

ROMANIA

Newsletter

Year 25, No. 3 (99), 3rd quarter of 2023

*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 the following:

- information of public interest communicated ex officio, provided in Article 5 paragraph 2 of Law no. 544/2001:

a) The 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. 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. 2318/2021 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:

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

d) The institution's contact data

e) Audiences

Business hours

f) Financial sources, budget and the balance sheet

Budget and funding source

Balance sheet

g) The institution's programmes and strategies

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Medicinal product batches recalled during the 3rd quarter of 2023

No.	Product recalled	Pharmaceutical form	Strength	INN	Manufacturer/MAH	Batch	Grounds for recall	Proposed action	Date of recall
1	Coxient 30 mg comprimate filmate	film-coated tablets	30 mg	Etoricoxibum	Alvogen Malta Operations (ROW) Ltd., Malta	ET2530002G, ET2530004G	voluntary recall from the market following exclusion from the CaNaMed	voluntary recall from the market	05.09.2023
2	Coxient 60 mg comprimate filmate	film-coated tablets	60 mg	Etoricoxibum	Alvogen Malta Operations (ROW) Ltd., Malta	ET2530002G, ET2530004G	voluntary recall from the market following exclusion from the CaNaMed	voluntary recall from the market	05.09.2023
3	Coxient 90 mg comprimate filmate	film-coated tablets	90 mg	Etoricoxibum	Alvogen Malta Operations (ROW) Ltd., Malta	ET2530002G, ET2530004G	voluntary recall from the market following exclusion from the CaNaMed	voluntary recall from the market	05.09.2023
4	Perindopril/Amlodipină Zentiva 4 mg/5 mg comprimate	tablets	4 mg/5 mg	Perindopril/Amlodipine	ZENTIVA, k.s., The Czech Republic	2501121	voluntary recall from the market following exclusion from the CaNaMed	voluntary recall from the market	05.09.2023
5	Perindopril/Amlodipină Zentiva 8 mg/5 mg comprimate	tablets	8 mg/5 mg	Perindopril/Amlodipine	ZENTIVA, k.s., The Czech Republic	2501121	voluntary recall from the market following exclusion from the CaNaMed	voluntary recall from the market	05.09.2023
6	Implicor 50 mg/5 mg comprimate filmate	film-coated tablets	50 mg/5 mg	Perindopril/Amlodipine	Les Laboratoires Servier, France		voluntary recall from the market	voluntary recall from the market	12.07.2023
7	Implicor 25 mg/7,5 mg comprimate	film-coated tablets	50 mg/5 mg	Perindopril/Amlodipine	Les Laboratoires Servier, France		voluntary recall from the market	voluntary recall from the market	12.07.2023

	filmate								
8	Implicor 50 mg/7,5 mg comprimata filmate	film-coated tablets	50 mg/ 5 mg	Perindopril/ Amlodipine	Les Laboratoires Servier, France		voluntary recall from the market	voluntary recall from the market	12.07.2023

**Applications for marketing authorisation/marketing authorisation renewal
received during the 2nd quarter of 2023**

In the 2nd quarter of 2023, 18 marketing authorisation/marketing authorisation renewal applications for medicinal products corresponding to the following therapeutic groups have been received:

AUTHORISATION	RENEWAL
M02 – TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	R05 - COUGH AND COLD DRUGS
M01 - ANTI-INFLAMMATORY AND ANTIRHEUMATIC DRUGS	TRADITIONAL HERBAL MEDICINAL PRODUCT
J01 - ANTIBACTERIAL DRUGS	TRADITIONAL HERBAL MEDICINAL PRODUCT
	C09 - AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
	C09 - AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
	N02B – OTHER ANALGESICS AND ANTIPYRETICS
	N06 - PSYCHOANALEPTICS
	N06 - PSYCHOANALEPTICS
	N06 - PSYCHOANALEPTICS
	N06 - PSYCHOANALEPTICS
	G03A – HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE
	S01 – OPHTHALMOLOGICAL DRUGS
	N02B - OTHER ANALGESICS AND ANTIPYRETICS
	N02B - OTHER ANALGESICS AND ANTIPYRETICS

Medicinal products authorised for marketing during the 2nd quarter of 2023

No.	INN	Trade name	Pharmaceutical form	Strength	MAH	Holding country	MA no.		
1	ACICLOVIRUM	ZIRVIN 200 mg	tablets	200mg	ZENTIVA K.S.	THE CZECH REPUBLIC	15020	2023	001
2	ACICLOVIRUM	ZIRVIN 400 mg	tablets	400mg	ZENTIVA K.S.	THE CZECH REPUBLIC	15021	2023	001
3	ACIDUM ACETYLSALICYLICUM	ACID ACETILSALICILIC KRKA 75 mg	gastroresistant tablets	75mg	KRKA, D.D., NOVO MESTO	SLOVENIA	15002	2023	001
4	ACIDUM ACETYLSALICYLICUM	ACID ACETILSALICILIC KRKA 100 mg	gastroresistant tablets	100mg	KRKA, D.D., NOVO MESTO	SLOVENIA	15003	2023	001
5	ALFACALCIDOLUM	ALFACALCIDOL STADA 0.25 micrograms	soft capsules	0.25 micrograms	STADA M&D SRL	ROMANIA	15037	2023	001
6	ALFACALCIDOLUM	ALFACALCIDOL STADA 0.5 micrograms	soft capsules	0.5 micrograms	STADA M&D SRL	ROMANIA	15038	2023	001
7	ALFACALCIDOLUM	ALFACALCIDOL STADA 1 microgram	soft capsules	1microgram	STADA M&D SRL	ROMANIA	15039	2023	001
8	ATAZANAVIRUM	ATAZANAVIR STADA 150 mg	capsules	150mg	STADA M&D SRL	ROMANIA	15013	2023	001
9	ATAZANAVIRUM	ATAZANAVIR STADA 300 mg	capsules	300mg	STADA M&D SRL	ROMANIA	15014	2023	001

10	AZTREONAM	AZACTAM 1000 mg	powder for solution for injection	1000mg	BRISTOL-MYERS SQUIBB ROMANIA SRL	ROMANIA	5	2023	001
11	BORTEZOMIBUM	BORTEZOMIB MSN 3.5 mg	powder for solution for injection	3.5mg	VIVANTA GENERICS S.R.O.	THE CZECH REPUBLIC	14973	2023	001
12	CARBOPLATINUM	CARBOPLATINA ACCORD 10 mg/ml	concentrate for solution for infusion	10mg/ml	ACCORD HEALTHCARE POLSKA SP. Z.O.O.	POLAND	14981	2023	001
13	CEFEPIMUM	CEFEPIMA APTAPHARMA 1 g	powder for solution for injection/infusion	1g	APTA MEDICA INTERNACIONAL D.O.O.	SLOVENIA	15043	2023	001
14	CEFEPIMUM	CEFEPIMA APTAPHARMA 2 g	powder for solution for injection/infusion	2g	APTA MEDICA INTERNACIONAL D.O.O.	SLOVENIA	15043	2023	001
15	COLECALCIFEROLUM	VITAMIN D3 KRKA 7000 UI	tablets	7000IU	KRKA, D.D., NOVO MESTO	SLOVENIA	15035	2023	001
16	COMBINATIONS	BENELYTE	solution for infusion		FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	15001	2023	001
17	COMBINATIONS (DORZOLAMIDUM+ TIMOLOLUM)	COSOPT FARA CONSERVANT 20 mg/ml+5 mg/ml	eye drops, solution	20mg/ml+5mg/ml	SANTEN OY	FINLAND	15045	2023	001
18	COMBINATIONS (COAGULATION FACTORS)	PROTHROMPLEX TOTAL 500 UI	powder and solvent for solution for injection	500IU	BAXALTA INNOVATIONS GMBH	AUSTRIA	15041	2023	001

19	COMBINATIONS (IBUPROFENUM+ CODEINUM)	BIOFEN PLUS 200 mg+12.80 mg	film-coated tablets	200 mg+ 12.80 mg	BIOFARM S.A.	ROMANIA	15006	2023	001
20	COMBINATIONS (PARACETAMOLUM+ IBUPROFENUM)	COMBOGESIC 32 mg/ml+9.6 mg/ml	oral suspension	32mg/ml+ 9.mg/ml	MEDOCHEMIE LTD.	CYPRUS	15017	2023	001
21	COMBINATIONS (SITAGLIPTINUM+ METFORMINUM)	JIVOLAR 50 mg/850 mg	film-coated tablets	50mg/ 850mg	MEDOCHEMIE LTD.	CYPRUS	14976	2023	001
22	COMBINATIONS (SITAGLIPTINUM+ METFORMINUM)	JIVOLAR 50 mg/ 1000 mg	film-coated tablets	50mg/ 1000mg	MEDOCHEMIE LTD.	CYPRUS	14977	2023	001
23	DASATINIBUM	DASATINIB SANDOZ 20 mg	film-coated tablets	20mg	SANDOZ PHARMACEUT ICALS S.R.L.	ROMANIA	14969	2023	001
24	DASATINIBUM	DASATINIB SANDOZ 50 mg	film-coated tablets	50mg	SANDOZ PHARMACEUT ICALS S.R.L.	ROMANIA	14970	2023	001
25	DASATINIBUM	DASATINIB SANDOZ 70 mg	film-coated tablets	70mg	SANDOZ PHARMACEUT ICALS S.R.L.	ROMANIA	14971	2023	001
26	DASATINIBUM	DASATINIB SANDOZ 100 mg	film-coated tablets	100mg	SANDOZ PHARMACEUT ICALS S.R.L.	ROMANIA	14972	2023	001
27	DEXAMETHASONUM	DEXAMED 8 mg/2 ml	solution for injection	8mg/2ml	MEDOCHEMIE LTD.	CYPRUS	14984	2023	001
28	DEXAMETHASONUM	DEXAMETAZONA KRKA 0.5 mg	tablets	0.5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	14994	2023	001

29	DINOPROSTONUM	PROPESS 10 mg/24 hours	vaginal suppositories	10mg/24hours	FERRING GMBH	GERMANY	14996	2023	001
30	DIOSMINUM	PHLEBODIA 600 mg	film-coated tablets	600mg	LABORATOIRE S INNOTHERA	FRANCE	14985	2023	001
31	ENTECAVIRUM	ENTECAVIR TERAPIA 0.5 mg	film-coated tablets	0.5mg	TERAPIA S.A.	ROMANIA	15015	2023	001
32	ENTECAVIRUM	ENTECAVIR TERAPIA 1 mg	film-coated tablets	1mg	TERAPIA S.A.	ROMANIA	15016	2023	001
33	EVEROLIMUS	EVEROLIMUS PHARMAZAC 2.5 mg	tablets	2.5mg	PHARMAZAC S.A.	GREECE	15010	2023	001
34	EVEROLIMUS	EVEROLIMUS PHARMAZAC 5 mg	tablets	5mg	PHARMAZAC S.A.	GREECE	15011	2023	001
35	EVEROLIMUS	EVEROLIMUS PHARMAZAC 10 mg	tablets	10mg	PHARMAZAC S.A.	GREECE	15012	2023	001
36	GLATIRAMER ACETAT	REMUREL 40 mg/ml	solution for injection in pre-filled syringe	40mg/ml	LABORMED PHARMA S.A.	ROMANIA	15034	2023	001
37	GLICOPIRONIUM BROMIDUM	AXHIDROX 2.2 mg/dose	cream	2.2mg/dose	DR. AUGUST WOLFF GMBH & CO. KG ARZNEIMITTE L	GERMANY	14974	2023	001
38	IBUPROFENUM	IBUPROFEN FARMALIDER 200 mg	film-coated tablets	200mg	FARMALIDER, S.A.	SPAIN	15046	2023	001
39	ICODEXTRINUM	POLITHERA	solution for peritoneal dialysis		VIVISOL S.R.L.	ITALY	14995	2023	001
40	IVABRADINUM	IVABRADINA LICONSA 5 mg	film-coated tablets	5mg	LABORATORI OS LICONSA S.A.	SPAIN	15031	2023	001

41	IVABRADINUM	IVABRADINA LICONSA 7.5 mg	film-coated tablets	7.5mg	LABORATORI OS LICONSA S.A.	SPAIN	15032	2023	001
42	KETOPROFENUM	KETONAL DUO 100 mg	prolonged-release tablets	100mg	SANDOZ S.R.L.	ROMANIA	15022	2023	001
43	LENALIDOMIDUM	LENALIDOMIDA SANDOZ 2.5 mg	capsules	2.5mg	SANDOZ PHARMACEUT ICALS S.R.L.	ROMANIA	15023	2023	001
44	LENALIDOMIDUM	LENALIDOMIDA SANDOZ 5 mg	capsules	5mg	SANDOZ PHARMACEUT ICALS S.R.L.	ROMANIA	15024	2023	001
45	LENALIDOMIDUM	LENALIDOMIDA SANDOZ 7.5 mg	capsules	7.5mg	SANDOZ PHARMACEUT ICALS S.R.L.	ROMANIA	15025	2023	001
46	LENALIDOMIDUM	LENALIDOMIDA SANDOZ 10 mg	capsules	10mg	SANDOZ PHARMACEUT ICALS S.R.L.	ROMANIA	15026	2023	001
47	LENALIDOMIDUM	LENALIDOMIDA SANDOZ 15 mg	capsules	15mg	SANDOZ PHARMACEUT ICALS S.R.L.	ROMANIA	15027	2023	001
48	LENALIDOMIDUM	LENALIDOMIDA SANDOZ 20 mg	capsules	20mg	SANDOZ PHARMACEUT ICALS S.R.L.	ROMANIA	15028	2023	001
49	LENALIDOMIDUM	LENALIDOMIDA SANDOZ 25 mg	capsules	25mg	SANDOZ PHARMACEUT ICALS S.R.L.	ROMANIA	15029	2023	001
50	LEVOCETIRIZINUM	LEVOCETIRIZINA TERAPIA 5 mg	film-coated tablets	5mg	TERAPIA S.A.	ROMANIA	14968	2023	001
51	LIDOCAINUM	INSTILLIDO 20 mg/ml	gel	20mg/ml	FARCO- PHARMA	GERMANY	14991	2023	001

					GMBH				
52	LINEZOLIDUM	ZOXILID 600 mg	film-coated tablets	600mg	MEDOCHEMIE LTD.	CYPRUS	15040	2023	001
53	MACROGOLUM	PROCTOLAX 4 g	powder for oral solution, sachet	4g	CASEN RECORDATI, S.L.	SPAIN	15036	2023	001
54	NALOXONUM	FORVEL 0.4 mg/ml	solution for injection/infusion	0.4mg/ml	MEDOCHEMIE LTD.	CYPRUS	14975	2023	001
55	OCTENIDINUM	OCTEANGIN 2.6 mg	tablets	2.6mg	M.C.M. KLOSTERFRAU VERTRIEBSGESELLSCHAFT MBH	GERMANY	14490	2023	001
56	ONDANSETRONUM	ONDANSETRON KABI 0.08 mg/ml	solution for infusion	0.08mg/ml	FRESENIUS KABI ROMANIA SRL	ROMANIA	14999	2023	001
57	ONDANSETRONUM	ONDANSETRON KABI 0.16 mg/ml	solution for infusion	0.16mg/ml	FRESENIUS KABI ROMANIA SRL	ROMANIA	15000	2023	001
58	OSELTAMIVIRUM	OSELTAMIVIR ACCORD 30 mg	capsules	30mg	ACCORD HEALTHCARE POLSKA SP. Z.O.O.	POLAND	14978	2023	001
59	OSELTAMIVIRUM	OSELTAMIVIR ACCORD 45 mg	capsules	45mg	ACCORD HEALTHCARE POLSKA SP. Z.O.O.	POLAND	14979	2023	001
60	OSELTAMIVIRUM	OSELTAMIVIR ACCORD 75 mg	capsules	75mg	ACCORD HEALTHCARE POLSKA SP. Z.O.O.	POLAND	14980	2023	001

61	PLANTE (EXTRACT DE IEDERA)	HEDELIX 50 mg	effervescent tablets	50mg	KREWEL MEUSELBACH GMBH	GERMANY	14989	2023	001
62	PLANTE (EXTRACT DE PATLAGINA)	FIORDATUSSI 30 mg/ml	syrup	30 mg/ml	PHYTOPHARM KLEKA S.A.	POLAND	15030	2023	001
63	PLERIXAFORUM	PLERIXAFOR MSN 20 mg/ml	solution for injection	20mg/ml	MSN LABS EUROPE LIMITED	MALTA	15042	2023	001
64	SALMETEROLUM+ FLUTICASONUM	ZOREEDA CIPHALER 50 micrograms/ 250 micrograms	inhalation powder	50micrograms/ 250micrograms	AMRING FARMA S.R.L.	ROMANIA	14982	2023	001
65	SALMETEROLUM+ FLUTICASONUM	ZOREEDA CIPHALER 50 micrograms/ 500 micrograms	inhalation powder	50micrograms/ 500micrograms	AMRING FARMA S.R.L.	ROMANIA	14983	2023	001
66	TAPENTADOLUM	DOLTEN 50 mg	film-coated tablets	50mg	MEDOCHEMIE LTD.	CYPRUS	14986	2023	001
67	TAPENTADOLUM	DOLTEN 75 mg	film-coated tablets	75mg	MEDOCHEMIE LTD.	CYPRUS	14987	2023	001
68	TAPENTADOLUM	DOLTEN 100 mg	film-coated tablets	100mg	MEDOCHEMIE LTD.	CYPRUS	14988	2023	001
69	THIOPENTALUM	THIOPENTAL SODIC PANPHARMA 500 mg	powder for solution for injection	500mg	PANPHARMA	FRANCE	15004	2023	001
70	THIOPENTALUM	THIOPENTAL SODIC PANPHARMA 1 g	powder for solution for injection	1g	PANPHARMA	FRANCE	15005	2023	001
71	THIOTEPUM	THIOTEPA FRESENIUS KABI 15 mg	powder for concentrate for solution for infusion	15mg	FRESENIUS KABI ROMANIA SRL	ROMANIA	14992	2023	001

72	THIOTEPUM	THIOTEPA FRESENIUS KABI 100 mg	powder for concentrate for solution for infusion	100mg	FRESENIUS KABI ROMANIA SRL	ROMANIA	14993	2023	001
73	TICAGRELOR	KOGAVANT 90 mg	film-coated tablets	90mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	14998	2023	001
74	TICAGRELOR	KOGAVANT 60 mg	film-coated tablets	60mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	14997	2023	001
75	TIMOLOLUM	GELISIA 1 mg/g	eye gel in single dose recipient	1mg/g	SIFI S.P.A.	ITALY	15033	2023	001
76	VANCOMYCINUM	VANCOMICINA VIATRIS 500 mg	powder for solution for infusion	500mg	VIATRIS LIMITED	IRELAND	15018	2023	001
77	VANCOMYCINUM	VANCOMICINA VIATRIS 1000 mg	powder for solution for infusion	1000mg	VIATRIS LIMITED	IRELAND	15019	2023	001
78	ZONISAMIDUM	ZOCAP 25 mg	capsules	25mg	CLINRES FARMACIJA D.O.O.	CROATIA	15007	2023	001
79	ZONISAMIDUM	ZOCAP 50 mg	capsules	50mg	CLINRES FARMACIJA D.O.O.	CROATIA	15008	2023	001
80	ZONISAMIDUM	ZOCAP 100 mg	capsules	100mg	CLINRES FARMACIJA D.O.O.	CROATIA	15009	2023	001

EMA centrally authorised medicinal products notified for marketing in Romania during the 2nd quarter of 2023

No.	INN	Trade name	Pharmaceutical form	Strength	MAH	Holding country	MA no.		
1	DABIGATRANUM ETEXILATUM	DABIGATRAN ETEXILATE ACCORD 75 mg	capsules	75mg	ACCORD HEALTHCARE S.L.U.	SPAIN	1665	2023	01
2	DABIGATRANUM ETEXILATUM	DABIGATRAN ETEXILATE ACCORD 110 mg	capsules	110mg	ACCORD HEALTHCARE S.L.U.	SPAIN	1665	2023	01
3	DABIGATRANUM ETEXILATUM	DABIGATRAN ETEXILATE ACCORD 150 mg	capsules	150mg	ACCORD HEALTHCARE S.L.U.	SPAIN	1665	2023	01
4	ECULIZUMABUM	BEKEMV 300 mg	concentrate for solution for infusion	300mg	AMGEN TECHNOLOGY (IRELAND) UC	IRELAND	1727	2023	01
5	MAVACAMTENUM	CAMZYOS 2.5 mg	capsules	2.5mg	BRISTOL MYERS SQUIBB PHARMA EEIG	IRELAND	1716	2023	01
6	MAVACAMTENUM	CAMZYOS 5 mg	capsules	5mg	BRISTOL MYERS SQUIBB PHARMA EEIG	IRELAND	1716	2023	01

7	MAVACAMTENUM	CAMZYOS 10 mg	capsules	10mg	BRISTOL MYERS SQUIBB PHARMA EEIG	IRELAND	1716	2023	01
8	MAVACAMTENUM	CAMZYOS 15 mg	capsules	15mg	BRISTOL MYERS SQUIBB PHARMA EEIG	IRELAND	1716	2023	01
9	MIRIKIZUMABUM	OMVOH 300 mg	concentrate for solution for infusion	300mg	ELI LILLY NEDERLAND B.V.	THE NETHERLANDS	1736	2023	01
10	MIRIKIZUMABUM	OMVOH 100 mg	solution for injection in pre- filled pen	100mg	ELI LILLY NEDERLAND B.V.	THE NETHERLANDS	1736	2023	01