 659,090 items, for which elements raising suspicions of counterfeiting were found. In this regard, sanctions up to 70,000 lei were applied.
In 2024, inspections were also carried out in order to check compliance of in-use medical devices with legal provisions. These inspections were carried out at the sites of professional users of medical devices/healthcare facilities, as follows:

- 54 hospitals inspected → in 48 of the hospitals, there was a lack of maintenance for in-use medical devices, a lack of control through periodic verification according to the legal provisions in force, as well as the existence of in-use medical devices beyond their shelf life. In these cases, legal fines were applied, namely 19 fines up to102,000 lei and 63 warnings;

- 457 dental offices → 194 were sanctioned with 206 warnings. For 11 dental offices, medical devices beyond their shelf life which were in use at the time of the inspection were identified, for which 11 legal fines were applied, up to 110,000 lei, and the complementary measure of prohibiting the use of expired medical devices. For 20 dental offices, in-use medical devices were identified, for which maintenance was not ensured, according to the legal provisions in force; in these cases, legal fines of 100,000 lei were imposed;
- 296 clinics/offices/medical centres → 133 were sanctioned. Following inspections conducted by the NAMMDR, irregularities were found such as the failure to carry out periodic checks and maintenance for in-use medical devices, the lack of a register of in-use medical devices and expired in-use medical devices, for which 138 warnings and 35 legal fines worth 187,000 lei were applied.

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

In 2024, 2393 advertising and educational materials in the field of human medicine and medical devices were registered, of which 824 advertising materials were assessed, 923 re-assessed and 94 rejected. Regarding educational materials, 217 were evaluated, 308 re-evaluated and 27 rejected, as seen in the chart below:



Regarding the sponsorship activity of 2024, the Advertising Service centralised the following statements:

- 235 sponsors through 76648 declaration forms for sponsorship activities carried out by manufacturers, MAHs or their representatives in Romania, as well as wholesale and retail

distributors of medicinal products and medical devices for healthcare professionals, professional organisations, patient organisations and any other type of organisation which performs activities related to human health, medical or pharmaceutical assistance;

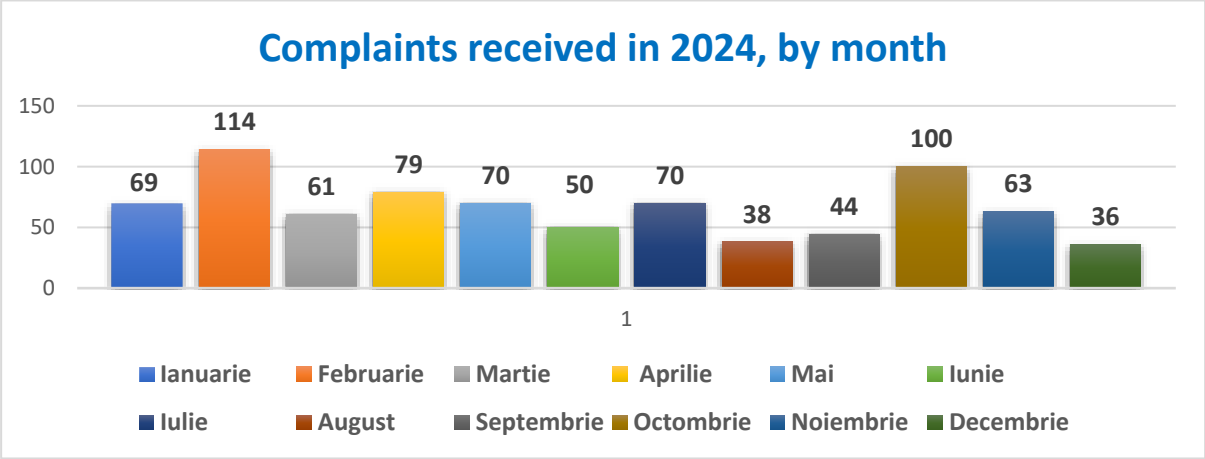
- 6380 sponsorship activity declaration forms by the beneficiaries of sponsorship activities, physicians, nurses, professional organisations, patient organisations and any other type of organisation which performs activities related to human health, medical or pharmaceutical assistance in the field of medicinal products for human use;
- 608 sponsorship activity declaration forms by the beneficiaries of sponsorship activities, physicians, nurses, professional organisations, patient organisations and any other type of organisation which performs activities related to human health, medical or pharmaceutical assistance in the field of medicinal products for human use.

COMMUNICATION AND PUBLIC RELATIONS

Through its communication in 2024, the NAMMDR ensured relations with all stakeholders, such as: patients, patient associations, the media, healthcare professionals, professional associations, the pharmaceutical industry, relevant national and international organisations.

In 2024, according to Law no. 544/2001 on free access to public information, 41 requests were received from mass media representatives, which were solved in compliance with the legislation in force, as well as numerous telephone notifications from patients, which were solved in an expeditious manner.

In 2024, 794 complaints were received and solved at lipsamedicament@anm.ro from patients, patients' relatives, hospitals, open circuit and hospital pharmacies, patient associations, pharmaceutical warehouses, as seen in the Table below, *Complaints received in 2024 by month*:



The Communication and Public Relations Service (SCRP) also monitors and manages the e-mail address comunicare@anm.ro.

An important tool of the communication with interested parties, showing the opening of the Agency to a constant, transparent communication and for the benefit of Romanian patients was achieved, as well, through permanent meetings with patient organisations, representatives of companies and professional societies *(e.g.: The Romanian Organisation for Serialisation of Medicinal Products (OSMR), The Romanian Association of Generic Medicine Producers (APMGR), the Romanian Association of International Medicines Producers (ARPIM), the Romanian College of Pharmacists, the Romanian College of Physicians, etc.), of other institutions in the healthcare field and not only (e.g. the Parliament of Romania, etc.).*

In 2024, together with the other professional structures, the SCRP also participated in the management of issues related to the proper functioning of the NAMMDR both in the European network of competent authorities in the field of human medicinal products and in the setup of an interface between the NAMMDR and stakeholders, on a national and international level.

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.
Also, throughout this period, one of the Agency's main objectives was the facilitation of the communication with the general public and the mass media, by sending prompt responses to requests received both through social media (the agency's social media pages) and by e-email/phone. Thus, the NAMMDR Facebook and LinkedIn pages were managed by: drafting announcements and NAMMDR press releases, posting EMA press releases on the re-evaluation of the safety profile of

some medicinal products/classes of medicinal products, formulating answers to messages addressed directly on the social media page.

In 2024, as in previous years, the NAMMDR coordinated various international communication campaigns about adverse reactions to medicinal products such as MedSafetyWeek, the information campaign on antibiotic consumption - European Awareness Antibiotic Day (EAAD), the information campaign regarding the Clinical Trials Information System (CTIS), the information campaign about the European Medicines Shortage Monitoring Platform (ESMP), created by the EMA for greater transparency regarding the availability of medicinal products in Eu states.

The NAMMDR, through the SCRP, organised working meetings with patient associations and several discussions with them on various topics, such as the lack of medicinal products or other issues faced by Romanian patients with chronic diseases and possible solutions which the Agency can implement in the short and medium term, in collaboration with other health institutions.

Moreover, in 2024, the SCRP represented the NAMMDR at a series of strategic events: the Romanian Research Gala, the "Opportunities in the Resilient Israeli Economy" Seminar, the Haemophilia Patients Association Conference – A Holistic Approach to Haemophilia, the "Future-proof Health Systems: Fostering Transformation, Performance, and Resilience/ Observatory" conference, the "Access of Romanian patients to Quality Oncology Services and Appropriate Therapies" debate, the "The Great AI Debate: Who Should Write the AI Future?", the "European Health Policies" conference, the Women's Health - Gender Medicine conference, the HPV Summit, the US Independence Day organised by the AmCham and the US Embassy.

Events in which the NAMMDR participated as organiser or co-organiser:

- The "Regulating access to innovation from the perspective of the European Pharmaceutical Strategy" workshop;
- EMA's multi-stakeholder workshop on GLP-1 receptor agonist discontinuations, Amsterdam. Discussions focused on stakeholder needs, the exchange of best practices and solutions to combat the shortage of these medicinal products, as well as effective communication in crisis situations;
- The "Prevention and education in priority chronic diseases - a necessary strategy for a sustainable and resilient healthcare system", organised under the aegis of the Health Innovation Hub;
- The "Why are medicinal products lacking in Romania" media training, with the aim of increasing the level of understanding and information management by journalists specialised in the healthcare field;
- Working meetings with organisations in the field such as the Association of Medical Products Suppliers (AFPM) to address the challenges regarding the implementation of Regulation 2017/745 on medical devices and Regulation 2017/746 on in vitro diagnostic medical devices;

- The NAMMDR press conference on the topic of the recall of some medicinal products, according to the European Commission decision;
- Summer internship for 24 students from 3 faculties (the Faculty of Pharmacy of the Carol Davila University of Medicine and Pharmacy; the Faculty of Medical Engineering – the National University of Science and Technology POLITEHNICA of Bucharest; the Faculty of Chemistry of the University of Bucharest), held at the NAMMDR headquarters.

LOGISTICS, INFORMATION AND ELECTRONIC DATA MANAGEMENT

In 2024, the NAMMDR Information and Communication Technology Service (STIC) continued to ensure, in optimal conditions, the institution's activity through provision of IT and technological support. Thus, it developed, maintained and administered programmes and applications for internal use, administered activity-specific databases, as well as other support activities, communication with the EMA, communication with the EMA and ensured a real-time exchange of information between the Agency and its external collaborators and collaborated with EMA groups in order to digitize its activity in the context of European projects, through:

- Management of the EU Network Training Center - Learning Management System portal;
- Management of the "IRIS Competent Authority Users" database of experts within the EMA Account Management Portal, as local administrator;
- Managing the "SPOR Competent Authority Users" database of experts within the EMA Account Management Portal, as local administrator;
- Ensuring NAMMDR connection to the Common Repository (Centralised Procedure Submissions) database;
- Ensuring NAMMDR connection to the Common European Submission Portal (CESP) database.
- Maintenance and update of the "IT solution for server virtualisation and RAID technology storage (redundancy, security and increased speed of retrieval of stored data)" platform with hardware and software components.

In 2024, the NAMMDR was represented by specialists in information technology within the "Coordination and Harmonisation of the Existing Systems against Shortage of Medicines - European Network" European project (CHESSMEN Code no. 101082419);

The modernisation of the NAMMDR communications network and the institution's digitization continued in 2024 through national projects, financed by Romania's National Recovery and Resilience Plan (PNRR):

- The "Digitization of the NAMMDR" project for specific investment I.3.2 - Digitization of institutions with attributions in the healthcare field subordinated to the Ministry of Health within Pillar II: Digital transformation;
- The "Modernisation of the electronic reporting system of drug stocks" project for specific investment I.3.2 - Digitization of institutions with attributions in the healthcare field subordinated to the Ministry of Health within Pillar II: Digital transformation.

Moreover, in 2024, the NAMMDR was represented by information technology experts and within the project "Supporting the consolidation of the capacity and skills of the EU regulatory network - IncreaseNET".

INTERNAL AUDIT

The objectives of the internal public audit activity in 2024 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.

4 system audit missions were planned for 2024, according to the Annual Internal Public Audit Plan, as follows:

1. Evaluation of the progress and results of the activities carried out by the National Procedure Directorate (13.03.2024 – 14.05.2024).
2. Evaluation of the progress and results of the activities carried out by the Pharmacovigilance and Risk Management Directorate (4.11.2024 – 23.12.2024).
3. Evaluation of the progress and results of the activities of the Clinical Trials Directorate (07.10.2024 – 29.11.2024).
4. Analysis of the conduct of the competition for the position of IA Expert Reviewer, superior studies, 6 years and 6 months of experience in the specialty (industrial chemistry, chemical technology), full-time, for an indefinite period (04.10.2024 – 18.10.2024).

The degree of achievement of the Internal Public Audit Plan at NAMMDR level (2024) was 100%.

SECTION III - PRIORITIES FOR 2024

In accordance with the National Health Strategy 2023–2030, the pharmaceutical strategy of the European Union and the strategy of the European Medicines Agencies network (EMRN), for 2025, the Agency aims to the following priority action directions:

- Easing the access of Romanian patients to medicinal products for human use and to safe and effective medical devices;
- Supporting and improving the quality and reliability of regulatory activities, maintaining a high standard for the agency's activities in accordance with best international practices.
- Building trust in regulatory decisions through continuous and transparent communication.
- Active participation in European surveillance of medicinal product discontinuations and proposing sustainable national solutions to prevent or reduce them;
- Continuation of the institution's digitisation, modernising and updating the Agency's IT system and strengthening interoperability with European platforms.
- Increasing, through information campaigns, the degree of involvement of healthcare professionals and patients in reporting adverse reactions to medicinal products;
- Promoting partnerships between the NAMMDR, the academic environment and the pharmaceutical industry in order to strengthen the clinical research and innovation framework for medicinal products and medical devices;
- Optimizing the available human resources by professional training, in accordance with the requirements of the Agency's activity and for benefit of the patients.

SECTION IV- INSTITUTIONAL TRANSPARENCY

IV.1. INCOMES

1. NAMMDR budget

1.1. Incomes

The NAMMDR budget approved for 2024 consisted of:

- self-funded (107,576,000 lei)
- revenues from non-refundable external projects of 583,000 lei
- revenues from PNRR projects of 19,239,000 lei.

1.2. Expenses:

1.2.1 Own revenues: 107,576,000 lei, of which:

- Title 10 - Staff expenses: 81,474,000 lei.
- Title 20 - Expenses on goods and services: 8,713,000 lei.

- Title 56 - Other community programmes (APC) financed between 2021-2027 – 160,000 lei
- Title 59 – Other expenses: 630,000 lei
- Title 70 - Capital expenses: 16,599,000 lei

1.2.2. Revenues from non-refundable external projects: 583,000 lei
1.2.3. Revenues from PNRR projects of 19,239,000 lei
1.3. NAMMDR budget execution:
Receipts:

- Own revenues: 105,975,749.04 lei
- Pre-financing from external non-refundable project: 578,376.90 lei
- Revenues from PNRR projects of 0 lei

Budgetary expenses: 38,497,661.86 lei, din care:

- Title 10 - Staff expenses: 40,427,004.56 lei
- Title 20 - Expenses on goods and services: 4,039,938.80 lei
- Title 56 - Other community programmes (APC) financed between 2021-2027: 44,817.64 lei
- Title 59 - Other expenses: 402,831.00 lei
- Title 60 – Non-refundable European funds: 1,249.50
- Title 70 - Capital expenses: 920,928.18 lei
- Title 85 - Payments made in previous years and recovered in the current year: 114,837.88 lei

IV.2. PUBLIC PROCUREMENT INFORMATION

2.2. Number of procurement processes per category (2024):

2.2.1. Negotiation without publishing an add:

- 1 procedure carried out through the Romanian Commodity Exchange with the aim of supplying natural gas for the premises administered by the NAMMDR;
- 1 procedure carried out by the Romanian Commodity Exchange with the aim of providing electricity for the premises administered by the NAMMDR.

2.2.2. Open auction:

- 1 open auction aiming to a framework agreement for a 24-month period, organised and conducted in order to award subsequent contracts for the supply of computer equipment and software licenses, split into 4 lots.

2.2.3. Simplified procedure:

- 1 Simplified procedure carried out online with the object of provision of "laboratory equipment", split into 9 lots.

2.2.4. Direct purchases:

- 92 direct purchases (products)
- 222 direct purchases (services)
- 2 direct purchases(works)

2.3. Purchases made through the electronic system:

- 1 open auction procedure
- 1 own procedure
- 142 online direct purchases of products/services/works.

2.4. Average duration of a public procurement process by procurement categories:

Procedure	**Average duration of a public procurement process**
Open auction	90 calendar days from the date of submission of documentation to the SEAP
Simplified procedure	60 calendar days from the date of submission of documentation to the SEAP
Negotiation without publishing an ad	30 calendar days after sending the invitation
Direct purchase of products/services/works	7 days from the date of approval of the report

No appeals were filed in the public procurement procedures carried out by the NAMMDR in 2024.

No award procedures were cancelled in 2024.

The detailed information regarding the public procurement held in 2024 is located on the website www.anm.ro/informatii-de-interes-public/.

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

There were 1081 litigations in which the NAMMDR was involved between January and December 2024, which involved requests for summons, objections, written conclusions, requests for evidence, written notes, requests for legalisation, notifications to the courts regarding the pending cases, as well as the representation and defence of NAMMDR's interests before the courts.

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

IV.4. ORGANISATIONAL CHART

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

IV.5. 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.

Between 01.01.2024-28.08.2024, the NAMMDR was structured in general directorates, directorates, services, offices and compartments. According to the new NAMMDR organisational structure, approved through Order of the Minister of Health no. 3994/25.07.2024, the Agency was structured in general directorates, directorates, services, offices and compartments.

On 01.01.2024, there were 340 employees, 326 by the end of 2024, as follows:

- 477 approved positions
- 326 positions occupied by 31.12.2024
- 151 vacant positions by 31.12.2024
- 315 - average number of remunerated positions by 31.12.2024

In 2024, 6 contractual execution positions were filled through competition.
In 2024, there were 21 terminations of activity, as follows:

- 13 executive contractual positions terminated by agreement of the parties;
- 2 executive contractual position terminated by transfer upon request;

- 1 executive contractual position terminated by death of the employee;
- 3 executive contractual positions terminated on the date of cumulative fulfilment of the standard age conditions and the minimum contribution period for retirement;
- 1 executive contractual position terminated by resignation;
- 1 executive contractual position ceased during the probationary period at the employee's initiative.

Management positions exercised on a temporary basis in 2024:

- 22 contractual leadership positions exercised on a temporary basis;

In 2024, the NAMMDR organised 4 competitions (for vacant executive contractual positions):

- 1 competition for the occupation of 12 vacant contract execution positions of physicians (1 was filled);
- 3 competitions for the occupation of 11 vacant contract execution positions (5 were filled, of which 2 – pharmacy and 3 – other specialties).

The staff turnover rate in 2024 was 6.66%.

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/.

SECTION V - RELATIONSHIP WITH THE COMMUNITY

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

In 2024, in line with Law no. 544/2001 on free access to information of public interest, 53 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 challenges shall be a main objective of the Agency during the following period.

SECTION VI - LEGISLATION - INFORMATION ON DRAFT REGULATORY DOCUMENTS INITIATED BY THE INSTITUTION

With regard to the legislative activity, in 2024, 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 on amendment of Order of the Minister of Health no. 888/2014 on approval of fees payable to the National Agency for Medicines and Medical Devices for services related to medicinal products for human use;

2. The draft Order on approval of Order of the Minister of Public Health no. 872/17.07.2006 on approval of the Norms on the procedure for grant of exemption of specific medicinal products label and package leaflet from the obligation that certain particulars shall appear and that the leaflet must be in Romanian, when the product is not intended to be delivered to the patient for self-administration

3. The draft Order on approval of the methodology for elaboration of the list of critical medicinal products of Romania;

4. The draft Order on amendment of Order of the Minister of Health no. 1473 of 22 November 2018 on setup of the framework for implementation of provisions of Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament

and of the Council by laying down detailed implementation rules for the features appearing on the packaging of medicinal products for human use;

5. The draft Order on amendment and supplementation of the Annex to Order of the Minister of Health no. 194/2015 on Rules for assessment and approval of advertising of medicinal products for human use;

6. The draft Order on approval of the procedural rules for the application of the provisions of Art. 5 paragraph (5) 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 on medical devices and in vitro diagnostic medical devices manufactured and used only within healthcare institutions

7. Revision of the draft Order on approval of the Methodological rules on clinical evidence, assessment of performance and studies on the performance of in vitro diagnostic medical devices;

8. Amendments submitted to the Senate – Health Committee and to the Ministry of Health and amendments submitted to the Chamber of Deputies – Committee on Health and Family and the Ministry of Health, concerning the draft Order on approval of Emergency Government Ordinance no. 33/2024 on amendment and supplementation of Emergency Government Ordinance no. 29/2022 regarding the establishment of an institutional framework and necessary measures for 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, repeal of Directive 2001/20/EC, as well as for amendment of certain regulatory rules in the healthcare field;

9. Amendments submitted to the Senate – Health Committee and to the Ministry of Health, on the draft law on approval of Emergency Government Ordinance no.150/2022 on amendment and supplementation of Law 95/2006 on healthcare reform and Law 151/2010 on integrated specialised health, education and social services for people with autism spectrum disorders and associated mental health disorders, as well as for establishing measures in the healthcare field;

10. Amendments on the draft Order on amendment Order of the Minister of Health no. 1.474/2021 regarding the establishment and operation of technical expert groups responsible for developing technical viewpoints on documents under debate at European level and ensuring representation at meetings of the working structures of European Union institutions;

11. Observations on the draft Order on approval of the amount of fees charged by the Academy of Medical Sciences for the notices issued by the National Bioethics Commission for Medicines and Medical Devices;

12. Viewpoint on the Draft Order on the regulation of the Technical Working Group dedicated to the pharmaceutical industry;

13. Amendments to the Draft Government Ordinance on amendment and supplementation of Law No. 95/2006 on healthcare reform, as well as on amendment and supplementation of some regulatory documents with an impact in the healthcare field;

14. Amendments to the Draft Order on daily reporting of stocks and trade operations carried out with medicinal products for human use included in the National Catalogue of Prices for medicinal products authorised for marketing in Romania by medicinal product wholesalers, importers, authorised manufacturers and closed- and open-circuit pharmacies;

***Annex to the NAMMDR 2024 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 inspecții 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 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	Comitetul pentru evaluarea riscurilor în materie de farmacovigilenţă - Pharmacovigilance Risk Assessment Committee
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