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National Agency for Medicines and Medical Devices

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Order no. 577/2018 of 2 May 2018 on repeal of Order of the Minister of Health no.399/2006 for approval of European templates for package leaflet, summary of product characteristics and label information for medicinal products authorised for marketing in Romania

ISSUED BY: MINISTERUL SĂNĂTĂŢII
PUBLISHED IN: the OFFICIAL GAZETTE OF ROMANIA NO. 428 of 21 May 2018

On seeing Approval Report no. SP4.401 of 25.04.2018 of the Medicinal Product and Medical Devices Policy Directorate of the Ministry of Health as well as notifications no. 45.690E/2014 and 31.793E/2017, respectively, National Agency for Medicines and Medical Devices, registered with the Ministry of Health under no. 61.160/2014 and 54.811/2017, respectively,

Taking into account provisions of Article 16 şi and of Article 64 (4) of Law no. 24/2000 on legislative drafting rules for set up of regulatory documents, republished as amended,

In consideration of provisions of Article 4 (2) a) and of Article 12 (9) of Government Decision no. 734/2010 on the organisation and operation of the National Agency for Medicines and Medical Devices, as amended,

Based on Article 7 (4) of Government Decision no. 144/2010 on the organisation and operation of the Ministry of Health, as amended,

the Minister of Health hereby issues the following Order:

Article 1

Order of the Minister of Health no.399/2006 for approval of European templates for package leaflet, summary of product characteristics and label information for medicinal products authorised for marketing in Romania, published in the Official Gazette of Romania, Part I, no. 355 of 20 April 2006as amended, shall be repealed.

Article 2

This order shall be published in the Official Gazette of Romania, Part I.

Minister of Health,
Sorina Pintea

Bucharest, 2 May 2018.
No. 577.

DECISION

Nr. 1/14.06.2018

for approval of The Organisational strategy of the National Agency for Medicines and Medical Devices 2018-2020

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health no. 757/13.06.2018, in accordance with the Regulation for the organisation and operation of the NAMMD Scientific Council, Article 8 (1), gathered on summons of the NAMMD President in ordinary meeting held on 14.06.2018 in line with provisions of Article 12 (5) of Government Decision no. 734/2010 on the organisation and operation of the National Agency for Medicines and Medical Devices, as amended, hereby adopts the following

DECISION

Single article – The Organisational strategy of the National Agency for Medicines and Medical Devices, 2018-2020 is approved.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines
and Medical Devices,

Prof. Anca-Dana Buzoianu, PhD

ORGANISATIONAL STRATEGY OF THE NATIONAL AGENCY FOR MEDICINES AND MEDICAL DEVICES 2018 - 2020

The organisational strategy of the National Agency for Medicines and Medical Devices (NAMMD) is a reflection of its thematic priorities and focus for the next three years.

The National Agency for Medicines and Medical Devices (NAMMD) is the national competent authority in the field of medicinal products for human use, medical devices and health technology assessment.

The NAMMD is a public institution subordinated to the Ministry of Health, whose organisation and operation have been approved pursuant to provisions of Government Decision no. 734 of July 21, 2010, as amended.

Government Decision no. 315 of 23 April, 2014, amending Government Decision no. 734/2010 on NAMMD organisation and operation, has redefined the Agency's main duties in the field of human medicines (including evaluation of documentation for marketing authorisation, in the therapeutic circuit through the pharmacovigilance and inspection activity, the authorization of the clinical trials and their places of development, the elaboration of regulations in the field of medicine approved by the Ministry of Health), in addition to collaboration with the Ministry of Health and the National Insurance House on set up of the list of medicinal products for human use included in the Index of Medicinal Products for Human Use to which insured persons are entitled on a prescription basis, with or without personal contribution. Thus, in 2014, the NAMMD also became the competent national authority for health technology assessment as well.

Law no. 132 of 9 October 2014 for approval of Government Emergency Ordinance no. 2/2014 on amendment of Law no. 95/2006 on healthcare reform as well some other regulatory documents, assigns the NAMMD as the national competent and decision-making authority in the field of medical devices. Therefore, the Agency is in charge of authorisation of conduct of clinical investigation on human subjects of medical devices, according to regulations in force, as well as of control of performance and safety of medical devices in use and assessment of capabilities of service providers in this field.

The NAMMD proposes regulatory documents to the Minister of Health, which transpose European directives or establish the frame for application of European Union (EU) Regulations in the field of human medicines or medical devices, as the case may be.

This organisational strategy covers the period 2018-2020, and has been developed and updated in the context of the high-level strategy of the EU Drug Agency network by 2020, for the first time adopting a single strategy applicable to the entire network to reflect the need for coordinated approach to address the multiple challenges and opportunities facing the network. The European medicinal product-related regulatory system is an exclusive regulatory model worldwide. The NAMMD is a member of this system, relying on a network of national drug regulatory authorities in EU Member States and the European Economic Area, joining the Heads of Medicines Agencies (HMA) and the European Medicines Agency (EMA), closely working together in an integrated manner, with support from other European bodies such as the European Directorate for the Quality of Medicines and HealthCare (EDQM) of the European Council.

Jointly, this tightly integrated network ensures European patients' access to safe, effective and good quality medicines, also providing appropriate information on medicines to patients, healthcare professionals and the general public.

National competent authorities (NCAs), NAMMD included, rely on each other's work so as to avoid overlaps and ensure efficient division of labour and sharing of scientific competences. For instance, Member States do not carry out inspections in each other's territories, avoid duplication of assessments and collaborate in official batch control of biological medicines, post-marketing surveillance and safety issues.

In relation to human medicinal products, network action is coordinated by the EMA and the HMA. Jointly with the other NCAs, the NAMMD works closely with the EMA by providing scientific expertise to its committees for evaluation of medicinal products proposed for authorisation by the centralised procedure, in orphan and paediatric medicines related activities and safety procedures at EU level through resources provided to EMA scientific committees (the CAT, CHMP, CVMP, HMPC, PDCO, PRAC) and working groups.

Similarly to the other NCAs, the NAMMD as well is represented at the HMA, which addresses core network strategic issues, ensures EU wide consistency, provides the frame for sharing best practices and warrants best use of resources available to the entire network. HMA, under which the CMDh operates, works closely with the EMA and the European Commission (EC) to ensure effective and efficient functioning of the European drug regulatory network.

NAMMD medical device specialists take active part in meetings coordinated by the EU Council and the EC.

The degree of NAMMD integration within the network has increased in recent years, which is amply demonstrated by its active participation in the monthly Pharmacovigilance Risk Assessment Committee (PRAC) meetings dealing with assessment of safety issues at EU level. Coordination of the inspection activity is becoming increasingly stronger, whereas, in preparation for application of the new Clinical Trial Regulation, the NAMMD has been working with members of the Voluntary Harmonization Procedure (VHP) network for evaluation of clinical trials.

Of late, the regulatory line of work has witnessed an increasing need for transparency accompanied by an increasing trend for patient involvement in the work of regulators, the NAMMD included.

NAMMD organisational strategy 2018-2020 focuses on key strategic priorities requiring Agency decisive intervention in the near future, as a member of the network, as well as contribution to the protection of public health.

This document is not an account of the entire work in the Agency remit, but a strategy aligning with the HMA-EMA high-level strategy by 2020, describing the steps to be taken and their foundation.

NAMMD MISSION and VISION

An organisation's *Mission* and *Vision* are a well individualised set of values meant for adoption and implementation at organisational level, at the same time strongly reflecting and a reflexion of the management culture content.

They are an expression of the way forward and development opportunities.

Features of a powerful mission and vision are:

• Adequacy - appropriateness for their respective organisations, in the given context, in line with the history and values of the organisation as well as with its performance, at the same time providing assessment of desired situations, attainable on condition certain courses of action are taken;

• Characterising the organisational purpose - provide true meaning and significance to the purpose of the organisation and the role of its employees;

• Proficiency in initiation and maintenance of urges to employee uncompromised intellectual and emotional involvement in development of organisation's work;

• Proficiency in conveying messages in an accessible form, so as to guideline decisions and actions of individuals called to their implementation;

• Proficiency in stimulating employees to self-improvement, to ensure accomplishment of strategic objectives of the organisation;
• Nationally unique character, in the context of distinctive competencies characteristic to the field of medicinal products and medical devices.

NAMMD mission:

The NAMMD mission consists in making a significant contribution to protection and promotion of public health by:

- Assessment at the highest scientific competence of documentation for authorisation for marketing of high quality, safe and effective medicinal products for human use;
- Assessment of documentation supporting authorisation of clinical trial conduct in Romania and their sites;
- Assessment of health technologies relying on scientific criteria adopted through legislation in force for inclusion/non-inclusion/retaining in/exclusion from the list annexed to Government Decision no. 720/2008 for the approval of the List of International Nonproprietary 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;
- Surveillance of the safety of medicinal products for human use in therapeutic use by means of inspection and pharmacovigilance activities;
- Ensuring access for healthcare professionals, the pharmaceutical industry, patients and the general public to useful and accurate information on medicinal products for human use authorised for marketing in Romania;
- Maintaining of a high level of performance and safety of medical devices in use by healthcare networks throughout the country, irrespective of ownership;
- Strictest assessment of service providing medical-technical units in the area of medical devices, for optimum delivery of competent and quality prosthetic and repair – maintenance services;
- Developing specific technical procedures in the field of medical devices;
- Ensuring institutional administrative effectiveness, efficiency and transparency of practices and procedures in use.

NAMMD vision:

– **Strengthening of its status as reference national authority** in the field of medicinal products for human use and control of the performance and safety of medical devices in use.
– **Strengthening of its status as expert and reliable source** of accurate and timely information in the field of medicinal products for human use, provided to stakeholders.

TOPIC 1: Contributing to protection of public health

The NAMMD has to work with the Ministry of Health to ensure patients' continued access to existing medicines, including by taking action before and after the occurrence of deficits.

This chapter gives an outline of the main strategic initiatives that the NAMMD will undertake in the next 3 years to contribute to improved public health.

Objective 1: Focus on key public health priorities, medicinal product availability included

1.1 Ensuring patients' early availability to novel, effective and safe medicinal products

1.1.1. Ensuring coverage of specific needs of the population including the elderly, children, patients with rare diseases, oncological diseases etc., by:
- Strengthened NAMMD capacity for scientific evaluation related to orphan designation of medicinal products by experts assigned for membership in the COMP;
- Strengthened capacity for health technologies assessment in line with the National Health Strategy;
- Strengthened capacity for assessment of Paediatric Investigation Plans (PIPs);
- Implementation of legislation in force on last resort treatments;
- Active participation in CHMP, PRAC, CAT assessments.

1.2 Reducing patient time to access to novel medicines

1.2.1 Development and introduction into legislation of scientific advice procedures granted to marketing authorisation holders (MAHs);
1.2.2 On-demand provision of scientific advice on priority medicines for both authorisation and health technology assessment procedures;
1.2.3 Implementation of prioritising measures related to medicinal product assessment and authorisation;
1.2.4 Strengthened capacity for scientific assessment of applications submitted to the Authorisation-Evaluation Department (DEA).

1.3 Ensuring availability of authorised medicinal products

1.3.1 Development of legislation governing the public service obligation;
1.3.2 Developing collaboration agreements with other agencies to manage disruptions in medicines supply;
1.3.3 Strengthening MS collaboration to monitor the market and improve availability;
1.3.4 Further implementation of legislative leverage ensuring better availability: authorisation to supply medicines for special needs (NSAs), parallel import authorisation (AIP), exemption from labelling;
1.3.5 Minimising the risk and impact of disruptions from manufacturing problems and quality defects by implementing effective action plans and developing good communication practices on medicine shortages;
1.3.6 Facilitating dialogue with MAHs and wholesalers to address issues leading to limited access for authorised products.

1.4 Stronger involvement of interested persons in relevant assessment work

1.4.1 Providing for patient participation in scientific assessment processes, HTA and benefit/risk ratio assessment

1.5 Ensuring effective support to conduct of pharmacovigilance work

1.5.1 Implementing the necessary tools for reporting and assessment of adverse reactions (RAs) emerging from clinical trials

1.5.2 Development of signal detection

1.6 Promoting a positive internal environment for clinical research and cooperation with interested bodies

1.6.1 Recruiting specialised personnel/Training staff in place for compliance with legal approval deadlines

1.6.2 Contributing with appropriate expertise to the debates of the relevant scientific committees of the European bodies

1.6.3 Further participation State in the VH Procedure and increased participations as Reference Member State

Objective 2: Development of NAMMD Laboratory Control Capacity

2.1 Purchase of adequate laboratory equipment in accordance with EDQM standards

2.1.1 Increased number of medicines included in the 15 annual testing plan, up to reaching the 10% threshold of the total number of medicines on the market

2.1.2 Increased number of staff specialised in laboratory work

Objective 3: Increased capacity for pharmaceutical inspection

3.1 Increased number of inspectors for check of compliance with GMP rules in respect of both national manufacturing sites and NAMMD involvement in EMA, WHO, EDQM joint audit teams

3.2 Increased number of inspectors for check of compliance with the GDP rules, in proportion to the number of authorised wholesalers

3.3 Increased number of inspectors for check of compliance with GLP and GVP rules

3.4 Development of medicines traceability system by providing for servers and platforms able to support real-time reporting and generation of alerts on potential entry of falsified medicines into the legal supply chain

3.5 Increased intervention capacity by setup of the relevant legal framework and a service with tasks in preventing entry of falsified medicinal products in both the legal supply chain and by other routes

3.6 Increased collaboration with law enforcement agencies (police, customs, the prosecutor's office)

3.7 Improvement of internal databases for manufacturers, importers, distributors to implement automatic upload of GMP/GDP authorisations and certificates into the EudraGMDP

Objective 4: Management of threats posed by illegal medicines chains

4.1 Providing for the necessary processes for MAH reporting of medicines in the supply chain, suspect to be falsified

4.1.1 Implementation of a Form for reporting medicines suspect to be falsified

4.2 Strengthened communication within the network, the Working Group of Enforcement Officers (WGEO) included

4.3 Revision of collaboration with the EDQM in relation to the sampling program samples for testing to increase the number of Active Pharmaceutical Ingredients (APIs) and medicines subject to parallel trade

Objective 5: NAMMD engagement in implementation of Directive 62/2011/EU to prevent entry of falsified medicinal products into the legal supply chain by 9 February 2019

5.1 Support to the Organisation for the Serialisation of Medicines in Romania (OSMR) for implementation of the Directive

5.1.1 Active participation in working groups established by the OSMR Board of Directors, where Agency representatives are to work closely with representatives of the Ministry of Health and the National Health Insurance House, MAHs, public and private pharmacies, wholesalers and parallel importers.

5.2 Carrying out the NAMMD role within the European Medicines Verification System in accordance with provisions of Article 43 of the Delegated Regulation 2016/161

5.2.1 Making available information to MAHs, manufacturers, wholesalers and bodies authorised or capacitated to dispense medicinal products to the public on request, on medicinal products placed on the market in Romania provided with the following safety features: two-dimensional bar code and anti-tampering device.

5.2.2 Compliance with the surveillance obligation of national repository operation to verify, if necessary, by means of investigations, compliance of the repository and the legal entity responsible for repository establishment and management with requirements set out by the Delegated Regulation 2016/161.

5.2.3 Submit activity surveillance reports to the European Medicines Agency (EMA), which makes them available to the other competent national authorities and the European Commission.

Objective 6. Development of the work system on medical devices (DM) so as to ensure their use in accordance with the law throughout the country, as well as conduct of all prosthetic and medical device repair/maintenance services at the highest quality and competence level.

6.1 Improved NAMMD market surveillance ensuring all necessary measures for putting on the market and/or into service in Romania of medical devices only complying with regulatory requirements in force

6.2 Permanent update of the Medical Devices National Registry

6.3 Educational activities for healthcare professionals and patients, and fostering reporting of incidents occurring in the use of medical devices

6.4 Development of legislation for medical device advertising

6.5. Improved control

6.5.1 Activities for the monitoring of medical device-related service providers

6.5.2 Medical devices-related information campaigns (use, prevention of counterfeiting, incident handling)

6.5.3 Set up of the related legal framework and of a structure with assignments in preventing entry of falsified medical devices into both the legal supply chain and by other routes

6.5.4 Increases number of medical devices sampled taken and reviewed in the Annual Sampling Plan.

TOPIC 2: IMPROVED NAMMD CONTRIBUTION TO NETWORK OPERATION

A critical success factor for the network is the existence and availability of sustainable and high-quality scientific and regulatory experience able to address progress in regulatory science. Scientific and operational procedures applied by one or several of the various network actors must be efficient and cost-effective and as much as possible reduce the administrative burden for the pharmaceutical industry, in proportion to public health.

To further strengthen a network of excellence, effective communication is essential, to promote proactive communication approaches at national and European level, to meet he objective of strengthening public and political agents' confidence in the work of regulators and the network. Trust is based not only on the quality of scientific competence and on regulators' results, but also on their commitment to actively engage stakeholders (in particular patients, healthcare professionals and the scientific community) in authorities' work.

Objective 1: Strengthen NAMMD scientific and regulatory capacity within the network

1.1 The NAMMD will adapt its available scientific and regulatory expertise in terms of both capacity and capability to meet new requirements at all times.

1.2 In order to further develop high-quality and appropriate scientific assessment process, it is necessary to ensure that the NAMMD, as a member of the network, has the necessary expertise, in terms of both capacity and capability.

1.3 Facilitate the widening of expertise also through closer collaboration with academic experts at national level, aiming at optimal dissemination of information to experts in the academia.

1.4 Given the increasing pressure on human and financial resources and the further increase in workload, NAMMD will have to ensure its viability in the coming years.

Objective 2: Achieving operational excellence

2.1 The NAMMD will improve its scientific and operational procedures as well as the quality of (scientific) results under the current regulatory framework.

2.2 The NAMMD will focus on achieving the most efficient link between national and EU information systems and, where appropriate, gradual convergence of national information systems.

2.3 Warranty of protection of personal data and confidential trade information is to be maintained as a point of interest.

2.4 The NAMMD will further participate in the benchmarking process (BEMA) benchmarking launched by the HMA, which is an essential tool for sharing best practices and finding ways for continued improvement.

Objective 3: Ensuring effective NAMMD communication nationally and at network level

3.1 Increased NAMMD effectiveness as regards communication of its strategic goals and communication with stakeholders, particularly in crisis situations.

3.2 An essential condition for NAMMD effectiveness within the network is use of efficient and collaborative communication methods.

3.3 the NAMMD will continuously pursue the set up and maintenance of civil society confidence as a whole in activities performed by the competent authority, by strengthening the latter's reputation and authority with stakeholders.

3.3.1 In order to generate understanding and confidence, in addition to implementing other initiatives such as, e.g., further improving the quality of results, the NAMMD will need to ensure that, in terms of both quality and deadlines, the communication adopted provides support to the general objective of public health protection.

3.3.2 Stakeholders' effective contribution to meeting such a general objective can only be achieved if confidence is stimulated

3.4 NAMMD Fully acknowledging that effective and safe use of medicines largely depends on successful communication with relevant stakeholders, particularly patients and healthcare professionals, the NAMMD will seek ways to provide medicinal product and product characteristics related information that better meet stakeholders' expectations and needs.

3.5 To further optimize work in this field, the NAMMD will further focus on a predominantly proactive approach to communication, as much as possible encouraging sending of a consistent message to stakeholders.

3.6 The NAMMD will further pursue to attach utmost importance to the management of healthcare crisis situations through prompt, consistent and effective communication to the general public.

Objective 4: Strengthening relations with other authorities and stakeholders

4.1 The NAMMD will strengthen its collaboration with authorities involved in achieving patient access to medicines and medical devices and will further improve its interactions with stakeholders. The HTA/pricing and reimbursement bodies play a key role in providing for patient access to medicines.

4.2 As regards assessment of medical technologies, the NAMMD will strengthen interaction and collaboration with the Ministry of Health and the National Health Insurance House, based on the distinct roles of each institution, for further consolidation of scientific assessment, while facilitating appropriate access to the prescribed treatments.

4.3 The NAMMD will strengthen collaboration among its institutional units sharing human medicines and medical devices responsibilities, mainly in the field of combined products, medical devices for "companion" diagnostics, border products and active substances with ancillary action to the device in which they are incorporated as an integral part.

4.4 As a network member, the NAMMD will also strengthen its interaction with the EDQM in areas such as establishing common quality requirements for medicines and ensuring their application, as well as in coordination of activities of the official network of drug control laboratories (OMCL).

TOPIC 4: CONTRIBUTION TO GLOBAL REGULATION

The greater complexity of global supply chains and dependence on clinical data generated outside the EU create a strong public healthcare need to ensure proper monitoring and control, as well as opportunities to develop closer links with international healthcare regulatory authorities facing the same challenges, such as increasing economic constraints, in the context of which collaboration can provide opportunities for synergy, avoidance of overlaps and facilitate the exchange of information and worksharing.

Objective 1: Providing for integrity of the supply chain and data

1.1 The NAMMD will intensify further measures to ensure integrity of medicines, the supply chain and data within increasingly complex global supply chains.

1.1.1 The NAMMD will focus further on exchange of information with other regulatory and control authorities, responsible for surveillance of the various stages of manufacturing and providing for application of the same standards regardless of location of the manufacturing site, in order to contribute to minimising possible problems.

1.1.2 Within the network, the NAMMD will collaborate with international partners to address challenges generated by increasingly complex supply chains, global industries and counterfeit and falsified medicines.

Objective 2: Convergence of global standards and contribution to international fora

Globalisation of pharmaceutical operations is an impetus towards achievement of convergence of international standards and approaches. Application of equivalent standards of good manufacturing practice and good clinical trial practice, as well as an equivalent level of protection for clinical trials subjects in countries with an international role as pharmaceutical suppliers, in which clinical trials are conducted, allow for enhanced cooperation and mutual trust, thus facilitating better use of collective resources, avoidance of duplication and ensuring a framework conducive to exchange of good practices.

The EU NCA network relies on equivalence between the different standards and approaches, therefore being able to facilitate extension to other regions of these standards and approaches. Certain aspects of the EU Falsified Drugs Directive, implemented in 2013, have been instrumental in establishing the principles of trust and international cooperation and have highlighted the importance of local regulators' surveillance of manufacturers and of mutual communication.

2.1 In order to contribute to convergence of global standards, the NAMMD provides support within the network to such international fora as the International Harmonization

Conference (ICH), the Pharmaceutical Inspection Convention (PIC) and the Pharmaceutical Inspection Cooperation Scheme (PIC/S).

2.2 The NAMMD will continue to work in alignment with the objective of the network to promote integrated and consistent approach to cooperation with countries such as India and China, given that these become major suppliers to the network, both in terms of manufacturing and as states in which an increasing number of clinical trials are conducted, bioequivalence studies included, and that regulatory authorities in these countries are the most important partners for the network as well as in the context of other mechanisms and international convergence networks.

Objective 3: Ensuring optimal use of resources by promoting mutual trust and work sharing

3.1 Within the network, the NAMMD will promote optimal use of global collective resources by improving information and worksharing with non-EU regulatory partners and by encouraging adoption of European regulatory approaches.

Objective 4: Support to training and capacity building activities and promotion of the EU regulatory model

4.1 The NAMMD it will further work in alignment with the network's policy of responding to requests for support from non-EU regulators, both in order to strengthen their capacities and as a model for regional harmonisation initiatives. In this respect, mutual priorities need to be established, followed by finding of mechanisms able to ensure coordinated response at network level.

DECISION

Nr. 2/14.06.2018

for approval of the Romanian version of the Good Pharmacovigilance Practice Guideline - Module XVI - Risk minimisation measures: selection of tools and effectiveness indicators (Rev. 2)

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health no. 104/09.02.2017, convened on summons by the NAMMD President in the ordinary session of 14.06.2018, in accordance with provisions of Article 12 (5) of Decision of the Romanian Government no. 734/2010 on organisation and operation of the National Agency for Medicines and Medical Devices, as amended, hereby adopts the following

DECISION

Single article – The Romanian version of the Good Pharmacovigilance Practice – Module XVI - Risk minimisation measures: selection of tools and effectiveness indicators (Rev. 2) is hereby approved

PRESIDENT
Of the Scientific Council
of the National Agency for Medicines
and Medical Devices,

Prof. Anca-Dana Buzoianu, PhD

ANNEX
to Scientific Council Decision
no. 2 /14.06.2018

Note:
The Annex to this Decision is a translation into Romanian and an adaptation of the document EMA/204715/2012 Rev 2*, "*Guideline on good pharmacovigilance practices (GVP) – Module XVI – Risk minimisation measures: selection of tools and effectiveness indicators (Rev 2)*" published by the Heads of Medicines Agencies and the European Medicines Agency. Adaptation consists in reference to respective Romanian healthcare regulatory provisions, transposing EU regulations. Therefore, for the Annex to this Decision, please see https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-module-xvi-risk-minimisation-measures-selection-tools_en-3.pdf

Medicinal product batches withdrawn/recalled during the 2nd quarter 2018

No.	Product recalled/ withdrawn	Pharm. form	Strength	INN	Manufacturer/ MAH	Batch	Grounds for recall/withdrawal	Action proposed	Recall/ Withdrawal date
1	METOCLOPRAMID SLAVIA 10 mg	tablets	10 mg	metoclopramid	Arena Group S.A./ Slavia Pharm S.R.L.	60 (exp. 05.2018), 61 (exp. 05.2018), 62 (exp. 08.2018), 63 (exp. 08.2018), 64 (exp. 01.2019), 65 (exp. 01.2019), 66 (exp. 09.2019), 67 (exp. 08.2019), 68 (exp. 09.2019), 69 (exp. 09.2019)	expiry of the 2-year period established pursuant to Order of the Minister of Health no.279/2005 after NAMMD approval of change to terms of MA no. 8859/2016/01 (18.04.2016)	Voluntary recall and destruction	24.05.2018
2	VORICONAZOL FRESENIUS KABI 200 mg	powder for solution for infusion	200 mg	voriconazol	Fresenius Kabi Deutschland GmbH GERMANy/ Fresenius Kabi Romania S.R.L.	50KEH006 (exp. 05.2019)	expiry of the 2-year period established pursuant to Order of the Minister of Health no.279/2005 after NAMMD approval of change to terms of MA no. 8129/2015/01 (29.04.2016)	Voluntary recall and destruction	30.05.2018
3	PARACOF 300 mg/30 mg	tablets	300 mg/ 30 mg	combinations (paracetamol + caffeine)	Sintofarm S.A., Romania	S0117001	One blister each missing in 7 outer packagings	Voluntary withdrawal and destruction	31.05.2018

Applications for marketing authorisation/marketing authorisation renewal submitted to the NAMMD during the 1st quarter of 2018

During the 1st quarter of 2018, 174 marketing authorisation/renewal applications for medicinal products corresponding to the following therapeutic groups have been received:

A02 – DRUGS FOR ACID RELATED DISORDERS
A06 – LAXATIVES
A11 – VITAMINS
A12 – MINERAL SUPPLEMENTS
A13 – TONICS
B01 – ANTITHROMBOTIC AGENTS
C03 – DIURETICS
C07 – BETA BLOCKING AGENTS
C08 – CALCIUM CHANNEL BLOCKERS
C09 – AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
C10 – LIPID MODIFYING AGENTS
D06 – ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE
D08 – ANTISEPTICS AND DISINFECTANTS
G02 – OTHER GYNECOLOGICALS
G03 – SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM
G04 – UROLOGICALS
J01 – ANTIBACTERIALS FOR SYSTEMIC USE
J02 – ANTIMYCOTICS FOR SYSTEMIC USE
J05 – ANTIVIRALS FOR SYSTEMIC USE
L01 – ANTINEOPLASTIC AGENTS
L04 – IMMUNOSUPPRESSANTS
M01 – ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS
M03 – MUSCLE RELAXANTS
N02 – ANALGESICS
N03 – ANTIEPILEPTICS
N05 – ANTIEPILEPTICS
N06 – PSYCHOANALEPTICS
N07 – OTHER NERVOUS SYSTEM DRUGS
R01 – NASAL PREPARATIONS
R03 – DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES
R03 – DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES R01 – NASAL PREPARATIONS
S01 – OPHTHALMOLOGICALS
V03 – ALL OTHER THERAPEUTIC PRODUCTS

Medicinal products authorised for marketing during the 1st quarter of 2018

INN	Trade Name	Pharm. Form	Strength	MAH	Holding country	MA no.		
ACIDUM GADOTERICUM	CLARISCAN 0.5mmol//ml	sol. for inj.	0.5mmol//ml	GE HEALTHCARE AS	NORWAY	10507	2018	01
ACIDUM GADOTERICUM	CLARISCAN 0.5mmol//ml	sol. for inj. in pre-filled pen	0.5mmol//ml	GE HEALTHCARE AS	NORWAY	10508	2018	01
ACIDUM TIOCTICUM (ALFA-LIPOICUM)	ACID TIOCTIC ROMPHARM 600 mg/24 ml	sol. for inj.	600mg/24ml	ROMPHARM COMPANY S.R.L.	ROMANIA	10582	2018	01
ALBUMINUM HUMANUM	ALBUMINA UMANA GRIFOLS 200g/l	sol. for inf.	200g/l	INSTITUTO GRIFOLS S.A.	SPAIN	10656	2018	01
AMIODARONUM	AMIODARONA HAMELN 50 mg/ml	conc. for sol. for inj./inf.	50mg/ml	HAMELN PHARMA PLUS GMBH	GERMANY	10587	2018	01
AMOXICILLINUM	OSPAMOX 125 mg/5 ml	powder for oral susp.	125mg/5ml	SANDOZ GMBH	AUSTRIA	10594	2018	01
AMOXICILLINUM	OSPAMOX 250 mg/5 ml	powder for oral susp.	250mg/5ml	SANDOZ GMBH	AUSTRIA	10595	2018	01
AMPICILLINUM	AMPICILINA FORTE 500 mg	caps.	500mg	FARMEX COMPANY S.R.L.	ROMANIA	10663	2018	01
ANAGRELIDUM	ANAGRELIDA DR. REDDY'S 0.5mg	caps.	0.5mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	10602	2018	01
ANAGRELIDUM	ANAGRELIDA ACCORD 0.5mg	caps.	0.5mg	ACCORD HEALTHCARE LIMITED	UK	10487	2018	01
ANAGRELIDUM	ANAGRELIDA ACCORD 1 mg	caps.	1mg	ACCORD HEALTHCARE LIMITED	UK	10488	2018	01
ANAGRELIDUM	ANAGRELIDA ZENTIVA 0.5mg	caps.	0.5mg	ZENTIVA, K.S.	CZECH REPUBLIC	10620	2018	01
ANAGRELIDUM	ANAGRELIDA TERAPIA 0.5mg	caps.	0.5mg	TERAPIA S.A.	ROMANIA	10626	2018	01
ANAGRELIDUM	GRENALVON 0.5mg	caps.	0.5mg	ALVOGEN MALTA OPERATIONS (ROW) LTD.	MALTA	10599	2018	01
ANAGRELIDUM	GRENALVON 1 mg	caps.	1mg	ALVOGEN MALTA OPERATIONS (ROW) LTD.	MALTA	10600	2018	01
ANAGRELIDUM	ANAGRELIDA TEVA 0.5mg	caps.	0.5mg	TEVA PHARMACEUTICALS	ROMANIA	10627	2018	01

INN	Trade Name	Pharm. Form	Strength	MAH	Holding country	MA no.		
				S.R.L.				
ANAGRELIDUM	ANAGRELIDA SANDOZ 0.5mg	caps.	0.5mg	SANDOZ S.R.L.	ROMANIA	10624	2018	01
ANAGRELIDUM	ANAGRELIDA GLENMARK 0.5mg	caps.	0.5mg	GLENMARK PHARMACEUTICALS S.R.O.	CZECH REPUBLIC	10625	2018	01
ATAZANAVIRUM	ATAZANAVIR ZENTIVA 150 mg	caps.	150mg	ZENTIVA, K.S.	CZECH REPUBLIC	10522	2018	01
ATAZANAVIRUM	ATAZANAVIR ZENTIVA 200 mg	caps.	200mg	ZENTIVA, K.S.	CZECH REPUBLIC	10523	2018	01
ATAZANAVIRUM	ATAZANAVIR ZENTIVA 300 mg	caps.	300mg	ZENTIVA, K.S.	CZECH REPUBLIC	10524	2018	01
ATOMOXETINUM	ATOMOXETINA MYLAN 10 mg	caps.	10mg	MYLAN S.A.S.	FRANCE	10528	2018	01
ATOMOXETINUM	ATOMOXETINA MYLAN 18 mg	caps.	18mg	MYLAN S.A.S.	FRANCE	10529	2018	01
ATOMOXETINUM	ATOMOXETINA MYLAN 25 mg	caps.	25mg	MYLAN S.A.S.	FRANCE	10530	2018	01
ATOMOXETINUM	ATOMOXETINA MYLAN 40 mg	caps.	40mg	MYLAN S.A.S.	FRANCE	10531	2018	01
ATOMOXETINUM	ATOMOXETINA MYLAN 60 mg	caps.	60mg	MYLAN S.A.S.	FRANCE	10532	2018	01
ATOMOXETINUM	ATOMOXETINA MYLAN 80 mg	caps.	80mg	MYLAN S.A.S.	FRANCE	10533	2018	01
ATOMOXETINUM	ATOMOXETINA MYLAN 100 mg	caps.	100mg	MYLAN S.A.S.	FRANCE	10534	2018	01
ATORVASTATINUM	STAVRA 10 mg	film-coated tabl.	10mg	ALKALOID-INT D.O.O.	SLOVENIA	10559	2018	01
ATORVASTATINUM	STAVRA 20 mg	film-coated tabl.	20mg	ALKALOID-INT D.O.O.	SLOVENIA	10560	2018	01
ATORVASTATINUM	STAVRA 40 mg	film-coated tabl.	40mg	ALKALOID-INT D.O.O.	SLOVENIA	10561	2018	01
ATORVASTATINUM	STAVRA 80 mg	film-coated tabl.	80mg	ALKALOID-INT D.O.O.	SLOVENIA	10562	2018	01
ATORVASTATINUM	ATORVASTATIN RANBAXY 10 mg	film-coated tabl.	10mg	RANBAXY (U.K.) LIMITED	UK	10543	2018	01
ATORVASTATINUM	ATORVASTATIN RANBAXY 20 mg	film-coated tabl.	20mg	RANBAXY (U.K.) LIMITED	UK	10544	2018	01
ATORVASTATINUM	ATORVASTATIN RANBAXY 40 mg	film-coated tabl.	40mg	RANBAXY (U.K.) LIMITED	UK	10545	2018	01
ATORVASTATINUM	ATORVASTATIN RANBAXY 80 mg	film-coated tabl.	80mg	RANBAXY (U.K.) LIMITED	UK	10546	2018	01
ATRACURIUM	ATRACURIUM KALCEKS 10 mg/ml	sol. for inj./for inf.	10mg/ml	AS KALCEKS	LATVIA	10499	2018	01

INN	Trade Name	Pharm. Form	Strength	MAH	Holding country	MA no.		
AZITHROMYCINUM	AZITROMICINA SANDOZ 250 mg	film-coated tabl.	250mg	SANDOZ S.R.L.	ROMANIA	10654	2018	01
AZITHROMYCINUM	AZITROMICINA SANDOZ 500 mg	film-coated tabl.	500mg	SANDOZ S.R.L.	ROMANIA	10655	2018	01
AZITHROMYCINUM	SUMAMED 250 mg	caps.	250mg	TEVA B.V.	THE NETHERLANDS	10608	2018	01
BORTEZOMIBUM	BORTEZOMIB PHARMAZAC 3.5 mg	powder for susp. for inf.	3.5mg	PHARMAZAC SA	GRECIA	10772	2018	01
BROMHEXINUM	BROMHEXIN LAROPHARM 12 mg	tabl.	12mg	LAROPHARM S.R.L.	ROMANIA	10593	2018	01
BROMHEXINUM	BROMHEXIN ROMPHARM 2mg/ml	oral drops/oral sol.	2mg/ml	ROMPHARM COMPANY S.R.L.	ROMANIA	10694	2018	01
CANDESARTANUM CILEXETIL	TANDESAR 32 mg	tabl.	32mg	TERAPIA S.A.	ROMANIA	10583	2018	01
CASPOFUNGINUM	CASPOFUNGINA TERAPIA 50 mg	powder for conc. for sol. for inf.	50mg	TERAPIA S.A.	ROMANIA	10501	2018	01
CASPOFUNGINUM	CASPOFUNGINA TERAPIA 70 mg	powder for conc. for sol. for inf.	70mg	TERAPIA S.A.	ROMANIA	10502	2018	01
CEFUROXIMUM	AXETINE 250 mg	film-coated tabl.	250mg	MEDOCHEMIE LTD.	CYPRUS	10659	2018	01
CEFUROXIMUM	AXETINE 500 mg	film-coated tabl.	500mg	MEDOCHEMIE LTD.	CYPRUS	10660	2018	01
CITIZINUM	NICOFERIN 1.5 mg	tabl.	1.5mg	PHARMACIA POLONICA SP. Z O.O.	POLONIA	10506	2018	01
COMBINATIONS	VICKS ANTIGRIP COMPLEX 500 mg/200 mg/10 mg	powder for oral sol.	500mg/ 200mg/ 10mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	10549	2018	01
COMBINATIONS	FARINGOSEPT RAPID MENTA 2 mg/0.6 mg/1.2 mg	pastilles	2mg/0.6mg/ 1.2mg	TERAPIA S.A.	ROMANIA	10512	2018	01
COMBINATIONS	FARINGOSEPT RAPID PORTOCALA 2 mg/0.6 mg/1.2 mg	pastilles	2mg/0.6mg/ 1.2mg	TERAPIA S.A.	ROMANIA	10513	2018	01
COMBINATIONS	FARINGOSEPT RAPID MIERE SI LAMAIE 2 mg/0.6 mg/1.2 mg	pastilles	2mg/0.6mg/ 1.2mg	TERAPIA S.A.	ROMANIA	10514	2018	01
COMBINATIONS	MICROLAX	rectal sol.		MCNEIL PRODUCTS LIMITED	UK	10634	2018	01

INN	Trade Name	Pharm. Form	Strength	MAH	Holding country	MA no.		
COMBINATIONS (ATORVASTATINUM+ PERINDOPRILUM)	PARVAXOR 10 mg/5 mg	caps.	10mg/5mg	EGIS PHARMACEUTICALS PLC.	HUNGARY	10563	2018	01
COMBINATIONS (ATORVASTATINUM+ PERINDOPRILUM)	PARVAXOR 20 mg/5 mg	caps.	20mg/5mg	EGIS PHARMACEUTICALS PLC.	HUNGARY	10564	2018	01
COMBINATIONS (ATORVASTATINUM+ PERINDOPRILUM)	PARVAXOR 40 mg/5 mg	caps.	40mg/5mg	EGIS PHARMACEUTICALS PLC.	HUNGARY	10565	2018	01
COMBINATIONS (ATORVASTATINUM+ PERINDOPRILUM)	PARVAXOR 10 mg/10 mg	caps.	10mg/10mg	EGIS PHARMACEUTICALS PLC.	HUNGARY	10566	2018	01
COMBINATIONS (ATORVASTATINUM+ PERINDOPRILUM)	PARVAXOR 20 mg/10 mg	caps.	20mg/10mg	EGIS PHARMACEUTICALS PLC.	HUNGARY	10567	2018	01
COMBINATIONS (ATORVASTATINUM+ PERINDOPRILUM)	PARVAXOR 40 mg/10 mg	caps.	40mg/10mg	EGIS PHARMACEUTICALS PLC.	HUNGARY	10568	2018	01
COMBINATIONS (ATORVASTATINUM+ PERINDOPRILUM)	EUVASCOR 10 mg/5 mg	caps.	10mg/5mg	LES LABORATOIRES SERVIER	FRANCE	10569	2018	01
COMBINATIONS (ATORVASTATINUM+ PERINDOPRILUM)	EUVASCOR 20 mg/5 mg	caps.	20mg/5mg	LES LABORATOIRES SERVIER	FRANCE	10570	2018	01
COMBINATIONS (ATORVASTATINUM+ PERINDOPRILUM)	EUVASCOR 40 mg/5 mg	caps.	40mg/5mg	LES LABORATOIRES SERVIER	FRANCE	10571	2018	01
COMBINATIONS (ATORVASTATINUM+ PERINDOPRILUM)	EUVASCOR 10 mg/10 mg	caps.	10mg/10mg	LES LABORATOIRES SERVIER	FRANCE	10572	2018	01
COMBINATIONS (ATORVASTATINUM+ PERINDOPRILUM)	EUVASCOR 20 mg/10 mg	caps.	20mg/10mg	LES LABORATOIRES SERVIER	FRANCE	10573	2018	01

INN	Trade Name	Pharm. Form	Strength	MAH	Holding country	MA no.		
COMBINATIONS (ATORVASTATINUM+ PERINDOPRILUM)	EUVASCOR 40 mg/10 mg	caps.	40mg/10mg	LES LABORATOIRES SERVIER	FRANCE	10574	2018	01
COMBINATIONS (BIMATOPROSTUM + TIMOLOLUM)	BIMATOPROST+TIMOLOL PHARMASWISS 0.3 mg/ml+5 mg/ml	eye drops, sol.	0.3mg/ml+ 5mg/ml	PHARMASWISS CESKA REPUBLIKA S.R.O.	CZECH REPUBLIC	10643	2018	01
COMBINATIONS (DORZOLAMIDUM+ TIMOLOLUM)	SIFIOPT 20 mg/5 mg/ml	eye drops, sol.	20mg/5mg/ml	OFTAFARMA ROMANIA S.R.L.	ROMANIA	10640	2018	01
COMBINATIONS (FLUTICASONUM+ FORMOTEROLUM)	FLUTIFORM 50 microgr./5 microgr.	press. susp. for inhal.	50microgr./5microgr.	MUNDIPHARMA GESELLSCHAFT M.B.H.	AUSTRIA	10611	2018	01
COMBINATIONS (FLUTICASONUM+ FORMOTEROLUM)	FLUTIFORM 125 microgr./5 microgr.	press. susp. for inhal.	125microgr./5microgr.	MUNDIPHARMA GESELLSCHAFT M.B.H.	AUSTRIA	10612	2018	01
COMBINATIONS (FLUTICASONUM+ FORMOTEROLUM)	FLUTIFORM 250 microgr./10 microgr.	press. susp. for inhal.	250microgr./10 microgr.	MUNDIPHARMA GESELLSCHAFT M.B.H.	AUSTRIA	10613	2018	01
COMBINATIONS (LAMIVUDINUM+ ZIDOVUDINUM)	LAMIVUDINA/ ZIDOVUDINA MYLAN 150 mg/300 mg	film-coated tabl.	150mg/ 300mg	MYLAN S.A.S.	FRANCE	10644	2018	01
COMBINATIONS (PARACETAMOLUM+ PHENYLEPHRINUM)	CAFFETIN COLDMAX 1000 mg/12,2 mg	powder for oral susp., sachet	1000mg/ 12,2mg	ALKALOID-INT D.O.O.	SLOVENIA	10629	2018	01
COMBINATIONS (PERINDOPRILUM+ INDAPAMIDUM)	PERINDOPRIL TOSILAT/INDAPAMIDA TEVA 2.5 mg/0.625 mg	film-coated tabl.	2.5mg/ 0.625mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	10630	2018	01
COMBINATIONS (PERINDOPRILUM+ INDAPAMIDUM)	PERINDOPRIL TOSILAT/INDAPAMIDA TEVA 5 mg/1.25 mg	film-coated tabl.	5mg/1.25mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	10631	2018	01
COMBINATIONS (TRAMADOLUM+ PARACETAMOLUM)	TRAMADOL/PARACETAMOL AMNEAL 37.5 mg/325 mg	film-coated tabl.	37.5mg/ 325mg	AMNEAL PHARMA EUROPE LIMITED	IRELAND	10486	2018	01
CYTARABINUM	CITARABINA KABI 100 mg/ml	sol. for inj./inf.	100mg/ml	FRESENIUS KABI ONCOLOGY PLC	UK	10585	2018	01

INN	Trade Name	Pharm. Form	Strength	MAH	Holding country	MA no.		
DARUNAVIRUM	DARUNAVIR TEVA 800 mg	film-coated tabl.	800mg	TEVA B.V.	THE NETHERLANDS	10542	2018	01
DEFERASIROXUM	DEFERASIROX TEVA 125 mg	tabl. for oral disp.	125mg	TEVA B.V.	THE NETHERLANDS	10525	2018	01
DEFERASIROXUM	DEFERASIROX TEVA 250 mg	tabl. for oral disp.	250mg	TEVA B.V.	THE NETHERLANDS	10526	2018	01
DEFERASIROXUM	DEFERASIROX TEVA 500 mg	tabl. for oral disp.	500mg	TEVA B.V.	THE NETHERLANDS	10527	2018	01
DESLORATADINUM	DESLORATADINA TERAPIA 5 mg	film-coated tabl.	5mg	TERAPIA SA	ROMANIA	10520	2018	01
DEXAMETHASONUM	DEXAMETAZONA KRKA 0.5mg	tabl.	0.5mg	KRKA D.D. NOVO MESTO	SLOVENIA	10614	2018	01
DICLOFENACUM	VOLTAREN 100 mg	suppos.	100mg	NOVARTIS PHARMA GMBH	GERMANY	10605	2018	01
DICLOFENACUM	VOLTAREN 50 mg	suppos.	50mg	NOVARTIS PHARMA GMBH	GERMANY	10604	2018	01
DICLOFENACUM	DICLOREUM 30 mg/g	cut. foam	30mg/g	ALFASIGMA S.P.A.	ITALY	10603	2018	01
DIOXID DE CARBON	DIOXID DE CARBON LINDE 100%	medicinal gas, liquefied	100%	LINDE GAZ MAGYARORSZAG ZRT.	HUNGARY	10521	2018	01
DIVERSE	BERES DROPS PLUS	oral drops-sol.		BERES PHARMACEUTICALS CO. LTD.	HUNGARY	10592	2018	01
DOXORUBICINUM	DOXORUBICINA ACCORD 2 mg/ml	conc. for sol. for inf.	2mg/ml	ACCORD HEALTHCARE LIMITED	UK	10647	2018	01
DROTAVERINUM	NO-SPA 40 mg	film-coated tabl.	40mg	SANOFI ROMANIA SRL	ROMANIA	10657	2018	01
DROTAVERINUM	NO-SPA 80 mg	film-coated tabl.	80mg	SANOFI ROMANIA SRL	ROMANIA	10658	2018	01
ENTACAPONUM	ENCAPIA 200 mg	film-coated tabl.	200mg	MEDOCHEMIE LTD.	CYPRUS	10628	2018	01
ENTECAVIRUM	ENTECAVIR ZENTIVA K.S. 0.5mg	film-coated tabl.	0.5mg	ZENTIVA, K.S.	CZECH REPUBLIC	10518	2018	01
ENTECAVIRUM	ENTECAVIR ZENTIVA K.S. 1 mg	film-coated tabl.	1mg	ZENTIVA, K.S.	CZECH REPUBLIC	10519	2018	01
ERLOTINIBUM	ERLOTINIB HEATON 100 mg	film-coated tabl.	100mg	HEATON K.S.	CZECH REPUBLIC	10504	2018	01
ERLOTINIBUM	ERLOTINIB HEATON 150 mg	film-coated tabl.	150mg	HEATON K.S.	CZECH REPUBLIC	10505	2018	01

INN	Trade Name	Pharm. Form	Strength	MAH	Holding country	MA no.		
ERLOTINIBUM	ERLOTINIB ZENTIVA 25 mg	film-coated tabl.	25mg	ZENTIVA K.S.	CZECH REPUBLIC	10515	2018	01
ERLOTINIBUM	ERLOTINIB ZENTIVA 100 mg	film-coated tabl.	100mg	ZENTIVA K.S.	CZECH REPUBLIC	10516	2018	01
ERLOTINIBUM	ERLOTINIB ZENTIVA 150 mg	film-coated tabl.	150mg	ZENTIVA K.S.	CZECH REPUBLIC	10517	2018	01
EXTRACT ALERGENIC STANDARDIZAT	STALORAL 300 IR/ml	spray sublingual	300IR/ml	STALLERGENES S.A.	FRANCE	10666	2018	01
EXTRACT ALERGENIC STANDARDIZAT	STALORAL 10 IR/ml	spray sublingual	10IR/ml	STALLERGENES S.A.	FRANCE	10664	2018	01
EXTRACT ALERGENIC STANDARDIZAT	STALORAL 100 IR/ml	spray sublingual	100IR/ml	STALLERGENES S.A.	FRANCE	10665	2018	01
FLUCONAZOLUM	FLUCONAZOL AUROBINDO 50 mg	caps.	50mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	10617	2018	01
FLUCONAZOLUM	FLUCONAZOL AUROBINDO 100 mg	caps.	100mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	10618	2018	01
FLUCONAZOLUM	FLUCONAZOL AUROBINDO 150 mg	caps.	150mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	10619	2018	01
GABAPENTINUM	GABALEPT 300 mg	caps.	300mg	TEVA B.V.	THE NETHERLANDS	10650	2018	01
GABAPENTINUM	GABALEPT 400 mg	caps.	400mg	TEVA B.V.	THE NETHERLANDS	10651	2018	01
GEMCITABINUM	GEMCITABIN STADA 38 mg/ml	conc. for sol. for inf.	38mg/ml	STADA ARZNEIMITTEL AG	GERMANY	10646	2018	01
GEMCITABINUM	GEMCITABINA KABI 40 mg/ml	conc. for sol. for inf.	40mg/ml	FRESENIUS KABI ONCOLOGY PLC.	UK	10586	2018	01
GLATIRAMER ACETAT	REMUREL 40 mg/ml	sol. for inj. in pre-filled pen	40mg/ml	ALVOGEN IPCO S.AR.L.	LUXEMBOURG	10601	2018	01
GLICLAZIDUM	GLYCLADA 30 mg	tabl. with prolonged release	30mg	KRKA, D.D., NOVO MESTO	SLOVENIA	10606	2018	01
IBUPROFENUM	IBALGIN 200 mg	oral susp., sachet	200mg	SANOFI ROMANIA S.R.L.	ROMANIA	10547	2018	01
IBUPROFENUM	IBALGIN FORTE 400 mg	oral susp., sachet	400mg	SANOFI ROMANIA S.R.L.	ROMANIA	10548	2018	01
IMATINIBUM	MEAXIN 100 mg	film-coated tabl.	100mg	KRKA, D.D., NOVO MESTO	SLOVENIA	10637	2018	01

INN	Trade Name	Pharm. Form	Strength	MAH	Holding country	MA no.		
IMATINIBUM	MEAXIN 400 mg	film-coated tabl.	400mg	KRKA, D.D., NOVO MESTO	SLOVENIA	10638	2018	01
IMATINIBUM	MEAXIN 100 mg	disp. tabl.	100mg	KRKA, D.D. NOVO MESTO	SLOVENIA	10538	2018	01
IMATINIBUM	MEAXIN 400 mg	disp. tabl.	400mg	KRKA, D.D. NOVO MESTO	SLOVENIA	10539	2018	01
IRBESARTANUM	CONVERIUM 75 mg	tabl.	75mg	MEDOCHEMIE ROMANIA S.R.L.	ROMANIA	10596	2018	01
IRBESARTANUM	CONVERIUM 150 mg	tabl.	150mg	MEDOCHEMIE ROMANIA S.R.L.	ROMANIA	10597	2018	01
IRBESARTANUM	CONVERIUM 300 mg	tabl.	300mg	MEDOCHEMIE ROMANIA S.R.L.	ROMANIA	10598	2018	01
IVABRADINUM	IVABRADINA TEVA 5 mg	film-coated tabl.	5mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	10632	2018	01
IVABRADINUM	IVABRADINA TEVA 7.5 mg	film-coated tabl.	7.5mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	10633	2018	01
KETOPROFENUM	KETOMAG 25 mg/g	gel	25mg/g	MAGISTRA C&C S.R.L.	ROMANIA	10667	2018	01
LACOSAMIDUM	KANILAD 50 mg	film-coated tabl.	50mg	MEDOCHEMIE LTD.	CYPRUS	10480	2018	01
LACOSAMIDUM	KANILAD 100 mg	film-coated tabl.	100mg	MEDOCHEMIE LTD.	CYPRUS	10481	2018	01
LACOSAMIDUM	KANILAD 150 mg	film-coated tabl.	150mg	MEDOCHEMIE LTD.	CYPRUS	10482	2018	01
LACOSAMIDUM	KANILAD 200 mg	film-coated tabl.	200mg	MEDOCHEMIE LTD.	CYPRUS	10483	2018	01
LAMIVUDINUM+ TENOFOVIRUM DISOPROXIL	LAMIVUDINA/TENOFOVIR DISOPROXIL CIPLA 300 mg/245 mg	film-coated tabl.	300mg/245mg	CIPLA (EU) LIMITED	UK	10584	2018	01
LANREOTIDUM	SOMATULINE PR 30 mg	powder+solv. for susp. for inj. with prolonged release.	30mg	IPSEN PHARMA	FRANCE	10662	2018	01
LATANOPROSTUM	AKISTAN 50 microgr./ml	eye drops, sol.	50microgr./ml	PHARMASELECT INTERNATIONAL BETEILIGUNGS GMBH	AUSTRIA	10497	2018	01
LATANOPROSTUM	LATANOPROST SANDOZ 50 microgr./ml	eye drops, sol.	50microgr./ml	SANDOZ S.R.L.	ROMANIA	10540	2018	01

INN	Trade Name	Pharm. Form	Strength	MAH	Holding country	MA no.		
LETROZOLUM	LETROZOL KABI 2.5 mg	film-coated tabl.	2.5mg	FRESENIUS KABI ONCOLOGY PLC.	UK	10645	2018	01
LETROZOLUM	LORTANDA 2.5 mg	film-coated tabl.	2.5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	10648	2018	01
MACROGOLUM	OLOPEG	conc. for sol. orala		MIP PHARMA GMBH	GERMANY	10668	2018	01
MEMANTINUM	MEMANTINA TORRENT 10 mg	film-coated tabl.	10mg	TORRENT PHARMA S.R.L.	ROMANIA	10556	2018	01
MEMANTINUM	MEMANTINA TORRENT 20 mg	film-coated tabl.	20mg	TORRENT PHARMA S.R.L.	ROMANIA	10557	2018	01
MEMANTINUM	MEMANTINA TORRENT 5 mg+10 mg+15 mg+20 mg (PACHET for INCEPEREA TRATAMENTULUI)	film-coated tabl.	5mg+10mg+ 15mg+20mg	TORRENT PHARMA S.R.L.	ROMANIA	10558	2018	01
MEROPENEMUM	MEROPENEM ACCORD 500 mg	powder for sol. for inj./inf.	500mg	ACCORD HEALTHCARE LIMITED	UK	10484	2018	01
MEROPENEMUM	MEROPENEM ACCORD 1 g	powder for sol. for inj./inf.	1g	ACCORD HEALTHCARE LIMITED	UK	10485	2018	01
MONTELUKASTUM	ASTMASAN 4 mg	granule	4mg	SANDOZ S.R.L.	ROMANIA	10498	2018	01
MONTELUKASTUM	MONTELUKAST AUROBINDO 10 mg	film-coated tabl.	10mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	10581	2018	01
MONTELUKASTUM	MONTELUKAST AUROBINDO 5 mg	tabl. mast.	5mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	10580	2018	01
MONTELUKASTUM	MONTELUKAST AUROBINDO 4 mg	tabl. mast.	4mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	10579	2018	01
MOXIFLOXACINUM	AVELOX 400 mg/250 ml	sol. for inf.	400mg/250ml	BAYER AG	GERMANY	10653	2018	01
MOXIFLOXACINUM	AVELOX 400 mg	film-coated tabl.	400mg	BAYER AG	GERMANY	10652	2018	01
OLMESARTANUM MEDOXOMILUM+ AMLODIPINUM	OLMESARTAN MEDOXOMIL/AMLODIPINA ACCORD 20 mg/5 mg	film-coated tabl.	20mg/5mg	ACCORD HEALTHCARE LIMITED	UK	10535	2018	01
OLMESARTANUM MEDOXOMILUM+ AMLODIPINUM	OLMESARTAN MEDOXOMIL/AMLODIPINA ACCORD 40 mg/5 mg	film-coated tabl.	40mg/5mg	ACCORD HEALTHCARE LIMITED	UK	10536	2018	01

INN	Trade Name	Pharm. Form	Strength	MAH	Holding country	MA no.		
OLMESARTANUM MEDOXOMILUM+ AMLODIPINUM	OLMESARTAN MEDOXOMIL/AMLODIPINA ACCORD 40 mg/10 mg	film-coated tabl.	40mg/10mg	ACCORD HEALTHCARE LIMITED	UK	10537	2018	01
OXYTOCINUM	OXITOCINA MEDIPHA SANTE 5 IU/ml	conc. for sol. for inf.	5IU/ml	MEDIPHA SANTE	FRANCE	10479	2018	01
PARACETAMOLUM	PARACETAMOL BIOFARM 500mg	tabl.	500mg	BIOFARM S.A.	ROMANIA	10610	2018	01
PARACETAMOLUM	PARACETAMOL ACCORD 10 mg/ml	sol. for inf.	10mg/ml	ACCORD HEALTHCARE LIMITED	UK	10550	2018	01
PARACETAMOLUM	PARACETAMOL FARMALIDER 500 mg	tabl.	500mg	FARMALIDER S.A.	SPAIN	10509	2018	01
PARACETAMOLUM	PARACETAMOL FARMALIDER 1000 mg	tabl.	1000mg	FARMALIDER S.A.	SPAIN	10510	2018	01
PEMETREXEDUM	PEMETREXED ZENTIVA 25 mg/ml	conc. for sol. for inf.	25mg/ml	ZENTIVA, K.S.	CZECH REPUBLIC	10503	2018	01
PEMETREXEDUM	PEMETREXED ALVOGEN 25 mg/ml	conc. for sol. for inf.	25mg/ml	ALVOGEN MALTA OPERATION (ROW) LTD.	MALTA	10623	2018	01
PIPERACILLINUM + TAZOBACTAMUM	PERASIN 2 g/0.25 g	powder for sol. for inf.	2g/0.25g	ANTIBIOTICE S.A.	ROMANIA	10551	2018	01
PIPERACILLINUM + TAZOBACTAMUM	PERASIN 4 g/0.50 g	powder for sol. for inf.	4g/0.50g	ANTIBIOTICE S.A.	ROMANIA	10552	2018	01
PIRACETAMUM	PIRACETAM MCC 400 mg	tabl.	400mg	MAGISTRA C & C S.R.L.	ROMANIA	10607	2018	01
PLANTE	SINUPRET	lozenges		BIONORICA SE	GERMANY	10609	2018	01
PLANTE	CANEPHRON FORTE	lozenges		BIONORICA SE	GERMANY	10500	2018	01
PLANTE	AGNUCASTON	film-coated tabl.		BIONORICA SE	GERMANY	10541	2018	01
PROPOFOLUM	PROPOFOL FRESENIUS 10 mg/ml	emulsion for inf./inj.	10mg/ml	FRESENIUS KABI DEUTSCHLAND GMBH	GERMANY	10590	2018	01
PROPOFOLUM	PROPOFOL FRESENIUS 20 mg/ml	emulsion for inf./inj.	20mg/ml	FRESENIUS KABI DEUTSCHLAND GMBH	GERMANY	10591	2018	01

INN	Trade Name	Pharm. Form	Strength	MAH	Holding country	MA no.		
RISPERIDONUM	RISPOLEPT 1 mg/ml	oral sol.	1mg/ml	JANSSEN PHARMACEUTICA N.V.	BELGIUM	10489	2018	01
RISPERIDONUM	RISPOLEPT CONSTA 25 mg	powder + solv. for susp. for inj. with prolonged release	25mg	JANSSEN PHARMACEUTICA N.V.	BELGIUM	10490	2018	01
RISPERIDONUM	RISPOLEPT CONSTA 50 mg	powder + solv. for susp. for inj. with prolonged release	50mg	JANSSEN PHARMACEUTICA N.V.	BELGIUM	10492	2018	01
RISPERIDONUM	RISPOLEPT CONSTA 37.5 mg	powder + solv. for susp. for inj. with prolonged release	37.5mg	JANSSEN PHARMACEUTICA N.V.	BELGIUM	10491	2018	01
ROSUVASTATINUM	STARCREST 5 mg	film-coated tabl.	5mg	LABORMED PHARMA S.A.	ROMANIA	10669	2018	01
ROSUVASTATINUM	STARCREST 10 mg	film-coated tabl.	10mg	LABORMED PHARMA S.A.	ROMANIA	10670	2018	01
ROSUVASTATINUM	STARCREST 20 mg	film-coated tabl.	20mg	LABORMED PHARMA S.A.	ROMANIA	10671	2018	01
ROSUVASTATINUM	STARCREST 40 mg	film-coated tabl.	40mg	LABORMED PHARMA S.A.	ROMANIA	10672	2018	01
TADALAFILUM	TADALAFIL CIPLA 20 mg	film-coated tabl.	20mg	CIPLA (EU) LIMITED	UK	10639	2018	01
TADALAFILUM	ARVALTI 2.5 mg	film-coated tabl.	2.5mg	CIPLA (EU) LIMITED	UK	10575	2018	01
TADALAFILUM	ARVALTI 5 mg	film-coated tabl.	5mg	CIPLA (EU) LIMITED	UK	10576	2018	01
TADALAFILUM	ARVALTI 10 mg	film-coated tabl.	10mg	CIPLA (EU) LIMITED	UK	10577	2018	01
TADALAFILUM	ARVALTI 20 mg	film-coated tabl.	20mg	CIPLA (EU) LIMITED	UK	10578	2018	01
TERLIPRESSINUM	GLYPRESSIN	pulb+solv. for sol. for inj.	1mg	FERRING GMBH	GERMANY	10495	2018	01
THIOPENTALUM	THIOPENTAL SODIC MOMAJA 500 mg	powder for susp. for inf.	500mg	MOMAJA S.R.O.	CZECH REPUBLIC	10641	2018	01
THIOPENTALUM	THIOPENTAL SODIC MOMAJA 1 g	powder for susp. for inf.	1g	MOMAJA S.R.O.	CZECH REPUBLIC	10642	2018	01

INN	Trade Name	Pharm. Form	Strength	MAH	Holding country	MA no.		
TOXINA BOTULINICA DE TIP A	DYSPORT 500 units	powder for sol. for inj.	500UI	IPSEN LIMITED	UK	10661	2018	01
TRAVOPROSTUM	TRAVOPROST PHARMATHEN INTERNATIONAL 30 microgr./ml	eye drops, sol	30microgr./ml	PHARMATHEN INTERNATIONAL S.A.	GRECIA	10511	2018	01
TROPICAMIDUM	TROPICAMIDA ROMPHARM 10 mg/ml	eye drops., sol.	10mg/ml	ROMPHARM COMPANY S.R.L.	ROMANIA	10494	2018	01
TROPICAMIDUM	TROPICAMIDA ROMPHARM 5 mg/ml	eye drops., sol.	5mg/ml	ROMPHARM COMPANY S.R.L.	ROMANIA	10493	2018	01
URAPIDILUM	TACHYBEN 25 mg	sol. for inj.	25mg	EVER NEURO PHARMA GMBH	AUSTRIA	10553	2018	01
URAPIDILUM	TACHYBEN 50 mg	sol. for inj.	50mg	EVER NEURO PHARMA GMBH	AUSTRIA	10554	2018	01
URAPIDILUM	TACHYBEN 100 mg	conc. for sol. for inf.	100mg	EVER NEURO PHARMA GMBH	AUSTRIA	10555	2018	01
VORICONAZOLUM	VERRIA 50 mg	film-coated tabl.	50mg	MEDOCHEMIE LTD.	CYPRUS	10588	2018	01
VORICONAZOLUM	VERRIA 200 mg	film-coated tabl.	200mg	MEDOCHEMIE LTD.	CYPRUS	10589	2018	01
ZOLPIDEMUM	EDLUAR 5 mg	subling. tabl.	5mg	MEDA PHARMA GMBH & CO. KG	GERMANY	10615	2018	01
ZOLPIDEMUM	EDLUAR 10 mg	subling. tabl.	10mg	MEDA PHARMA GMBH & CO. KG	GERMANY	10616	2018	01

Centrally authorised medicinal products notified for marketing in Romania during the 1st quarter of 2018

INN	Trade Name	Pharm. Form	Strength	MAH	Holding country	MA no.		
ANAGRELIDUM	ANAGRELIDA MYLAN 0.5mg	caps.	0.5mg	MYLAN S.A.S	FRANCE	1256	2018	01
ANAGRELIDUM	ANAGRELIDA MYLAN 1 mg	caps.	1mg	MYLAN S.A.S	FRANCE	1256	2018	02
BENRALIZUMABUM	FASENRA 30 mg	sol. for inj. in pre-filled pen	30mg	ASTRAZENECA AB	SUEDIA	1252	2018	01
DARUNAVIRUM	DARUNAVIR KRKA 400 mg	film-coated tabl.	400mg	KRKA, D.D., NOVO MESTO	SLOVENIA	1248	2018	02
DARUNAVIRUM	DARUNAVIR KRKA 800 mg	film-coated tabl.	800mg	KRKA, D.D., NOVO MESTO	SLOVENIA	1248	2018	09
DARUNAVIRUM	DARUNAVIR KRKA 600 mg	film-coated tabl.	600mg	KRKA, D.D., NOVO MESTO	SLOVENIA	1248	2018	06
DARVADSTROCELUM	ALOFISEL 5 million cells/ml	susp. for inj.	30 million cells /6ml	TAKEDA PHARMA A/S	DANEMARCA	1261	2018	01
EFAVIRENZUM+ EMTRICITABINUM+ TENOFOVIRUM DISOPROXIL	EFAVIRENZ/ EMTRICITABINA/ TENOFOVIR DISOPROXIL KRKA 600 mg/200 mg/245 mg	film-coated tabl.	600mg/200mg/245mg	KRKA, D.D., NOVO MESTO	SLOVENIA	1263	2018	01
EMICIZUMABUM	HEMLIBRA 30 mg/ml	sol. for inj.	30mg/ml	ROCHE REGISTRATION GMBH	GERMANY	1271	2018	01
EMICIZUMABUM	HEMLIBRA 150 mg/ml	sol. for inj.	150mg/ml	ROCHE REGISTRATION GMBH	GERMANY	1271	2018	02
INSULINUM GLARGINE	SEMGLEE 100 units/ml	sol. for inj. in pre-filled pen	100units/ml	MYLAN S.A.S.	FRANCE	1270	2018	01
OCRELIZUMAB	OCREVUS 300 mg	conc. for sol. for inf.	300mg	ROCHE REGISTRATION GMBH	GERMANY	1231	2018	01
TRASTUZUMABUM	HERZUMA 150 mg	powder for conc. for sol. for inf.	150mg	CELLTRION HEALTHCARE HUNGARY KFT.	HUNGARY	1257	2018	01