

*ROMANIA*

*Newsletter*

**Year 27, No. 2 (106), 2<sup>nd</sup> quarter of 2025**

*National Agency  
for Medicines and Medical Devices  
of Romania*

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ISSN 1583-347X

The Newsletter of the National Agency for Medicines and Medical Devices of Romania contains information of public interest communicated ex officio, provided in Article 5 paragraph 2 of Law no. 544/2001:

**a) Ruling provisions regulating the organisation and operation of the NAMMDR are the following:**

Law no. 134 of 12 July 2019 on reorganisation of the National Agency for Medicines and Medical Devices and amendment of further ruling provisions, as further amended and supplemented;

Order no. 1412 of 13 September 2019 on approval of the organisational structure of the National Agency for Medicines and Medical Devices of Romania;

Order no. 1522 of 9 October 2019 on approval of the Regulation for organisation and operation of the National Agency for Medicines and Medical Devices of Romania;

Order of the Minister of Health no. 2318/2021 on approval of the organisational structure of the National Agency for Medicines and Medical Devices of Romania;

Order of the Minister of Health no. 857/2022 on approval of the Regulation for the organisation and operation of the National Agency for Medicines and Medical Devices of Romania;

Order of the Minister of Health no. 3994 of 2024 on approval of the organisational structure of the National Agency for Medicines and Medical Devices of Romania.

**b) The public institution's organisation chart, attributions of each department, working programme, audience programme:**

Order of the Minister of Health no. 3994 of 2024 on approval of the organisational structure of the National Agency for Medicines and Medical Devices of Romania

Regulation for organisation and operation of the National Agency for Medicines and Medical Devices of Romania

**c) Names and surnames of the persons of the public institution's management, responsible for the dissemination of public information**

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**(published in the Official Gazette of Romania no. 454 of 16 May 2025)**

Law 46/2025 on amendment of paragraph (2) of Article 34 of Patients' Rights Law 46/2003.  
**(published in the Official Gazette of Romania no. 327 of 11 April 2025)**

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**(published in the Official Gazette of Romania no. 351 of 22 April 2025)**

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**(published in the Official Gazette of Romania no. 327 of 11 April 2025)**

Government Decision no. 25/2025 on amendment of the procedure for approval of independent practice offices for public services related to the medical act of physiotherapy and physiotherapy activities, approved through Decision of the National Council of the College of Physiotherapists of Romania no. 63/2023.  
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- Moving forward together: a simpler, faster and more ambitious Union – COM(2025) 45 final;  
**(published in the Official Gazette of Romania no. 397 of 5 May 2025)**

## **Orders**

Order of the President of the National Health Insurance House no. 835/2025 on amendment and supplementation of Order of the President of the National Health Insurance House no. 563/2023 on approval of supporting documents regarding the reporting of the activity carried out by providers of medical services and medicinal products – unique forms per country, without special regime  
**(published in the Official Gazette of Romania no. 611 of 30 June 2025)**

Order of the Minister of Health no. 2.157/2025 on amendment and supplementation of Annexes 1 and 2 la Order of the Minister of Health no. 5.994/2024 on approval of the maximum prices of medicinal products for human use, valid in Romania, which can be used/marketed by Marketing Authorisation Holders of medicinal products or their representatives, wholesale distributors and providers of medical services and medicinal products for those medicinal products subject to a contractual relationship with the Ministry of Health, health insurance houses and/or county public health departments and the public health department of Bucharest, included in the National Catalogue of prices of medicinal products authorised for marketing in Romania, of reference prices of generic and innovative medicinal products;  
**(published in the Official Gazette of Romania no. 602 of 27 June 2025)**

Order of the Minister of Health no. 2.103/2025 on amendment of Annex 1 to Order of the Minister of Health no. 5.994/2024 on approval of the maximum prices of medicinal products for human use, valid in Romania, which can be used/marketed by Marketing Authorisation Holders of medicinal products or their representatives, wholesale distributors and providers of medical services and medicinal products for those medicinal products subject to a contractual relationship with the Ministry of Health, health insurance houses and/or county public health departments and the public health department of Bucharest, included in the National Catalogue of prices of medicinal products authorised for marketing in Romania, of reference prices of generic and innovative medicinal products; **(published in the Official Gazette of Romania no. 601 of 27 June 2025)**

Order of the Minister of Health and of the President of the National Health Insurance House no. 1.981/836/2025 on amendment of Annexes 1 and 2 to Order of the Minister of Health and of the President of the National Health Insurance House no. 564/499/2021 on approval of 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;  
**(published in the Official Gazette of Romania no. 599 of 27 June 2025)**

Order of the Minister of Health no. 2.105/2025 on amendment of the Annex to Order of the Minister of Health no. 2.494/2023 on approval of the maximum prices of medicinal products for human use valid in Romania which can be used/marketed solely by community pharmacies/local distribution offices/closed-circuit pharmacies and drugstores that are not in a contractual relationship with health insurance houses and/or county public health departments and the Bucharest public health department or/and with the Ministry of Health, included in the Public Catalogue  
**(published in the Official Gazette of Romania no. 596 of 26 June 2025)**

Order of the Minister of Health no. 2.104/2025 on amendment of Annex 1 to Order of the Minister of Health no. 5.994/2024 on approval of the maximum prices of medicinal products for human use, valid in Romania, which can be used/marketed by Marketing Authorisation Holders of medicinal products or their representatives, wholesale distributors and providers of medical services and medicinal products for those medicinal products subject to a contractual relationship with the Ministry of Health, health insurance houses and/or county public health departments and the public health department of Bucharest, included in the National Catalogue of prices of medicinal products authorised for marketing in Romania, of reference prices of generic and innovative medicinal products;  
**(published in the Official Gazette of Romania no. 588 of 24 June 2025)**

Order of the Minister of Health no. 1.833/2025 on supplementation of Order of the Minister of Health no. 5/2020 on approval of the administration, financing and implementation of priority actions for the monitoring, treatment and care of critical patients in adult/child ICU and neonatal intensive care units;  
**(published in the Official Gazette of Romania no. 579 of 23 June 2025)**

Order of the Minister of Health no. 1.786/2025 on amendment and supplementation of Order of the Minister of Health no. 63/2024 on the regulation of the methodology for monitoring the prescription and release at national level of medicinal products considered antibiotics and antifungals for systemic use;  
**(published in the Official Gazette of Romania no. 578 of 23 June 2025)**

Order of the Minister of Health no. 1.866/2025 on amendment and supplementation of Annex 1 to Order of the Minister of Health no. 5.994/2024 on approval of the maximum prices of medicinal products for human use, valid in Romania, which can be used/marketed by Marketing Authorisation Holders of medicinal products or their representatives, wholesale distributors and providers of medical services and medicinal products for those medicinal products subject to a contractual relationship with the Ministry of Health, health insurance houses and/or county public health departments and the public health department of Bucharest, included in the National

Catalogue of prices of medicinal products authorised for marketing in Romania, of reference prices of generic and innovative medicinal products;  
**(published in the Official Gazette of Romania no. 571 of 19 June 2025)**

Annex to Order of the Minister of Health no. 1.838/2025 on amendment and supplementation of the Annex to Order of the Minister of Health no. 2.494/2023 on approval of the maximum prices of medicinal products for human use valid in Romania which can be used/marketed solely by community pharmacies/local distribution offices/closed-circuit pharmacies and drugstores that are not in a contractual relationship with health insurance houses and/or county public health departments and the Bucharest public health department or/and with the Ministry of Health, included in the Public Catalogue;  
**(published in the Official Gazette of Romania no. 567bis of 19 June 2025)**

Order of the Minister of Health no. 1.838/2025 on amendment and supplementation of the Annex to Order of the Minister of Health no. 2.494/2023 on approval of the maximum prices of medicinal products for human use valid in Romania which can be used/marketed solely by community pharmacies/local distribution offices/closed-circuit pharmacies and drugstores that are not in a contractual relationship with health insurance houses and/or county public health departments and the Bucharest public health department or/and with the Ministry of Health, included in the Public Catalogue;  
**(published in the Official Gazette of Romania no. 567 of 19 June 2025)**

Order of the Minister of Health no. 1.837/2025 on supplementation of Order of the Minister of Health no. 368/2017 on approval of Rules on the method for calculation and procedure for approval of maximum prices of medicinal products for human use;  
**(published in the Official Gazette of Romania no. 565 of 18 June 2025)**

Annexes 1-9 la Order of the President of the National Health Insurance House no. 762/2025 on amendment and supplementation of Annex 1 to Order of the President of the National Health Insurance House no. 141/2017 on approval of specific forms for verifying compliance with the eligibility criteria related to therapeutic protocols for medicinal products ranked (\*\*) $1$ , (\*\*) $1\Omega$  and (\*\*) $1\beta$  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, approved through Government Decision no. 720/2008, as further amended and supplemented, and of the methodology for transmitting them to the health insurance IT platform;  
**(published in the Official Gazette of Romania no. 560bis of 17 June 2025)**

Order of the President of the National Health Insurance House no. 762/2025 on amendment and supplementation of Annex 1 to Order of the President of the National



Health Insurance House no. 141/2017 on approval of specific forms for verifying compliance with the eligibility criteria related to therapeutic protocols for medicinal products ranked (\*\*)<sup>1</sup>, (\*\*)<sup>1</sup> $\Omega$  and (\*\*)<sup>1</sup> $\beta$  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, approved through Government Decision no. 720/2008, as further amended and supplemented, and of the methodology for transmitting them to the health insurance IT platform; **(published in the Official Gazette of Romania no. 560 of 17 June 2025)**

Order of the Deputy Prime Minister, the Minister of Internal Affairs and the Minister of Health No. 74/1.626/2025 on approval of the Index of emergency medical stock products and of the Methodology for use, removal, free use, replenishment and refreshment of emergency medical stock products **(published in the Official Gazette of Romania no. 551 of 16 June 2025)**

Order of the Minister of Health and of the President of the National Health Insurance House no. 1.717/726/2025 on amendment and supplementation of Annex 2 to Order of the Minister of Health and of the President of the National Health Insurance House no. 1.605/875/2014 on approval of the calculation method, the list of trade names and reimbursement prices of medicinal products provided to patients within national health programmes and the methodology for their calculation; **(published in the Official Gazette of Romania no. 537 of 11 June 2025)**

Annex to Order of the Minister of Health no. 1.686/2025 for enforcement during the first quarter of 2025 of provisions of Art. 38 of Emergency Government Ordinance no. 77/2011 regarding the establishment of some contributions for financing some expenses in the healthcare field; **(published in the Official Gazette of Romania no. 530bis of 6 June 2025)**

Order of the Minister of Health no. 1.686/2025 for enforcement during the first quarter of 2025 of provisions of [Art. 38 of Emergency Government Ordinance no. 77/2011](#) regarding the establishment of some contributions for financing some expenses in the healthcare field; **(published in the Official Gazette of Romania no. 530 of 6 June 2025)**

Order of the Minister of Health no. 1.644/2025 on supplementation of the Technical Rules for the implementation of national public health programmes, approved through Order of the Minister of Health no. 964/2022; **(published in the Official Gazette of Romania no. 516 of 5 June 2025)**

Order of the Minister of Health no. 1.617/2025 on amendment and supplementation of Annexes 1 and 2 to Order of the Minister of Health no. 5.994/2024 on approval of the maximum prices of medicinal products for human use, valid in Romania, which can be used/marketed by Marketing Authorisation Holders of medicinal products or

their representatives, wholesale distributors and providers of medical services and medicinal products for those medicinal products subject to a contractual relationship with the Ministry of Health, health insurance houses and/or county public health departments and the public health department of Bucharest, included in the National Catalogue of prices of medicinal products authorised for marketing in Romania, of reference prices of generic and innovative medicinal products; **(published in the Official Gazette of Romania no. 516 of 3 June 2025)**

Annex to Order of the Minister of Health and of the President of the National Health Insurance House no. 1.612/712/2025 on amendment 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; **(published in the Official Gazette of Romania no. 508bis of 30 May 2025)**

Order of the Minister of Health and of the President of the National Health Insurance House no. 1.612/712/2025 on amendment 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; **(published in the Official Gazette of Romania no. 508 of 30 May 2025)**

Order of the President of the National Health Insurance House no. 753/2025 on amendment and supplementation of Technical norms for the implementation of national curative health programs, approved through [Order of the President of the National Health Insurance House no. 180/2022](#); **(published in the Official Gazette of Romania no. 502 of 29 May 2025)**

Annex to Order of the Minister of Health no. 1.599/2025 on amendment of [the Annex to Order of the Minister of Public Health no. 1.344/2006](#) on approval of the National list of medical experts; **(published in the Official Gazette of Romania no. 494bis of 27 May 2025)**

Order of the Minister of Health no. 1.599/2025 on amendment of the Annex to Order of the Minister of Public Health no. 1.344/2006 on approval of the National list of medical experts;  
**(published in the Official Gazette of Romania no. 494 of 27 May 2025)**

Order of the Minister of Health no. 1424/2025 on amendment and supplementation of [the Annex to Order of the Minister of Health no. 2.494/2023](#) on approval of the maximum prices of medicinal products for human use, valid in Romania, which can be used/marketed by Marketing Authorisation Holders of medicinal products or their representatives, wholesale distributors and providers of medical services and medicinal products for those medicinal products not subject to a contractual relationship with the Ministry of Health, health insurance houses and/or county public health departments and the public health department of Bucharest, included in the National Catalogue of prices;  
**(published in the Official Gazette of Romania no. 475 of 22 May 2025)**

Order of the Minister of Health no. 1.524/2025 on supplementation of [Annex 1 to Order of the Minister of Health no. 5.994/2024](#) on approval of the maximum prices of medicinal products for human use, valid in Romania, which can be used/marketed by Marketing Authorisation Holders of medicinal products or their representatives, wholesale distributors and providers of medical services and medicinal products for those medicinal products subject to a contractual relationship with the Ministry of Health, health insurance houses and/or county public health departments and the public health department of Bucharest, included in the National Catalogue of prices of medicinal products authorised for marketing in Romania, of reference prices of generic and innovative medicinal products;  
**(published in the Official Gazette of Romania no. 471 of 21 May 2025)**

Order of the Minister of Health and of the President of the National Health Insurance House no. 1.425/664/2025 on amendment and supplementation of [Annex 2 to Order of the Minister of Health and of the President of the National Health Insurance House no. 1.605/875/2014](#) on approval of the calculation method, the list of trade names and reimbursement prices of medicinal products provided to patients within national health programmes and the methodology for their calculation;  
**(published in the Official Gazette of Romania no. 454 of 16 May 2025)**

Order of the Minister of Health no. 216/2025 on amendment and supplementation of the Annex to Order of the Minister of Health no. 607/2019 on approval of the list of vaccines purchased under national health programmes for which quarterly contributions are not due, calculated in line with Emergency Government Ordinance no. 77/2011 on the establishment of contributions for the financing of certain expenses in the healthcare field;  
**(published in the Official Gazette of Romania no. 430 of 9 May 2025);**

Order of the Minister of Health no. 1.289/2025 on amendment of Order of the Minister of Health no. 1.473/2018 on setup of the framework for implementation of provisions of Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed implementation rules for the features appearing on the packaging of medicinal products for human use; **(published in the Official Gazette of Romania no. 422 of 8 May 2025);**

Order of the Minister of Health no. 1.296/2025 on amendment and supplementation of Annexes 1 and 2 to Order of the Minister of Health no. 5.994/2024 on approval of the maximum prices of medicinal products for human use, valid in Romania, which can be used/marketed by Marketing Authorisation Holders of medicinal products or their representatives, wholesale distributors and providers of medical services and medicinal products for those medicinal products subject to a contractual relationship with the Ministry of Health, health insurance houses and/or county public health departments and the public health department of Bucharest, included in the National Catalogue of prices of medicinal products authorised for marketing in Romania, of reference prices of generic and innovative medicinal products; **(published in the Official Gazette of Romania no. 402 of 6 May 2025)**

Order of the President of the National Tax Administration Agency no. 8.541/2025 on repeal of Order of the President of the National Tax Administration Agency no. 1.194/2016 on approval of Technical rules for the use of the Export Control System; **(published in the Official Gazette of Romania no. 362 of 24 April 2025)**

Order of the President of the National Health Insurance House no. 597/2025 on amendment and supplementation of Annex 1 to Order of the President of the National Health Insurance House no. 141/2017 on approval of specific forms for verifying compliance with the eligibility criteria related to therapeutic protocols for medicinal products ranked (\*\*)<sub>1</sub>, (\*\*)<sub>1Ω</sub> and (\*\*)<sub>1β</sub> into the List of International Non-proprietary Names of on-prescription medicinal products as provided to insurants, irrespective of personal contribution, in the frame of the health insurance system, as well as of International Non-proprietary Names of medicinal products provided in national health insurance programs, approved through Government Decision no. 720/2008, as further amended and supplemented, and of the methodology for transmitting them to the health insurance IT platform; **(published in the Official Gazette of Romania no. 362 of 24 April 2025)**

Annexes 1-8 to Order of the President of the National Health Insurance House no. 597/2025 on amendment and supplementation of Annex 1 to Order of the President of the National Health Insurance House no. 141/2017 on approval of specific forms for verifying compliance with the eligibility criteria related to therapeutic protocols for medicinal products ranked (\*\*)<sub>1</sub>, (\*\*)<sub>1Ω</sub> and (\*\*)<sub>1β</sub> into the List of International Non-proprietary Names of on-prescription medicinal products as provided to insurants, irrespective of personal contribution, in the frame of the health insurance system, as well as of International Non-proprietary Names of medicinal products

provided in national health insurance programs, approved through Government Decision no. 720/2008, as further amended and supplemented, and of the methodology for transmitting them to the health insurance IT platform; **(published in the Official Gazette of Romania no. 362bis of 24 April 2025)**

Order of the President of the National Health Insurance House no. 549/2025 on amendment and supplementation of [Order of the President of the National Health Insurance House no. 516/2023](#) on approval of the rules for confirmation from the viewpoint of clinical and medical data at patient level for cases hospitalised in continuous and day hospitalisation, as well as the methodology for evaluating unconfirmed cases from the viewpoint of clinical and medical data for which reconfirmation is requested; **(published in the Official Gazette of Romania no. 343 of 16 April 2025)**

Order of the Minister of Health and of the President of the National Health Insurance House no. 1.118/509/2025 on amendment of Annexes 1 and 2 to Order of the Minister of Health and of the President of the National Health Insurance House no. 735/976/2018 regarding the contract model, the methodology for negotiation, conclusion and monitoring of the implementation and execution of cost-volume/cost-volume-result contracts; **(published in the Official Gazette of Romania no. 341 of 16 April 2025)**

Order of the Minister of Health and of the President of the National Health Insurance House no. 1.065/575/2025 on amendment of [Annexes 1 and 2 to Order of the Minister of Health and of the President of the National Health Insurance House no. 564/499/2021](#) on approval of 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; **(published in the Official Gazette of Romania no. 333 of 14 April 2025)**

Order of the Minister of Health no. 1.148/2025 on amendment and supplementation of [Annex 1 to Order of the Minister of Health no. 5.994/2024](#) on approval of the maximum prices of medicinal products for human use, valid in Romania, which can be used/marketed by Marketing Authorisation Holders of medicinal products or their representatives, wholesale distributors and providers of medical services and medicinal products for those medicinal products subject to a contractual relationship with the Ministry of Health, health insurance houses and/or county public health departments and the public health department of Bucharest, included in the National Catalogue of prices of medicinal products authorised for marketing in Romania, of reference prices of generic and innovative medicinal products; **(published in the Official Gazette of Romania no. 332 of 14 April 2025)**

Order of the Minister of Health and of the President of the National Health Insurance House no. 1.080/538/2025 on amendment and supplementation of Annex 2 to Order of the Minister of Health and of the President of the National Health Insurance House no. 1.605/875/2014 on approval of the calculation method, the list of trade names and reimbursement prices of medicinal products provided to patients within national health programmes and the methodology for their calculation;  
**(published in the Official Gazette of Romania no. 316 of 9 April 2025)**

Order of the Minister of Health no. 941/2025 on repeal of Art. 2 of Order of the Minister of Health no. 1.584/2023 on approval of Specific rules for the organisation and operation of teleradiology;  
**(published in the Official Gazette of Romania no. 285 of 1 April 2025)**

Annexes 1-3 to Order of the Minister of Health and of the President of the National Health Insurance House no. 1.018/528/2025 on amendment of Methodological Rules for enforcement of Government Decision no. 521/2023 on approval of service packages and the Framework Contract regulating the conditions for provision of medical assistance, medicinal products and medical devices within the social health insurance system, approved through Order of the Minister of Health and of the President of the National Health Insurance House no. 1.857/441/2023;  
**(published in the Official Gazette of Romania no. 284bis of 1 April 2025)**

Order of the Minister of Health and of the President of the National Health Insurance House no. 1.018/528/2025 on amendment of Methodological Rules for enforcement of Government Decision no. 521/2023 on approval of service packages and the Framework Contract regulating the conditions for provision of medical assistance, medicinal products and medical devices within the social health insurance system, approved through Order of the Minister of Health and of the President of the National Health Insurance House no. 1.857/441/2023;  
**(published in the Official Gazette of Romania no. 284 of 1 April 2025)**

Order of the Minister of Health no. 955/2025 on amendment and supplementation of the Annex to Order of the Minister of Health no. 2.494/2023 on approval of the maximum prices of medicinal products for human use valid in Romania which can be used/marketed solely by community pharmacies/local distribution offices/closed-circuit pharmacies and drugstores that are not in a contractual relationship with health insurance houses and/or county public health departments and the Bucharest public health department or/and with the Ministry of Health, included in the Public Catalogue  
**(published in the Official Gazette of Romania no. 283 of 1 April 2025)**

## **Decisions**

Decision of the National Council of the Romanian College of Pharmacists no. 1/2025 on amendment and supplementation of Decision of the National Council of the Romanian College of Pharmacists no. 5/2021 on approval of the procedure for control and evaluation of pharmaceutical units with regard to the Rules of Good Pharmaceutical Practice **(published in the Official Gazette of Romania no. 557 of 17 June 2025)**

Decision of the Romanian College of Dentists no. 2/2CN/2025 on the Minimal Dental Emergency Kit **(published in the Official Gazette of Romania no. 292 of 3 April 2025)**

## **Regulations**

Commission Implementing Regulation (EU) 2025/1234 of 25 June 2025 amending Implementing Regulation (EU) 2021/2226 as regards the medical devices for which the instructions for use may be provided in electronic form



## Medicinal product batches recalled during the 2<sup>nd</sup> quarter of 2025

No.	Product recalled	Pharmaceutical form	Strength	INN	Manufacturer/MAH/parallel import authorisation holder	Batch	Grounds for recall	Proposed action	Date of recall
1	Gripoff granules for oral solution in sachets	Granules for oral solution	500mg/200mg/4mg	Paracetamolum+ Acidum ascorbicum+ Chlorphenaminum	S.C. Slavia Pharm S.R.L., Romania	230943/exp. 06.2025	Out-of-specification outcomes	Withdrawal upon NAMMDR request	07.04.2025
2	Onglyza 5 mg film-coated tablets	Film-coated tablets	5 mg	Saxagliptinum	AstraZeneca AB, Sweden		Expiry of the validity of the maximum price in the National Catalogue of the Prices of Medicinal Products Authorised for Marketing in Romania (also known as the CANAMED).	Voluntary withdrawal	28.05.2025



## Applications for marketing authorisation/marketing authorisation renewal received during the 1<sup>st</sup> quarter of 2025

**15** marketing authorisation/marketing authorisation renewal applications for medicinal products have been received during the 1<sup>st</sup> quarter of 2025, corresponding to the following therapeutic groups:

<b>AUTHORISATION</b>	<b>RENEWAL</b>
R06 - ANTIHISTAMINES FOR SYSTEMIC USE	M01 – ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS
B01 – ANTITHROMBOTIC AGENTS	M02 – TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN
B01 – ANTITHROMBOTIC AGENTS	A02 - DRUGS FOR ACID RELATED DISORDERS
B01 – ANTITHROMBOTIC AGENTS	A02 - DRUGS FOR ACID RELATED DISORDERS
B01 – ANTITHROMBOTIC AGENTS	A07 - ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTI-INFECTIVE AGENTS
B01 – ANTITHROMBOTIC AGENTS	M01 - ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS
	V03 – ALL OTHER THERAPEUTIC PRODUCTS
	N02 - ANALGESICS
	G04 – UROLOGICALS

## Medicinal products authorised for marketing during the 1<sup>st</sup> quarter of 2025

No.	INN	Trade name	Pharmaceutical form	Strength	MAH	Holding country	MA no.	
1	OLOPATADINUM	OLOPATADINA ROMPHARM 1 mg/ml	eye drops, solution	1mg/ml	ROMPHARM COMPANY S.R.L.	ROMANIA	1590	2025
2	ERTAPENEMUM	ERTAPENEM ATB 1 g	powder for concentra solution for infusion	1g	ANTIBIOTICE S.A.	ROMANIA	1590	2025
3	EPLERENONUM	APLERIA 25 mg	film-coated tablets	25mg	KRKA, D.D., NOVO MESTO	SLOVENIA	1583	2025
4	EPLERENONUM	APLERIA 50 mg	film-coated tablets	50mg	KRKA, D.D., NOVO MESTO	SLOVENIA	1583	2025
5	FULVESTRANTUM	FULVESTRANT EVER PHARMA 250 mg	solution for injection in pre-filled syringe	250mg	EVER VALINJECT GMBH	AUSTRIA	1589	2025
6	SUFENTANILUM CITRATUM	SOFENTIL 5 micrograms/ml	solution for injection/infusion	5 micrograms/ ml	MEDOCHEMIE LTD.	CYPRUS	1593	2025
7	SUFENTANILUM CITRATUM	SOFENTIL 50 micrograms/ml	solution for injection/infusion	50 micrograms/ ml	MEDOCHEMIE LTD.	CYPRUS	1593	2025
8	AMOROLFINUM	EXODERIL SET 50 mg/ml	medicated nail polish	50 mg/ml	SANDOZ PHARMACEUTICALS S	ROMANIA	1580	2025
9	COMBINATIONS (OLMESARTANUM MEDOXOMILUM+ AMLODIPINUM)	ALMACOR DUO 20 mg/5 mg	film-coated tablets	20 mg/5mg	ANTIBIOTICE S.A.	ROMANIA	1590	2025

10	COMBINATIONS (OLMESARTANUM MEDOXOMILUM+ AMLODIPINUM)	ALMACOR DUO 40 mg/5 mg	film-coated tablets	40mg/5mg	ANTIBIOTICE S.A.	ROMANIA	1590	2025
11	COMBINATIONS (OLMESARTANUM MEDOXOMILUM+ AMLODIPINUM)	ALMACOR DUO 40 mg/10 mg	film-coated tablets	40mg/10mg	ANTIBIOTICE S.A.	ROMANIA	1590	2025
12	COMBINATIONS	ESSENTIALE MAX 600 mg	capsules	600mg	OPELLA HEALTHCARE ROMANIA SRL	ROMANIA	1581	2025
13	ACIDUM ASCORBICUM	VITAMINA C GALENIKA 100 mg/ml	solution for injection/infusion	100mg/ml	GALENKA INTERNATIONAL KFT.	HUNGARY	1581	2025
14	LEVOFLOXACINUM	LEVOFLOXACINA ATB 250 mg	film-coated tablets	250mg	ANTIBIOTICE S.A.	ROMANIA	1590	2025
15	LEVOFLOXACINUM	LEVOFLOXACINA ATB 500 mg	film-coated tablets	500mg	ANTIBIOTICE S.A.	ROMANIA	1590	2025
16	LENALIDOMIDUM	LENALIDOMIDA ALKALOID-INT	capsules	5mg	ALKALOID-INT D.O.O.	SLOVENIA	1591	2025
17	LENALIDOMIDUM	LENALIDOMIDA ALKALOID-INT mg	capsules	10mg	ALKALOID-INT D.O.O.	SLOVENIA	1591	2025
18	LENALIDOMIDUM	LENALIDOMIDA ALKALOID-INT mg	capsules	15mg	ALKALOID-INT D.O.O.	SLOVENIA	1591	2025
19	LENALIDOMIDUM	LENALIDOMIDA ALKALOID-INT mg	capsules	25mg	ALKALOID-INT D.O.O.	SLOVENIA	1591	2025

20	DASATINIBUM	DASATINIB KRKA 20 mg	film-coated tablets	20mg	KRKA, D.D., NOVO MESTO	SLOVENIA	1589	2025
21	DASATINIBUM	DASATINIB KRKA 50 mg	film-coated tablets	50mg	KRKA, D.D., NOVO MESTO	SLOVENIA	1589	2025
22	DASATINIBUM	DASATINIB KRKA 70 mg	film-coated tablets	70mg	KRKA, D.D., NOVO MESTO	SLOVENIA	1589	2025
23	DASATINIBUM	DASATINIB KRKA 80 mg	film-coated tablets	80mg	KRKA, D.D., NOVO MESTO	SLOVENIA	1589	2025
24	DASATINIBUM	DASATINIB KRKA 100 mg	film-coated tablets	100mg	KRKA, D.D., NOVO MESTO	SLOVENIA	1589	2025
25	DASATINIBUM	DASATINIB KRKA 140 mg	film-coated tablets	140mg	KRKA, D.D., NOVO MESTO	SLOVENIA	1589	2025
26	LENALIDOMIDUM	LENALIDOMIDA GRINDEKS 2.5 mg	capsules	2.5mg	AS GRINDEKS	LATVIA	1583	2025
27	LENALIDOMIDUM	LENALIDOMIDA GRINDEKS 5 mg	capsules	5mg	AS GRINDEKS	LATVIA	1583	2025
28	LENALIDOMIDUM	LENALIDOMIDA GRINDEKS 7.5 mg	capsules	7.5 mg	AS GRINDEKS	LATVIA	1583	2025
29	LENALIDOMIDUM	LENALIDOMIDA GRINDEKS 10 mg	capsules	10mg	AS GRINDEKS	LATVIA	1583	2025
30	LENALIDOMIDUM	LENALIDOMIDA GRINDEKS 15 mg	capsules	15mg	AS GRINDEKS	LATVIA	1583	2025
31	LENALIDOMIDUM	LENALIDOMIDA GRINDEKS 20 mg	capsules	20mg	AS GRINDEKS	LATVIA	1583	2025

32	LENALIDOMIDUM	LENALIDOMIDA GRINDEKS 25 mg	capsules	25mg	AS GRINDEKS	LATVIA	1583	2025
33	SEVELAMER	CLORHIDRAT DE SEVELAMER WAYMADE 800 mg	film-coated tablets	800mg	WAYMADE B.V.	THE NETHER LANDS	1585	2025
34	ALPROSTADILUM	ALPROSTADIL ROMPHARM 20 micrograms	powder for solution for infusion	20 micrograms	ROMPHARM COMPANY S.R.L.	ROMANIA	1581	2025
35	ROSUVASTATINUM+ AMLODIPINUM+ PERINDOPRILUM	ROXAMPEX 10 mg/5 mg/ 4 mg	film-coated tablets	10mg/5mg/ 4mg	KRKA, D.D., NOVO MESTO	SLOVENIA	1579	2025
36	ROSUVASTATINUM+ AMLODIPINUM+ PERINDOPRILUM	ROXAMPEX 10 mg/5 mg/ 8 mg	film-coated tablets	10mg/5mg/ 8mg	KRKA, D.D., NOVO MESTO	SLOVENIA	1579	2025
37	ROSUVASTATINUM+ AMLODIPINUM+ PERINDOPRILUM	ROXAMPEX 10 mg/10 mg/ 8 mg	film-coated tablets	10mg/10mg/ 8mg	KRKA, D.D., NOVO MESTO	SLOVENIA	1579	2025
38	ROSUVASTATINUM+ AMLODIPINUM+ PERINDOPRILUM	ROXAMPEX 20 mg/5 mg/ 4 mg	film-coated tablets	20mg/5mg/ 4mg	KRKA, D.D., NOVO MESTO	SLOVENIA	1579	2025
39	ROSUVASTATINUM+ AMLODIPINUM+ PERINDOPRILUM	ROXAMPEX 20 mg/5 mg/ 8 mg	film-coated tablets	20mg/5mg/ 8mg	KRKA, D.D., NOVO MESTO	SLOVENIA	1579	2025
40	ROSUVASTATINUM+ AMLODIPINUM+ PERINDOPRILUM	ROXAMPEX 20 mg/10 mg/ 8 mg	film-coated tablets	20mg/10mg/ 8mg	KRKA, D.D., NOVO MESTO	SLOVENIA	1579	2025

41	RABEPRAZOLUM	RELITAZ 10 mg	gastroresistant tablets	10mg	DR. REDDY'S LABORATORIES ROMANIA SRL	ROMANIA	1578	2025
42	RABEPRAZOLUM	RELITAZ 20 mg	gastroresistant tablets	20mg	DR. REDDY'S LABORATORIES ROMANIA SRL	ROMANIA	1578	2025
43	AZITHROMYCINUM	AZITROMICINA ROMPHARM 500	powder for solution for infusion	500mg	ROMPHARM COMPANY S.R.L.	ROMANIA	1586	2025
44	COMBINATIONS (DUTASTERIDUM+TAMSULOSINUM)	RIMRIL 0.5 mg/0.4 mg	capsules	0.5 mg/0.4mg	HEATON K.S.	THE CZECH REPUBLIC	1581	2025
45	SALMETEROLUM+FLUTICASONUM	EVERIO AIRMASTER 50 micrograms/100 micrograms	single-dose powder for inhalation	50micrograms/100micrograms	ZENTIVA, K.S.	THE CZECH REPUBLIC	1591	2025
46	SALMETEROLUM+FLUTICASONUM	EVERIO AIRMASTER 50 micrograms/250 micrograms	single-dose powder for inhalation	50micrograms/250micrograms	ZENTIVA, K.S.	THE CZECH REPUBLIC	1591	2025
47	SALMETEROLUM+FLUTICASONUM	EVERIO AIRMASTER 50 micrograms/500 micrograms	single-dose powder for inhalation	50micrograms/500micrograms	ZENTIVA, K.S.	THE CZECH REPUBLIC	1591	2025
48	CEFTAZIDIMUM	CEFTAZIDIMA APTAPHARMA 1 g	powder for solution for injection/infusion	1g	APTA MEDICA INTERNACIONAL D.O.O.	SLOVENIA	1587	2025
49	CEFTAZIDIMUM	CEFTAZIDIMA APTAPHARMA 2 g	powder for solution for injection/infusion	2g	APTA MEDICA INTERNACIONAL D.O.O.	SLOVENIA	1588	2025
50	TRIFAROTEN	AKLIEF 50 micrograms/g	cream	50micrograms/g	GALDERMA INTERNATIONAL	FRANCE	1584	2025

51	DEXAMETHASONUM	DEXAMETAZONA FOSFAT KRKA 8 mg/2 ml	solution for injection/infusion	8mg/2ml	KRKA, D.D., NOVO MESTO	SLOVENIA	1588	2025
52	DEXAMETHASONUM	DEXAMETAZONA FOSFAT KRKA 4 mg/ml	solution for injection/infusion	4mg/ml	KRKA, D.D., NOVO MESTO	SLOVENIA	1588	2025
53	ESTRADIOLUM	ESTRADIOL BESINS 0.75 mg/dose	gel transdermic	0.75mg/dose	BESINS HEALTHCARE SA	BELGIUM	1586	2025
54	IBUPROFENUM	IBUPROFEN B. BRAUN 200 mg	solution for infusion	200mg	B. BRAUN MELSUNGEN AG	GERMANY	1578	2025
55	AZACITIDINUM	AZACITIDINE ZENTIVA 25 mg/ml	Powder for suspension for injection	25mg/ml	ZENTIVA, K.S.	THE CZECH REPUBLIC	1593	2025
56	DEXMEDETOMIDINUM	DEXMEDETOMIDINA KALCEKS 100 micrograms/ml	concentrate for solution for infusion	100 Micrograms /ml	AS KALCEKS	LATVIA	1589	2025
57	FINGOLIMODUM	FINGOLIMOD RICHTER 0.5 mg	capsules	0.5 mg	GEDEON RICHTER PLC.	HUNGARY	1587	2025
58	NORADRENALINUM	NORADRENALINA KALCEKS 1 mg/ml	concentrate for solution for infusion	1mg/ml	AS KALCEKS	LATVIA	1581	2025
59	CLINDAMYCINUM	OVYX 100 mg	ovules	100mg	MAGNAPHARM MARKETING & SALES ROMANIA S.R.L.	ROMANIA	1586	2025
60	DICLOFENACUM	VOLTAREN 140 mg	medicated plaster	140mg	HALEON ROMANIA S.R.L.	ROMANIA	1590	2025
61	RIVAROXABANUM	XERDOXO 2.5 mg	film-coated tablets	2.5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	1592	2025

62	RIVAROXABANUM	XERDOXO 10 mg	film-coated tablets	10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	1592	2025
63	RIVAROXABANUM	XERDOXO 15 mg	film-coated tablets	15mg	KRKA, D.D., NOVO MESTO	SLOVENIA	1592	2025
64	RIVAROXABANUM	XERDOXO 20 mg	film-coated tablets	20mg	KRKA, D.D., NOVO MESTO	SLOVENIA	1593	2025
65	TADALAFILUM	TADULAN 10 mg	film-coated tablets	10mg	STADA M&D SRL	ROMANIA	1577	2025
66	TADALAFILUM	TADULAN 20 mg	film-coated tablets	20mg	STADA M&D SRL	ROMANIA	1577	2025
67	AZACITIDINUM	LAZIROX 25 mg/ml	powder for susp. inj.	25mg/ml	STADA M&D S.R.L.	ROMANIA	1582	2025
68	EZETIMIBUM	CEXADO 10 mg	tablets	10mg	ZENTIVA K.S.	THE CZECH REPUBLIC	1582	2025
69	COMBINATIONS (VILDAGLIPTINUM+ METFORMINUM)	MELKART DUO 50 mg/850 mg	film-coated tablets	50mg/850mg	G.L. PHARMA GMBH	AUSTRIA	1584	2025
70	COMBINATIONS (VILDAGLIPTINUM+ METFORMINUM)	MELKART DUO 50 mg/1000 mg	film-coated tablets	50mg/1000mg	G.L. PHARMA GMBH	AUSTRIA	1584	2025
71	ACIDUM GADOXETICUM	PRIMOVID 0.25 mmol/ml	sol. inj. in pre-filled sy	181,430mg	BAYER AG	GERMANY	1584	2025
72	NAFTIFINUM	VIDRIL 10 mg/ml	Cutaneous solution	10mg/ml	DR. MAX PHARMA S.R.O.	THE CZECH REPUBLIC	1585	2025
73	CABAZITAXELUM	CABAZITAXEL SANDOZ 10 mg/ml	concentrate for solution for infusion	10mg/ml	SANDOZ PHARMACEUTICALS S	ROMANIA	1587	2025



74	COMBINATIONS (CLORMADINONA+ ETINILESTRADIOL)	BELARA CONTINU 2 mg/0.03 mg	film-coated tablets	2mg/0.03mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	1590	2025
75	SOMATROPINUM	NORDITROPIN NORDIFLEX 10 mg/1.5 ml	Solution for injection in pre-filled pen	10mg/1.5ml	NOVO NORDISK A/S	DENMARK	1578	2025
76	COMBINATIONS (IBUPROFENUM+ PARACETAMOLUM)	SYNOCAM 200 mg/500 mg	film-coated tablets	200mg/500mg	DR. REDDY'S LABORATORIES ROMA SRL	ROMANIA	1592	2025
77	COLCHICINUM	COLCHICINA IASIS 0.25 mg/ml	oral solution	0.25mg/ml	IASIS PHARMACEUTIC HELLAS S.A.	GREECE	1576	2025
78	COMBINATIONS (PHENTERMINUM+ TOPIRAMATUM)	QSIVA 3.75 mg/23 mg	modified-release capsules.	3.75mg/23mg	VIVUS BV	THE NETHER LANDS	1576	2025
79	COMBINATIONS (PHENTERMINUM+ TOPIRAMATUM)	QSIVA 7,5 mg/46 mg	modified-release capsules.	7.5 mg/46mg	VIVUS BV	THE NETHER LANDS	1576	2025
80	COMBINATIONS (PHENTERMINUM+ TOPIRAMATUM)	QSIVA 11.25 mg/69 mg	modified-release capsules.	11.25mg/69mg	VIVUS BV	THE NETHER LANDS	1576	2025
81	COMBINATIONS (PHENTERMINUM+ TOPIRAMATUM)	QSIVA 15 mg/92 mg	modified-release capsules.	15mg/92mg	VIVUS BV	THE NETHER LANDS	1576	2025
82	EDOXABANUM	CAGLUEN 15 mg	film-coated tablets	15mg	VIATRIS LIMITED	IRELAND	1577	2025
83	EDOXABANUM	CAGLUEN 30 mg	film-coated tablets	30mg	VIATRIS LIMITED	IRELAND	1577	2025
84	EDOXABANUM	CAGLUEN 60 mg	film-coated tablets	60mg	VIATRIS LIMITED	IRELAND	1577	2025

85	APIXABANUM	APIXABAN GEDEON RICHTER 2	film-coated tablets	2.5mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	1577	2025
86	APIXABANUM	APIXABAN GEDEON RICHTER 5	film-coated tablets	5mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	1577	2025
87	EDOXABANUM	KYMBEK 15 mg	film-coated tablets	15mg	EGIS PHARMACEUTICALS PLC	HUNGARY	1577	2025
88	EDOXABANUM	KYMBEK 30 mg	film-coated tablets	30mg	EGIS PHARMACEUTICALS PLC	HUNGARY	1577	2025
89	EDOXABANUM	KYMBEK 60 mg	film-coated tablets	60mg	EGIS PHARMACEUTICALS PLC	HUNGARY	1577	2025
90	COMBINATIONS (OCTENIDINUM+ PHENOXYETHANOL)	OCTIZY 1 mg/g+20 mg/g	cutaneous spray, solu	1mg/g+20mg/g	EGIS PHARMACEUTICALS PLC.	HUNGARY	1578	2025
91	BUPROPIONUM	AXABAL 150 mg	modified-release tablets	150mg	TERAPIA SA	ROMANIA	1578	2025
92	BUPROPIONUM	AXABAL 300 mg	modified-release tablets	300mg	TERAPIA SA	ROMANIA	1578	2025
93	NINTEDANIBUM	GEVESLA 100 mg	soft capsules	100mg	SANDOZ PHARMACEUTICALS S	ROMANIA	1578	2025
94	NINTEDANIBUM	GEVESLA 150 mg	soft capsules	150mg	SANDOZ PHARMACEUTICALS S	ROMANIA	1578	2025
95	DIMETHYL FUMARATE	TIGITRAX 120 mg	gastroresistant capsules	120mg	ADALVO LIMITED	MALTA	1578	2025

96	DIMETHYL FUMARATE	TIGITRAX 240 mg	gastroresistant capsules	240mg	ADALVO LIMITED	MALTA	1579	2025
97	MOXIFLOXACINUM	MOXIFLOXACINA MISOM 5 mg/ml	eye drops, solution	5mg/ml	MISOM LABS LIMITED	MALTA	1579	2025
98	DIMETHYL FUMARATE	DIMETIL FUMARAT FRONTIER 120 mg	gastroresistant capsules	120mg	FRONTIER BIOPHARMA SP. O.O.	ROMANIA	1579	2025
99	DIMETHYL FUMARATE	DIMETIL FUMARAT FRONTIER 240 mg	gastroresistant capsules	240mg	FRONTIER BIOPHARMA SP. O.O.	ROMANIA	1579	2025
100	POMALIDOMIDUM	POMALIDOMIDA GRINDEKS 1 mg	capsules	1mg	AS GRINDEKS	LATVIA	1580	2025
101	POMALIDOMIDUM	POMALIDOMIDA GRINDEKS 2 mg	capsules	2mg	AS GRINDEKS	LATVIA	1580	2025
102	POMALIDOMIDUM	POMALIDOMIDA GRINDEKS 3 mg	capsules	3mg	AS GRINDEKS	LATVIA	1580	2025
103	POMALIDOMIDUM	POMALIDOMIDA GRINDEKS 4 mg	capsules	4mg	AS GRINDEKS	LATVIA	1580	2025
104	LEVOSIMENDANUM	LEVATROP 2.5 mg/ml	concentrate for solution for infusion	2.5mg/ml	PHARMASELECT INTERNATIONAL BETEILIGU GMBH	AUSTRIA	1580	2025
105	DABIGATRANUM ETEXILATUM	DABIGATRAN ETEXILAT LABORATORIOS LICONSA 75 mg	capsules	75mg	LABORATORIOS LICONSA, S.A.	SPAIN	1580	2025
106	DABIGATRANUM ETEXILATUM	DABIGATRAN ETEXILAT LABORATORIOS LICONSA 110 mg	capsules	110mg	LABORATORIOS LICONSA, S.A.	SPAIN	1580	2025

107	DABIGATRANUM ETEXILATUM	DABIGATRAN ETEXILAT LABORATORIOS LICONSA 150 mg	capsules	150mg	LABORATORIOS LICONSA, S.A.	SPAIN	1580	2025
108	METRONIDAZOLUM	METRONIDAZOL NORIDEM 500 mg/100 ml	solution for infusion	5mg/ml	NORIDEM ENTERPRISES LIMITED	CYPRUS	1580	2025
109	TIGECYCLINUM	TIGECICLINA DEPO MED 50 mg	powder for solution for infusion	50mg	DEPO MED SRL	ROMANIA	1581	2025
110	VACCIN GRIPAL INACTIVAT	EFLUELDA	suspension for injection in pre-filled syringe		SANOFI WINTHROP INDUSTRIE	FRANCE	1582	2025
111	VACCIN GRIPAL INACTIVAT	VAXIGRIP	suspension for injection in pre-filled syringe		SANOFI WINTHROP INDUSTRIE	FRANCE	1584	2025
112	COMBINATIONS (CANDESARTANUM CILEXETIL+ INDAPAMIDUM)	CO-KARBIS 8 mg/2.5 mg	tablets	8mg/2.5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	1581	2025
113	COMBINATIONS (CANDESARTANUM CILEXETIL+ INDAPAMIDUM)	CO-KARBIS 16 mg/2.5 mg	tablets	16mg/2.5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	1581	2025
114	COMBINATIONS (NEBIVOLOLUM+ AMLODIPINUM)	NESYRGY 5 mg/5 mg	film-coated tablets	5mg/5mg	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LUXEMBOURG	1581	2025
115	COMBINATIONS (NEBIVOLOLUM+ AMLODIPINUM)	NESYRGY 5 mg/10 mg	film-coated tablets	5mg/10mg	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LUXEMBOURG	1581	2025

116	COMBINATIONS	DORITHRICIN MENTA 0.5 mg/1.0 mg/1.5 mg	orodispersible tablets	0.5 mg/1.0mg/	MEDICE PHARMA GMBH & CO. KG	GERMANY	1582	2025
117	COMBINATIONS (EZETIMIBUM+ ATORVASTATINUM)	CO-ATORIS 10 mg/10 mg	film-coated tablets	10mg/10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	1582	2025
118	COMBINATIONS (EZETIMIBUM+ ATORVASTATINUM)	CO-ATORIS 10 mg/20 mg	film-coated tablets	10mg/20mg	KRKA, D.D., NOVO MESTO	SLOVENIA	1582	2025
119	COMBINATIONS (EZETIMIBUM+ ATORVASTATINUM)	CO-ATORIS 10 mg/40 mg	film-coated tablets	10mg/40mg	KRKA, D.D., NOVO MESTO	SLOVENIA	1582	2025
120	COMBINATIONS (EZETIMIBUM+ ATORVASTATINUM)	CO-ATORIS 10 mg/80 mg	film-coated tablets	10mg/80mg	KRKA, D.D., NOVO MESTO	SLOVENIA	1582	2025
121	EZETIMIBUM	ISOVUREX 10 mg	tablets	10mg	MSN LABS EUROPE LIMITED	MALTA	1582	2025
122	LANREOTIDUM	LANREOTIDA ZENTIVA 120 mg	solution for injection in filled syringe	120mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	1585	2025
123	MELPHALANUM	MELFALAN TEVA 50 mg	Powder and solvent for solution for injection/infusion	50mg	TEVA B.V.	THE NETHERLANDS	1582	2025
124	CLADRIBINUM	LEUJECT 2 mg/ml	solution for injection	2mg/ml	ATNAHS PHARMA NETHERLANDS B.V.	DENMARK	1583	2025
125	CALCII FOLINAS	FOLINAT DE CALCIU KALCEKS mg/ml	solution for injection/infusion	10mg/ml	AS KALCEKS	LATVIA	1584	2025
126	APREMILASTUM	APREMILAST STADA 30 mg	film-coated tablets	30mg	STADA ARZNEIMITTEL AG	GERMANY	1584	2025

127	APREMILASTUM	APREMILAST STADA 10mg+20mg+30mg	film-coated tablets	10mg+20mg+30mg	STADA ARZNEIMITTEL AG	GERMANY	1584	2025
128	DICLOFENACUM	EGRETIRAL 10 mg/g	gel	10mg/g	TERAPIA S.A.	ROMANIA	1584	2025
129	DICLOFENACUM	EGRETIRAL 50 mg/g	gel	50mg/g	TERAPIA S.A.	ROMANIA	1584	2025
130	ACICLOVIRUM	BRAVILON 50 mg	mucoadhesive buccal tablets	50mg	VECTANS PHARMA	FRANCE	1585	2025
131	COMBINATIONS (CLOPIDOGRELUM+ ACIDUM ACETYLSALICYLICUM)	CLOPIDOGREL/ACID ACETILSALICILIC MSN 75 mg/75 mg	prolonged-release tablets	75mg/75mg	MSN LABS EUROPE LIMITED	MALTA	1585	2025
132	DROPERIDOLUM	DROPERIDOL AGUETTANT 2.5 mg/ml	solution for injection	2.5mg/ml	LABORATOIRE AGUETTANT	FRANCE	1585	2025
133	PIRACETAMUM	PIRACETAM-AC 400 mg	tablets	400mg	AC HELCOR PHARMA S.R.L.	ROMANIA	1585	2025
134	PIRACETAMUM	PIRACETAM-AC 800 mg	tablets	800mg	AC HELCOR PHARMA S.R.L.	ROMANIA	1585	2025
135	COMBINATIONS (ADAPALENUM+ BENZOYLIS PEROXIDUM)	SILSEQ 1 mg/g/25 mg/g	gel	1mg/g/25mg/g	EGIS PHARMACEUTICALS P	HUNGARY	1585	2025
136	COMBINATIONS (ADAPALENUM+ BENZOYLIS PEROXIDUM)	SILSEQ 3 mg/g/25 mg/g	gel	3mg/g/25mg/g	EGIS PHARMACEUTICALS P	HUNGARY	1585	2025

137	COMBINATIONS (BECLOMETASONUM+ FORMOTEROLUM)	BECLOMETAZONA/ FORMOTEROL STADA 100/6 micrograms/per dose	pressurised solution for inhalation	100/ 6micrograms/ per dose	STADA M&D S.R.L.	ROMANIA	1586	2025
138	COMBINATIONS (BECLOMETASONUM+ FORMOTEROLUM)	BECLOMETAZONA/ FORMOTEROL STADA 200/6 micrograms/per dose	pressurised solution for inhalation	200/ 6micrograms/ per dose	STADA M&D S.R.L.	ROMANIA	1586	2025
139	ALFACALCIDOLUM	ALFACALCIDOL GEMAX PHARM micrograms	soft capsules	0.5micrograms	GEMAX PHARMA S.R.O.	THE CZECH REPUBLIC	1586	2025
140	PLANTE (MENTA)	DIGESTOPRET 182 mg	soft gastroresistant capsules	182mg	BIONORICA SE		1586	2025
141	IMATINIBUM	IMATINIB STADA 100 mg	film-coated tablets	100mg	STADA ARZNEIMITTEL AG	GERMANY	1586	2025
142	IMATINIBUM	IMATINIB STADA 400 mg	film-coated tablets	400mg	STADA ARZNEIMITTEL AG	GERMANY	1586	2025
143	CEFIXIMUM	CEFIXIMA CODAL 400 mg	film-coated tablets	400mg	CODAL-SYNTO LIMITED	CYPRUS	1586	2025
144	LANREOTIDUM	LANREOTIDA TERAPIA 60 mg	solution for injection in pre-filled syringe	60mg	TERAPIA S.A.	ROMANIA	1587	2025
145	LANREOTIDUM	LANREOTIDA TERAPIA 90 mg	solution for injection in pre-filled syringe	90mg	TERAPIA S.A.	ROMANIA	1587	2025
146	LANREOTIDUM	LANREOTIDA TERAPIA 120 mg	solution for injection in pre-filled syringe	120mg	TERAPIA S.A.	ROMANIA	1587	2025

147	AMOXICILLINUM + ACIDUM CLAVULANICUM	AMOXICILINA/ACID CLAVULAN GEMAX PHARMA 875 mg/125 mg	film-coated tablets	875mg/125mg	GEMAX PHARMA S.R.O.	THE CZECH REPUBLIC	1587	2025
148	FERRI CARBOXYMALTOSUM	CARBOXIMALTOZA FERICA VIA 50 mg/ml	dispersion for injection /infusion	50mg/ml	VIATRIS LIMITED	IRELAND	1588	2025
149	APIXABANUM	AVOCLOD 2.5 mg	film-coated tablets	2.5mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	1588	2025
150	APIXABANUM	AVOCLOD 5 mg	film-coated tablets	5mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	1588	2025
151	COMBINATIONS (OCTENIDINUM+ PHENOXYETHANOL)	ALPHASEPT 1 mg/ml+20 mg/ml	cutaneous spray, solution	1mg/ml+20mg	LAVIPHARM S.A.	GREECE	1587	2025
152	MIDAZOLAMUM	MIDAZOLAM PANPHARMA 1 mg/ml	solution for injection/infusion	1mg/ml	PANPHARMA	FRANCE	1587	2025
153	MIDAZOLAMUM	MIDAZOLAM PANPHARMA 5 mg/ml	solution for injection/infusion	5mg/ml	PANPHARMA	FRANCE	1587	2025
154	COMBINATIONS (BECLOMETASONUM+ FORMOTEROLUM)	BECLOMETAZONA/ FORMOTEROL GENETIC 100 micrograms/ 6 micrograms per dose	pressurised solution f inhalation	100micrograms micrograms/ per dose	GENETIC S.P.A.	ITALY	1588	2025
155	COMBINATIONS (BECLOMETASONUM+ FORMOTEROLUM)	BECLOMETAZONA/ FORMOTEROL GENETIC 200 micrograms/ 6 micrograms per dose	pressurised solution f inhalation	200microgram micrograms/ per dose	GENETIC S.P.A.	ITALY	1588	2025



156	ABIRATERONUM	ZILFENAN 500 mg	film-coated tablets	500mg	ALKALOID – INT D.O.O.	SLOVENIA	1588	2025
157	CELECOXIBUM	CELECOXIB TEVA BV 100 mg	capsules	100mg	TEVA B.V.	THE NETHERLAND	1589	2025
158	CELECOXIBUM	CELECOXIB TEVA BV 200 mg	capsules	200mg	TEVA B.V.	THE NETHERLAND	1589	2025
159	COMBINATIONS (VALSARTANUM+ INDAPAMIDUM)	VALOMINDO 80 mg/1.5 mg	modified-release tablets	80mg/1.5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	1588	2025
160	TIGECYCLINUM	TIGECICLINA NORIDEM 50 mg	powder for solution for infusion	50mg	NORIDEM ENTERPRISES LIMITED	CYPRUS	1590	2025
161	RIVAROXABANUM	ENKIA 2.5 mg	film-coated tablets	2.5mg	MEDOCHEMIE LTD.	CYPRUS	1591	2025
162	PALIPERIDONUM	PALMEUX 25 mg	prolonged-release suspension for injection in pre-filled syringe	25mg	ADVANZ PHARMA LIMITED	IRELAND	1591	2025
163	PALIPERIDONUM	PALMEUX 50 mg	prolonged-release suspension for injection in pre-filled syringe	50mg	ADVANZ PHARMA LIMITED	IRELAND	1591	2025
164	PALIPERIDONUM	PALMEUX 75 mg	prolonged-release suspension for injection in pre-filled syringe	75mg	ADVANZ PHARMA LIMITED	IRELAND	1592	2025

165	PALIPERIDONUM	PALMEUX 100 mg	Prolonged-release suspension for injection in pre-filled syringe	100mg	ADVANZ PHARMA LIMITED	IRELAND	1592	2025
166	PALIPERIDONUM	PALMEUX 150 mg	Prolonged-release suspension for injection in pre-filled syringe	150mg	ADVANZ PHARMA LIMITED	IRELAND	1592	2025
167	DABIGATRANUM ETEXILATUM	DABIGATRAN ETEXILAT LICON	capsules	75mg	LABORATORIOS LICONSA, S.A.	SPAIN	1592	2025
168	DABIGATRANUM ETEXILATUM	DABIGATRAN ETEXILAT LICON	capsules	110mg	LABORATORIOS LICONSA, S.A.	SPAIN	1592	2025
169	DABIGATRANUM ETEXILATUM	DABIGATRAN ETEXILAT LICON	capsules	150mg	LABORATORIOS LICONSA, S.A.	SPAIN	1592	2025
170	ABIRATERONUM	ABIRATERONA MSN 250 mg	film-coated tablets	250mg	MSN LABS EUROPE LIMITED	MALTA	1593	2025
171	ABIRATERONUM	ABIRATERONA MSN 500 mg	film-coated tablets	500mg	MSN LABS EUROPE LIMITED	MALTA	1593	2025
172	VINCRISTINUM	VINCRISTINA TEVA 1 mg/ml	solution for injection	1mg/ml	TEVA B.V.	THE NETHERLANDS	1593	2025
173	SILDENAFILUM	SILESTO 25 mg	chewable tablets	25mg	STADA M&D S.R.L.	ROMANIA	1593	2025
174	SILDENAFILUM	SILESTO 50 mg	chewable tablets	50mg	STADA M&D S.R.L.	ROMANIA	1593	2025
175	OMEPRAZOLUM	OMVAZOL 20 mg	capsules	20mg	SLAVIA PHARM S.R.L.	ROMANIA	1593	2025
176	SACCHAROMYCES BOULARDII	ENTEROL FORTE 500 mg	powder for oral suspension in sachet	500mg	BIOCODEX	FRANCE	1594	2025

## EMA centrally authorised medicinal products notified for marketing in Romania during the 1<sup>st</sup> quarter of 2025

No.	INN	Trade name	Pharmaceutical form	Strength	MAH	Holding country	MA no	MA date
1	DENOSUMABUM	STOBOCLO 60 mg	solution for injection in pre-filled syringe	60mg/ml	CELLTRION HEALTHCARE HUNGARY KFT.	HUNGARY	1905	2025
2	EPLONTERSENUM	WAINZUA 45 mg	solution for injection in pre-filled pen	45mg	ASTRAZENECA AB	SWEDEN	1875	2025
3	SELADELPARUM	LYVDELZI 10 mg	capsules	10mg	GILEAD SCIENCE IRELAND UC	IRELAND	1898	2025
4	DENOSUMABUM	OSENVELT 120 mg	solution for injection	70mg/ml	CELLTRION HEALTHCARE HUNGARY KFT.	HUNGARY	1904	2025
5	PNEUMOCOCCAL POLYSACCHARIDE CONJUGATE VACCINE (21-VALENT)	CAPVAXIVE	solution for injection in pre-filled syringe		MERCK SHARP & DOHME B.V.	THE NETHERLANDS	1913	2025
6	AFLIBERCEPTUM	EYDENZELT 40 mg/ml	solution for injection in pre-filled syringe	40mg/ml	CELLTRION HEALTHCARE HUNGARY KFT.	HUNGARY	1895	2025
7	AFLIBERCEPTUM	EYDENZELT 40 mg/ml	solution for injection	40mg/ml	CELLTRION HEALTHCARE HUNGARY KFT.	HUNGARY	1895	2025

8	SERPLULIMABUM	HETRONIFLY 10 mg/ml	concentrate for solution for infusion	10mg/ml	ACCORD HEALTHCARE S.L.U.	SPAIN	1870	2025
9	BELZUTIFANUM	WELIREG 40 mg	film-coated tablets	40mg	MERCK SHARP & DOHME B.V.	THE NETHERLANDS	1893	2025
10	ELTROMBOPAG	ELTROMBOPAG ACCORD 25 mg	film-coated tablets	25mg	ACCORD HEALTHCARE S.L.U.	SPAIN	1903	2025
11	ELTROMBOPAG	ELTROMBOPAG ACCORD 50 mg	film-coated tablets	50mg	ACCORD HEALTHCARE S.L.U.	SPAIN	1903	2025