ROMANIA

Newsletter

Year 21, No. 3 (83), 3rd quarter 2019

National Agency for Medicines and Medical Devices o of Romania

Laws

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The Parliament of Romania

LAW no. 134

of 12 July 2019

on reorganisation of the National Agency for Medicines and Medical Devices and amendment of further ruling provisions

Published in the Official Journal of Romania, Part I, 587 of 17 July 2019

Promulgated by Decree no. 576 of 12 July 2019

The Parliament of Romania hereby adopts this law.

Chapter I
General Provisions

Article 1 - (1) The National Agency for Medicines and Medical Devices of Romania, hereinafter the NAMMDR, is hereby established by reorganisation of the National Agency for Medicines and Medical Devices, to be hereafter dissolved, as a public institution and legal entity, a specialised body of central public administration in the field of medicinal products for human use, medical devices and assessment of health technologies, under the Ministry of Health.

(2) The headquarters of the NAMMDR is located in Bucharest, str. Aviator Sănătescu str. 48, sector 1.

(3) The NAMMDR is organised and operates in accordance with provisions of this law and its own organisation and operation rules, approved by order of the Minister of Health.

(4) For the purpose of its tasks, by decision of the President, the NAMMDR may establish territorial units without legal personality.

Article 2 - The scope of the NAMMDR is:

a) Marketing authorisation of medicinal products for human use, authorisation of manufacturing and wholesale distribution units for medicinal products for human use;

b) Surveillance of manufacturing units and wholesale distribution as well as of the quality of medicinal products on the market and in-use control of medicinal products for human use;

c) Inspection for surveillance of activities conducted in community pharmacies, local distribution units, closed-circuit pharmacies and chemist’s shops, at least once every 5 years or whenever required;

d) Regulation of medical devices;

e) Surveillance of the medical device market;

f) Approval of establishments for the trade and servicing of medical devices;

g) Registration of medical devices placed on the market or commissioned in Romania, of domestic manufacturers, authorised representatives, medical device importers and wholesalers;

h) Inspection and control of medical devices in operation;

i) Assessment of health technologies related to medicinal products for human use, high-performance medical devices and equipment.

Article 3. – For its purposes, the NAMMDR performs the following functions:

a) development of national regulations, policies and strategies related to medicinal products for human use, medical devices and health assessment of technologies;

b) control to ensure surveillance and verification of compliance with specific regulations in its field;

c) internal and external representation on behalf of the Romanian state and the Ministry of Health under its scope.

CHAPTER II
NAMMDR duties

Article 4. - (1) For the purpose of specific objectives in its scope, the NAMMDR cooperates with the Ministry of Health, bodies of central and local administration, professional bodies as well as with other healthcare national and international organisations.

(2) For the purpose of its specific tasks, the NAMMDR may work with external experts, in compliance with legal provisions in its field.

(3) In accordance with legal provisions, the NAMMDR has the following main medicinal product related duties:

1. establishing mandatory rules and other regulatory provisions concerning medicinal products for human use, submitted to the Ministry of Health for approval;

2. grant of marketing authorisations, marketing authorisation renewal and variation for medicinal products for human use; grants authorisations for parallel import, their renewal and variation; ensures monthly advising of the Ministry of Health on marketing authorisations granted;

3. surveillance and control of the quality of medicinal products for human use in the frame of their manufacture, import, wholesale and retail, by periodic inspections and planned control operations, as well as under all circumstances of alerts/complaints concerning medicinal product quality and outcomes and responds to requests of the Ministry of Health for performance of inspections and operations in its scope;

4. inspection for surveillance of operations conducted by community pharmacies, local distribution offices, closed circuit pharmacies and chemist’s shops at least every 5 years or whenever necessary;

5. authorisation and control of conduct, in accordance with good clinical practice guidelines, of clinical trials on medicinal products for human use as well as of their respective sites, in line with legal provisions if force;

6. performs laboratory testing of the quality of medicinal products for human use for purposes of authorisation, quality monitoring, official batch release, respectively, for immunological or human blood-/plasma-derived medicinal products, as well as on request by other central and local public administration bodies;

7. organisation, guidance and control of pharmacovigilance work, conduct of studies on the use of medicinal products for human use, preparation of notifications on pharmacovigilance operations;

8. approval and control of advertising and readability related to medicinal products for human use, in accordance with regulations in force;

9. development and update of the Index of Medicinal Products for Human Use authorised for marketing in Romania, specifying their respective classification for supply;

10. annual notification of the European Commission and the other Member States on changes operated in the Index of Medicinal Products for Human Use authorised for marketing in Romania;

11. cooperation with national and international bodies for development of the European Pharmacopoeia;

12. operation of a service for information on medicinal products for human use; prepares and publishes, in electronic format, the NAMMDR Newsletter, specific specialist publications and information;

13. cooperation with the Ministry of Health and the National Health Insurance House in setting up the list of medicinal products for human use in the Index of Medicinal Products for Human Use provided on prescription to insurants irrespective of personal contribution;

14. decision on the suspension, recall/withdrawal of marketing authorisations or variation to marketing authorisations terms for medicinal products for human use, as required, as well as notification within 48 hours of the Ministry of Health and the National Health Insurance House on the respective decision;

15. provision of scientific advice and conduct of specific activities within its scope;

16. initiation, negotiation and conclusion of agreements and national and international cooperation documents within its legal scope;

17. organisation of working meetings, training courses, research projects and scientific events in the field of medicinal products for human use;

18. ascertaining of violation of legal provisions in its field and enforcement of appropriate penalties, in accordance with legislation in force;

19. conduct of other specific operations assigned by the Ministry of Health;

20. Good Manufacturing Practice certification of active substance/medicinal product manufacturers in third countries, based on favourable inspection reports by NAMMDR inspectors;

21. authorisation for operation to wholesalers of human medicinal product distributors, or wholesale distribution authorisations in the storage/custody system to wholesalers of medicinal product for human use based on favourable inspection reports by NAMMDR inspectors as well as good distribution practice certification;

22. authorisation of manufacturing/import to Romanian manufacturers/importers of medicinal products/investigational medicinal products for human use based on favourable inspection reports by NAMMDR inspectors as well as Good Manufacturing Practice certification;

23. Good Laboratory Practice certification for sites involved in conduct of non-clinical studies and the bioequivalence studies, respectively, under the law for authorisation of medicinal products for human use;

24. inspection of marketing authorisation holders for verification of compliance with their obligations as regards both pharmacovigilance and other obligations under legislation related to medicinal products for human use;

25. certification of Qualified Persons for applicants meeting conditions under the law;

26. grant of the certificate of pharmaceutical product in the format recommended by the World Health Organisation (WHO) and approval of export declarations for medicinal products for human use;

27. authorisations for supply of special needs medicines;

28. conduct of operations to prevent the entry into the legal supply chain of falsified medicinal products in accordance with legal provisions;

29. conduct of operations related to record and surveillance of brokers of medicinal products for human use;

30. conduct of and participation in assessments of the quality, efficacy and safety of medicines for human use authorised through centralised procedure (as per CAT, PRAC, PDCO, CHMP work), through its own or external experts.

31. participation in meetings and working groups at EU level in the field of medicinal products for human use;

32. enters information on marketing authorisations granted into the European Union database operated by the European Medicines Agency on behalf of the European Union, and provides, on the request of the European Commission or any Member State, all appropriate information on individual marketing authorisations granted;

33. monitoring or the medicinal product market for compliance and enforcement of specific legislation, monitoring of statistics and forecasts related to its scope, for the purpose of developing and proposing regulatory provisions;

34. undertaking of legal steps for ensuring uninterrupted supply of an adequate range of medicines to meet patients' needs;

35. may decide on maintaining/exclusion from the market of products nationally authorised before 2006, only based on marketing authorisation holders' risk-benefit reports and documents submitted in support of the application for authorisation;

36. notification of the Ministry of Health on medicinal product shortages as evident from monthly reports on market placement in in Romania.

(4) As regards the medical devices area, in accordance with legal provisions, the NAMMDR main duties are as follows:

1. development of rules and other mandatory regulations related to medical devices, submitted for Ministry of Health approval;
2. participation as members of inter-ministerial working groups in development of rules for harmonisation and implementation of medical device related regulations, on request by the Ministry of Health;
3. participation in EU medical device related meetings and working groups;
4. technical development of Romania's standpoint and the representation mandate regarding proposals of Community regulatory provisions and topics of European Union working groups related to medical devices, submitted to the Ministry of Health;
5. preparation of the lists of Romanian standards adopting European standards harmonised with European directives on medical devices, submitted for Minister of Health approval;
6. organisation of working meetings, training courses, research projects and scientific events in the field of medical devices;
7. assessment and designation of certification bodies for medical devices, submission to Minister of Health approval of the list of bodies designated and notification of such bodies through the electronic procedure operated by the European Commission;
8. assessment of notified body capability based on methodological rules developed by order of the Minister of Health and withdrawal of notification where the notified body no longer meets specified criteria underlying designation;
9. assessment and approval of entities conducting marketing and servicing of medical devices, in accordance with legislation in force;
10. record of medical devices placed on the market or commissioned in Romania, medical device domestic manufacturers, authorised representatives, importers and wholesalers, according to regulations in force;
11. setup and update of the national data base in accordance with national legislation provisions transposing European directives;
12. provides entry into the Eudamed European database of data entered into the national base, according to provisions of Commission Decision 2010/227/ EU of 19 April 2010 on the European Database on medical devices - Eudamed;
13. decision on medical device classification in the event of disputes between the manufacturer and the conformity assessment responsible body;
14. authorisation, in duly justified cases, of the placing on the market and commissioning of individual medical devices, for the purposes of the health protection policy;
15. authorisation of the conduct of the clinical investigation/assessment of performance procedure with investigational medical devices;
16. surveillance of the medical devices market, according to regulations in force;

17. request of appropriate measures for market withdrawal or prohibition/ restriction of market placement/commissioning medical devices potentially harmful to patients and users' health and/or safety;

18. record and assessment of information on the reported incidents and proposed corrective actions in relation to medical devices and enforcement of the vigilance procedure according to harmonised legislation in force;

19. administrative cooperation with competent authorities of the Member States of the European Union, related to provision of medical device services, through the Ministry of Health and the internal market information system - IMI, established by the European Commission;

20. provision of scientific advice and activities specific in its scope;

21. provision of specialised technical expertise, inspection and/or control, as appropriate;

22. coordination and running of national information programs developed with internal and/or external financing, in its scope;

23. approval, confirmation and certification of registration in accordance with specific legal provisions in force;

24. ascertaining of violation of legal provisions in its field and enforcement of appropriate penalties, in accordance with legislation in force;

25. performance and safety testing and checks for used medical devices;

26. performance and safety testing and checks for used in vitro diagnostic medical devices;

27. approval for use of both used medical devices and used in vitro diagnostic medical devices;

28. control by periodical verification of medical devices in operation;

29. grant of customs notice, in accordance with specific legislation in force;

30. free sale certification according to the specific legislation in force;

31. upon request, grant of out-of-scope notifications related to classification of certain products as medical devices.

(5) As national competent authority for health technology assessment, the NAMMDR has the following main duties:

1. development and periodical review of national methodological guidelines for assessment of health technologies and formats of health technology assessment reports, in accordance with international standards; development and implementation of priority-setting mechanisms related to health technology assessment, approved by order of the Minister of Health;

2. review and assessment of reports prepared by relevant institutions, organisations, external experts or researchers, on assessment of health technologies for objectivity, validity, compliance and scientific rigour, or request of suppliers or the Ministry of Health;

3. collaboration with professional bodies in the healthcare system and the academia for assessment of health technologies;

4. collection and analysis of statistical data relevant to health technology assessment from all healthcare services;

5. ensuring transparency of the process for substantiation of decisions on health technology assessment;

6. assessment of documentation based on the health technologies assessment mechanism and decides on the inclusion, extension of indications, non-inclusion or exclusion of medicines in/from the List of INNs of on - prescription medicines provided to insurants irrespective of personal contribution, in the healthcare social insurance system, as well as INNs of medicines supplied in the frame of the national health programs;

7. constant development of institutional capacity for health technology assessment, including training activities; organisation of working meetings, training courses, research projects and scientific events in the field;

8. participation in exchange of scientific information, development of models and assessment tools, as well as in studies and development of material in cooperation with Member States of the European network for Health Technology Assessment;

9. participation together with the Ministry of Health in international projects with similar institutions;

10. request from specialised commissions of the Ministry of Health to develop therapeutic protocols;

11. critical examination and approval of therapeutic protocols developed and/or revised by the specialised committees of the Ministry of Health.

Article 5. – (1) The NAMMDR takes adequate steps for the withdrawal, prohibition and/or restriction of market placing of any product intended for human consumption deemed potentially harmful for users' health and/or safety.

(2) When performing its control duties, NAMMDR/NAMMDR territorial units authorised personnel is entitled to demand for documents and public and private economic agents and units are legally required to provide such documents as well as respond to any other requirements necessary to check compliance with legislation on the quality of medicinal products for human use and medical devices.

CHAPTER III
NAMMDR organisation and operation

Article 7. – (1) The NAMMDR is run by a president and 2 vice-presidents appointed in accordance with the law, by order of the Minister of Health.

(2) The Ministry of Health organises a hiring competition for the president and vice-president positions, and the competition methodology is approved by order of the Minister of Health.

(3) As regards their wages, the president and vice-presidents' respective positions are equivalent to the Ministry of Health positions of secretary of state and undersecretary of state, respectively.

(4) In performance of their duties, the NAMMDR president issues decisions and instructions.

(5) The NAMMDR president is a tertiary budget manager and represents the institution in its relations with the ministries, public administration authorities, with other national/foreign authorities and public institutions, with natural and legal entities, as well as in court.

(6) The NAMMDR structure is approved by its president. By decision of the president, within the approved maximum number of positions, the NAMMDR structure may include services, bureaus, laboratories and compartments, territorial units for inspection and/or control and medicinal products/medical devices market surveillance or medical device in-use surveillance as well as for assessment of medical equipment and control by regular verification of medical devices.

(7) The maximum number of positions is 500 positions, the president and the two vice-presidents included.

(8) The job list is approved by order of the Minister of Health, on proposal by the president and on approval of the Management Board.

(9) Territorial units for inspection and/or control and medicinal products/medical devices market surveillance or medical device in-use surveillance as well as for assessment of medical equipment and control by regular verification of medical devices are entities without legal personality, employing healthcare and/or specialist technical staff.

Article 8. – (1) The NAMMDR Management Board is established by order of the Minister of Health, for a 4-year mandate, and includes the following members:

a) the NAMMDR president;

b) the 2 NAMMDR vice-presidents;

c) 2 representatives of the Ministry of Health.

(2) The NAMMDR president is also the president of the Management Board.

(3) The heads of NAMMDR departments may be invited to meetings of the Management Board, without the right to vote.

Article 9. – The Management Board has the following duties:

a. approval of the NAMMDR economic and financial policy;

b. approval of proposed fees for NAMMDR operations, approved by order of the Minister of Health;

c. approval of the NAMMDR annual report;

d. approval of the income and revenues budget as well as its execution;

e. endorsement of the NAMMDR organisational structure, submitted for approval by order of the Minister of Health;

f. endorsement of the NAMMDR organisation and operation rules, submitted for approval by order of the Minister of Health;

g. endorsement of the NAMMDR job list, submitted for approval by order of the Minister of Health;

Article 10. – (1) The Management Board is summoned by the NAMMDR president or representatives of the Ministry of Health, whenever necessary.

(2) The agenda of Management Board meetings is established by the NAMMDR president, based on proposals by the president, representatives of the Ministry of

Health and of such proposals as voted by simple majority of the total number of Management Board members.

(3) The Management Board operates legally under attendance by the simple majority of the total number of its members.

(4) NAMMDR Management Board decisions are approved by vote of a simple majority of the total number of attending members.

(5) The agenda and its attached documents are transmitted to Management Board members within terms established in the Management Board organisation and operation rules.

(6) The Management Board organisation and operation rules is approved by decision of the NAMMDR President within 30 days as of this law coming into force.

(7) NAMMDR Management Board decisions of ruling character are submitted for approval by order of the Minister of Health and published in the Official Journal of Romania, Part I, as appropriate; other non-ruling Management Board decisions are transmitted to the Ministry of Health for information and published on the NAMMDR website.

(8) According to law, persons who, directly or through their spouse or relatives up to the 4th degree included, work or hold interests in companies involved in manufacture, distribution or import of medicinal products for human use or medical devices may not be members of the NAMMDR Management Board.

Article 11. – (1) The NAMMDR Scientific Council is set by order of the Minister of Health, on proposal of the NAMMDR president, and it consists of the following:

a) the NAMMDR president, vice-presidents and three NAMMDR representatives;

b) one representative of medicine faculties as proposed by the Association of Medicine and Pharmacy Universities in Romania;

c) one representative of pharmacy faculties as proposed by the Association of Pharmacy Faculty Deans in Romania;

d) one representative of the Minister of Health;

e) one representative of the College of Pharmacists in Romania;

f) one representative of the College of Physicians in Romania;

g) one representative of the medical Bioengineering university Chair, as proposed by the Association of Medicine Faculty Deans in Romania.

h) one representative of the Public health university Chair medicine faculties as proposed by the associations of medicine and pharmacy universities;

i) one representative of patients' organisations;

(2) Nomination of members mentioned under (1) is performed by the legal representative of institution/organisation involved, as appropriate, on request by the NAMMDR president.

(3) The president of the Scientific Council is elected from among its members.

(4) The Scientific Council establishes the NAMMDR scientific policy.

(5) The Scientific Council shall meet at least 3 times a year or whenever necessary, on summons by the NAMMDR president, one Ministry of Health representative or one third of its members.

(6) The agenda of NAMMDR Scientific Council meetings is established by its president, based on proposals by the president, and primarily consists of the following: the NAMMDR scientific activity between two sessions, approach of NAMMDR scientific policy implementation, proposals of the NAMMDR president, the Ministry of Health, the Medical Science Academy or proposals voted by one third of the Scientific Council members.

(7) The Scientific Council may only deliberate on condition of attendance by simple majority of the total number of its members.

(8) Scientific Council decisions are approved by simple majority of the total number of its members.

(9) Scientific Council decisions of ruling character are submitted for approval by order of the Minister of Health and published in the Official Journal of Romania, Part I; other, non-ruling Scientific Council decisions, are transmitted to the Ministry of Health for information and published on the NAMMDR website.

(10) The NAMMDR Scientific Council organisation and operation rules are adopted within 30 days as of the date of this decision coming into force.

Article 12. – Membership to the Scientific Council is approved for a 4-year mandate, and the mandate may be renewed.

Article 13. – (1) According to law, persons who, directly or through their spouse or relatives up to the 4th degree included, work or hold interests in companies involved in manufacture, distribution or import of medicinal products for human use or medical devices, may not be members of the NAMMDR Scientific Council.

(2) Before nomination, whenever needed or in the case of changes thereof, members of the Scientific Council shall declare their own interests as well as interests of their spouse or relatives up to the 4th degree included, in companies involved in manufacture, distribution or import of medicinal products for human use or medical devices at home and abroad.

(3) Scientific Council members shall declare their conflicting interests as to one of the issues covered during Scientific Council meetings, abstain from voting and leave the meeting room.

Article 14. – In agreement, the NAMMDR Management Board and Scientific Council develop collaborations between the National Agency and representatives of patients', consumers', economic agents' organisations and the academia, such as participation of the latter in Agency organised events, under terms previously established by the Management board in agreement with the Scientific Council.

CHAPTER IV
Joint provisions

Article 15. – (1) The NAMMDR president and two vice-presidents shall implement decisions of the NAMMDR Management Board and Scientific Council.

Article 16. – On this law entry into force, based on protocol, the NAMMDR shall take over all rights and obligations as well as all other assets currently in NAMMD patrimony.

(2) The NAMMDR shall take over all NAMMD staff, with maintenance of salary rights on takeover date.

(3) Within 30 days from this law entry into force, the NAMMDR organisation and operation rules shall be approved by order of the Minister of Health.

Chapter V
Funding

Article 17. - (1) NAMMDR funding is from its own revenues as resulting from the collection of the fees established according to legislation in force, and a subsidy granted from the state budget.

(2) Revenues obtained from tariffs collected in relation to conduct of its specific activities constitute NAMMDR own revenues.

(3) Revenues obtained from fees collected by the NAMMDR in accordance with legal provisions in force constitute revenues to the state budget.

(4) Unused own revenues are carried over to the next year, with the same purpose.

Chapter V
Staff and payroll

Article 18. - (1) NAMMDR staff consists of staff under contract.

(2) The hiring, promotion to both higher positions and professional degrees/ levels as well as personnel release shall be conducted according to legal provisions in force; staff and its classification and remuneration comply with legal provisions in force related to personnel salary from public funds.

(3) For NAMMDR employees appointed as holders or substitutes in the Management Board of the European Medicines Agency (EMA), scientific committees and working groups of the European Agency, the Heads of Medicines Agencies (HMA), the Coordination Group for the Mutual Recognition and Decentralised Procedures (CMDh), of the European Directorate for the Quality of Medicines (EDQM), of the Council of Europe, of the Council of the European Union, the Pharmaceutical Inspection Co-operation Scheme (PIC/S) and of the European Commission, as well as for the employees nominated, by decision of the President, to participate as members of mixed teams for conduct of specific activities, and staff participating in the process of evaluation-authorisation, supervision and control of medicinal products for human use, health technologies assessment and medical devices related activities, the NAMMDR Management Board may approve grant of monthly financial incentives, within the amount of two gross national minimum wages, within the approved budget, according to article 193 (61) of Law no. 95/2006 on healthcare reform, republished as amended.

Article 19. - The following shall be repealed on this law entry into force:

a) article III of Government Emergency Ordinance on reorganisation of healthcare facilities and amendment of public health legislation and amendment of healthcare regulatory provisions, published in the Official Journal of Romania, Part I, no. 452 of July 2, 2010;

b) Government Decision no. 734/2010 on the organisation and operation of the National Agency for Medicines and Medical Devices, published in the Official Journal of Romania, Part I, no. 531 of July 29, 2010, as amended as well as any provisions to the contrary.

Article 20. - Within 30 days as of this law entry into force, the Ministry of Health shall develop rules for implementation of provisions provided in article 5 of this law.

Article 21. - Throughout Law no. 95/2006 on healthcare reform, republished as amended in the Official Journal of Romania, Part I, no. 652 of August 28, 2015, the phrase "National Agency for Medicines and Medical Devices" shall be replaced with "National Agency for Medicines and Medical Devices of Romania", whereas the phrase "NAMMD", shall be replaced with "NAMMDR".

This law has been adopted by the Parliament of Romania, pursuant to provisions of article 75 and of article 76 (2) of the Constitution of Romania, as republished.

PRESIDENT OF THE CHAMBER OF DEPUTIES

ION-MARCEL CIOLACU

PRESIDENT OF THE SENATE

CĂLIN-CONSTANTIN-ANTON POPESCU-TĂRICEANU

Medicinal product batches recalled/withdrawn in the 3rd quarter 2019

No.	Product recalled/ withdrawn	Pharmaceutical form	Strength	INN	Manufacturer/ MAH	Batch	Grounds for recall/withdrawal	Action proposed	Recall/ Withdrawal date
1	REMUREL 40 mg/ml	solution for injection in pre-filled syringe	40 mg/ml	glatiramer acetate	Synthon BV, NETHERLANDS/ Alvogen IPCo, Luxemburg	1802222E	market withdrawal triggered by rapid alert from the authority in Poland resulting from find of nonconformity (particles in suspension over acceptable limits)	Withdrawal and destruction	02.07.2019
2	FUCIDIN 20 mg/g	crema	20 mg/g	fusidic acid	Leo Laboratories Ltd, IRELAND/Leo Pharma A/S, Denmark	all marketed batches	market withdrawal in result of change of classification for release (to OTC), i.e. withdrawal from the CaNaMed and The Public Catalogue (CIM:W59985001) as of 02.08.2019	Voluntary withdrawal and destruction	20.08.2019
3	FUCIDIN 20 mg/g	unguent	20 mg/g	fusidic acid	Leo Laboratories Ltd, IRELAND/Leo Pharma A/S, Denmark	all marketed batches	market withdrawal in result of change of classification for release (to OTC), i.e. withdrawal from the CaNaMed and The Public Catalogue (CIM:W59986001) as of 02.08.2019	Voluntary withdrawal and destruction	20.08.2019

Applications for marketing authorisation/marketing authorisation renewal submitted to the NAMMD in the 2nd quarter 2019

During the II quarter 2019, 29 marketing authorisation/renewal applications for medicinal products corresponding to the following therapeutic groups have been submitted:

ATC CODE
N02 - ANALGESICS
A03 – DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS
B01 - ANTITHROMBOTIC AGENTS
A07 - ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS
J04 - ANTIMYCOBACTERIALS
C09 – AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
N01 – ANESTHETICS
N07 – OTHER NERVOUS SYSTEM DRUGS
M01 - ANTI-INFLAMMATORY AND ANTIRHEUMATIC PRODUCTS
A02 – DRUGS FOR ACID RELATED DISORDERS
N04 - ANTI-PARKINSON DRUGS
N03 - ANTIEPILEPTICS
J01 - ANTIBACTERIALS FOR SYSTEMIC USE

Medicinal products authorised for marketing in the 2nd quarter 2019

INN	Trade name	Pharm. form	Strength	MAH	Country	MA number	INN	Trade name
ABACAVIRUM+ LAMIVUDINUM	ABACAVIR/LAMIVUDINA TERAPIA 600 mg/300 mg	film-coated tabl.	600mg/ 300mg	S.C. TERAPIA S.A.	ROMANIA	J05AR02	11655	11.04.2019
ABACAVIRUM+ LAMIVUDINUM	ABACAVIR/LAMIVUDINA GLENMARK 600 mg/300 mg	film-coated tabl.	600mg/ 300mg	GLENMARK PHARMACEUTICALS S.R.O.	CZECH REPUBLIC	J05AR02	11625	05.04.2019
ACICLOVIRUM	ACICLOVIR AUROBINDO 200 mg	tabl.	200mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	J05AB01	11623	05.04.2019
ACICLOVIRUM	ACICLOVIR AUROBINDO 400 mg	tabl.	400mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	J05AB01	11624	05.04.2019
ALLOPURINOLUM	ALLOSPES 100 mg	tabl.	100mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	M04AA01	11839	27.05.2019
ALLOPURINOLUM	ALLOSPES 300 mg	tabl.	300mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	M04AA01	11840	27.05.2019
AMOROLFINUM	AMOROLFINA LABORATOIRES GERDA 50 mg/ml	medicinal nail lacquer	50mg/ml	LABORATOIRES GERDA	FRANCE	D01AE16	11869	31.05.2019

INN	Trade name	Pharm. form	Strength	MAH	Country	MA number	INN	Trade name
AMOROLFINUM	EXODERIL SET 50 mg/ml	medicinal nail lacquer	50mg/ml	LABORATOIRES GERDA	FRANCE	D01AE16	12081	21.06.2019
ATAZANAVIRUM	ATAZANAVIR ACCORD 150 mg	caps.	150mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	J05AE08	11845	27.05.2019
ATAZANAVIRUM	ATAZANAVIR ACCORD 200 mg	caps.	200mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	J05AE08	11846	27.05.2019
ATAZANAVIRUM	ATAZANAVIR ACCORD 300 mg	caps.	300mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	J05AE08	11847	27.05.2019
BOSENTANUM	BOSENTAN GEN.ORPH 62.5 mg	film-coated tabl.	62.5mg	GEN - ORPH SAS	FRANCE	C02KX01	11688	19.04.2019
BOSENTANUM	BOSENTAN GEN.ORPH 125 mg	film-coated tabl.	125mg	GEN - ORPH SAS	FRANCE	C02KX01	11689	19.04.2019
CAPECITABINUM	CAPECITABINA KOANAA 150 mg	film-coated tabl.	150mg	KOANAA HEALTHCARE GMBH	AUSTRIA	L01BC06	11774	15.05.2019
CAPECITABINUM	CAPECITABINA KOANAA 500 mg	film-coated tabl.	500mg	KOANAA HEALTHCARE GMBH	AUSTRIA	L01BC06	11775	15.05.2019

INN	Trade name	Pharm. form	Strength	MAH	Country	MA number	INN	Trade name
CLOFARABINUM	CLOFARABINA VIVANTA 1 mg/ml	conc. for sol. for inf.	1mg/ml	VIVANTA GENERICS S.R.O	CZECH REPUBLIC	L01BB06	11636	10.04.2019
COMBINATIONS	ESSENTIALE MAX 600 mg	caps.	600mg	SANOFI ROMANIA SRL	ROMANIA	A05BA	11619	04.04.2019
COMBINATIONS	PROSINUS 500 mg/30 mg	film-coated tabl.	500mg/ 30mg	S.C. FITERMAN PHARMA S.R.L.	ROMANIA	N02BE51	11792	17.05.2019
COMBINATIONS	SINDOLOR	tabl.	250mg/ 150mg/ 50mg	S.C. FITERMAN PHARMA S.R.L.	ROMANIA	N02BE51	11679	17.04.2019
COMBINATIONS (AMLODIPINUM+ VALSARTANUM)	AMLODIPINA/VALSARTAN HCS 5 mg/320 mg	film-coated tabl.	5mg/ 320mg	HCS BVBA	BELGIUM	C09DB01	11650	11.04.2019
COMBINATIONS (AMLODIPINUM+ VALSARTANUM)	AMLODIPINA/VALSARTAN HCS 10 mg/320 mg	film-coated tabl.	10mg/ 320mg	HCS BVBA	BELGIUM	C09DB01	11651	11.04.2019
COMBINATIONS (CHLORHEXIDINUM + LIDOCAINUM)	CEBANGIN LAMAIE 5 mg/1 mg	lozenges	5mg/1mg	CEBIS INTERNATIONAL SRL ROMANIA	ROMANIA	R02AA05	11822	23.05.2019
COMBINATIONS (CHLORHEXIDINUM + LIDOCAINUM)	CEBANGIN MENTOL 5 mg/1 mg	lozenges	5mg/1mg	CEBIS INTERNATIONAL SRL ROMANIA	ROMANIA	R02AA05	11823	23.05.2019

INN	Trade name	Pharm. form	Strength	MAH	Country	MA number	INN	Trade name
COMBINATIONS (CINARIZINUM + DIMENHIDRINATUM)	AZALONUM 20 mg/40 mg	tabl.	20mg/ 40mg	MEDOCHEMIE LIMITED	CYPRUS	N07CA52	11816	23.05.2019
COMBINATIONS (DESOGESTRELUM+ ETINILESTRADIOLUM)	DESORELLE ZILNIC 150 micrograms/ 30 micrograms	film-coated tabl.	0.15mg/ 0.03mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	G03AA09	12040	21.06.2019
COMBINATIONS (EMTRICITABINUM+ TENOFOVIRUM)	EMTRICITABINA/ TENOFOVIR DISOPROXIL ACCORDPHARMA 200 mg/245 mg	film-coated tabl.	200mg/ 245mg	ACCORD HEALTHCARE POLSKA SP. Z.O.O.	POLAND	J05AR03	12084	21.06.2019
COMBINATIONS (METOPROLOLUM+ IVABRADINUM)	ARBALIOR 25 mg/5 mg	film-coated tabl.	25mg/5mg	ANPHARM PZEDSIEBIOSTWO FARMACEUTYCZNE S.A.	POLAND	C07FX05	11643	10.04.2019
COMBINATIONS (METOPROLOLUM+ IVABRADINUM)	ARBALIOR 50 mg/5 mg	film-coated tabl.	50mg/5mg	ANPHARM PZEDSIEBIOSTWO FARMACEUTYCZNE S.A.	POLAND	C07FX05	11644	10.04.2019
COMBINATIONS (METOPROLOLUM+ IVABRADINUM)	ARBALIOR 25 mg/7.5 mg	film-coated tabl.	25mg/ 7.5mg	ANPHARM PZEDSIEBIOSTWO FARMACEUTYCZNE S.A.	POLAND	C07FX05	11645	10.04.2019
COMBINATIONS (METOPROLOLUM+ IVABRADINUM)	ARBALIOR 50 mg/7.5 mg	film-coated tabl.	50mg/ 7.5mg	ANPHARM PZEDSIEBIOSTWO FARMACEUTYCZNE S.A.	POLAND	C07FX05	11646	10.04.2019
COMBINATII (OLMESARTANUN+ AMLODIPINUM)	OLMESARTAN MEDOXOMIL/ AMLODIPINA FLOMI 20 mg/5 mg	film-coated tabl.	20mg/5mg	FLOMI FARMA S.R.L.	ROMANIA	C09DB02	11875	31.05.2019

INN	Trade name	Pharm. form	Strength	MAH	Country	MA number	INN	Trade name
COMBINATIONS (OLMESARTANUN+ AMLODIPINUM)	OLMESARTAN MEDOXOMIL/ AMLODIPINA FLOMI 40 mg/5 mg	film-coated tabl.	40mg/5mg	FLOMI FARMA S.R.L.	ROMANIA	C09DB02	11876	31.05.2019
COMBINATIONS (OLMESARTANUN+ AMLODIPINUM)	OLMESARTAN MEDOXOMIL/ AMLODIPINA FLOMI 40 mg/10 mg	film-coated tabl.	40mg/ 10mg	FLOMI FARMA S.R.L.	ROMANIA	C09DB02	11877	31.05.2019
COMBINATIONS (PARACETAMOLUM + CHLORPHENAMINUM)	FERVEX RACEALA and GRIPA 500 mg/4 mg	film-coated tabl.	500mg/ 4mg	UPSA SAS	FRANCE	R05X	11838	27.05.2019
COMBINATIONS (ROSUVASTATINUM+ EZETIMIBUM)	SUVEZEN 10 mg/10 mg	film-coated tabl.	10mg/ 10mg	SANOFI ROMANIA SRL	ROMANIA	C10BA06	11631	10.04.2019
COMBINATIONS (ROSUVASTATINUM+ EZETIMIBUM)	SUVEZEN 20 mg/10 mg	film-coated tabl.	20mg/ 10mg	SANOFI ROMANIA SRL	ROMANIA	C10BA06	11632	10.04.2019
COMBINATIONS (ROSUVASTATINUM+ EZETIMIBUM)	SUVEZEN 40 mg/10 mg	film-coated tabl.	40mg/ 10mg	SANOFI ROMANIA SRL	ROMANIA	C10BA06	11633	10.04.2019
DASATINIBUM	DASATINIB TEVA 20 mg	film-coated tabl.	20mg	TEVA PHARMACEUTICALS S.R.L	ROMANIA	L01XE06	11914	11.06.2019
DASATINIBUM	DASATINIB TEVA 50 mg	film-coated tabl.	50mg	TEVA PHARMACEUTICALS S.R.L	ROMANIA	L01XE06	11915	11.06.2019

INN	Trade name	Pharm. form	Strength	MAH	Country	MA number	INN	Trade name
DASATINIBUM	DASATINIB TEVA 70 mg	film-coated tabl.	70mg	TEVA PHARMACEUTICALS S.R.L	ROMANIA	L01XE06	11916	11.06.2019
DASATINIBUM	DASATINIB TEVA 80 mg	film-coated tabl.	80mg	TEVA PHARMACEUTICALS S.R.L	ROMANIA	L01XE06	11917	11.06.2019
DASATINIBUM	DASATINIB TEVA 100 mg	film-coated tabl.	100mg	TEVA PHARMACEUTICALS S.R.L	ROMANIA	L01XE06	11918	11.06.2019
DASATINIBUM	DASATINIB STADA 20 mg	film-coated tabl.	20mg	STADA M&D SRL	ROMANIA	L01XE06	11669	17.04.2019
DASATINIBUM	DASATINIB STADA 50 mg	film-coated tabl.	50mg	STADA M&D SRL	ROMANIA	L01XE06	11670	17.04.2019
DASATINIBUM	DASATINIB STADA 100 mg	film-coated tabl.	100mg	STADA M&D SRL	ROMANIA	L01XE06	11671	17.04.2019
VARIA	APA PENTRU PREPARATE INJECTABILE CSL BEHRING	solv. for prep. parent.		CSL BEHRING GMBH	GERMANY	V07AB	11635	10.04.2019
ERLOTINIBUM	ERLOTINIB ACTAVIS 25 mg	film-coated tabl.	25mg	ACTAVIS GROUP PTC EHF.	ICELAND	L01XE03	11699	19.04.2019

INN	Trade name	Pharm. form	Strength	MAH	Country	MA number	INN	Trade name
ERLOTINIBUM	ERLOTINIB ACTAVIS 100 mg	film-coated tabl.	100mg	ACTAVIS GROUP PTC EHF.	ICELAND	L01XE03	11700	19.04.2019
ERLOTINIBUM	ERLOTINIB ACTAVIS 150 mg	film-coated tabl.	150mg	ACTAVIS GROUP PTC EHF.	ICELAND	L01XE03	11701	19.04.2019
FEBUXOSTATUM	FEBUXOSTAT UNIVERSAL FARMA 80 mg	film-coated tabl.	80mg	UNIVERSAL FARMA S.L.	SPAIN	M04AA03	11697	19.04.2019
FEBUXOSTATUM	FEBUXOSTAT UNIVERSAL FARMA 120 mg	film-coated tabl.	120mg	UNIVERSAL FARMA S.L.	SPAIN	M04AA03	11698	19.04.2019
FLECAINIDUM	AMARHYTON 50 mg	caps. prolonged release	50mg	SWYSSI AG	GERMANY	C01BC04	12077	21.06.2019
FLECAINIDUM	AMARHYTON 100 mg	caps. prolonged release	100mg	SWYSSI AG	GERMANY	C01BC04	12078	21.06.2019
GADOTERIDOLUM	PROHANCE 0.5 mmol/ml	sol. for inj.	0.5mmol/ml	BRACCO IMAGING S.P.A.	ITALY	V08CA04	11933	11.06.2019
GADOTERIDOLUM	PROHANCE 0.5 mmol/ml	sol. for inj. in pre-filled syringe	0.5mmol/ml	BRACCO IMAGING S.P.A.	ITALY	V08CA04	11934	11.06.2019

INN	Trade name	Pharm. form	Strength	MAH	Country	MA number	INN	Trade name
HOMEOPATHIC	CAMILIA	single dose oral sol.		BOIRON	FRANCE	XRNIT	12090	28.06.2019
NORMAL HUMAN IMMUNOGLOBULIN	CUTAQUIG 165 mg/ml	sol. for inj.	165mg/ml	OCTAPHARMA (IP) SPRL	BELGIUM	J06BA01	12086	21.06.2019
KETOROLACUM TROMETHAMIN	KETOROLAC TROMETAMOL ROMPHARM 5 mg/ml	pic. oft., sol.	5mg/ml	S.C. ROMPHARM COMPANY S.R.L.	ROMANIA	S01BC05	11620	04.04.2019
LEVOFLOXACINUM	LEVOFLOXACINA ATB 250 mg	film-coated tabl.	250mg	ANTIBIOTICE S.A.	ROMANIA	J01MA12	12202	28.06.2019
LEVOFLOXACINUM	LEVOFLOXACINA ATB 500 mg	film-coated tabl.	500mg	ANTIBIOTICE S.A.	ROMANIA	J01MA12	12203	28.06.2019
MELPHALANUM	MELPHALAN PHARMEXON 50 mg	powder and solv. for sol. for inj./inf.	50mg	PHARMEXON CONSULTING SRO	CZECH REPUBLIC	L01AA03	11841	27.05.2019
MEROPENEMUM	MEROPENEM APTAPHARMA 500 mg	powder for sol. for inj./inf.	500mg	APTA MEDICA INTERNACIONAL D.O.O.	SLOVENIA	J01DH02	11691	19.04.2019
MEROPENEMUM	MEROPENEM APTAPHARMA 1000 mg	powder for sol. for inj./inf.	1000mg	APTA MEDICA INTERNACIONAL D.O.O.	SLOVENIA	J01DH02	11692	19.04.2019

INN	Trade name	Pharm. form	Strength	MAH	Country	MA number	INN	Trade name
MIDAZOLAMUM	MIDAZOLAM BAXTER 1 mg/ml	sol. for inj./inf.	1mg/ml	BAXTER HOLDING B.V.	NETHERLANDS	N05CD08	12065	21.06.2019
MIDAZOLAMUM	MIDAZOLAM BAXTER 5 mg/ml	sol. for inj./inf.	5mg/ml	BAXTER HOLDING B.V.	NETHERLANDS	N05CD08	12066	21.06.2019
MIDAZOLAMUM	MIDAZOLAM SUN 1 mg/ml	sol. for inj. /inf. in pre-filled syringe	1mg/ml	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	NETHERLANDS	N05CD08	11872	31.05.2019
MIDAZOLAMUM	MIDAZOLAM SUN 2 mg/ml	sol. for inj. /inf. in pre-filled syringe	2mg/ml	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	NETHERLANDS	N05CD08	11873	31.05.2019
MOXIFLOXACINUM	MOXIFLOXACINA VIVANTA 400 mg	film-coated tabl.	400mg	VIVANTA GENERICS S.R.O.	CZECH REPUBLIC	J01MA14	11985	18.06.2019
NATRII IODIDUM (131I)	FID-NA-131-I-T 37-5500 MBq	caps. for therapeutic use	37-5500MBq	S.C. FIDELIO FARM SRL	ROMANIA	V10XA01	11768	09.05.2019
OCTREOTIDUM	OCTREOTIDA TEVA 10 mg	powder and solv. for susp. for inj. with prolonged release	10mg	TEVA PHARMACEUTICALS S.R.L	ROMANIA	H01CB02	12182	28.06.2019
OCTREOTIDUM	OCTREOTIDA TEVA 20 mg	powder and solv. for susp. inj. cu prolonged release	20mg	TEVA PHARMACEUTICALS S.R.L	ROMANIA	H01CB02	12183	28.06.2019

INN	Trade name	Pharm. form	Strength	MAH	Country	MA number	INN	Trade name
OCTREOTIDUM	OCTREOTIDA TEVA 30 mg	powder and solv. for susp. inj. cu prolonged release	30mg	TEVA PHARMACEUTICALS S.R.L	ROMANIA	H01CB02	12184	28.06.2019
OLMESARTANUM MEDOXOMILUM+ AMLODIPINUM	SALVO 20 mg/5 mg	film-coated tabl.	20mg/5mg	TERAPIA SA	ROMANIA	C09DB02	11788	17.05.2019
OLMESARTANUM MEDOXOMILUM+ AMLODIPINUM	SALVO 40 mg/5 mg	film-coated tabl.	40mg/5mg	TERAPIA SA	ROMANIA	C09DB02	11789	17.05.2019
OLMESARTANUM MEDOXOMILUM+ AMLODIPINUM	SALVO 40 mg/10 mg	film-coated tabl.	40mg/ 10mg	TERAPIA SA	ROMANIA	C09DB02	11790	17.05.2019
PANCREATINUM	PANCREATINA FORTE MYLAN 35000	gastrores. caps.	420mg	MYLAN HEALTHCARE GMBH	GERMANY	A09AA02	11657	11.04.2019
PANCREATINUM	KREON 20000	gastrores. caps.	300mg	MYLAN HEALTHCARE GMBH	GERMANY	A09AA02	11656	11.04.2019
HERBAL	SINUPRET	syrup		BIONORICA SE	GERMANY	R05X	11793	17.05.2019
POSACONAZOLUM	POSACONAZOL MSN LABORATORIES 300 mg	conc. for sol. for inf.	300mg	VIVANTA GENERICS S.R.O.	CZECH REPUBLIC	J02AC04	11649	11.04.2019

INN	Trade name	Pharm. form	Strength	MAH	Country	MA number	INN	Trade name
POSACONAZOLUM	POSACONAZOL MYLAN 40 mg/ml	oral susp.	40mg/ml	MYLAN IRELAND LIIMTED	IRELAND	J02AC04	11634	10.04.2019
PROTIONAMIDUM	PROTIONAMIDA ATB 250 mg	film-coated tabl.	250mg	ANTIBIOTICE S.A.	ROMANIA	J04AD01	11848	31.05.2019
RACECADOTRILUM	RACECADOTRIL SANOFI 100 mg	caps.	100mg	SANOFI ROMANIA SRL	ROMANIA	A07XA04	11648	11.04.2019
SILODOSINUM	SIDARSO 4 mg	caps.	4mg	KRKA D.D., NOVO MESTO	SLOVENIA	G04CA04	11870	31.05.2019
SILODOSINUM	SIDARSO 8 mg	caps.	8mg	KRKA D.D., NOVO MESTO	SLOVENIA	G04CA04	11871	31.05.2019
SOLIFENACINUM SUCCINATE	SOLIFENACIN MSN LABORATORIES 5 mg	film-coated tabl.	5mg	VIVANTA GENERICS S.R.O.	CZECH REPUBLIC	G04BD08	11621	05.04.2019
SOLIFENACINUM SUCCINATE	SOLIFENACIN MSN LABORATORIES 10 mg	film-coated tabl.	10mg	VIVANTA GENERICS S.R.O.	CZECH REPUBLIC	G04BD08	11622	05.04.2019
SOMATROPINUM	SAIZEN 5.83 mg/ml	sol. for inj.	5,83mg/ml	MERCK ROMANIA SRL	ROMANIA	H01AC01	11813	23.05.2019
SOMATROPINUM	SAIZEN 8 mg/ml	sol. for inj.	8mg/ml	MERCK ROMANIA SRL	ROMANIA	H01AC01	11814	23.05.2019
SOMATROPINUM	NORDITROPIN NORDIFLEX 10 mg/1.5 ml	sol. for inj. in pre-filled pen	6,7mg/ml	NOVO NORDISK A/S	DENMARK	H01AC01	12112	28.06.2019
SUNITINIBUM	SUNITINIB SANDOZ 12.5 mg	caps.	12.5mg	S.C. SANDOZ S.R.L.	ROMANIA	L01XE04	11805	23.05.2019
SUNITINIBUM	SUNITINIB SANDOZ 25 mg	caps.	25mg	S.C. SANDOZ S.R.L.	ROMANIA	L01XE04	11806	23.05.2019
SUNITINIBUM	SUNITINIB SANDOZ 37.5 mg	caps.	37.5mg	S.C. SANDOZ S.R.L.	ROMANIA	L01XE04	11807	23.05.2019
SUNITINIBUM	SUNITINIB SANDOZ 50 mg	caps.	50mg	S.C. SANDOZ S.R.L.	ROMANIA	L01XE04	11808	23.05.2019
SUNITINIBUM	SUNITINIB ALVOGEN 12.5 mg	caps.	12.5mg	ALVOGEN MALTA OPERATIONS (ROW) LTD.	MALTA	L01XE04	11702	19.04.2019
SUNITINIBUM	SUNITINIB ALVOGEN 25 mg	caps.	25mg	ALVOGEN MALTA OPERATIONS (ROW) LTD.	MALTA	L01XE04	11703	19.04.2019

INN	Trade name	Pharm. form	Strength	MAH	Country	MA number	INN	Trade name
SUNITINIBUM	SUNITINIB ALVOGEN 37.5 mg	caps.	37.5mg	ALVOGEN MALTA OPERATIONS (ROW) LTD.	MALTA	L01XE04	11704	19.04.2019
SUNITINIBUM	SUNITINIB ALVOGEN 50 mg	caps.	50mg	ALVOGEN MALTA OPERATIONS (ROW) LTD.	MALTA	L01XE04	11705	19.04.2019
SUNITINIBUM	SUNITINIB STADA 12.5 mg	caps.	12.5mg	STADA M&D SRL	ROMANIA	L01XE04	11672	17.04.2019
SUNITINIBUM	SUNITINIB STADA 25 mg	caps.	25mg	STADA M&D SRL	ROMANIA	L01XE04	11673	17.04.2019
SUNITINIBUM	SUNITINIB STADA 50 mg	caps.	50mg	STADA M&D SRL	ROMANIA	L01XE04	11674	17.04.2019
SUNITINIBUM	SUNITINIB MYLAN 12.5 mg	caps.	12.5mg	MYLAN IRELAND LIMITED	IRELAND	L01XE04	11615	04.04.2019
SUNITINIBUM	SUNITINIB MYLAN 25 mg	caps.	25mg	MYLAN IRELAND LIMITED	IRELAND	L01XE04	11616	04.04.2019
SUNITINIBUM	SUNITINIB MYLAN 37.5 mg	caps.	37.5mg	MYLAN IRELAND LIMITED	IRELAND	L01XE04	11617	04.04.2019
SUNITINIBUM	SUNITINIB MYLAN 50 mg	caps.	50mg	MYLAN IRELAND LIMITED	IRELAND	L01XE04	11618	04.04.2019
TADALAFILUM	TADALAFIL AOP 20 mg	film-coated tabl.	20mg	AOP ORPHAN PHARMACEUTICALS AG	AUSTRIA	G04BE08	11658	11.04.2019
TENOFOVIRUM DISOPROXIL	TENOFOVIR STADA 245 mg	film-coated tabl.	245mg	STADA M&D SRL	ROMANIA	J05AF07	11675	17.04.2019
TOPIRAMATUM	EPITEL 25 mg	film-coated tabl.	25mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	N03AX11	11718	24.04.2019
TOPIRAMATUM	EPITEL 50 mg	film-coated tabl.	50mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	N03AX11	11719	24.04.2019
TOPIRAMATUM	EPITEL 100 mg	film-coated tabl.	100mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	N03AX11	11720	24.04.2019
TOPIRAMATUM	EPITEL 200 mg	film-coated tabl.	200mg	ACCORD HEALTHCARE POLSKA SP. Z O.O.	POLAND	N03AX11	11721	24.04.2019

INN	Trade name	Pharm. form	Strength	MAH	Country	MA number	INN	Trade name
TRAVOPROSTUM	TRAVOCOM 40 micrograms/ml	pic. oft., sol.	40 micrograms/ml	S.C. ROMPHARM COMPANY S.R.L.	ROMANIA	S01EE04	12142	28.06.2019
TREOSULFANUM	TREOSULFAN TILLOMED 5 g	powder for sol. for inf.	5g	LABORATORIOS TILLOMED SPAIN S.L.U	SPAIN	L01AB02	11659	11.04.2019
LIVE ATTENUATED MEASLES, RUBELLA, MUMPS, VARICELLA, VACCINE	PRIORIX-TETRA	powder and solv. for sol. for inj. in pre-filled syringe		GLAXOSMITHKLINE (GSK) S.R.L.	ROMANIA	J07BD54	11722	24.04.2019
VINORELBINUM	VINORELBINA ALVOGEN 20 mg	soft caps.	20mg	ALVOGEN MALTA OPERATIONS (ROW) LTD.	MALTA	L01CA04	11694	19.04.2019
VINORELBINUM	VINORELBINA ALVOGEN 30 mg	soft caps.	30mg	ALVOGEN MALTA OPERATIONS (ROW) LTD.	MALTA	L01CA04	11695	19.04.2019
VINORELBINUM	VINORELBINA ALVOGEN 80 mg	soft caps.	80mg	ALVOGEN MALTA OPERATIONS (ROW) LTD.	MALTA	L01CA04	11696	19.04.2019

Centrally authorised medicinal products notified for marketing in Romania in the 2nd quarter 2019

DCI	Trade name	Pharm. form	Strength.	MAH	Country	ATC Code	MA no.	MA date
ADALIMUMABUM	IDACIO 40 mg/0.8 ml	sol. for inj.	40mg/0.8ml	FRESENIUS KABI DEUTSCHLAND GMBH	GERMANY	L04AB04	1356	02.04.2019
ADALIMUMABUM	IDACIO 40 mg	sol. for inj. in pre-filled syringe	40mg/0.8ml	FRESENIUS KABI DEUTSCHLAND GMBH	GERMANY	L04AB04	1356	02.04.2019
ADALIMUMABUM	IDACIO 40 mg	sol. for inj. in pre-filled pen	40mg/0.8ml	FRESENIUS KABI DEUTSCHLAND GMBH	GERMANY	L04AB04	1356	02.04.2019
APALUTAMIDUM	ERLEADA 60 mg	film-coated tabl.	60mg	JANSSEN-CILAG INTERNATIONAL NV	BELGIUM	L02BB05	1342	14.01.2019
ARSENICUM TRIOXIDUM	TRISENOX 2 mg/ml	conc. for sol. for inf.	2mg/ml	TEVA B.V.	NETHERLANDS	L01XX27	204	05.03.2002
ATAZANAVIRUM	ATAZANAVIR KRKA 150 mg	caps.	150mg	KRKA, D.D., NOVO MESTO	SLOVENIA	J05AE08	1353	25.03.2019
ATAZANAVIRUM	ATAZANAVIR KRKA 200 mg	caps.	200mg	KRKA, D.D., NOVO MESTO	SLOVENIA	J05AE08	1353	25.03.2019

DCI	Trade name	Pharm. form	Strength.	MAH	Country	ATC Code	MA no.	MA date
ATAZANAVIRUM	ATAZANAVIR KRKA 300 mg	caps.	300mg	KRKA, D.D., NOVO MESTO	SLOVENIA	J05AE08	1353	25.03.2019
BICTEGRAVIRUM+ EMTRICITABINUM+ TENOFOVIRUM	BIKTARVY 50 mg/200 mg/25 mg	film-coated tabl.	50mg/200mg/ 25mg	GILEAD SCIENCES IRELAND UC	IRELAND	J05AR20	1289	21.06.2018
COMBINATIONS (GLECAPREVIRUM + PIBRENTASVIRUM)	MAVIRET 100 mg/40 mg	film-coated tabl.	100mg/40mg	ABBVIE DEUTSCHLAND GMBH & CO. KG	GERMANY	J05AP57	1213	26.07.2017
EDOXABANUM	ROTEAS 15 mg	film-coated tabl.	15mg	DAIICHI SANKYO EUROPE GMBH	GERMANY	B01AF03	1152	20.04.2017
EDOXABANUM	ROTEAS 30 mg	film-coated tabl.	30mg	DAIICHI SANKYO EUROPE GMBH	GERMANY	B01AF03	1152	20.04.2017
EDOXABANUM	ROTEAS 60 mg	film-coated tabl.	60mg	DAIICHI SANKYO EUROPE GMBH	GERMANY	B01AF03	1152	20.04.2017
FEBUXOSTATUM	FEBUXOSTAT KRKA 80 mg	film-coated tabl.	80mg	KRKA, D.D., NOVO MESTO	SLOVENIA	M04AA03	1347	28.03.2019
FEBUXOSTATUM	FEBUXOSTAT KRKA 120 mg	film-coated tabl.	120mg	KRKA, D.D., NOVO MESTO	SLOVENIA	M04AA03	1347	28.03.2019

DCI	Trade name	Pharm. form	Strength.	MAH	Country	ATC Code	MA no.	MA date
FREMANEZUMABUM	AJOVY 225 mg	sol. for inj. in pre-filled syringe	150mg/ml	TEVA GMBH	GERMANY	N02	1358	28.03.2019
METHOTREXATUM	JYLAMVO 2 mg/ml	sol. orala	2mg/ml	THERAKIND (EUROPE) LIMITED	IRELAND	L01BA01	1172	29.03.2017
OPICAPONUM	ONGENTYS 50 mg	caps.	50mg	BIAL - PORTELA & CA, S.A.	PORTUGAL	N04	1066	24.06.2016
PEGFILGRASTIMUM	FULPHILA 6 mg	sol. for inj. in pre-filled syringe	6mg	MYLAN S.A.S.	FRANCE	L03AA13	1329	20.11.2018
RISANKIZUMABUM	SKYRIZI 75 mg	sol. for inj. in pre-filled syringe	75mg/0.83ml	ABBVIE DEUTSCHLAND GMBH & CO. KG	GERMANY	L04AC	1361	26.04.2019
SEMAGLUTIDUM	OZEMPIC 0,25 mg	sol. for inj. in pre-filled pen	1.34mg/ml	NOVO NORDISK A/S	DENMARK	A10BJ06	1251	08.02.2018
SEMAGLUTIDUM	OZEMPIC 0.5 mg	sol. for inj. in pre-filled pen	1.34mg/ml	NOVO NORDISK A/S	DENMARK	A10BJ06	1251	08.02.2018
SEMAGLUTIDUM	OZEMPIC 1 mg	sol. for inj. in pre-filled pen	1.34mg/ml	NOVO NORDISK A/S	DENMARK	A10BJ06	1251	08.02.2018

DCI	Trade name	Pharm. form	Strength.	MAH	Country	ATC Code	MA no.	MA date
TERIPARATIDUM	TERROSA 20 micrograms/ 80 microlitres	sol. for inj.	20micrograms/ 80microlitri	GEDEON RICHTER PLC.	HUNGARY	H05AA02	1159	04.12.2017
TERIPARATIDUM	MOVYMIA 20 micrograms/ 80 microlitres	sol. for inj.	20micrograms/ 80microlitri	STADA ARZNEIMITTEL AG	GERMANY	H05AA02	1161	11.01.2017
SEROGROUP B MENINGOCOCCAL VACCINE	TRUMENBA	susp. for inj. in pre-filled syringe	60micrograms/ 60micrograms	PFIZER EUROPE MA EEIG	BELGIUM	J07AH09	1187	24.05.2017