THE MINISTRY OF HEALTH
THE NATIONAL AGENCY FOR MEDICINES
AND MEDICAL DEVICES OF ROMANIA
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YEARLY ACTIVITY REPORT
2023

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Table of contents

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FOREWORD

" This year, together with the team of experts, we continued the strategic activities we have initially proposed and came up with solutions to most of the challenges that arose.

In 2023 as well, the global shortage of medicinal products had a significant impact on the Romanian patients. Together with the Ministry of Health and other healthcare entities - industry, manufacturers or distributors of medicinal products, healthcare professionals and patient associations, we have been involved in mitigating the negative consequences of discontinuations in the supply of medicinal products.

Whether we are referring to topics of interest to patient associations or to the industry, the orientation towards finding quick and effective solutions is proof of our openness and involvement in everything that falls within the competence of the NAMMDR – medicinal products and medical devices."

Răzvan-Mihai Prisada

President

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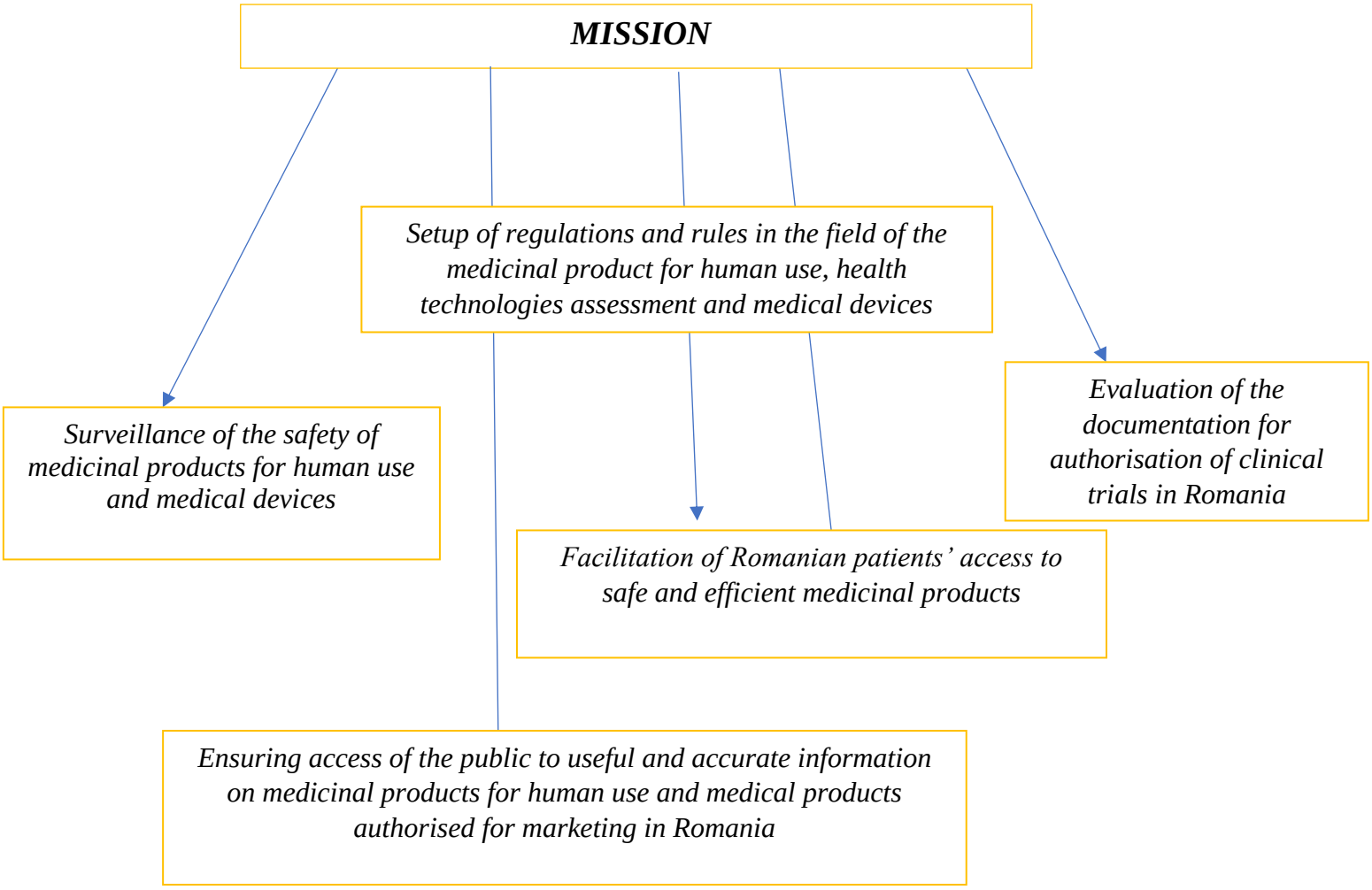
SECTION I – ORGANISATIONAL PROFILE

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 2023 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

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 mainstream media.
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.
Patients, patient associations, healthcare professionals, governmental and professional organisations, as well as the media, continued to request various information from the NAMMDR in 2023 as well, 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.
With regard to its legislative activity, in 2023, the NAMMDR developed and submitted for approval to the Ministry of Health draft regulatory documents, needed in order to achieve the objectives in its field of activity.

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 2023, there were 5 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 15.03.2023:**
   - Approval of the NAMMDR job list, submitted for approval to the Ministry of Health.
2. **The AC meeting of 30.05.2023:**
   - Approval of the income and expenditure budget for 2023;
   - Approval of the financial statements of the NAMMDR for the financial year 2022;

- Approval of the Partnership Agreement between the NAMMDR and the "Carol Davila" University of Medicine and Pharmacy, Bucharest, the National Commission for Bioethics of Medicines and Medical Devices, the Association of Romanian Medicines Manufacturers (ARPIM), the Local American Working Group Association, the Association of Companies Conducting Clinical Trials in Romania.

3. **The AC meeting of 12.07.2023:**
   - Approval of the income and expenditure budget on 30.06.2023;
   - Approval of the centralizers of inventory items, fixed assets such as inventory items, tangible and intangible fixed assets proposed for decommissioning/downgrading during the 2022 inventory;
   - Approval of the NAMMDR activity report (2022).
4. **The AC meeting of 26.09.2023:**
   - Approval of the income and expenditure budget of 2023;
5. **The AC meeting of 11.12.2023:**
   - Approval of the income and expenditure budget of 2024;
   - Approval of the income and expenditure budget of 2024- 1/12;
   - Approval of the organisational structure of the NAMMDR.

II.1.b. ACTIVITY OF NAMMDR COMMISSIONS

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

In 2023, 10 meetings were organised, during which a number of 586 medicinal products were discussed (459 – European procedures, 37 – National procedure, 90 – National procedure – Parallel import);

Marketing authorisations (MAs) and Annexes 1, 2, 3, 4 and 5 were issued for 429 medicinal products, of which 396 were related to the European procedures and 33 to the national procedure.

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

76 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**

3 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**

In 2023, this Commission has completed:

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

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

In 2023, the Agency 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. These 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 2023, 86 files were drawn up through the National Procedure, of which 37 applications for authorisation and 46 authorisations for renewal were validated, 92 parallel import authorisations (PIA) (of which 87 medicinal products were granted a PIA, and 5 au were discontinued upon applicant request), 38 applications for PIA variations.

STATUS OF AUTHORISATIONS THROUGH NATIONAL PROCEDURE – 2023							
Marketing Authorisation Applications		Applications for Renewal		Applications for variation to parallel import authorisations		Applications for parallel import authorisations	
40		46		38		92	
VALIDATED	REQUESTS	VALIDATED	REQUESTS	APPROVED	PENDING	APPROVED	DISCONTINUED
37	3	46	0	38	0	87	5

During 2022, 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

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No.	Type	Received in 2023	Solved in 2023 (including files registered between 2015-2023)
1.	MA transfer	**35**	**24**
2.	Type I variations	**3109**	**3654**
3.	Type II variations	**125**	**165**
4.	Modification of packaging design and imprinting	**164**	**186**
	Total 1+2+3+4	**3433**	**4029**

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 in 2015-2023

No.	Document type	Total number
1.	Amendment to MA terms	**265**
2.	Annexes to MA	**1274**

In 2023, 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)
- 26 Efficacy/clinical safety reports - authorisation (initial report)
- 4 Efficacy/clinical safety reports - authorisation (report for supplementation)
- 19 Non-clinical safety reports - authorisation (initial report)
- 16 Non-clinical safety reports - authorisation (report for supplementation)
- 9 Quality reports of bioequivalence study protocols (initial)
- 21 Quality reports of bioequivalence study protocols (supplementation)
- 29 Quality reports of bioequivalence study protocols (initial)
- 10 Quality reports of bioequivalence study protocols (supplementation)
- 51 Assessment reports – ANS (authorisation for special needs) - patient

- 25 Assessment reports – ANS (authorisation for special needs) - commission
- 3 Reports for medicinal products on grounds of public health

AUTHORISATION THROUGH EUROPEAN PROCEDURES

6318 requests sent to the institution were completed in 2023, as follows:

OVERALL REPORTING FOR ISSUED/ELABORATED APPROVALS - 2023 (01.01.2023-31.12.2023)

Variations with RO-SMI: type IA/IA/G	**2894**
Variations with RO-SMI: type IB/IB/G+WS	**2453**
Variations with RO-SMI: type II/II/G+WS	**596**
Type P notifications in line with Article 61 (3) of Directive 2001/83/EC	**68**
National notifications in line with Order of the Minister of Health no.1205/2006	**53**
MA transfers in line with Order of the Minister of Health no. 1206/2006	**132**
Variations with RO-SMR: type IA/IA/G+IB/IB/G+II/WS	**122**
Overall total number of approvals per number of MAs	**6318**

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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:

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

Variations	Number of variations **submitted in 2023** (full set*) Per strength= number of MAs	Number of variations **finished in 2023** (registered in 2022-2023)** Per strength= number of MAs	**Notes**
Type IA variations/groups of variations	**31**	**19 (2023)** **28 (2022)** **Total 47**	**6 pending - European stage**
Type IB variations/groups of variations	**40**	**34 (2023)** **30 (2022)** **Total 64**	**1 pending - European stage**
Type II variations/groups of variations	**6**	**11 (2022)** **Total 11**	**6 pending - European stage**
National notifications in line with Order of the Minister of Health no. 1205/2006	**0**	**0**	**Not submitted in 2023**
Type P notifications - Art. 61 (3) of Directive 2001/83/EC	**0**	**0**	**Not submitted in 2023**
TOTAL NUMBER	**77**	**122**	**13** **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 2022 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 2023** (full set*/ databases from previous years 2022+2021)	**Finished approved variations (corrective documents included) in 2023**
Variations/groups of Type IA variations	**3098**	**Total number of Type IA variations=2894**
Variations/groups of Type IB variations	**2408**	**Total number of Type IB variations=2453**
Variations/groups of Type II variations	**585**	**Total number of Type II variations=596**
National notifications in line with Order of the Minister of Health no. 1205/2006	**57**	**Total number of NN notifications=53**
Type P notifications - Art. 61 (3) of Directive 2001/83/EC	**60**	**Total number of P notifications=68**
Transfer APP conform OMS 1206/2006	**235**	**Total number of MA transfers= 132**
TOTAL	**6373**	**6196**

Note: full set*: complete submissions with Letter of Intent, Payment Form, Payment to the Economic Department, documentation supporting the variation/transfer/notification) ** - various stages - submission phase, in progress, suspended, completed SMR, in the national stage, assigned to the assessors, upon request, assigned to Renewal)

HEALTH TECHNOLOGIES ASSESSMENT

In 2023, through the Directorate for Medical Technologies Assessment (DETM), the Agency completed a number of 165 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).

Of these, 156 evaluation reports were requests submitted by the MAH or MAH representatives from Romania, and 9 were drawn up by the Directorate for Medical Technologies Assessment (DETM), following requests received from other authorised institutions.

Following the evaluations carried out by the DETM in 2023, the following decisions were issued:

- 38 decisions for unconditional inclusions in the List, of which 10 were related to the therapeutic area of oncology, 7 to the therapeutic area of haematology, 5 to the therapeutic area of rheumatology, 4 to the therapeutic area of ophthalmology, 3 to the therapeutic area of neurology, 3 to the therapeutic area gastroenterology, 3 to the therapeutic area of dermatology, 2 to the therapeutic area of endocrinology, and 1 targeted to the therapeutic area of otorhinolaryngology;
- 62 decisions for conditional inclusion in the List, of which 21 were related to the therapeutic area of oncology, 8 to the therapeutic area of haematology, 7 to the therapeutic area of gastroenterology, 7 to the therapeutic area of neurology, 5 to the therapeutic area of ophthalmology, 4 to the therapeutic area of nephrology, 3 targeted the therapeutic area of pneumology, 2 targeted the therapeutic area of endocrinology, 2 targeted the therapeutic area of rheumatology, 1 decision was related to the therapeutic area of orthopaedics, 1 decision was related to the therapeutic area of dermatology and 1 to the therapeutic area of infectious diseases;
- 13 Decisions for non-inclusion in the List;
- 24 Decisions to add a new strength or pharmaceutical form;
- 25 Decisions to add a population segment;
- 1 Decision for exclusion from the List;
- 1 Decision for addition to the List;

Out of the 165 completed reports, 80 files were submitted in 2023, 81 files in 2022, 1 file in 2021 (its evaluation being suspended at the request of the company, in order to complete the documentation) and 3 evaluation reports were drawn up as a result of appeal hearings held during 2023. After an appeal hearing, it was decided to review the evaluation report, without issuance of a new decision.

The List of International Non-proprietary Names of on-prescription medicinal products as provided to insurants, irrespective of personal contribution, in the frame of the health insurance system, as well as of International Non-proprietary Names of medicinal products provided in national health insurance programmes, as well as the means for appeal thereof, as further amended and supplemented, was updated 3 times during 2023, but only one of the updates was made as a result of decisions for evaluation of medical technologies.

The completion of the evaluation reports related to the requests received by the DETM took place in Decision no. 331 of 12 April 2023, published in the Official Gazette no. 322 of 18 April 2023, which amended and supplemented Government Decision no. 720/2008, as further amended and supplemented.

Order of the Minister of Health and of the National Health Insurance House no. 564/499/2021 on amendment and supplementation of Annex 1 to 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 6 times in 2023, as follows:

1. ORDER of the Minister of Health no. 689 of 10 March 2023 and of the National Health Insurance House no. 157 of 13 March 2023;
2. ORDER of the Minister of Health no. 1837 of 29 May 2023 and of the National Health Insurance House no. 447 of 30 May 2023;
3. ORDER of the Minister of Health no. 3241 of 20 September 2023 and of the National Health Insurance House no. 800 of 22 September 2023;
4. ORDER of the Minister of Health no. 3278 of 22 September 2023 and of the National Health Insurance House no. 804 of 25 September 2023;
5. ORDER of the Minister of Health no. 3987 of 22 November 2023 and of the National Health Insurance House no. 1156 of 27 November 2023;
6. ORDER of the Minister of Health no. 4335 of 21 December 2023 and of the National Health Insurance House no. 1269 of 27 December 2023.

MEDICINAL PRODUCT QUALITY ASSESSMENT AND CONTROL

The Directorate for medicinal product quality assessment and control (DECCM) has the status of a Medicines Control Laboratory (OMCL), full active member of the General European OMCL Network (GEON), coordinated by the 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. Between 28 and 30 March 2023, the NAMMDR OMCL was re-audited by the European Directorate for the Quality of Medicines (EDQM) through the MJA (Mutual Joint Audit) procedure and was re-accredited with the EDQM/MJA-190 certificate of 05.12.2023.

In 2023, the DECCM was involved in the testing of nationally authorised medicinal products, within the Sampling Plan or following complaints, in the OCABR procedure, as well as in the testing of medicinal products authorised through European procedures and in interlaboratory studies.

In 2023, 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).

As regards laboratory control, the following types of testing were performed in 2023:

- laboratory control of domestic/imported biological medicinal products (of each batch) (in case there is no OCABR certificate), together with the analysis of quality certificates and the

evaluation of batch protocol summaries, followed by the issuance of analysis bulletins and of the Official Batch Release Certificate (EU Procedure), as OMCL;

- laboratory analyses during the marketing authorisation/marketing authorisation renewal procedure of the MA, scientific evaluation of the documentation related to the control methods in the documentation for authorisation and issuance of certificates of analysis/certificates of compliance;

- laboratory analyses for medicinal products included in the National Market Surveillance Programme;
- laboratory analyses for medicinal products authorised through the special needs procedure;
- laboratory analyses for medicinal products claimed from the territory by health units, by natural or legal persons;
- provision of expertise for the control of medicinal products with quality deficiencies or suspected of being harmful to public health (falsified medicinal products and illegal medicinal products/products/samples);
- laboratory analyses on the quality of the medicinal product, coordinated by the EDQM: Proficiency Testing Studies (PTS);
- laboratory analyses on the quality of the medicinal products, coordinated by the EDQM: Chemical/Biological Reference Substances (CRS/BRP) standardisation studies
- laboratory analyses on the quality of the medicinal product, coordinated by the EDQM: market surveillance studies for medicinal products authorised through MRP/DCP (Marketing Surveillance Studies - MSS);
- laboratory analyses on the quality of the medicinal product, coordinated by the EDQM: testing of samples of medicinal products authorised for marketing by the EMA through centralised procedure;

As regards the evaluation activity, the DECCM carried out the evaluation of the quality documentation, in order to ensure the following:

- marketing authorisation for all biological medicinal products submitted through the national procedure and European procedures;
- marketing authorisation/marketing authorisation renewal for biological medicinal products submitted through the centralised procedure;
- renewal of MA for all biological medicinal products submitted through the national procedure and European procedures;
- assessment of quality variations/design changes/MA transfer for all biological medicinal products submitted through the national procedure;
- assessment of quality variations for all biological medicines, submitted through European MRP/DCP;
- assessment of active substance master files (ASMF) for synthetic medicinal products;
- assessment of quality variations for active substances of synthetic medicinal products (including radiopharmaceuticals);
- evaluation of quality documentation submitted within other procedures such as the authorisation for special needs (ANS), compassionate use, exemptions, etc., in the case of biological medicinal products;

- evaluation of quality documentation submitted for the purpose of authorising the conduct of clinical trials for investigational medicinal products of biological origin;
- evaluation of quality documentation submitted within the reporting of quality defects, in the case of biological medicinal products.

ASSESSMENT AND AUTHORISATION OF CLINICAL TRIALS

In 2023, 230 requests for evaluation and authorisation of clinical trials with medicinal products for human use were received (submitted through CTIS in line with Regulation (EU) No. 536/2014 and Directive 2001/20/EC), and 194 reply addresses were issued, of which:

Regulation (EU) no. 536/2014			**Directive 2001/20/EC**	
Initial trials	Transactional trials	Notifications for rejection Initial trials	Initial trials	Notifications for rejection Initial trials
94	**52**	**2**	**43**	**3**

In 2023, the DSC received 889 requests for evaluation and approval of important amendments, of which 773 requests were submitted according to Directive 2001/20/EC and 116 through the CTIS, in line with Regulation (EU) no. 536/2014). Throughout the year, 873 reply addresses were issued, of which:

770 applications for authorisation of trials submitted through Directive 2001/20/EC and 59 applications for authorisation of trials submitted through CTIS in line with Regulation (EU) no.

- 871 notifications for approval
- 2 notifications for withdrawal

With regard to observational studies with medicinal products for human use, during 2023, 13 requests for evaluation and approval were submitted to the NAMMDR, of which 4 authorisations were issued. In 2023, 7 authorisations of medical units were issued for the conduct of clinical trials and 15 requests for changes to the initial authorisations (adding work points or specialties);
Note: Starting from 23.03.2022, the authorisations of medical units shall be automatically extended until 31.01.2025, in accordance with Emergency Government Ordinance no. 29/23.03.2022.

The DSC received and managed non-substantial amendments to approved clinical trials, various notifications and addresses with requests for various information, such as:

- 1003 various notifications (first patient inclusion notification, study closure notifications, temporary interruptions, non-substantial amendments);
- 197 annual study reports;
- 16 non-interventional study notifications.

In 2023, the DSC performed:

- clinical trial tariff regularisations – 17;
- tariff adjustments amendments –13.
- Moreover, the DSC ensured the 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: 324 DSURs and 521 SUSARs.

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 2023 it prepared:

• 18 evaluation reports for the authorisation of medicinal products, as last-resort treatment;
• 13 evaluation reports for the renewal of medicinal product authorisations, as last-resort treatment;
• 30 evaluation reports for changes to the authorisations of medicinal products authorised as last-resort treatments;
• 44 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 2023, 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 611 medicinal products;
- Renewed marketing authorisations for 297 medicinal products;
- Newly issued special needs authorisations for 76 medicinal products;
- Renewed special needs authorisations for 38 medicinal products;
- Approved variations for 1765 medicinal products;
- Marketing authorisations which have expired or have been discontinued by decisions for termination for 503 medicinal products;

As regards the "Discontinuations" section, the following information was updated during 2023:

- Notifications of temporary and permanent interruption of marketing for 402 medicinal products;
- Notifications of resumption of marketing for 258 medicinal products;
- Notifications of marketing for 1694 medicinal products;

- 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 687 medicinal products.

In 2023, there were 104 requests for exemption from the Sunset clause, from which the NAMMDR approved exemptions for 93 medicinal products.

GENERAL DIRECTORATE FOR PHARMACEUTICAL INSPECTION

In 2023, the following activities were carried out by the structures of the General Directorate of Pharmaceutical Inspection (DGIF):

- Amendments were made in accordance with the legislation in force for 140 manufacturing authorisations and 19 import authorisations as well as their annexes/certificates of compliance with the good manufacturing practice (GMP);
- Manufacturing authorisations for manufacturing/import activities and for independent control units, as well as certificates of compliance with the good manufacturing practice were drawn up, issued and/or suspended/withdrawn, as follows:
  - 170 manufacturing authorisations, also for independent control units and annexes;
  - 32 import authorisations, including their annexes;
  - 46 GMP certificates for Romanian manufacturers and 10 GMP certificates for foreign manufacturers;
  - 1 declaration of non-compliance with the good manufacturing practice, where non-compliance with the legislation was found;
  - 1 suspension/withdrawal of the manufacturing authorisation/certificates of GMP compliance at the request of the applicant and 1 suspension/withdrawal of the manufacturing authorisation/certificates of GMP compliance following the issuance of the GMP non-compliance declaration.

• The necessary documentation for the issuance of the qualified person certificate for 38 applicants was checked and 24 certificates were issued attesting to the status of qualified person;
• 2 certificates attesting to the compliance with the good laboratory practice were issued.
• The following were carried out:

- 34 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;
- 11 inspections for authorisation, respectively certification of good manufacturing practice for the import activities of medicinal products for human use, including investigational medicinal products;
- 12 inspections for GMP certification at the sites of manufacturers of medicinal products, investigational medicinal products and active substances from third countries;
- 2 unannounced inspections in connection with the investigation of self-reports/notices regarding the activity of units in the field of GMP, including the activity of the qualified person;

• 3 Good Laboratory Practice (GLP) certification inspections at specialised bioanalytical laboratories for pharmacokinetic determinations, as well as at preclinical and toxicological laboratories or laboratories granting authorisations for marketing of medicinal products;
• There were 4 findings of violation of legal provisions in the field of GMP and the application of appropriate sanctions, according to the legislation in force;
• The existence of complete documentation necessary for issuance of an agreement on the registration of manufacturers and importers of active substances used as raw materials for human medicinal products was verified for 20 manufacturers and 13 importers.
• 3 agreements on the registration of manufacturers and importers of active substances used as starting materials for medicinal products for human use were drawn up and issued for manufacturers and 6 such agreements were drawn up for importers.
• 18 standard files of the pharmacovigilance systems of the MAHs were assessed in preparation for inspections.
• 81 inspections were carried out for authorisation, respectively certification of the good distribution practice (GDP) of wholesale distribution units of medicinal products for human use;
• 6 unannounced inspections were carried out in connection with the investigation of self-reports/notices regarding the activity of units in the field of GDP;
• 15 situations of violation of legal provisions in the field of GDP were found and the appropriate sanctions were applied, according to the legislation in force;

- 139 checks were carried out on the existence of complete documentation required to amend the wholesale distribution authorisation and its annexes/certificate of compliance with the good distribution practice;
- Wholesale distribution authorisations and certificates of compliance with the good distribution practice were drawn up and issued, as follows:
  - 220 distribution authorisations, including their annexes;
  - 105 GDP certificates;
  - 7 suspensions/withdrawals of wholesale distribution authorisations/certificates of compliance with the good distribution practice, at the request of the applicant;
  - 11 checks of the existence of complete documentation required for issuing the agreement on the registration of importers and distributors of active substances used as starting materials for medicinal products for human use;
  - 4 agreements on the registration of importers and distributors of active substances used as starting materials for medicinal products for human use;

There were 60 actions related to the analysis of data from notifications regarding intra-community deliveries and reports submitted by wholesale distributors, as well as monitoring the medicinal product market in order to comply with the public service obligation and to apply specific legislation;
The information included in the wholesale distribution authorisations and in the GDP/GMP certificates issued throughout 2023 as well as in the declarations regarding non-compliance with GDP/GMP were entered into the EudraGMDP database.
The update of the List of Authorised Wholesale Distribution Units was published on the NAMMDR website;

The update of 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, the list of qualified persons and the list of GLP certified laboratories were all published on the NAMMDR website;

As regards the activity of supervising the quality of medicinal products, in 2023, through the General Directorate of Pharmaceutical Inspection, the NAMMDR undertook the following activities:

• Elaborated the Yearly Sampling and Testing Plan for 15 medicinal products;
• Elaborated the Thematic Plans for Surveillance Inspections for 2 medicinal products (medicinal product quality + narcotics);
• Managed 110 reports on suspected quality non-compliances in medicinal products reported by marketing authorisation holders or medicinal product manufacturers;

- Solved 8 notifications/complaints regarding suspected quality non-compliances in medicinal products, received from patients, natural or legal persons, healthcare professionals, national or international authorities or bodies, professional associations, mass media, etc. (calitate@anm.ro);
- Solved 139 notifications/complaints regarding the lack of medicinal products on the market, received from health units and pharmacies, at the request of the Communication and Public Relations Service (lipsamedicament@anm.ro);
- Performed:
  - 166 thematic inspections for supervision of the quality of medicinal products in the distribution network and thematic inspections for supervision of the activity of pharmaceutical units (community pharmacies, rural/seasonal community offices, closed-circuit pharmacies and medicinal product stores);
  - 7 unannounced inspections in connection with the investigation of self/notices regarding the activity of pharmaceutical units (community pharmacies, rural/seasonal community offices, closed-circuit pharmacies and medicinal product stores);
  - 18 inspections for sampling of medicinal products, active substances, raw materials, including excipients, primary and secondary packaging materials used in the manufacturing process of medicinal products, intermediate products or bulk finished products, for testing within the framework of the Yearly Sampling and Testing Plan;
  - 4 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), at the request of the DECCM and for the Year Sampling and Testing Programme of centrally authorised medicinal products (CAP Sampling & Testing Programme), at the request of the EMA;
  - 25 evaluations of files submitted for approval of the provision of free medical samples and maintenance of electronic records regarding the periodic reporting of marketing authorisation holders regarding the provision of free medical samples;
- Checked the existence of the complete documentation necessary for the approval of export declarations and maintained the database of approved export declarations: 10686 approved declarations + 12 addresses requesting additions/rejecting requests.

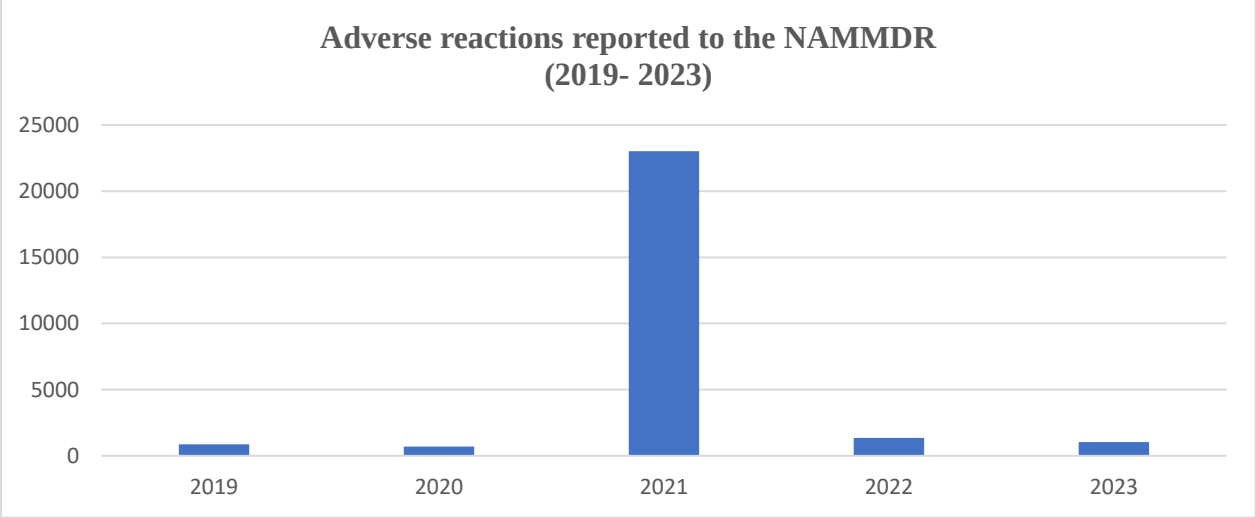
- Checked the existence of complete documentation required to issue donation notices for medicinal products and maintain the database regarding donation notices issued for 198 donation notices and 15 additions/rejections.
- Monitored the correctness of the recall of medicinal products with quality non-compliances, initiated by marketing authorisation holders or ordered by the NAMMDR or other competent authorities in the field, from all relevant actors in the distribution chain:
  - ordered by the NAMMDR
  - voluntarily, by manufacturers/MAHs: 17
- It found 94 cases of violation of legal provisions in the field of medicinal product quality and/or the activity of pharmaceutical units and applied appropriate sanctions, according to the legislation in force;
- Managed 481 rapid alerts and non-urgent information received through the Rapid Alert Systems (RAN, PIC/S, WHO) regarding suspected quality non-compliances in authorised medicinal products, as well as cases of falsified or stolen medicinal products (rapid.alert@anm.ro), of which:
  - nitrosamine impurities: 30 (17 unauthorised + 13 authorised in Romania);
  - medicinal product batches distributed in Romania: 7;
  - medicinal products authorised but not marketed in Romania: 11;
  - medicinal products not authorised for marketing in Romania and other products which are not medicinal products (food supplements, care products, etc.): 103;
  - quality non-compliances of centrally authorised medicinal products: 41;
  - suspensions/withdrawals/reinstatements of CEP certificates: 9;
  - declarations of non-compliance with GMP or suspensions/reinstatements of GMP certificates: 157;
  - declarations of non-compliance with GDP or suspensions/reinstatements of GDP certificates: 9;
  - thefts of medicinal products: 11;
  - counterfeit medicinal products: 83.

• Took measures to prevent the entry of medicinal products with quality non-compliances (blocking or withdrawing batches), counterfeit or stolen from the legal distribution chain;
• Managed notifications regarding intra-community deliveries sent to the NAMMDR by wholesale distributors according to Order of the Minister of Health no. 269/2017 (raportarenotificari@anm.ro): 3971 notifications, with 202362 notified products.
• Managed 80 reports on imported medicinal products submitted by importers according to Order of the Minister of Health no. 1295/2015 (raportareimporturi@anm.ro).
• Managed information on the traceability of medicinal products throughout the distribution chain from monthly reports submitted by authorised wholesale distributors/importers/manufacturers according to Order of the Minister of Health no. 502/2013 (raportaremedicamente@anm.ro).
• Published the List of notifications regarding intra-community deliveries received from wholesale distributors on the NAMMDR website.
• Investigated 787 potential incidents of falsification of medicinal products identified in level 5 alerts sent by the Romanian Organisation for Serialisation of Medicinal Products (OSMR) (alertaosmranm@anm.ro).

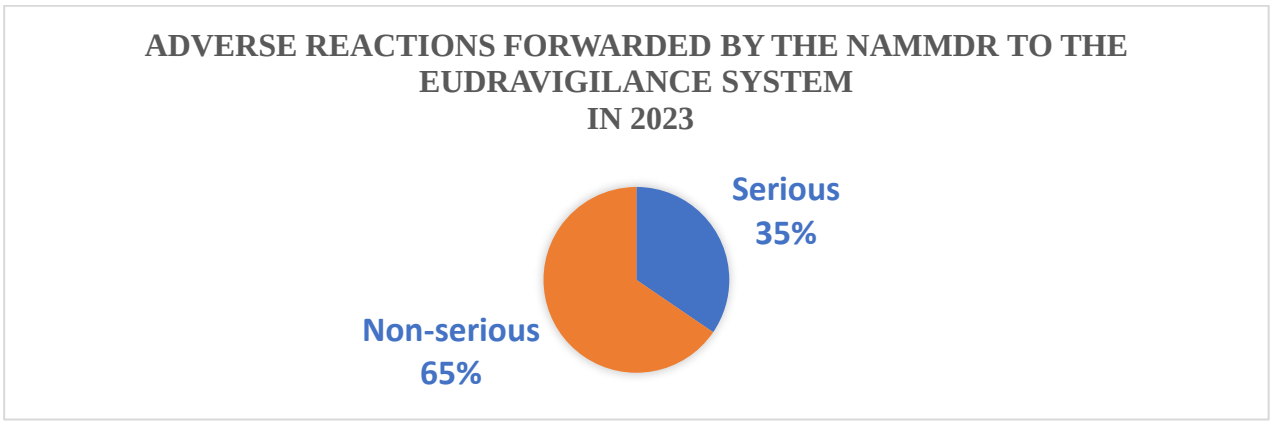
• Undertook specific activities related to the serialization of medicinal products, communicating with the OSMR and end users of the National Medicines Verification System (SNVM) in various specific cases related to the serialization of medicinal products.
Received 561462 alert messages generated by the SNVM on the email address alertaosmranm@anm.ro, to which level 5 alerts generated in the SNVM are sent, and elaborated and sent 7 responses to the requests formulated by the OSMR.

PHARMACOVIGILANCE AND RISK MANAGEMENT

In 2023, the NAMMDR received and managed a total number of 1034 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 2023, the NAMMDR transmitted to the EMA Eudravigilance database, in electronic format, 406 serious adverse reactions and 770 non-serious adverse reactions, received from patients and healthcare professionals (from the INSP-CNSCBT as well), reported from Romania.



In 2023, 4 information addresses were prepared and sent quarterly to the Romanian College of Physicians (CMR) and to the Romanian College of Pharmacists (CFR) and 238 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.

5084 adverse reaction reports submitted by marketing authorisation holders (MAHs)/sponsors were managed in the EudraVigilance database.

Periodic safety update reports (PSURs) 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) - for the active substance “BCG vaccine freeze-dried”, as well as the PSURs submitted in line with the non-PSUSA procedure, were assessed.

48 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:

- 3 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;
- 3 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);
• 35 checks of pharmacovigilance documentation submitted by applicants for administrative validation in the national marketing authorisation procedure;
• 29 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;
• 70 verifications of the authorisation procedure for medicinal products for special needs (ANS)
• 3 documentation checks for the granting of marketing authorisations for medicinal products needed on grounds of public health;
• 18 checks for authorisation and 13 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 pharmacovigilance documentation assessment activity consisted of:

• Evaluation of the pharmacovigilance documentation for the renewal of the MA 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 – 38 validations;
• Evaluation of the pharmacovigilance documentation for the renewal of the MA through the national procedure – 26 procedures;
• Evaluation of the pharmacovigilance documentation in procedures for variation to the terms of the marketing authorisation of medicinal products authorised through European procedures (DCP/MRP/E) with RO-SMI – according to the schedules for the procedures received from the Validation and Administration of the Variations Department of the European Procedures Department;
• One procedure 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;
• 16 procedures for evaluation of the pharmacovigilance documentation in the shared procedure (work-sharing=WS) for variation to the terms of the marketing authorisations of medicinal products authorised through the national procedure;
• 13 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;

Regarding the reduction of risks associated with the use of medicinal products for human use by taking appropriate measures and regulatory actions regarding safety, 63 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 16 responses to requests for information related to certain medicinal products or classes of medicinal products, received from other member states.
In 2023, the NAMMDR, through the Pharmacovigilance and Risk Management Directorate, assessed, approved and published 22 communications to healthcare professionals of the direct healthcare professional communication (DHPC) type regarding medicinal product safety aspects, 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 Medical Devices Regulation and 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 2023, as shown in the table below:

Romanian manufacturers	2023	Total
Registered in line with the MDR	25	59 (2021-2023)
Registered in line with the MDD	3	332 (2013-2023)

Authorised representatives	**2023**	**Total**
Registered in line with the MDR	1	3 (2021-2023)
Registered in line with the MDD	0	33 (2013-2023)

In order to verify the compliance and validity of the documents from the files registered with the NAMMDR, the information related to the registrations made by economic agents in the Eudamed 2 European database for medical devices was viewed on a permanent basis.
In 2023, 118 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:

- 33 manufacturers
- 8 authorised representatives

- 77 importers

Also, during 2023, the following documents were issued by the DRSP:

- 7 waivers from compliance assessment procedures;
- 76 waivers from language requirements;
- 55 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;
- 24 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);
- 61 free sale certificates;
- 24 donation notices;

As regards the conduct of clinical investigations with medical devices and clinical studies assessing the performance of in vitro diagnostic devices, 21 authorisations were issued in 2023 as well as 21 approvals of their subsequent amendments;

The NAMMDR participated in clinical investigations, performance evaluation studies and studies with medical devices used in combination with medicinal products or multinational companion devices (IVD in combination with medicinal products) to increase the quality of clinical outcomes, according to regulations. SR CIC members are following the results of the conducted COMBINE study.

Information notices were also issued in response to frequent requests for information on national legal provisions for the application of the MDR on clinical investigations and the IVDR on clinical performance studies.

In 2023, 3 decisions were also issued to classify borderline products in the medical device category, at the request of manufacturers or authorised representatives.

Details of the DRSP activity in 2023:

Type of activity	**Deadline / Type of activity**	**Number of completed requests**
F1 (registration of custom-made class I, Is medical devices) and F2 (registration of IVD)	30 days	177
Free sale certificates	30 days	61
Customs notices	30 days	24
Out-of-scope notices	30 days	55
Product or border product classification decisions	30 days	3

Clinical Investigation (authorisations/validation addresses/classification of notifications/evaluation of interim and final reports/serious adverse event evaluation, amendments)	maximum 60 days	54
Validations into the EUDAMED		132

Other types of activities	**Deadline / Type of activity**	**Number of completed requests**
Email notifications and responses to petitions and information requests	30 days	592
Email responses to requests for completion of various types of files	30 days	379
Responses to petitions / information requests	30 days	149
Registration and information notices in line with art. 16 of the MDR (F5)	30 days	6
Waivers from compliance assessment procedures (F3)	30 days	7
Exceptions for the translation into Romanian of the information provided by the manufacturer together with the DM (F4)	30 days	76
Approvals for donation	30 days	24
Filing notices	30 days	46

Compared to 2022, the share of works performed in 2023, by type of activity, is shown below:

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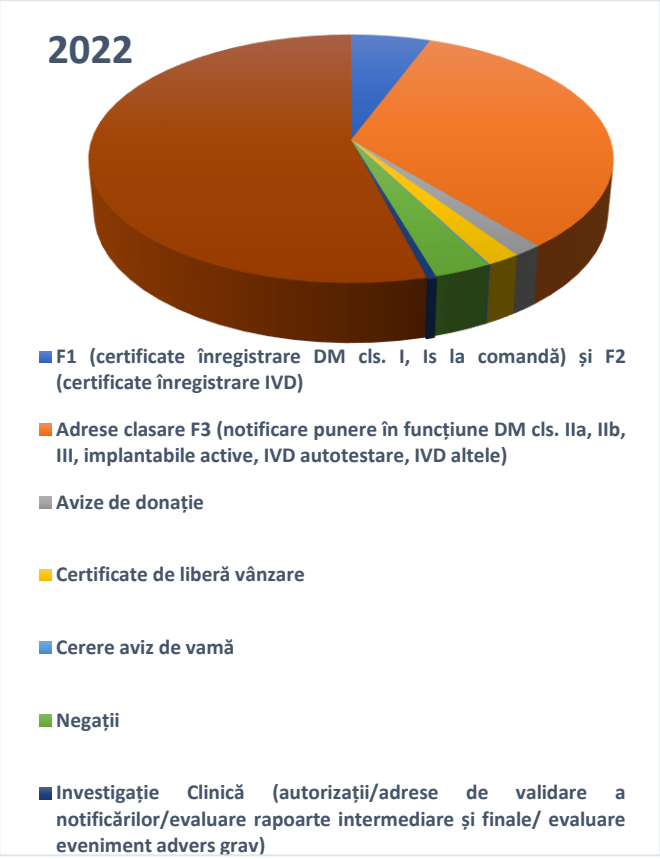

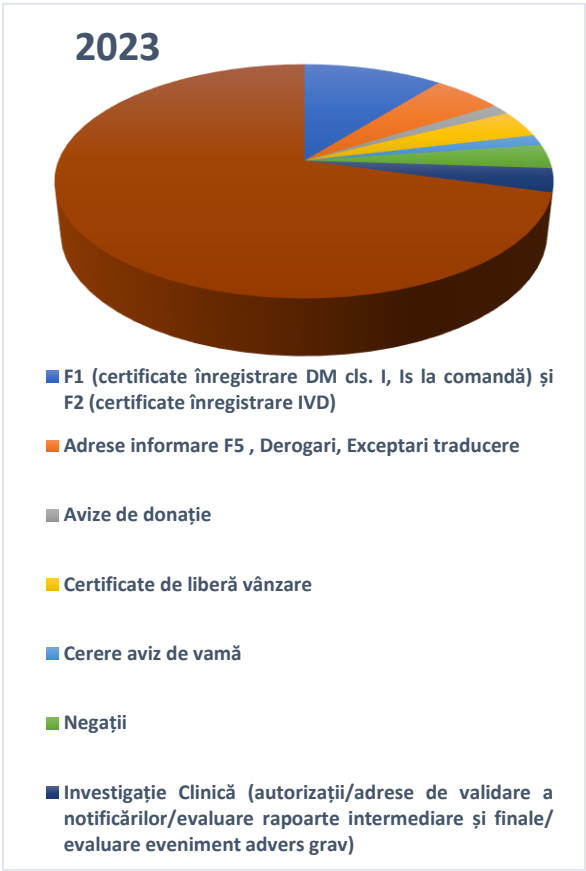

Text captions:

2022

	F1 (certificates for registration of custom-made class I, Is medical devices) and F2 (certificates for registration of IVD)
	F3 filing notices (notifications for commissioning class IIa, IIb, III medical devices, active implantable medical devices, in vitro diagnostic devices for self-testing, other in vitro diagnostic devices)
	Approvals for donation
	Free sale certificates
	Request for customs approval
	Out-of-scope notices
	Clinical Investigation (authorisations/validation addresses/classification of notifications/evaluation of interim and final reports/serious adverse event evaluation, amendments)

2023

	F1 (certificates for registration of custom-made class I, Is medical devices) and F2 (certificates for registration of IVD)
	F5 filing notices, waivers, exceptions for translation
	Approvals for donation
	Free sale certificates
	Request for customs approval
	Out-of-scope notices
	Clinical Investigation (authorisations/validation addresses/classification of notifications/evaluation of interim and final reports/serious adverse event evaluation, amendments)

During 2023, draft methodological regulations were developed for the application of the provisions of Emergency Government 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, as well as for the application of Emergency Government Ordinance no. 137 of 12 October 2022 regarding the establishment of an institutional framework and necessary measures for implementation 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.

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 2023, the NAMMDR, through the market surveillance service, carried out control actions at the premises of 1776 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 the controls, 727 economic operators were sanctioned. 485 warnings and 467 minor fines were applied for a total amount of 1,914,000 lei.

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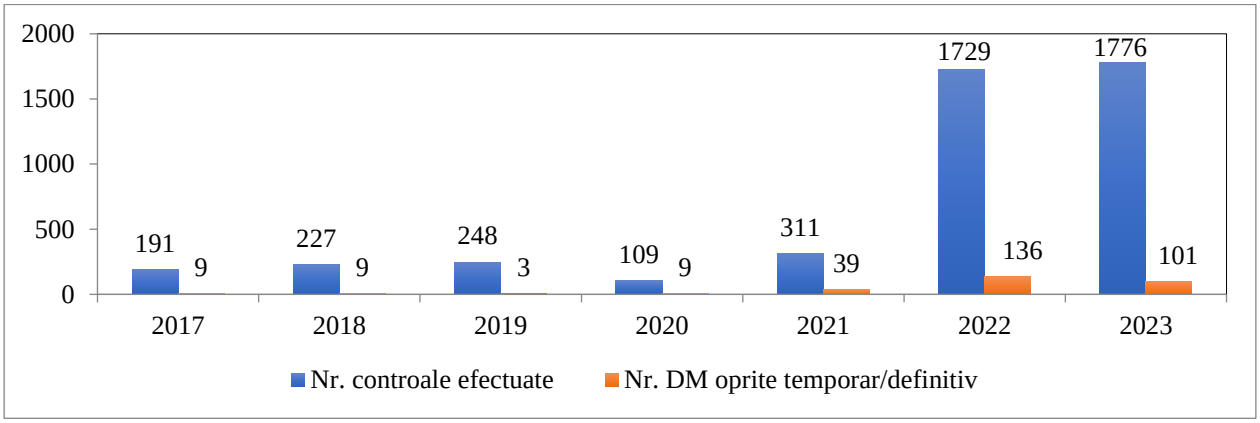
Following the controls performed by inspectors, 100 types of non-compliant medical devices, totalling 43,497 pieces, were identified in 2023. The value of the fines applied for the respective situations was 196,000 lei.

The comparative situation of the controls carried out and noncompliant medical devices (DMs) - 2017-2023



Text caption:

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

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

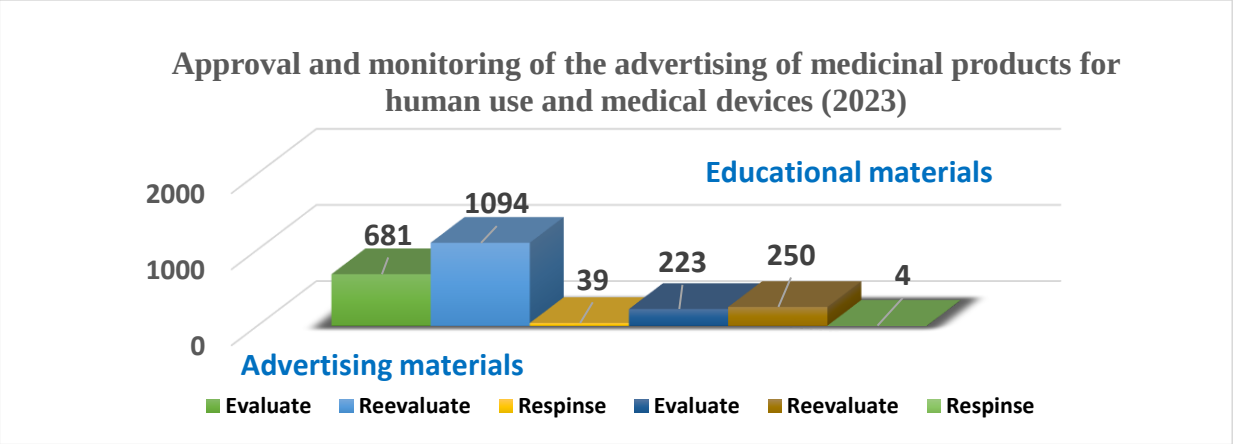
Following the controls carried out in 2023, 25 types of devices were identified, totalling 16,029 pieces, for which elements raising suspicions of counterfeiting were found. In this regard, sanctions totalling 64,000 lei were applied.

In 2023, inspections were also carried out in order to check compliance with legal provisions in the case of medical devices in use. These inspections were carried out at the sites of professional users of medical devices/healthcare facilities, as follows:

- out of 14 hospitals inspected, legal sanctions were applied to 11 of them, with 13 fines totalling 74,000 lei and 19 warnings being applied, the deficiencies found being the lack of maintenance for medical devices in use and the lack of control through periodic verification, according to the legal provisions in force, as well as the existence of medical devices in use, beyond their expiration date;
- out of the 460 dental offices checked, 187 were sanctioned. 182 warnings were applied because control was not ensured through periodic checking of medical devices, according to the provisions of the Order in force, and two legal sanctions with a fine of 10,000 lei each were applied for the same situation. In the case of 22 dental offices, medical devices in use, beyond their validity period (expired), were identified, and 30 legal sanctions with a fine totalling 215,000 lei and the complementary measure of prohibiting the use of expired medical devices were applied. In the case of 9 dental offices, medical devices in use were identified for which maintenance was not ensured according to the legal provisions in force, and in these cases, legal sanctions of 30,000 lei and 2 warnings were applied, as well as the complementary measure of temporary prohibition of use until the non-compliance was solved. In the case of a dental office, it was found that it was using second-hand medical devices for which it had not obtained a special use permit in accordance with the legal provisions in force, issued by the NAMMDR, and was consequently sanctioned with a fine of 5,000 lei and a ban on use until the performance was assessed and the permit was granted by the NAMMDR;
- In the case of controls carried out at 306 clinics/offices/medical centres, 126 warnings and 39 legal sanctions worth 198,000 lei were applied for failure to carry out periodic checks and maintenance for medical devices in use, lack of a register of the medical devices in use and for situations in which expired medical devices in use were found.

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

In 2023, 2291 advertising and educational materials in the field of human medicine and medical devices were registered, of which 681 advertising materials were assessed, 1094 re-assessed and 39 rejected. Regarding educational materials, 223 were evaluated, 250 re-evaluated and 4 rejected, as seen in the chart below:



Text caption:

	Assessed
	Re-assessed
	Rejected
	Assessed
	Re-assessed
	Rejected

Regarding the sponsorship activity of 2023, the Advertising Service centralised the following statements:

- 222 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;
- 6447 sponsorship activity declaration forms by the beneficiaries of sponsorship activities, physicians, nurses, professional organisations, patient organisations and any other type of organization which performs activities related to human health, healthcare or pharmaceuticals in the field of medicinal products for human use;
- 993 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, healthcare or pharmaceuticals in the field of medical devices.

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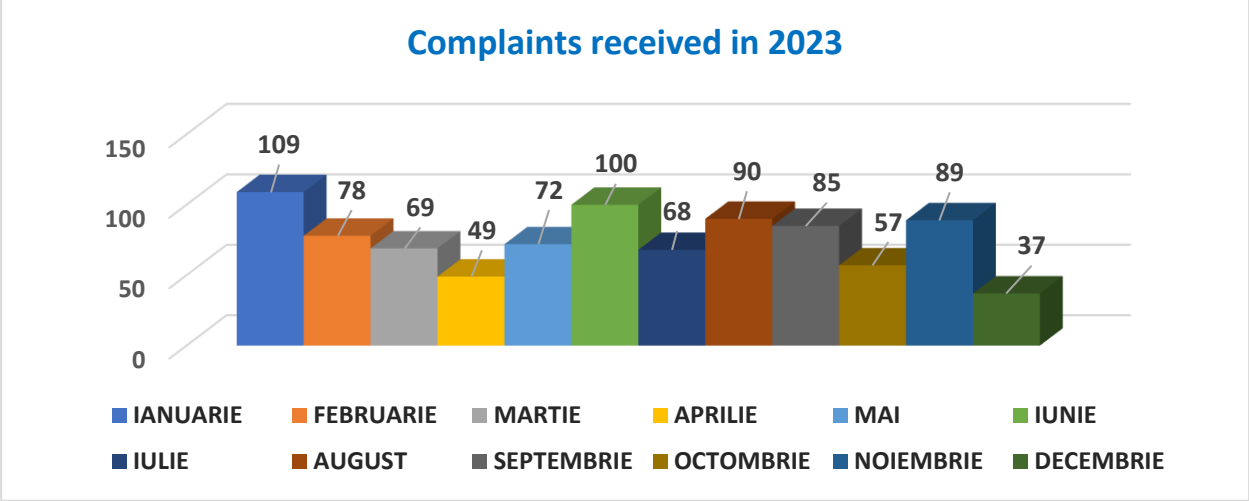
COMMUNICATION AND PUBLIC RELATIONS

Through the communication activity carried out in 2023, 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 2023, 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 2023, 903 complaints were received and solved at lipsamedicament@anm.ro from patients, patients' relatives, hospitals, open circuit and hospital pharmacies, patient associations, pharmaceutical warehouses, as follows (*Complaints received in 2023 by month*):



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

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 Association of Generic Medicines Producers from Romania, 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, the Department for the Relation with

Romanians Abroad (the Department of Romanians Everywhere), the National Authority of Quality Management in Health, etc.).
In 2023, 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 creation 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, a main objective was the facilitation of the communication process 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 2023, as in previous years, the NAMMDR coordinated various international communication campaigns such as MedSafetyWeek, as well as the information campaign regarding the information system for clinical trials (CTIS), on topics such as pharmacovigilance, medicinal product safety or clinical trials, organised by European institutions.
The NAMMDR organised work meetings with patient associations and several discussions with them on various topics, such as the issues faced by Romanian patients with chronic diseases and possible solutions which could be implemented by the Agency in the short and medium term, in collaboration with other health institutions: Consultative meeting between transplant patients, industry representatives and representatives of the Ministry of Health; work meeting with the Romanian Transplant Association and the Hepatitis Patients Association (organisation and coordination).

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

- A workshop for journalists - proactive communication workshop with the Romanian press;
- Media Training on Clinical trials;
- Launch of the Health Innovation Hub at the Palace of Parliament;
- The "Romania: developing a competitive model for clinical trials" workshop.

LOGISTICS, INFORMATION AND ELECTRONIC DATA MANAGEMENT

In 2023, 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:

- administration of the EU Network Training Center - Learning Management System portal;
- management of the database of "IRIS Competent Authority Users" experts within the EMA Account Management Portal, as local administrator;
- managing the database of "SPOR Competent Authority Users" 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.

In 2023, the NAMMDR was represented by specialists in information technology within the European project "Coordination and Harmonization of the Existing Systems against Shortage of Medicines - European Network" (CHESSMEN Code no. 101082419);

INTERNAL AUDIT

In 2023, the Internal Audit Bureau (BAI) 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, with the following purposes:

- to provide a reasonable assurance that they work and that they support the achievement of the proposed objectives and goals.
- formulated recommendations for optimising the functioning of the activities of audited structures in terms of efficiency and effectiveness.

The BAI team took into account the assignment of audit resources in an appropriate manner, to the audits with significant risks, to optimize NAMMDR activities and sub-activities, and saving resources following a risk analysis has been a priority.

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

- the reliability and integrity of operational information;

• the effectiveness and efficiency of the processes/activities/operations specific to the audited structures;

• the safeguarding of the heritage;

• the application of laws, regulations and procedures.

The purpose of the internal public audit missions was to examine the responsibilities assumed by the management of the audited structures and the executive staff regarding the organisation and enforcement of activities and the fulfilment of obligations in an efficient and effective manner.

At NAMMDR level, for the year 2023, according to the Annual Internal Public Audit Plan, 6 system audit missions were planned, as follows:

1. Evaluation of the progress and results of the activities of the Health Technologies Assessment Directorate (DETM) during the period 13.01.2023 – 17.03.2023.
2. Evaluation of the progress and results of the activities of the Information Technology and Communications Service (STIC) during the period 23.03.2023 – 29.05.2023.
3. The Corruption Prevention System, 2023 (SNA) during the period 03.07.2023 – 04.09.2023.
4. Evaluation of the progress and results of the activities of the National Critical Infrastructures Department (CICN) during the period 25.05.2023 – 28.07.2023.
5. Evaluation of the progress and results of the activities of the General Directorate of Pharmaceutical Inspection (DGIF) during the period 16.08.2023 – 20.10.2023;
6. Evaluation of the progress and results of the activities of the Communication and Public Relations Service (SCRP) during the period 16.10.2023 – 20.12.2023.

Following the findings of the internal public audit missions carried out in 2023, recommendations (proposed measures) were made for each structure and the activities carried out were analysed, following the setup of procedures.

The degree of achievement of the Internal Public Audit Plan at NAMMDR level (2023) was 100%.

SECTION III - PRIORITIES FOR 2024

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. Easy access of Romanian patients to medicinal products for human use and to safe and effective medical devices;
2. Finding solutions to the health threats posed by the danger of counterfeit medicinal products for human use and medical devices entering the market;
3. Revising and improving the legislative framework regarding the regulation of the advertising of medicinal products for human use in social media, benefiting the Romanian patient;

4. Digitization of the institution by modernizing and updating the IT system in accordance with technological evolution and current requirements;
5. Increasing collaboration and engagement with stakeholders, international partners and decision-makers and adequate preparation for implementation of new European legislation;
6. Orientation towards strategic projects that ensure the long-term financial sustainability of the Agency;
7. Building trust in regulatory decisions through continuous and transparent communication.

SECTION IV- INSTITUTIONAL TRANSPARENCY

IV.1. INCOMES

1.1. Incomes
The NAMMDR budget approved for 2023 was self-funded (85,348,000 lei) as well as made of revenues from non-reimbursable external projects of 163,000 lei.

1.2. Expenses:
1.2.1 Self-funded expenses: 85,348,000 lei, of which:

- Title 10 – Staff expenses: 59,320,000 lei.
- Title 20 – Expenses on goods and services: 9,908,000 lei.
- Title 58 – Other community programmes (APC) financed between 2021-2027– 49,000 lei
- Title 59 - Amounts for disabled persons: 435,000 lei
- Title 70 – Capital expenses: 15,636,000 lei

1.2.2. Expenses from non-refundable external projects: 163,000 lei

1.3. NAMMDR budget execution:

Receipts: 101,555,846.85 lei

Budgetary expenses: 38.497.661,86 lei, of which:

- Title 10 - Staff expenses: 34,880,841.43 lei
- Title 20 - Expenses on goods and services: 3,018,156.62 lei
- Title 58 - Other community programmes financed between 2021-2027: 70,793.07 lei
- Title 59 - Amounts for disabled persons: 369,654.00 lei
- Title 70 – Capital expenses: 537,861.05 lei
- Title 85 - Payments made in previous years and recovered in the current year: - 379.644,61 lei

IV.2. PUBLIC PROCUREMENT INFORMATION

Number of procurement processes per category (2023):

Negotiation without publishing an add – 6 procurement processes, of which:

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

OPEN AUCTION – 3 procedures/products and services:

- OPEN AUCTION aiming to a framework agreement for a 24-month period, with the focus on international air transport services.
- 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 stationery products and OEM and compatible toner cartridges, split into 2 lots.
- OPEN AUCTION organised and conducted in order to award the "laboratory equipment" supply contract, divided into 12 lots.

Procurement processes through own procedure – 20 procedures, of which:

- Own procedure for the purpose of a framework agreement for a 24-month period, organised and carried out for the award of subsequent contracts having as object HOTEL SERVICES (online and offline) - 1 piece;
- Own procedures carried out online and offline with the aim of awarding the public procurement contract(s) for professional training services - 19 pieces.

Direct purchases:

- Direct purchases (products) - 112 processes.
- Direct purchases (services) - 228 processes.
- Direct purchases (works) - 2 processes.

Purchases made through the electronic system out of the total purchases carried out during the reporting calendar year:

- OPEN AUCTION - 3 procedures.
- Own procedure - 20 procedures.
- Online direct purchases - 160 direct purchases of products/services/works.

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

There were no appeals filed with the National Council for the Resolution of Disputes.

Procedures cancelled or in cancellation procedure: - 10 procedures:

- 5 award procedures - Negotiation without publication of an announcement, carried out through the Romanian Commodity Exchange, having as object the supply of electricity (1 piece), respectively natural gas (4 pieces) for the premises under the administration of the NAMMDR - no offers were submitted;
- 5 own procedures having as object professional training services - (no offers were submitted / non-compliant offers were submitted, as well as taking into account the provisions of art. I – (1), letter f) of Emergency Government Ordinance no. 90/2023 on approval of the measures to reduce budgetary expenditures for 2023 in order to meet the budget deficit target assumed by the Convergence Program, as well as for the amendment and supplementation of certain regulatory documents, starting with 27.10.2023, the date of entry into force of the aforementioned regulatory document, public authorities and institutions cannot conclude legal commitments for the categories of expenses provided for in the article referring to the budgetary expenditure for professional training).

Detailed information on public procurements carried out in 2023 is available online: https://www.anm.ro/informatii-de-interes-public/.

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

There were 578 litigations in which the NAMMDR was involved between January and December 2023, 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. The NAMMDR structure consists of 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-use medical devices, approval of activities in the field of medical devices can be organised, as well as control through periodic check of medical devices, observing the maximum number of positions approved, namely 500 positions.

On 01.01.2023, there were 345 employees, 340 by the end of 2023, as follows:

- Number of approved positions: 500
- Number of positions occupied by 01.12.2023: 340
- Number of vacant positions by 01.12.2023: 160
- Average number of remunerated positions by 01.12.2023: 325

In 2023, 31 hires were made, as follows:

• 1 contractual management position filled through secondment;
• 30 contractual execution positions filled through competition;
- 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 2023, there were 35 terminations of activity, as follows:

• 3 management contractual positions terminated by agreement of the parties

• 10 executive contractual positions terminated by agreement of the parties;

• 1 executive contractual position terminated by transfer upon request;

• 1 executive contractual position terminated by death of the employee;

- 16 executive contractual positions terminated on the date of cumulative fulfilment of the standard age conditions and the minimum contribution period for retirement;
- 4 executive contractual position terminated by resignation.

Management positions exercised on a temporary basis in 2023:

- 25 contractual leadership positions exercised on a temporary basis;

Number of competitions organised in 2023:

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

- 6 competitions for the occupation of 33 vacant contract execution positions of physicians (0 were filled);
- 5 competitions for the occupation of 145 vacant contract execution positions (30 were filled, of which 9 – pharmacy and 21 – other specialties).

The staff turnover rate in 2023 was 10.29%.

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 ACCORDANCE WITH LAW 544/2001, AS FURTHER AMENDED AND SUPPLEMENTED

In 2023, according to Law no. 544/2001 on free access to information of public interest by media representatives, 100 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, in terms of amendments of legislation, shall be a main objective of the Agency in the coming period.

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

With regard to the legislative activity, in 2023, 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 and supplementation of some regulatory documents in the field of medical devices and in vitro diagnostic medical devices**, which has become Order of the Minister of Health no. 3876/2023, published in the Official Gazette of Romania no. 1061 of 24 November 2023;
2. **The draft Order on approval of the methodological rules on clinical evaluation and clinical investigations with medical devices and for repeal of Order of the Minister of Public Health no. 792/2006 regarding the conduct of the clinical investigation procedure and the performance evaluation procedure for medical devices**, which has become Order of the Minister of Health no. 330/2023, published in the Official Gazette of Romania no. 120 of 13 February 2023;
3. **The draft Order on approval of the methodological rules on clinical evidence, evaluation of the performance and studies related to the performance of in vitro diagnostic medical devices,** which are on the approval circuit;
4. **The draft Order on amendment of Order of the Minister of Health no. 3969/2022 on approval of the Methodological Rules for assessment, designation and notification of the bodies assessing medical device compliance, as well as for monitoring and reassessment of notified bodies**, which has become Order of the Minister of Health no. 3277/2023, published in the Official Gazette of Romania no. 887 of 3 October 2023;
5. **The draft Order on amendment of the Rules for implementation of provisions of Article 883 of Law 95/2006 on healthcare reform regarding the authorisation for marketing of some medicinal products needed on grounds of public health, approved through Order of the Minister of Health no. 1.540/2021**, which has become Order of the Minister of Health no. 1355/2023, published in the Official Gazette of Romania no. 335 of 21 April 2023;
6. **The draft Order on approval of the procedure regarding medical devices and in vitro diagnostic medical devices manufactured and used only within healthcare institutions,** which is in the approval circuit;
7. **The draft Order on amendment of Annexes 1 - 3 to Order of the Minister of Health no. 861/2014 for 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 programmes, as well as the means for appeal thereof**, which has become Order of the

Minister of Health no. 1356/2023, published in the Official Gazette of Romania no. 364 of 28 April 2023;

8. The draft Order on approval of the List of Romanian standards adopting harmonised European standards in the field of medical devices falling under the scope of Regulation (EU) 2017/745, and of the List of Romanian standards adopting harmonised European standards in the field of in vitro medical devices falling under the scope of Regulation (EU) 2017/746, which has become Order of the Minister of Health no. 3362/2023, published in the Official Gazette of Romania no. 906 of 9 October 2023;

9. The draft Order on approval of the methodological rules for placement on the market of medical devices and registration of economic operators into the European database on medical devices (EUDAMED), as well as into the national database, and on waiver from compliance assessment procedures, which has become Order of the Minister of Health no. 3753/2023, published in the Official Gazette of Romania no. 1033 of 14 November 2023;

10. The draft Order on approval of the procedure for taking over and destroying confiscated medicinal products, which is on the approval circuit.

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***Annex to the NAMMDR 2023 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 și 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	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