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EMERGENCY ORDINANCE No. 8/2018
of 22 February 2018 on regulation of certain healthcare measures

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Given requirement by objectives set by the Healthcare Strategy for development of national registries to monitor the main areas of public healthcare intervention, of national registers facilitating instant access of emergency units to information of strict necessity for life saving medical emergency intervention on patients with chemical substance poisonings,

Considering reach in the last 15-20 years to very serious threat to public health level for population worldwide through continuous increase of microbial resistance to antibiotics and in light of the unfortunately severe situation in Romania in that respect,

taking into account determinants of good healthcare system operation having regard to development of strategies and action plans by both specialised international bodies and at national or international political level (the European Union),

taking account of the request of the World Health Organization to Member States to develop national action plans to limit antibiotic resistance in 2017, it is imperative to develop both national action plans to limit antibiotic resistance, and national registers,

with a view to efficient management of human and financial public healthcare resources and close and prompt capture of real community healthcare needs, it is urgent to establish the legal framework for the rural telemedicine system and the Defence telemedicine computer system.

The need for emergency implementation of the telemedicine system in the Ministry of National Defence healthcare network derives from NATO medical assistance related commitments undertaken of by the Romanian Army, from the risks facing Romanian and foreign militaries by participation in complex military exercises conducted in shooting ranges/training bases, as well as from military missions in theatres of operations, in remote or hard-to-reach areas.

Emergency implementation of the defence telemedicine IT system results in achievement of the medical act through rapid diagnosis of military personnel and prompt application of medical protocols.

If maintained, the current situation would lead to perpetuation of identified risks (imprecise diagnosis, requiring longer time, less effective interventions and the possibility of complications).

Considering that lack of this legal framework is an impediment to operationalisation and implementation of the rural telemedicine system and the Defence telemedicine system, namely the impossibility of its extension at national level,

taking account of provisions of EC Regulation no. (EC) No 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) 339/93, EC Regulation no. No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law and animal health and animal welfare rules and European Standard SR EN ISO 17020: 2005 for independent, impartial and transparent implementation of tasks of control structures, so as to ensure the quality and consistency of official controls at all levels,

Noting that, in the event of non-adoption of the proposed measures, impartial conduct of tasks assigned as main role of control units may not be ensured, elements envisaging public interest and represent emergency and extraordinary circumstances,

considering that the implementation of the measures by state healthcare inspectors may only be conducted by use of seals, as action ensuring the control body with of compliance with measures for the blocking of non-compliant products or for closing the unit, thus eliminating potential risks to public health by disregard by the economic operator of penalties imposed,

given the need for a number of measures to reduce bureaucracy in the funding process and ensure implementation of outcome-, indicator-based financing, respectively, to ensure sustainability of projects with non-reimbursable external financing where funding is based on simplified costs, it is imperative to clarify the legal framework for funding from the Ministry of Health budget of expenditures incurred within national public healthcare programs based on substantiated requests of specialised units, certified for data genuineness and regularity.

Taking into account the importance of emergency medical assistance, to ensure delivery continuity beyond the baseline program, by the medical assistant, the emergency registrar and the dispatcher/radiotelephone operator, as well as by the ambulance driver/worker, provided they do not benefit from free time in line with time worked in addition to their normal working hours,

whereas maintenance of current legislation leads to improper use of an annex other than that of Framework Law no. 153/2017 regarding the salary of staff paid from public funds, as amended, which is available as Annex no. II, and not as Annex no. III as formerly provided in Framework Law no. 284/2010 on unitary salary of staff paid from public funds,

having in mind the likely major impact of all such aspects on the public as disregard of this measure leads to non-provision of these services, necessary for smooth running of emergency care,

considering that, according to healthcare measures included in the Governance Program 2017 - 2020, as approved by Decision of the Romanian Parliament no. 1/2018 for pass of a vote of confidence in the Government, a priority investment for the Ministry of Health is the building of a republican hospital and 8 regional emergency hospitals, the "republican hospital" and "regional emergency hospital" concepts need to be defined and clarified, respectively.

Taking into account that lack of a legal framework for arrangement and operation of a heliport is such as to prevent the smooth running of prompt and real time medical services,

whereas the legal framework needs to be set out for reorganisation of public healthcare units at the level of both unit management and hospital board of administration, a number of measures are introduced to improve the work for public healthcare unit organisation and operation.

For efficient management of public healthcare human and financial resources as well as for accurate and prompt capture of actual community healthcare needs, steps have to be taken to ensure continuity in healthcare units administration; therefore, during the 30 to 90 days from the date of vacancy of the Head of department, Head of Laboratory or Head of Medical Service positions, when the hiring competition is organised, the vacancy shall remain as such.

Having in mind the need to regulate the organisation of the healthcare system and its financing, in order to reduce costs and ensure optimal conditions for patients hospitalised, in outpatient medical care or requiring care in emergency units, urgent regulation is necessary for public hospital revenues from the renting of certain areas on their premises.

Taking into account the healthcare measures provided for in the Governance Program 2017 – 2020, relating to system proximity to the patient, with the ultimate goal to eliminate the need for insured persons to seek quality medical care in a different location, urgent legislative intervention is required to amend and supplement regulations on conditions and manner of prescribing and dispensing of medicines for improved insured person’s access to medicines provided in the frame of the social health insurance system.

Considering that certain medicinal products for serious conditions are initiated and continued by the specialist physician and that there are areas not covered by such specialists and taking into account that therapy discontinuation would lead to aggravated health status of such patients, set up of a legal framework is required to regulate the possibility of doctors to prescribe medication as part of the health insurance system pursuant to therapy initiation by medical letter whereas costs of respective medicines is not recovered if the insured person was entitled to benefit.

According to the measure stipulated in the Governance Program, namely "A barrier-free society for people with disabilities", approved by the Decision of the Romanian Parliament no. 1/2018, it is the obligation of public authorities to ensure access of persons with severe or advanced disabilities to sanitary materials and prostheses and orthoses, including assistive technologies and devices, with an aim

for both protection and promotion of the rights of persons with disabilities and protection of their physical and mental health.

Taking into account the patient's right to receive medicines under the social health insurance system as well as high costs of medicines given for serious conditions, lack of urgent regulation would render medicines inaccessible, with insured persons having to either cover such costs or give up treatment, which would result in aggravation of their health.

Considering that, for economic or social reasons, insured persons exist who are unable to change location to receive necessary treatment, according to current regulations, a legal framework is necessary to ensure their protection.

Having regard to the main purpose of health insurance, i.e. to protect insurants against any costs in case of illness or accident, absence of such regulations would violate one of the core social health insurance principles, potentially leading to insurants having to cover the costs of medicines,

taking into account the need for harmonisation of provisions of Government Emergency Ordinance no. 2/2018 for extension of certain timelines stipulated in Law no. 227/2015 regarding the Fiscal Code with those of Law no. 95/2006 on healthcare reform, republished as amended concerning the status as insurant within the social health insurance system, to enable natural persons required to pay social health insurance contribution, other than those on salary income, for whom the deadline for submission of the income declaration has been extended to 15 April 2018, to further benefit from provision of medical services, medicines and medical devices,

given that, according to provisions of Law no. 227/2015 regarding the Fiscal Code, as subsequently amended, the obligation to pay social health insurance contribution for employees is the responsibility of the employer and that, should the latter not pay the contribution, beneficiaries would be deprived of their insurant status and, in consequence, would no longer be able to benefit from medical services and medicines, leading to limitation of their right to the basic medical services package, the 3-month term for maintenance of insurant for this category of persons shall run from the date of employment or service termination,

taking into account that, to establish a person’s insurant status and category and their right to the basic package of medical services and medicines as well as to certain additional rights for particular categories of persons, data shall be delivered by authorities and institutions managing such data in order to avoid situations likely to affect insurants’ rights to medical services and medicinal products, with adverse public health consequences, the legal framework needs regulation of the date as of which such data shall apply.

Having in mind that the services provided on subscription are provided outside the health insurance system and taking into account that services included within are not reimbursed by the social health insurance system,

to avoid misinterpretation of the rules, because, unlike services provided by medical service insurers, medical services do not cover the risks, the phrase “medical services on subscription" must be redefined to highlight those reimbursed

from the budget of the Unique National Health Insurance Social Fund and those settled under the voluntary health insurance, respectively.

considering that, as a full Member State of the European Union, it is Romania's task to transpose and implement directives adopted by the European Union,

with an aim to avoid penalty payments against Romania under provisions of Article 260 (3) of the Treaty on the Functioning of the European Union accelerating the mechanism for the imposition of penalty payments where the European Commission, by bringing an action for failure to fulfil obligations before the Court of Justice, considers that the Member State has failed to fulfil its obligation to notify measures transposing a directive adopted under a legislative procedure,

given that all such aspects may have major impact on the state budget,

taking into account that parliamentary procedures for law approval do not allow for timely adoption, in the form of a draft law, of the transposition of European directives, given Romania's obligation, as a member of the European Union, by 31 March 2018 at the latest, to transpose provisions of Commission Directive (EU) 2017/1572 of 15 September 2017 supplementing Directive 2001/83/EC of the European Parliament and of the Council as regards good manufacturing principles and guidelines for medicinal products for human use,

taking into account that all such elements are of public interest and constitute emergency and extraordinary situations,

having regard to amendments to Government Emergency Ordinance no. 158/2005 on sickness and maternity social benefits, approved as amended by Law no. 399/2006, as amended, introduced by Government Emergency Ordinance no. 99/2017 implying that, as of 1 January 2018, the minimum insurance period in the health insurance system required to benefit from sickness insurance benefits has been increased from one to 6 months in the last 12 months preceding the month for which sick leave is granted,

taking into account that women are also included in the category of insured persons who, on 1 January 2018, meet the minimum monthly insurance period completed in the last 12 months preceding the month for which sick leave is granted, who may not benefit from maternity leave and compensation as well as from sick child care leave on grounds of increase of minimum insurance period from one to 6 months,

emergency legislative intervention is required to establish a derogation from the general rule on the minimum 6-month insurance period so as to allow persons insured under the sickness insurance scheme who on 1 January 2018 meet the minimum one-month insurance period to benefit from sick leave allowances for temporary work incapacity because of ordinary illness or work unrelated accidents, pregnancy and lactation medical leave, sick child care leave, under the law.

Taking into account that, at the date of submission by insured persons of the insurance statements for leave and allowances, the minimum contribution period for leave and allowances was one month during the last 12 months preceding the month for which sick leave is granted,

taking into account the necessity to grant medical leave and maternity related allowances, as well as for sick child care, as failure to do so would be harmful to the health of such persons,

in consideration that persons insured for leaves and indemnities in the sickness insurance scheme, who, prior to 1 January 2018 had fulfilled the minimum contribution period, may not benefit from leaves and indemnities for temporary work incapacity because of ordinary illness or work unrelated accidents, maternity and, sick child care, for failure to meet the increased minimum 6-month contribution period,

in the absence of a derogatory rule on circumstances of abovementioned persons, in spite of their status as insured in the social health insurance system and of meeting conditions for benefit from related rights until 1 January 2018, they will not benefit from sickness insurance indemnity for sick leave for temporary work incapacity from ordinary illnesses or out-of-work accidents, maternity medical leaves, medical leave for sick child care.

Considering that these elements are of general public interest and constitute urgent and extraordinary situations whose regulation may not be deferred,

taking into account that non-adoption of this normative act would directly impact the health of persons concerned and prevent timely access to sickness leave and sickness insurance indemnities for sick leave for temporary work incapacity from ordinary illness or out-of-work accidents, maternity medical leave, medical leave for sick child care,

conduct of medical proceedings in educational establishments is an important objective of local public administration. In order to improve health care services carried out in educational establishments, local public administration authorities may participate in their financing with amounts allocated from the local budget for payment of staff costs.

Based on provisions of Article 115 (4) of the Constitution of Romania, as amended,

the **Government of Romania** hereby adopts the following Emergency Ordinance.

ART. I

Law no. 95/2006 on healthcare reform, republished as amended in the Official Gazette of Romania, Part I, no. 652 of 28 August 2015, is hereby amended as follows:

……

36. Points 17 and 19 of Article 699 are hereby amended and shall read as follows:

"17. Medicinal product wholesale distribution – all activities consisting of procuring, holding, supplying or exporting medicinal products, apart from supplying medicinal products to the public, i.e. retail activities. Such activities are carried out by manufacturers or their depositories, importers, other wholesalers or

dispensing pharmacies in exceptional circumstances stipulated under Article 2 (7) of the Law of Pharmacy no. 266/2008, republished, as amended".

.....

"19. Public service obligation: the obligation placed on marketing authorisation holders/ marketing authorisation holder representatives and wholesalers to warrant permanent and adequate ranges of medicinal products so as to meet the requirements of a specific geographical area and to deliver the supplies requested over the whole of the area in question within the shortest time possible after order, as well as the obligation of dispensing pharmacies to purchase medicines if out of stock at the time of the orders; conditions specific on compliance with the public service obligation are established by order of the Minister of Health;".

37. Following pt. 40 Article of 699, three further points (points 41 – 43) shall be introduced, reading as follows:

"41. Manufacturer – any entity carrying out activities requiring the manufacturing authorisation stipulated under Article 755(1) and (3);

42. Pharmaceutical Quality System – all organisational steps taken to ensure expected quality of medicinal products for human use in line with their intended purpose;

43. Good Manufacturing Practice – Quality Assurance domain warranting consistent compliance with quality standards in medicinal product manufacture, importation and control, corresponding to its respective intended purpose".

38. One new article shall be introduced after Article701, i.e. Article 701^1, reading as follows:

„Article 701^1

(1) The NAMMD authorises and controls clinical trials with/without therapeutic benefit conducted with human medicinal products by verifying compliance with good clinical practices, as well as sites thereof.

(2) Clinical trials shall be conducted in accordance with the Principles and detailed guidelines for Good Clinical Practice in conduct of clinical trials on investigational medicinal products, approved through order of the Minister of Health, with Rules for authorisation of their sites as well as with Rules on implementation of Good Clinical Practice rules in the conduct of clinical trials on medicinal products for human use, approved by order of the Minister of Health, as proposed by the NAMMD."

39. Twenty-three new articles shall be introduced after Article 761, i.e. Articles 761^1 - 761^23, reading as follows:

"Article 761^1

The NAMMD shall take all necessary measures in accordance with its powers and responsibilities, by means of inspection and control, to ensure that operations for manufacturing of medicinal products for human use, those intended exclusively for export purposes included, are carried out compliant with Good Manufacturing Practice and the manufacturing authorisation.

ARTICLE 761^2

For medicinal products imported from third countries, the NAMMD shall take all necessary measures in accordance with its powers and responsibilities, by means of

inspection and control, to ensure that manufacture thereof meets standards at least equivalent to good manufacturing practice standards laid down in the European Union as well as by legally authorised manufacturers.

ARTICLE 761^3

The NAMMD shall take all necessary steps in accordance with its powers and responsibilities, by means of inspection and control, to ensure that all operations for manufacture or import of medicinal products are subject to a marketing authorisation in line with information provided in the marketing authorisation dossier.

ARTICLE 761^4

(1) Manufacturers shall repeatedly review their manufacturing processes in line with scientific and technical progress.

(2) Where a change to the marketing authorisation dossier is required, this shall be carried out using the mechanisms provided for in Regulation (EC) no. 1.234/2008 of the Commission of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations granted for medicinal products for human and veterinary use.

ARTICLE 761^5

The NAMMD shall take all necessary measures in accordance with its powers and responsibilities, by means of inspection and control, to ensure the establishment, application and maintenance by manufacturers of a pharmaceutical quality system.

ARTICLE 761^6

At each manufacture or import site, manufacturers shall have at their disposal a sufficient number of suitably trained personnel to achieve the objective of the pharmaceutical quality system.

ARTICLE 761^7

Tasks of the management and supervisory staff as well as of persons referred to in Article 766, who are responsible for the implementation and application of good manufacturing practice, are described in the pharmaceutical quality system.

ARTICLE 761^8

Staff referred to in Article 761^7 shall be entrusted with the authority necessary for proper conduct of their respective duties.

ARTICLE 761^9

Staff shall be provided with initial and ongoing training, the effectiveness of which shall be verified and include the theory and application of the concept of quality assurance and good manufacturing practice.

ARTICLE 761^10

Manufacturers shall establish and comply with hygiene plans adapted to activities to be carried out; in particular, such plans should include procedures relating to health, hygiene practices and staff equipment.

ARTICLE 761^11

Manufacturers shall locate, design, build, adapt and maintain their manufacturing sites and equipment in a manner appropriate to the intended operations.

ARTICLE 761^12

Manufacturers shall position, design and operate their manufacturing premises and equipment in such a way as to minimize the risk of error and allow effective cleaning and maintenance to avoid contamination, cross-contamination and any general adverse effects on drug quality.

ARTICLE 761^13

Sites and equipment used by manufacturers in manufacturing or import operations, which are critical to product quality, shall be subject to appropriate qualifications and validations.

ARTICLE 761^14

(1) Manufacturers shall establish and maintain a documentation system based on specifications, manufacturing formulas and processing and packaging instructions, procedures and records covering the various manufacturing operations performed.

(2) The documentation system shall ensure data quality and integrity; documents shall be clear, error-free and kept up to date.

(3) Pre-established procedures for manufacturing operations and general conditions at the disposal of manufacturers shall be available together with the specific manufacturing documents for each batch; this set of documents shall allow tracking the manufacturing history of each batch.

(4) Manufacturers shall keep the documentation relating to a medicinal product batch for at least one year from the date of expiry of the respective batch or at least 5 years after the certification provided for in Article 769(3), depending on which is longer.

ARTICLE 761^15

(1) Where electronic, photographic or other data processing systems are used instead of written documents, manufacturers shall first validate such systems, thereby demonstrating proper storage of data for the intended duration; data stored using such systems should be readily available to the NAMMD in legible form and provided on request.

(2) Data stored electronically shall be protected against unauthorised access, loss or damage, using such methods as back-up and transfer to a different storage system; audit trails shall be kept up to date.

ARTICLE 761^16

(1) The NAMMD shall take all necessary measures in accordance with its powers and responsibilities, by means of inspection and control, to ensure that manufacturers' performance of the various manufacturing operations is compliant with the pre-established instructions and procedures and good manufacturing practice.

(2) Manufacturers shall provide adequate and sufficient resources to carry out in-process controls.

(3) All process deviations and product nonconformities shall be thoroughly documented and investigated.

ARTICLE 761^17

Manufacturers shall take appropriate technical and organisational measures to avoid cross-contamination and mix-ups.

ARTICLE 761^18

(1) All new product manufacture processes or any major changes of the manufacturing process shall be validated.
(2) Critical stages of manufacturing processes shall be periodically revalidated.
ARTICLE 761^19
(1) Manufacturers shall establish and maintain a quality control system under the authority of a person with all the necessary qualifications and independent from manufacturing as such.
(2) Such persons shall have at their disposal/have access to one or more quality control laboratories, sufficiently and adequately staffed, to carry out the necessary verifications and tests on raw and starting materials, packaging materials and the necessary tests for intermediate and finite products.
ARTICLE 761^20
For medicinal products, imported from third countries included, manufacturers may use contracted laboratories if authorised in accordance with provisions of Articles 761^23 and 729 b).
ARTICLE 761^21
During the final control of the finished medicinal product, before its release for sale or distribution, the manufacturer's quality system shall also take into account, in addition to respective analytical results, such key information as: manufacturing conditions, results of interphase tests, assessment of manufacturing documents and product conformity with its specifications, the final packaging included.
ARTICLE 761^22
(1) Manufacturers shall keep samples of each finished product batch for at least one year from their respective expiry dates.
(2) Samples of raw and starting materials used in the manufacturing process, other than solvents, gases or water, should be kept for at least 2 years after product release.
(3) The term referred to in (2) may be shortened if, as provided in the relevant specifications, the stability of the material is lower.
(4) Samples provided for under (1) and (2) shall be made available on NAMMD request.
(5) In the frame of the manufacturing authorisation process, in agreement with the NAMMD, manufacturers may establish different conditions for sampling and storage of raw materials and certain products manufactured individually or in small quantities or where storage may pose particular problems.
ARTICLE 761^23
(1) Any outsourced manufacturing or import/manufacturing- or import-related operation shall be subject to a written contract.
(2) The contract shall clearly define each party's responsibilities and, in particular, the contract beneficiary's obligation to comply with Good Manufacturing Practice rules as well as the batch release qualified person's referred to in Article 766 manner to carry out assigned tasks.
(3) The contract beneficiary may subcontract parts of the work under contract on Contractor's written agreement only.

(4) The contract beneficiary shall comply with Good Manufacturing Practice principles and guidelines applicable to operations concerned as established in the European Union and allow inspections carried out by the NAMMD pursuant to Article 857."

40. Two new articles shall be introduced after Article 769, i.e. Articles 769^1 and 769^2, reading as follows:

„Article 769^1

(1) The NAMMD shall take all necessary measures in accordance with its powers and responsibilities, by means of inspection and control, to ensure that manufacturers implement a system for record and assessment of complaints and an effective system for prompt and timely recall of medicines from the distribution network.

(2) Manufacturers shall record and investigate all non-compliance complaints.

(3) Manufacturers shall inform the NAMMD and, where appropriate, the marketing authorisation holder, of any non-compliance potentially leading to recall or abnormal stock shortages as well as of their countries of destination, where known.

(4) Stock recalls shall be performed in accordance with provisions of Article 879.

ARTICLE 769^2

Manufacturers shall perform repeated self-inspections within the pharmaceutical quality system to monitor implementation of and compliance with Good Manufacturing Practice rules and propose remedial action and/or necessary preventive action; manufacturers shall keep records of such self-inspections as well as of any subsequent corrective action taken."

41. Article 784 is hereby amended and shall read as follows:

„Article 784

The secondary packaging and the leaflet may include symbols or pictograms designed to clarify certain information provided for in Article 774 and Article 781(1) as well as other Summary of Product Characteristics compatible information deemed useful to the patient, excluding any advertising item."

42. Paragraphs 1) and (8) of Article 800 are hereby amended and shall read as follows:

„Article 800

(1) Medicinal product wholesalers established in Romania shall carry out their activities based on a medicinal product wholesale authorisation issued by the NAMMD, stating their headquarters/premises for which the authorisation is valid.

.....

(8) The Ministry of Health shall suspend or revoke the authorisation provided for in (3) where authorisation conditions are no longer met."

43. The introduction to Article 803 and letter c) thereof are hereby amended and shall read as follows:

„Article 803

Holders of the wholesale distribution authorisation shall meet the following minimum requirements:

.....

c) supply medicinal products only to persons who, in their turn, hold a wholesale distribution authorisation, to pharmaceutical units authorised by the Ministry of Health to dispense medicines to the public or persons entitled to supply medicinal products to the public in Romania, on NAMMD proposal and approved by order of the Minister of Health."

44. Paragraph (2) of Article 804 is hereby amended and shall read as follows:

"(2) Within the limits of their responsibilities, medicinal product marketing authorisation holders/marketing authorisation holder representatives and wholesalers of respective products actually placed on the Romanian market shall ensure adequate and continuous stocks of products in question to dispensing pharmaceutical units and legal entities entitled to supply medicines to the public in such a way as to cover the needs of patients in Romania, under conditions laid down by order of the Minister of Health; by order of the Minister of Health, the Ministry of Health sets out the obligation of medicine wholesale sites, importers, authorised manufacturers and closed-circuit dispensing pharmacies to report medicinal product stocks and trade operations, distribution outside Romania included, carried out with medicinal products for human use in their portfolio/stock, priced as approved in accordance with provisions of this Title."

45. Four new paragraphs shall be introduced after Article 804(2), i.e., paragraphs (2^1) - (2^4), reading as follows:

"(2^1) In order to ensure market availability of medicinal product adequate and continuous stocks, in accordance with the law and in consultation with the NAMMD, the Ministry of Health may establish temporary restrictive measures on distribution outside Romania, approved by order of the Minister of Health.

(2^2) The NAMMD shall monitor the medicinal product market for compliance with and implementation of specific legislation, pursue statistics and forecasts related to its scope, with a view to developing and proposing ruling acts.

(2^3) The NAMMD shall undertake legal measures to ensure constant and adequate ranges of medicines meeting patient needs.

(2^4) The NAMMD shall notify the Ministry of Health and submit monthly reports to the Minister of Health on disruptions in medicinal product supply, as resulting from monthly reports on placement on the Romanian market."

46. Article 809 is hereby amended and shall read as follows:

„Article 809

Provisions of Article 799 and Article 803 c) shall not apply to third country medicinal product wholesale distribution. Provisions of Article 803 lit. (b) and (d) shall not apply to medicinal products received directly from a third country, without importation. In such cases however, wholesalers shall ensure that medicinal products are obtained only from persons authorised or entitled to supply medicinal products in accordance with legal provisions applicable in the third country concerned. Where wholesalers supply medicinal products to persons from third countries, they shall ensure that medicinal products are supplied only to persons authorised or entitled to receive medicines for wholesale or dispensing purposes, in accordance with the law applicable in the third country concerned.

Provisions of Article 805 shall apply to supply of medicinal products to third country persons authorised or entitled to supply medicinal products to the public."

47. Paragraph (4) of Article 814 is hereby amended and shall read as follows:

"(4) Information given in the forms provided for (3) shall be published on the websites of the NAMMD, of paying/sponsoring/benefit providing entities, as well as on respective websites of their beneficiaries."

48. Four new paragraphs shall be introduced after paragraph (2) of Article 857, i.e., paragraphs (2^1) - (2^4), reading as follows:

"(2^1) By means of the repeated inspections provided for in (2), the NAMMD shall ensure that manufacturers authorised in accordance with Article 755 (1) and (3) comply with good manufacturing practice principles and guidelines laid down in Articles 761^1 - 761^23 and Article 769^1 and 769^2. The NAMMD shall comply with European Union inspection and information exchange procedures as published by the European Commission.

(2^2) Manufacturers and the NAMMD shall construe and apply Good Manufacturing Practice principles, guidelines and terms described in Articles 761^1 - 761^23 and Article 769^1-769^2 in accordance with guideline provisions referred to in Article 764. For advanced therapy medicinal products, provisions shall apply of the guideline on Good Manufacturing Practice specific to advanced therapy medicinal products as laid down in Article 5 of Regulation (EC) no. 1782/2003 and Regulation (EC) no. 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) 726/2004.

(2^3) In carrying out its inspection and control duties, the NAMMD shall take all measures necessary and implement a pharmaceutical quality system in its own inspection service, to be complied with by inspection service staff and management.

(2^4) The quality system set out in (2^3) shall be updated as necessary."

49. Two new letters shall be introduced after paragraph (8) d) of Article 857, i.e. e) and f), reading as follows:

"e) inspect clinical NAMMD trial sites approved in accordance with Article 701^1;

f) collect documents, copies of relevant documents, respectively, and take photographs of the premises and equipment, potentially serving as proof of the activity inspected."

50. Article 875 is hereby amended and shall read as follows:

„Article 875

(1) Insofar not committed under such conditions as to be considered as criminal offences pursuant to criminal law, the following shall be deemed as offences and are punishable as follows:

a) imposition of a 50.000 lei - 100.000 lei fine on manufacturers/importers/ wholesalers, and closure of respective sites, in the case of operation of the respective medicinal product manufacturing/ wholesale site in the absence of a manufacturing/wholesale authorisation granted by the NAMMD; the same fine is imposed on manufacturers/importers/wholesalers and revocation of the medicinal product manufacturing/wholesale authorisation for operation of the respective

manufacturing/wholesale site whose manufacturing/wholesale authorisation has been suspended by the NAMMD;
b) imposition of a 10.000 lei - 30.000 lei fine on laboratories, for noncompliance with Good Laboratory Practice Principles, approved through Government Decision no. 63/2002 on approval of Good Laboratory Practice Principles, as well as inspection and verification of compliance therewith in the case of testing on chemical substances, as amended, by laboratories conducting pharmacotoxicologic testing for preparation of marketing authorisation dossiers for medicinal products for human use;
c) imposition of a 50.000 lei-100.000 lei fine on manufacturers/importers/ wholesalers/ marketing authorisation holders, as is the case, for the following: conduct at the respective sites of activities other than included in the authorisation granted pursuant to Article 757(3) or Article 800(1); the same fine shall be imposed for distribution of medicinal products outside their shelf life;
d) imposition of a 30.000 lei-50.000 lei fine on marketing authorisation holders/marketing authorisation holder representatives for noncompliance with obligations pursuant to Articles 774, 776 - 778, 779, 781, Article 785(1) and (2);
e) imposition of a 50.000 lei-100.000 lei fine and cu suspension of the medicinal product manufacturing/wholesale authorisation to manufacturers/importers/ wholesalers for noncompliance, as the case may be, of provisions of Article 756, Article 761 lit. a), d), e) and g), Article 802, Article 803 lit. a) - d), noncompliance with obligations imposed by the NAMMD pursuant to Article 865; the same fine shall be imposed on medicinal product brokers and exclusion from the Register of brokers for noncompliance with provisions of Article 810(1) and (2);
f) imposition of a 30.000 lei-50.000 lei fine on manufacturers/importers/ wholesalers, for noncompliance with provisions of Article 761 b), c), f), h) and i) or of Article 803 e), f), g), h), i) and j);
g) imposition of a 50.000 lei-100.000 lei fine and 1-year suspension of the medicinal product manufacture/import/wholesale authorisation for offences specified under c), d), f), h) and j) and repeated within 3 months;
h) imposition of a 10.000 lei 30.000 lei fine on marketing authorisation holders for noncompliance with provisions of Article 735(1), Article 736(2), Article 737, Article 830(1) - (4), as well as for noncompliance with the obligation imposed by the NAMMD pursuant to Article 830(5), Article 835, noncompliance with obligations imposed by the NAMMD pursuant to Article 865(1) a) - e);
i) imposition of a 10.000 lei-30.000 lei fine on importers infringing their commitment for reporting to the NAMMD of the status of each import, in line with provisions of Order of the Minister of Health no. 1.295/2015 on manufacturing authorisation of manufacturers, importers of human medicinal product, investigational medicinal products included, independent control sites and grant of the Good Manufacturing Practice Certificate or in case of mistaken or incomplete reports;
j) imposition of a 10.000 lei-30.000 lei fine on manufacturers/importers/ wholesalers, as is the case for noncompliance with the obligation stipulated in Article 803 k) or in case of mistaken or incomplete reports;

k) imposition of a 50.000 lei-100.000 lei fine on wholesalers and dispensing pharmacies, for noncompliance with obligations stipulated or established, as is the case, pursuant to Article 699, 19) or Article 804(2) and (2^1); the same fine shall be imposed on marketing authorisation holders/marketing authorisation holder representatives in Romania for noncompliance with obligations under Article 699 19), Article 799(6) or Article 804(2) and (2^1); where the same offence is found recommitted within 3 months since the last finding, the distribution/operation authorisation shall be revoked, as required;
l) imposition of a 10.000 lei-20.000 lei fine on the qualified person in line with Article 766, for noncompliance with provisions of Article 769;
m) imposition of a 10.000 lei-30.000 lei fine on the qualified person in line with Article 766, and 1-year suspension of the Qualified Person Certificate for repeated offence as per l) within 6 months; suspension of the Qualified Person Certificate may be lifted is only possible on submission of a document showing that the Qualified Person has attended at least one training session on medicinal product Good Manufacturing Practice during suspension;
n) imposition of a 30.000 lei-50.000 lei fine on the main investigator and termination of the trials for clinical trials not authorised by the NAMMD for conduct in Romania;
o) imposition of a 30.000 lei-50.000 lei fine on the site and termination of trials for conduct of clinical trials in Romania at sites not authorised by the NAMMD for conduct of clinical trials on medicinal products for human use;
p) imposition of a 10.000 lei-30.000 lei fine on the site and suspension of the authorisation for conduct of clinical trials for noncompliance with conditions for authorisation as clinical trial sites in line with provisions of Article 701^1(2);
q) imposition of a 30.000 lei-50.000 lei fine on the main investigator and the sponsor, as well as termination of clinical trial conduct for noncompliance with regulations in force on Good Clinical Practice related to medicinal products, as approved through order of the Minister of Health;
r) imposition of a 10.000 lei-30.000 lei fine on active substance manufacturers/ importers/wholesalers, for noncompliance with provisions of Article 771*)(1)-(5);
s) imposition of a 10.000 lei-20.000 lei fine on wholesalers not holding a marketing authorisation, for noncompliance with provisions of Article 799(4);
ș) imposition of a 10.000 lei- 30.000 lei fine on manufacturers/importers/ wholesalers/ marketing authorisation holders/marketing authorisation holder representatives, as is the case, for noncompliance with situations provided for under Articles 812 - 814, Article 816, Article 820(1) - (3) or Article 822;
t) imposition of a 50.000 lei-100.000 lei fine on marketing by marketing authorisation holders/marketing authorisation holder representatives of medicinal products for absence of manufacture prices approved by the Ministry of Health in line with provisions of Article 890, except for in cases of price non-approval within the legal time limit; the same fine shall be imposed on wholesalers and dispensing pharmacies for product distribution/dispensing products in the absence of manufacture prices approved by the Ministry of Health in line with provisions of Article 890, except for in cases of price non-approval within the legal time limit;

ţ) imposition of a 50.000 lei-100.000 lei fine on marketing authorisation holders/marketing authorisation holder representatives for using higher manufacture prices than approved by the Ministry of Health in line with provisions of Article 890;
u) imposition of a 50.000 lei-100.000 lei fine on wholesalers for using higher wholesale prices than approved by the Ministry of Health in line with provisions of Article 890;
v) imposition of a 50.000 lei-100.000 lei fine on dispensing pharmacies for using higher retail prices than approved by the Ministry of Health in line with provisions of Article 890;
x) imposition of a 10.000 lei-30.000 lei fine on medicinal product importers, authorised manufacturers, wholesalers and dispensing pharmacies for noncompliance with the obligation for reporting the status of products distributed pursuant to provisions of order of the Minister of Health pursuant to Article 804(2) or in case of mistaken or incomplete reports;
y) imposition of a 75.000 lei-100.000 lei fine on a legal entity responsible for marketing of a medicinal product for noncompliant with provisions of Article 704.
(2) Offences are found and penalties under (1) are imposed by NAMMD inspectors."
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*) Although not accurate, the phrase “Article 771" has been taken over as published on page 12 of the Official Gazette of Romania, Part I, no 190 of 1 March 2018.
51. One new article shall be introduced after Article 926, i.e., Article 926^1, reading as follows:
„Article 926^1
The National Catalogue of Medical Devices, including settlement prices for medical devices, the technical manner for establishing settlement prices and the categories of devices for which settlement prices are set under the law are approved by order of the Minister of Health, in consultation with the NAMMD and the National Health Insurance House."
52. In the body of the law, the phrase "medical devices" shall be replaced with "medical devices, technologies and assistive devices".
ARTICLE II
(1) Provisions of Article I 50 shall come into force 30 days as of publication of this Emergency Ordinance in the Official Gazette of Romania, Part I.
(2) Provisions of Article I 28 shall come into force on January 1st 2019.ART. III
……
*
Paragraphs 37, 39, 40 and 48 of Article I of this Emergency Ordinance ensure transposition of Commission Directive 2017/1572/EU of 15 September 2017 supplementing Directive 2001/83/EC of the European Parliament and of the Council as regards principles and guidelines for good manufacturing practice for medicinal products human use, published in the Official Journal of the European Union (JOUE) series L no. 238/44 of 16 September 2017.

PRIME-MINISTER
VASILICA-VIORICA DĂNCILĂ

Countersigned:
Minister of Health,
Sorina Pintea

p. Viceprime-minister, Minister of Regional development and Public Administration,
Sirma Caraman,
Secretary of state

Minister of National Defence,
Mihai-Viorel Fifor

p. Minister of Internal Affairs,
Gheorghe Nucu Marin,
Secretary of stat

Minister of Transportation,
Lucian Şova

Minister of Labour and Social Justice,
Lia-Olguţa Vasilescu

Minister of Communications and the Informaţion Society,
Petru Bogdan Cojocaru

Minister of Public Finance,
Eugen Orlando Teodorovici

Minister of Economy,
Dănuţ Andruşcă

Minister of External Affairs,
Teodor-Viorel Meleşcanu

Minister delegate for European Affairs,
Victor Negrescu

Minister of National Education,
Valentin Popa

Bucharest, 22 February 2018.
Nr. 8.

ORDER Nr. 40/2018 of 16 January 2018

on supplementation of Order of the Minister of Health no. 861/2014 on approval of criteria and methodology for assessment of health technologies, of documentation to be submitted by applicants, methodological means used in the assessment for inclusion, extension of indications, non-inclusion into or exclusion from the List of International 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, as well as the means for appeal thereof

IESSUED BY: MINISTER OF HEALTHI
PUBLISHED IN: OFFICIAL GAZETTE No. 73 of 25 January 2018

On seeing Approval Report no. F.B. 379 of 15.01.2017 of the Medicinal Product and Medical Devices Policy Directorate of the Ministry of Health notification no. 53.183E of 5.12.2017 of the National Agency for Medicines and Medical Devices, registered with the Ministry of Health under no. 66.177 of 5.12.2017,

Taking into account provisions of Article 243 of Law no. 95/2006 on healthcare reform, republished as amended,

In consideration of provisions of Articles (3) and (5) 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 Minster of Health no. 861/2014 on approval of criteria and methodology for assessment of health technologies, of documentation to be submitted by applicants, methodological means used in the assessment for inclusion, extension of indications, non-inclusion into or exclusion from the List of International 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, as well as the means for appeal thereof, published in the Official Gazetter of Romania Part I, no 557 of 28 July 2014, as amended, shall be supplemented as follows:

- Table no. 8 shall be introduced after Table no. 7 in annex no. 1, reading as follows:

" Table no. 8 – Criteria for assessment of new INNs plasmatic derivatives for the treatment of rare diseases for which the respective INNs are the only therapeutic alternative

Criterion	Score
New INNs plasmatic derivatives for the treatment of rare diseases for which the respective INNs are the only therapeutic alternative	80"

Article II
This Order shall be published in the Official Gazette of Romania Part I.

Minister of Health,
Florian-Dorel Bodog

Bucharest, 16 January 2018.
Nr. 40.

Medicinal product batches recalled during the 1st quarter of 2018

No.	Product recalled/ withdrawn	Pharmaceutical form	Strength	INN	Manufacturer/ MAH	Batch	Grounds for recall/withdrawal	Action proposed	Recall/ Withdrawal date
1	LISINOPRIL SANDOZ 20mg	tablets	20 mg	lisinopril	Salutas Pharma GmbH, Germany/ Hexal AG, Germany	All batches under MA no. 6107/2005/01	product whose 2-year shelf-life has expired (as stipulated by Order of the Minister of Health no. 279/2005) following NAMMD approval (on 27.11.2015) of changes to MA	Voluntary recall and destruction	19.01.2018
2	DUODART 0,5 mg/0,4 mg	capsules	0,5 mg/ 0,4 mg	combinations (dutasteride+ tamsulosin)	Catalent Germany Schorndorf GmbH, Germany/GSK SRL Romania	batch 14351456F under (MA no. 2641/01-02-03)	product whose 2-year shelf-life has expired (as stipulated by Order of the Minister of Health no. 279/2005) following NAMMD approval (on 30.09.2015) of changes to MA	Voluntary recall and destruction	19.01.2018
3	DUOFILM	cutaneous solution		combinations	Stiefel Laboratories Ltd. Ireland/GSK Consumer Healthcare SRL, Romania	C1B43	product whose 2-year shelf-life has expired (as stipulated by Order of the Minister of Health no. 279/2005) following NAMMD approval (on 22.12.2015) of changes to MA	Voluntary recall and destruction	29.01.2018
4	XTANDI 40 mg	soft capsules	40 mg	enzalutamide	Astelas Pharma Europe B.V., The Netherlands	17C0623	product (66 boxes) whose bilingual Slovenian-Croatian packaging and leaflet have been delivered to Mediplus Exim SRL wholesaler instead of a different batch, withdrawn at pharmacy/patient level	Voluntary recall at pharmacy/ hospital level and destruction	29.01.2018

5	PARACOF 300 mg/30 mg	tablets	300 mg/ 30 mg	combinations (paracetamol + caffeine)	Sintofarm S.A., Romania	S0117001	Batch withdrawn in result of the complaint of Farmexpert DCI wholesaler on missing 1 blister from each 7 outer packages	Recall at warehouse and pharmacy levels, allowing for re-packaging, on condition of provision by the manufacturer of additional information on risk assessment as related to product quality	14.02.2018
6	BONDULC 40µg/ml	eye drops, solution	40µg/ml	travoprost	Pharmaten SA GREECE, Balkan Pharma AD Bulgaria/Actavis Group PTC EHF Iceland	1TR030415A (exp. 04.2018)	batch distributed in Romania belonging to the bulk batch 1TR030415, subject to Rapid Alert issued by the Polish competent authority on quality non-conformity consisting of leakage from vials rendering batch and expiry date illegible on the primary packaging	Withdrawal at pharmacy/ hospital level and destruction	20.02.2018
7	FLOXAL 3mg/ml	eye drops, solution	3 mg/ml	ofloxacin	Dr. Gerhard Mann Chem Pharm Fabrik GmbH, Germany	705, 725, 776, 796, 816, 836, 866 (MA 5040/2004/01)	product whose 2-year shelf-life has expired (as stipulated by Order of the Minister of Health no. 279/2005) following NAMMD approval (on 09.12.2015) of changes to MA	Voluntary recall and destruction	12.03.2018

8	FLOXAL 3mg/g	eye ointment	3mg/g	ofloxacin	Dr. Gerhard Mann Chem Pharm Fabrik GmbH, Germany	235, 285, 365, 385, 395, 475, 515, 545, 576, 636 (MA 5039/2004/01)	product whose 2-year shelf-life has expired (as stipulated by Order of the Minister of Health no. 279/2005) following NAMMD approval (on 09.12.2015) of changes to MA	Voluntary recall and destruction	12.03.2018
9	LYNPARZA	capsules	50 mg	olaparib	Astra Zeneca UK, Great Britain/ Astra Zeneca AB, Sweden	NG656, NF300	Batches with out-of-specification results for "L polymorph"	Voluntary recall at pharmacy/hospital level and destruction	12.03.2018
10	PANADOL ARTRO	prolonged release tablets	665 mg	paracetamol	GSK Dungarvan Ltd Ireland/GSK Consumer Healthcare Romania SRL	all batches	suspension of MA no. 6231/2014/01-04, in result of Commission Decision C(2018)1151 of 19.02.2018 on suspension of marketing authorisation for medicinal products containing “paracetamol with modified and prolonged release"	Withdrawal and destruction	15.03.2018
11	DORETA EP	prolonged release tablets	75 mg/ 650 mg	combinations (tramadol + paracetamol)	KRKA Novo Mesto DD Slovenia	all batches	suspension of MA no. 8527/2016/01-14, in result of Commission Decision C(2018)1151 of 19.02.2018 on suspension of marketing authorisation for medicinal products containing “paracetamol with modified and prolonged release"	Withdrawal and destruction	15.03.2018

12	OSSEOR	granules for oral suspension	2 g	strontium ranelate	Les Laboratoires Servier France	all batches	definitive cessation of marketing on commercial grounds	Voluntary recall and destruction	30.03.2018

Applications for marketing authorisation/marketing authorisation renewal submitted to the NAMMD during the 4th quarter of 2017

During the 4th quarter of 2017, 173 marketing authorisation/renewal applications for medicinal products corresponding to the following therapeutic groups have been received:

A01 – STOMATOLOGICAL PREPARATIONS
A02 – DRUGS FOR ACID RELATED DISORDERS
A03 – DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS
A07 – ANTIDIARRHEALS, INTESTINAL ANTI-INFLAMMATORY/ANTI-INFECTIVE AGENTS
A10 – DRUGS USED IN DIABETES
B01 – ANTITHROMBOTIC AGENTS
B02 – ANTIHEMORRHAGICS
B05 – BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS
C01 – CARDIAC THERAPY
C03 – DIURETICS
C09 – AGENTS ACTING ON THE RENIN–ANGIOTENSIN SYSTEM
C10 – LIPID MODIFYING AGENTS
G02 – OTHER GYNECOLOGICALS
G03 – SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM
G04 – UROLOGICALS
H01 – PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES
H03 – THYROID THERAPY
J01 – ANTIBACTERIALS FOR SYSTEMIC USE
J02 – ANTIMYCOTICS FOR SYSTEMIC USE
J04 – ANTIMYCOBACTERIALS
L01 – ANTINEOPLASTIC AGENTS
M01 – ANTI-INFLAMMATORY AND ANTIRHEUMATIC PRODUCTS
M04 – OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM
M05 – DRUGS FOR TREATMENT OF BONE DISEASES
N01 – ANESTHETICS
N02 – ANALGESICS
N04 – ANTI-PARKINSON DRUGS
N05 – PSYCHOLEPTICS
N06 – PSYCHOANALEPTICS
N07 – OTHER NERVOUS SYSTEM DRUGS
R01 – ASAL PREPARATIONS
R02 – THROAT PREPARATIONS
R03 – DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES
R05 – COUGH AND COLD PREPARATIONS
S01 – OPHTHALMOLOGICALS

Medicinal products authorised for marketing during the 4th quarter of 2017

INN	Trade Name	Pharmaceutical Form	Strength	MAH	Holding country	MA no.		
ABACAVIRUM+ LAMIVUDINUM	ABACAVIR/LAMIVUDINA ZENTIVA 600 mg/300 mg	film-coated tablets	600mg/ 300mg	ZENTIVA, K.S.	CZECH REPUBLIC	10452	2017	01
ABACAVIRUM+ LAMIVUDINUM	ABACAVIR/LAMIVUDINA VALE 600 mg/300 mg	film-coated tablets	600mg/ 300mg	VALE PHARMACEUTICALS LTD.	IRELAND	10408	2017	01
ACETYLCYSTEINUM	ACC CU AROMA DE MURE 600 mg	oral powder (sachets)	600mg	SANDOZ S.R.L.	ROMANIA	10295	2017	01
ACICLOVIRUM	ZOVIRAX 30 mg/g	eye ointment	30mg/g	THE WELLCOME FOUNDATION LIMITED	GREAT BRITAIN	10458	2017	01
ACICLOVIRUM	ACEVIREX 50 mg/g	cream	50mg/g	THE WELLCOME FOUNDATION LIMITED	GREAT BRITAIN	10459	2017	01
ACICLOVIRUM	ZOVIRAX 50 mg/g	cream	50mg/g	GLAXOSMITHKLINE CONSUMER HEALTHCARE S.R.L.	ROMANIA	10457	2017	01
ACIDUM ACETYLSALICYLICUM	ACID ACETILSALICILIC TAMPONAT MCC 500 mg	tablets	500mg	MAGISTRA C&C S.R.L.	ROMANIA	10301	2017	01
ACIDUM ACETYLSALICYLICUM	ACID ACETILSALICILIC MCC 500 mg	tablets	500mg	MAGISTRA C&C S.R.L.	ROMANIA	10300	2017	01
ACIDUM IBANDRONICUM	ACID IBANDRONIC MYLAN 150 mg	film-coated	150mg	GENERICS (UK) LIMITED	GREAT BRITAIN	10369	2017	01

INN	Trade Name	Pharmaceutical Form	Strength	MAH	Holding country	MA no.		
		tablets						
ACIDUM URSODEOXYCHOLICUM	URSOSAN 250 mg	caps.	250mg	PRO. MED. CS PRAHA A.S.	CZECH REPUBLIC	10322	2017	01
ALFACALCIDOLUM	ALFACALCIDOL ELC GROUP 0,25 micrograms	soft caps.	0,25 microgr.	ELC GROUP S.R.O.	CZECH REPUBLIC	10349	2017	01
ALFACALCIDOLUM	ALFACALCIDOL ELC GROUP 0,50 micrograms	soft caps.	0,50 microgr.	ELC GROUP S.R.O.	CZECH REPUBLIC	10350	2017	01
ALFACALCIDOLUM	ALFACALCIDOL ELC GROUP 1,0 micrograms	soft caps.	1,0 microgr.	ELC GROUP S.R.O.	CZECH REPUBLIC	10351	2017	01
AMBROXOLUM	FLAVAMED 30 mg/5 ml	oral sol.	30mg/5ml	BERLIN-CHEMIE AG (MENARINI GROUP)	GERMANY	10328	2017	01
AMOXICILLINUM + ACIDUM CLAVULANICUM	AUGMENTIN FB 400 mg/57 mg/5 ml	powd. for oral susp.	400mg/ 57mg/5ml	GLAXOSMITHKLINE (GSK) S.R.L.	ROMANIA	10396	2017	01
ATORVASTATINUM	ASCORD 10 mg	film-coated tablets	10mg	TERAPIA SA	ROMANIA	10435	2017	01
ATORVASTATINUM	ASCORD 20 mg	film-coated tablets	20mg	TERAPIA SA	ROMANIA	10436	2017	01
ATORVASTATINUM	ASCORD 40 mg	film-coated tablets	40mg	TERAPIA SA	ROMANIA	10437	2017	01
ATORVASTATINUM	ASCORD 80 mg	film-coated tablets	80mg	TERAPIA SA	ROMANIA	10438	2017	01

INN	Trade Name	Pharmaceutical Form	Strength	MAH	Holding country	MA no.		
ATORVASTATINUM	ATORVASTATINA ACCORD 10 mg	film-coated tablets	10mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	10286	2017	01
ATORVASTATINUM	ATORVASTATINA ACCORD 20 mg	film-coated tablets	20mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	10287	2017	01
ATORVASTATINUM	ATORVASTATINA ACCORD 40 mg	film-coated tablets	40mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	10288	2017	01
ATORVASTATINUM	ATORVASTATINA ACCORD 80 mg	film-coated tablets	80mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	10289	2017	01
BEMIPARINUM	ZIBOR 25000 UI anti-XA/ml	sol. for inj. in pre-filled syringe	25000UIanti-XA/ml	FROSST IBERICA S.A.	SPAIN	10290	2017	01
BILASTINUM	BORENAR 2,5 mg/ml	oral sol.	2,5 mg/ml	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LUXEMBOURG	10367	2017	01
BILASTINUM	BORENAR 10 mg	orodispersible tablets	10mg	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A.	LUXEMBOURG	10366	2017	01
BORTEZOMIBUM	BORTEZOMIB TEVA 2,5 mg	powd. for sol. for inj.	2,5mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	10309	2017	01

INN	Trade Name	Pharmaceutical Form	Strength	MAH	Holding country	MA no.		
BORTEZOMIBUM	BORTEZOMIB ZENTIVA 3,5 mg	powd. for sol. for inj.	3,5mg	ZENTIVA K.S.	CZECH REPUBLIC	10326	2017	01
BUPIVACAINUM	SANERGY SPINAL 5 mg/ml	sol inj.	5mg/ml	AS GRINDEKS	LATVIA	10347	2017	01
BUPIVACAINUM	BUPIVACAINA GRINDEKS 5 mg/ml	sol inj.	5mg/ml	AS GRINDEKS	LATVIA	10336	2017	01
CAPECITABINUM	XALVOBIN 150 mg	film-coated tablets	150mg	ALVOGEN IPCO S.AR.L.	LUXEMBOURG	10262	2017	01
CAPECITABINUM	XALVOBIN 500 mg	film-coated tablets	500mg	ALVOGEN IPCO S.AR.L.	LUXEMBOURG	10263	2017	01
CASPOFUNGINUM	CASOKAN 50 mg	powd. for conc. for sol. for inf.	50mg	HEATON K.S.	CZECH REPUBLIC	10398	2017	01
CASPOFUNGINUM	CASOKAN 70 mg	powd. for conc. for sol. for inf.	70mg	HEATON K.S.	CZECH REPUBLIC	10399	2017	01
CLOFARABINUM	CLOFARABINA TEVA 1 mg/ml	conc. for sol. for inf.	1mg/ml	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	10337	2017	01
COMBINATII	TRATUL PLUS	gastrores. caps.		LANNACHER HEILMITTEL GES.M.B.H.	AUSTRIA	10456	2017	01
COMBINATII	VOLULYTE 6%	sol. for inf.	6%	FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	10443	2017	01
COMBINATII	NEFROSOL FARA POTASIU	sol. for haemofiltr.		B. BRAUN AVITUM AG	GERMANY	10465	2017	01

INN	Trade Name	Pharmaceutical Form	Strength	MAH	Holding country	MA no.		
COMBINATII	NEFROSOL cu 2 mmol/l potasiu	sol. for haemofiltr.		B. BRAUN AVITUM AG	GERMANY	10466	2017	01
COMBINATII	NEFROSOL cu 4 mmol/l potasiu	sol. for haemofiltr.		B. BRAUN AVITUM AG	GERMANY	10467	2017	01
COMBINATII	NEIRAXIN	sol inj.		AS KALCEKS	LATVIA	10266	2017	01
COMBINATII	SMOFKABIVEN EXTRA NITROGEN	emulsion for inf.		FRESENIUS KABI ROMANIA	ROMANIA	10274	2017	01
COMBINATII	SMOFKABIVEN EXTRA NITROGEN FARA ELECTROLITI	emulsion for inf.		FRESENIUS KABI ROMANIA	ROMANIA	10275	2017	01
COMBINATII	SEPTOLETE OMNI LAMAIE SI MIERE 3 mg/1 mg	lozenges	3mg/1mg	KRKA, D.D., NOVO MESTO	SLOVENIA	10388	2017	01
COMBINATII	SEPTOLETE OMNI LAMAIE SI SOC 3 mg/1 mg	lozenges	3mg/1mg	KRKA, D.D., NOVO MESTO	SLOVENIA	10389	2017	01
COMBINATII	PLENVU	powd. for oral sol.		NORGINE B.V.	THE NETHERLANDS	10468	2017	01
COMBINATII	COLDREX RACEALA SI TUSE 500 mg/200 mg/10 mg	powd. for oral sol.	500mg/ 200mg/ 10mg	HIPOCRATE 2000 S.R.L.	ROMANIA	10472	2017	01
COMBINATII (ETINILESTRADIOLUM + DROSPIRENONUM)	VEYANN 0,02 mg/3 mg	film-coated tablets	0,02mg/3mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	10327	2017	01

INN	Trade Name	Pharmaceutical Form	Strength	MAH	Holding country	MA no.		
COMBINATII (PIOGLITAZONUM + METFORMINUM)	PIOGLITAZONA/ METFORMIN TORRENT 15 mg/850 mg	film-coated tablets	15mg/ 850mg	TORRENT PHARMA S.R.L.	ROMANIA	10453	2017	01
COMBINATII (VILDAGLIPTINUM + METFORMINUM)	DALTEX 50 mg/850 mg	film-coated tablets	50mg/ 850mg	MEDOCHEMIE LTD.	CYPRUS	10462	2017	01
COMBINATII (VILDAGLIPTINUM + METFORMINUM)	DALTEX 50 mg/1000 mg	film-coated tablets	50mg/ 1000mg	MEDOCHEMIE LTD.	CYPRUS	10463	2017	01
COMBINATII (ACICLOVIRUM+ HYDROCORTISONUM)	ZOVIRAX DUO 50 mg/10 mg/g	cream	50mg/ 10mg/g	GLAXOSMITHKLINE CONSUMER HEALTHCARE S.R.L.	ROMANIA	10368	2017	01
COMBINATII (AMLODIPINUM+ VALSARTANUM)	DIPPERAM 5 mg/80 mg	film-coated tablets	5mg/80mg	SANDOZ S.R.L.	ROMANIA	10355	2017	01
COMBINATII (AMLODIPINUM+ VALSARTANUM)	DIPPERAM 5 mg/160 mg	film-coated tablets	5mg/160mg	SANDOZ S.R.L.	ROMANIA	10356	2017	01
COMBINATII (AMLODIPINUM+ VALSARTANUM)	DIPPERAM 10 mg/160 mg	film-coated tablets	10mg/ 160mg	SANDOZ S.R.L.	ROMANIA	10357	2017	01
COMBINATII (AMLODIPINUM+ VALSARTANUM)	NORTIVANCOMBI 5 mg/80 mg	film-coated tablets	5mg/80mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	10429	2017	01

INN	Trade Name	Pharmaceutical Form	Strength	MAH	Holding country	MA no.		
COMBINATII (AMLODIPINUM+ VALSARTANUM)	NORTIVANCOMBI 5 mg/160 mg	film-coated tablets	5mg/160mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	10430	2017	01
COMBINATII (AMLODIPINUM+ VALSARTANUM)	NORTIVANCOMBI 10 mg/160 mg	film-coated tablets	10mg/ 160mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	10431	2017	01
COMBINATII (BIMATOPROSTUM + TIMOLOLUM)	BIMATOPROST/TIMOLOL SANDOZ 0,3 mg/5 mg/ml	eye drops, sol.	0,3mg/ 5mg/ml	SANDOZ S.R.L.	ROMANIA	10325	2017	01
COMBINATII (BIMATOPROSTUM + TIMOLOLUM)	BIMATOPROST/TIMOLOL MYLAN 0,3 mg/5 mg/ml	eye drops, sol.	0,3mg/ 5mg/ml	MYLAN S.A.S.	FRANCE	10334	2017	01
COMBINATII (CANDESARTANUM CILEXETIL+HCT)	CANZENO HCT 8 mg/12,5mg	tablets	8mg/12,5mg	ZENTIVA, K.S.	CZECH REPUBLIC	10329	2017	01
COMBINATII (CANDESARTANUM CILEXETIL+HCT)	CANZENO HCT 16 mg/12,5mg	tablets	16mg/ 12,5mg	ZENTIVA, K.S.	CZECH REPUBLIC	10330	2017	01
COMBINATII (CINARIZINUM +DIMENHIDRINATUM)	VERTIGIX 20 mg/40 mg	tablets	20mg/40mg	GALENICA S.A.	GREECE	10404	2017	01
COMBINATII (ETINILESTRADIOLUM + DROSPIRENONUM)	DROSPIRENONA/ ETINILESTRADIOL SANDOZ 0,02mg+3mg	film-coated tablets	0,02mg+ 3mg	SANDOZ S.R.L.	ROMANIA	10464	2017	01

INN	Trade Name	Pharmaceutical Form	Strength	MAH	Holding country	MA no.		
COMBINATII (ETONOGESTRELUM+ ETINILESTRADIOLUM)	ORNIBEL 0,120 mg/0,015 mg/24 de ore	vaginal release system	0,120mg/ 0,015mg/ 24h	EXELTIS MAGYARORSZÁG KFT	HUNGARY	10307	2017	01
COMBINATII (ETONOGESTRELUM+ ETINILESTRADIOLUM)	UNIRING 0, 120 mg/0,015 mg/24 de ore	vaginal release system	0,120mg/ 0,015mg/ 24h	PHARMASWISS CESKÁ REPUBLIKA S.R.O.	CZECH REPUBLIC	10338	2017	01
COMBINATII (ETONOGESTRELUM+ ETINILESTRADIOLUM)	TEYLA 0,120 mg/0,015 mg/24 de ore	vaginal release system	0,120mg/ 0,015mg/ 24deore	HEATON K.S.	CZECH REPUBLIC	10294	2017	01
COMBINATII (LAMIVUDINUM+ ZIDOVUDINUM)	LAMIVUDINA/ ZIDOVUDINA AUROBINDO 150 mg/300 mg	film-coated tablets	150mg/ 300mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	10381	2017	01
COMBINATII (LAMIVUDINUM+ ZIDOVUDINUM)	LAMIVUDINA/ ZIDOVUDINA SANDOZ 150 mg/300 mg	film-coated tablets	150mg/ 300mg	SANDOZ S.R.L.	ROMANIA	10471	2017	01
COMBINATII (LOSARTANUM+ HYDROCHLOROTHIAZIDUM)	LORISTA HL 100 mg/12,5 mg	film-coated tablets	100mg/ 12,5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	10425	2017	01
COMBINATII (MIFEPRISTONUM+ MISOPROSTOLUM)	MEDABON (see G02AD06)	tablets+vag. tablets	200mg+ 0,2mg	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	THE NETHERLANDS	10424	2017	01
COMBINATII (MIFEPRISTONUM+ MISOPROSTOLUM)	MEDABON (see G03XB01)	tablets+vag. tablets	200mg+ 0,2mg	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	THE NETHERLANDS	10424	2017	01

INN	Trade Name	Pharmaceutical Form	Strength	MAH	Holding country	MA no.		
COMBINATII (OLMESARTANUM+ AMLODIPINUM)	OLMESARTAN MEDOXOMIL/ AMLODIPINA ZENTIVA 20 mg/5 mg	film-coated tablets	20mg/5mg	ZENTIVA, K.S.	CZECH REPUBLIC	10449	2017	01
COMBINATII (OLMESARTANUM+ AMLODIPINUM)	OLMESARTAN MEDOXOMIL/ AMLODIPINA ZENTIVA 40 mg/5 mg	film-coated tablets	40mg/5mg	ZENTIVA, K.S.	CZECH REPUBLIC	10450	2017	01
COMBINATII (OLMESARTANUM+ AMLODIPINUM)	OLMESARTAN MEDOXOMIL/ AMLODIPINA ZENTIVA 40 mg/10 mg	film-coated tablets	40mg/10mg	ZENTIVA, K.S.	CZECH REPUBLIC	10451	2017	01
COMBINATII (OLMESARTANUM+ AMLODIPINUM)	OLSSA 20 mg/5 mg	film-coated tablets	20mg/5mg	HCS BVBA	BELGIUM	10360	2017	01
COMBINATII (OLMESARTANUM+ AMLODIPINUM)	OLSSA 40 mg/5 mg	film-coated tablets	40mg/5mg	HCS BVBA	BELGIUM	10361	2017	01
COMBINATII (OLMESARTANUM+ AMLODIPINUM)	OLSSA 40 mg/10 mg	film-coated tablets	40mg/ 10mg	HCS BVBA	BELGIUM	10362	2017	01
COMBINATII (OLMESARTANUM+ AMLODIPINUM)	OLMESARTAN MEDOXOMIL/ AMLODIPINA SANDOZ 20 mg/5 mg	film-coated tablets	20mg/5mg	SANDOZ S.R.L.	ROMANIA	10426	2017	01
COMBINATII (OLMESARTANUM+ AMLODIPINUM)	OLMESARTAN MEDOXOMIL/ AMLODIPINA SANDOZ 40 mg/5 mg	film-coated tablets	40mg/5mg	SANDOZ S.R.L.	ROMANIA	10427	2017	01
COMBINATII (OLMESARTANUM+ AMLODIPINUM)	OLMESARTAN MEDOXOMIL/ AMLODIPINA SANDOZ 40 mg/10 mg	film-coated tablets	40mg/ 10mg	SANDOZ S.R.L.	ROMANIA	10428	2017	01

INN	Trade Name	Pharmaceutical Form	Strength	MAH	Holding country	MA no.		
COMBINATII (OLMESARTANUM+HCT)	OLMICOMBI 40 mg/12,5 mg	film-coated tablets	40mg/ 12,5mg	KRKA D.D., NOVO MESTO	SLOVENIA	10269	2017	01
COMBINATII (OLMESARTANUM+HCT)	OLMICOMBI 40 mg/25 mg	film-coated tablets	40mg/ 25mg	KRKA D.D., NOVO MESTO	SLOVENIA	10270	2017	01
COMBINATII (OLMESARTANUM+HCT)	OLMICOMBI 20 mg/12,5 mg	film-coated tablets	20mg/ 12,5mg	KRKA D.D., NOVO MESTO	SLOVENIA	10267	2017	01
COMBINATII (OLMESARTANUM+HCT)	OLMICOMBI 20 mg/25 mg	film-coated tablets	20mg/ 25mg	KRKA D.D., NOVO MESTO	SLOVENIA	10268	2017	01
COMBINATII (OXICODONUM+ NALOXONUM)	OXICODONA/NALOXONA SANDOZ 5 mg/2,5 mg	tablets with prolonged release	5mg/2,5mg	SANDOZ S.R.L.	ROMANIA	10416	2017	01
COMBINATII (OXICODONUM+ NALOXONUM)	OXICODONA/NALOXONA SANDOZ 10 mg/5 mg	tablets with prolonged release	10mg/5mg	SANDOZ S.R.L.	ROMANIA	10417	2017	01
COMBINATII (OXICODONUM+ NALOXONUM)	OXICODONA/NALOXONA SANDOZ 20 mg/10 mg	tablets with prolonged release	20mg/10mg	SANDOZ S.R.L.	ROMANIA	10418	2017	01
COMBINATII (OXICODONUM+ NALOXONUM)	OXICODONA/NALOXONA SANDOZ 30 mg/15 mg	tablets with prolonged release	30mg/15mg	SANDOZ S.R.L.	ROMANIA	10419	2017	01
COMBINATII (OXICODONUM+ NALOXONUM)	OXICODONA/NALOXONA SANDOZ 40 mg/20 mg	tablets with prolonged release	40mg/20mg	SANDOZ S.R.L.	ROMANIA	10420	2017	01
COMBINATII (PERINDOPRILUM+ AMLODIPINUM)	PERINDOPRIL/ AMLODIPINA ZENTIVA 4 mg/5 mg	tablets	4mg/5mg	ZENTIVA, K.S.	CZECH REPUBLIC	10310	2017	01

INN	Trade Name	Pharmaceutical Form	Strength	MAH	Holding country	MA no.		
COMBINATII (PERINDOPRILUM+ AMLODIPINUM)	PERINDOPRIL/ AMLODIPINA ZENTIVA 4 mg/10 mg	tablets	4mg/10mg	ZENTIVA, K.S.	CZECH REPUBLIC	10311	2017	01
COMBINATII (PERINDOPRILUM+ AMLODIPINUM)	PERINDOPRIL/ AMLODIPINA ZENTIVA 8 mg/5 mg	tablets	8mg/5mg	ZENTIVA, K.S.	CZECH REPUBLIC	10312	2017	01
COMBINATII (PERINDOPRILUM+ AMLODIPINUM)	PERINDOPRIL/ AMLODIPINA ZENTIVA 8 mg/10 mg	tablets	8mg/10mg	ZENTIVA, K.S.	CZECH REPUBLIC	10313	2017	01
COMBINATII (TRAVOPROSTUM+ TIMOLOLUM)	TRAVOPROST/ TIMOLOL ZENTIVA 40 microgram/ml+5 mg/ml	eye drops, sol.	40microgr/ml+ 5mg/ml	ZENTIVA, K.S.	CZECH REPUBLIC	10293	2017	01
COMBINATII (TRAVOPROSTUM+ TIMOLOLUM)	TRAVOPROST/ TIMOLOL MYLAN 40 microgram/ml+5 mg/ml	eye drops, sol.	40microgr/ml+ 5mg/ml	MYLAN S.A.S.	FRANCE	10305	2017	01
COMBINATII (PARACETAMOLUM+ DIFENHIDRAMINUM)	PINEX NOAPTE 500 mg/25 mg (see R06AA02)	film-coated tablets	500mg/ 25mg	ACTAVIS GROUP PTC EHF.	ICELAND	10319	2017	01
COMBINATII (PARACETAMOLUM+ DIFENHIDRAMINUM)	PINEX NOAPTE 500 mg/25 mg (see N02BE01)	film-coated tablets	500mg/ 25mg	ACTAVIS GROUP PTC EHF.	ICELAND	10319	2017	01
DESLORATADINUM	DESLORATADINA SANDOZ 0.5 mg/ml	oral sol.	0,5 mg/ml	SANDOZ S.R.L.	ROMANIA	10423	2017	01

INN	Trade Name	Pharmaceutical Form	Strength	MAH	Holding country	MA no.		
DESLORATADINUM	DESLORATADINA AUROBINDO 5 mg	film-coated tablets	5mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	10378	2017	01
DICLOFENACUM	VOLTAREN OPHTHA CD 1 mg/ml	eye drops, sol.	1mg/ml	LABORATOIRES THEA	FRANCE	10281	2017	01
DICLOFENACUM	DICLAC 75 ID	tablets with modified release	75mg	HEXAL AG	GERMANY	10382	2017	01
DICLOFENACUM	DICLAC 10 mg/ml	gel	10mg/ml	HEXAL AG	GERMANY	10461	2017	01
DICLOFENACUM	RAPLON 12,5 mg	film-coated tablets	12,5mg	MEDOCHEMIE LTD	CYPRUS	10358	2017	01
DIOSMINUM	FLEBAZOL 500 mg	film-coated tablets	500mg	KRKA, D.D., NOVO MESTO	SLOVENIA	10272	2017	01
DIOSMINUM	FLEBAZOL 1000 mg	film-coated tablets	1000mg	KRKA, D.D., NOVO MESTO	SLOVENIA	10273	2017	01
EFAVIRENZUM+ EMTRICITABINUM+ TENOFOVIRUM DISOPROXIL	PADVIRAM 600 mg/200 mg/245 mg	film-coated tablets	600mg/ 200mg/ 245mg	SANDOZ S.R.L.	ROMANIA	10402	2017	01
EMTRICITABINUM+ TENOFOVIRUM DISOPROXIL	EMTRICITABINA/ TENOFOVIR DISOPROXIL SANDOZ 200 mg/245 mg	film-coated tablets	200mg/ 245mg	SANDOZ S.R.L.	ROMANIA	10345	2017	01
ENOXAPARINUM	LOSMINA 2000 UI (20 mg)/0,2 ml	sol inj. in pre-filled syringe	2000UI (20mg)/ 0,2ml	LABORATORIOS FARMACEUTICOS ROVI, S.A.	SPAIN	10383	2017	01

INN	Trade Name	Pharmaceutical Form	Strength	MAH	Holding country	MA no.		
ENOXAPARINUM	LOSMINA 4000 UI (40 mg)/0,4 ml	sol inj. in pre-filled syringe	4000UI (40mg)/ 0,4ml	LABORATORIOS FARMACEUTICOS ROVI, S.A.	SPAIN	10384	2017	01
ENOXAPARINUM	LOSMINA 6000 UI (60 mg)/0,6 ml	sol inj. in pre-filled syringe	6000UI (60mg)/ 0,6ml	LABORATORIOS FARMACEUTICOS ROVI, S.A.	SPAIN	10385	2017	01
ENOXAPARINUM	LOSMINA 8000 UI (80 mg)/0,8 ml	sol inj. in pre-filled syringe	8000UI (80mg)/ 0,8ml	LABORATORIOS FARMACEUTICOS ROVI, S.A.	SPAIN	10386	2017	01
ENOXAPARINUM	LOSMINA 10000 UI (100 mg)/1,0 ml	sol inj. in pre-filled syringe	10000UI (100mg)/ 1,0ml	LABORATORIOS FARMACEUTICOS ROVI, S.A.	SPAIN	10387	2017	01
ENTECAVIRUM	ENTECAVIR WELDING 0,5 mg	film-coated tablets	0,5mg	WELDING GMBH & CO. KG	GERMANY	10405	2017	01
ENTECAVIRUM	ENTECAVIR WELDING 1 mg	film-coated tablets	1mg	WELDING GMBH & CO. KG	GERMANY	10406	2017	01
EPLERENONUM	EPLERENONA SANDOZ 25 mg	film-coated tablets	25mg	SANDOZ S.R.L.	ROMANIA	10323	2017	01
EPLERENONUM	EPLERENONA SANDOZ 50 mg	film-coated tablets	50mg	SANDOZ S.R.L.	ROMANIA	10324	2017	01
ERTAPENEMUM	ERTAPENEM ATB 1 g	powd. for conc. for sol. for inf.	1g	ANTIBIOTICE S.A.	ROMANIA	10414	2017	01
ESCITALOPRAMUM	ESTAN 5 mg	film-coated tablets	5mg	MEDOCHEMIE LTD.	CYPRUS	10379	2017	01

INN	Trade Name	Pharmaceutical Form	Strength	MAH	Holding country	MA no.		
ESCITALOPRAMUM	ESTAN 10 mg	film-coated tablets	10mg	MEDOCHEMIE LTD.	CYPRUS	10380	2017	01
ESOMEPRAZOLUM	HELIDES 20 mg	gastrores. caps.	20mg	ZENTIVA, K.S.	CZECH REPUBLIC	10439	2017	01
ESOMEPRAZOLUM	HELIDES 40 mg	gastrores. caps.	40mg	ZENTIVA, K.S.	CZECH REPUBLIC	10440	2017	01
EXTRACT USCAT DE VALERIANA	EXIGAN 210 mg	tablets	210mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	10409	2017	01
EZETIMIBUM	LIPOBON 10 mg	tablets	10mg	EGIS PHARMACEUTICALS PLC	HUNGARY	10304	2017	01
FEBUXOSTATUM	PEXALIT 80 mg	film-coated tablets	80mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	10373	2017	01
FEBUXOSTATUM	PEXALIT 120 mg	film-coated tablets	120mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	10374	2017	01
FLUCONAZOLUM	FUNGOLON UNO 150 mg	caps.	150mg	ACTAVIS GROUP PTC EHF.	ICELAND	10392	2017	01
FULVESTRANTUM	FALVAX 250 mg	sol inj. in pre-filled syringe	250mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	10375	2017	01

INN	Trade Name	Pharmaceutical Form	Strength	MAH	Holding country	MA no.		
GADOBUTROLUM	GADOVIST 1,0 mmol/ml	sol inj. in pre-filled syringe	1,0mmol/ml	BAYER PHARMA AG	GERMANY	10460	2017	01
GEMCITABINUM	GEMSOL 40 mg/ml	conc. for sol. for inf.	40mg/ml	EBEWE PHARMA GES.M.B.H NFG. KG	AUSTRIA	10441	2017	01
GEMCITABINUM	GEMCIRENA 38 mg/ml	powd. for sol. for inf.	38mg/ml	FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	10403	2017	01
IBUPROFENUM	IBALGIN JUNIOR 200 mg	oral powder	200mg	SANOFI ROMANIA S.R.L.	ROMANIA	10331	2017	01
IBUPROFENUM	IBALGIN FORTE 400 mg	oral powder	400mg	SANOFI ROMANIA S.R.L.	ROMANIA	10332	2017	01
IBUPROFENUM	IBUPROFEN FARMALIDER 200 mg	film-coated tablets	200mg	FARMALIDER, S.A.	SPAIN	10348	2017	01
IBUPROFENUM	MASIPREN 100 mg	oral susp. in sachet	100mg	PHARMASWISS CESKÁ REPUBLIKA S.R.O.	CZECH REPUBLIC	10393	2017	01
IBUPROFENUM	MASIPREN 200 mg	oral susp. in sachet	200mg	PHARMASWISS CESKÁ REPUBLIKA S.R.O.	CZECH REPUBLIC	10394	2017	01
IBUPROFENUM	MASIPREN 400 mg	oral susp. in sachet	400mg	PHARMASWISS CESKÁ REPUBLIKA S.R.O.	CZECH REPUBLIC	10395	2017	01

INN	Trade Name	Pharmaceutical Form	Strength	MAH	Holding country	MA no.		
IMUNOGLOBULINA ANTI-D	RHESONATIV 750 UI/ml	sol. for inj.	750UI/ml	OCTAPHARMA (IP) LIMITED	GREAT BRITAIN	10306	2017	01
IRINOTECANUM	IRINOTECAN KOANAA 20 mg/ml	conc. for sol. for inf.	20mg/ml	KOANAA HEALTHCARE LIMITED	AUSTRIA	10370	2017	01
LETROZOLUM	FEMARA 2,5 mg	film-coated tablets	2,5mg	NOVARTIS PHARMA GMBH	GERMANY	10292	2017	01
LINEZOLIDUM	LINEZOLID AUROBINDO 2 mg/ml	sol. for inf.	2mg/ml	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	10265	2017	01
LINEZOLIDUM	LINEZOLID ACCORD 2 mg/ml	sol. for inf.	2mg/ml	ACCORD HEALTHCARE LTD.	GREAT BRITAIN	10422	2017	01
MELOXICAMUM	TROSICAM 7,5 mg	orodispersible tablets	7,5mg	ALPEX PHARMA (UK) LIMITED	GREAT BRITAIN	10371	2017	01
MELOXICAMUM	TROSICAM 15 mg	orodispersible tablets	15mg	ALPEX PHARMA (UK) LIMITED	GREAT BRITAIN	10372	2017	01
METFORMINUM	GLUCOPHAGE XR 750 mg	tablets with prolonged release	750mg	MERCK SANTE S.A.S.	FRANCE	10260	2017	01
METFORMINUM	GLUCOPHAGE XR 1000 mg	tablets with prolonged release	1000mg	MERCK SANTE S.A.S.	FRANCE	10261	2017	01

INN	Trade Name	Pharmaceutical Form	Strength	MAH	Holding country	MA no.		
METHOTREXATUM	METHOFILL 2,5 mg	tablets	2,5mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	10342	2017	01
METHOTREXATUM	METHOFILL 10 mg	tablets	10mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	10343	2017	01
MITOMICINUM	MITOMICINA ACCORD 40 mg	powd. for sol. for inj./perf.	40mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	10401	2017	01
MONTELUKASTUM	SINGULAIR 10 mg	film-coated tablets	10mg	MERCK SHARP & DOHME ROMANIA S.R.L.	ROMANIA	10455	2017	01
MONTELUKASTUM	SINGULAIR 5 mg	tablets mast.	5mg	MERCK SHARP & DOHME ROMANIA S.R.L.	ROMANIA	10454	2017	01
NADROPARINUM	FRAXIPARINE 9500 UI Xa anti-factor /1 ml multidose	sol. for inj.	9500 UI AFXa/1 ml	ASPEN PHARMA TRADING LIMITED	IRELAND	10303	2017	01
NALOXONUM	FORVEL 0,4 mg/ml	sol inj./perf.	0,4mg/ml	MEDOCHEMIE LTD.	CYPRUS	10400	2017	01
NEBIVOLOLUM	NEBIVOLOL AUROBINDO 5 mg	tablets	5mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	10407	2017	01

INN	Trade Name	Pharmaceutical Form	Strength	MAH	Holding country	MA no.		
OLANZAPINUM	OLANZAPINA ACTAVIS 5 mg	orodispersible tablets	5mg	ACTAVIS GROUP PTC EHF.	ICELAND	10314	2017	01
OLANZAPINUM	OLANZAPINA ACTAVIS 10 mg	orodispersible tablets	10mg	ACTAVIS GROUP PTC EHF.	ICELAND	10315	2017	01
OLANZAPINUM	OLANZAPINA ACTAVIS 15 mg	orodispersible tablets	15mg	ACTAVIS GROUP PTC EHF.	ICELAND	10316	2017	01
OLANZAPINUM	OLANZAPINA ACTAVIS 20 mg	orodispersible tablets	20mg	ACTAVIS GROUP PTC EHF.	ICELAND	10317	2017	01
OXALIPLATINUM	OXALIPLATIN ACTAVIS 5 mg/ml	powd. for sol. for inf.	5mg/ml	ACTAVIS S.R.L.	ROMANIA	10282	2017	01
OXIGENUM	OXIGEN LINDE 100%	cryogenic medicinal gas	100%	LINDE GAZ A.S.	CZECH REPUBLIC	10333	2017	01
OXYTOCINUM	OFOST 8,3 micrograms/ml	sol for inj./inf.	8,3microgr/ml	AS GRINDEKS	LATVIA	10291	2017	01
PARACETAMOLUM	PARACETAMOL SANDOZ 500 mg	tablets	500mg	SANDOZ S.R.L.	ROMANIA	10477	2017	01
PARACETAMOLUM	PARACETAMOL SANDOZ 1000 mg	tablets	1000mg	SANDOZ S.R.L.	ROMANIA	10478	2017	01
PEMETREXEDUM	PEMETREXED TEVA 25 mg/ml	conc. for sol. for inf.	25mg/ml	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	10318	2017	01

INN	Trade Name	Pharmaceutical Form	Strength	MAH	Holding country	MA no.		
PERINDOPRILUM	PRENESSA 4 mg	orodispersible tablets	4mg	KRKA, D.D., NOVO MESTO	SLOVENIA	10390	2017	01
PERINDOPRILUM	PRENESSA 8 mg	orodispersible tablets	8mg	KRKA, D.D., NOVO MESTO	SLOVENIA	10391	2017	01
PLANTE	MUCOPLANT IEDERA 1,54 mg/ml	syrup	1,54mg/ml	DR. THEISS NATURWAREN GMBH	GERMANY	10346	2017	01
PLANTE	ROSACTA	cream		MEDIS GMBH	AUSTRIA	10476	2017	01
PREGABALINUM	SIRANALEN 20 mg/ml	oral sol.	20mg/ml	MEDOCHEMIE LTD.	CYPRUS	10397	2017	01
QUETIAPINUM	QUETIAPINA SANDOZ 200 mg	tablets with prolonged release	200mg	SANDOZ S.R.L.	ROMANIA	10339	2017	01
QUETIAPINUM	QUETIAPINA SANDOZ 300 mg	tablets with prolonged release	300mg	SANDOZ S.R.L.	ROMANIA	10340	2017	01
QUETIAPINUM	QUETIAPINA SANDOZ 400 mg	tablets with prolonged release	400mg	SANDOZ S.R.L.	ROMANIA	10341	2017	01
RACECADOTRILUM	HIDRASEC 10 mg	oral powder	10mg	BIOPROJET PHARMA	FRANCE	10432	2017	01
RACECADOTRILUM	HIDRASEC 30 mg	oral powder	30mg	BIOPROJET PHARMA	FRANCE	10433	2017	01
RACECADOTRILUM	HIDRASEC 100 mg	caps.	100mg	BIOPROJET PHARMA	FRANCE	10434	2017	01

INN	Trade Name	Pharmaceutical Form	Strength	MAH	Holding country	MA no.		
REPAGLINIDUM	REPAGLINIDA ARENA 0,5 mg	tablets	0,5mg	ARENA GROUP S.A.	ROMANIA	10283	2017	01
REPAGLINIDUM	REPAGLINIDA ARENA 1 mg	tablets	1mg	ARENA GROUP S.A.	ROMANIA	10284	2017	01
REPAGLINIDUM	REPAGLINIDA ARENA 2 mg	tablets	2mg	ARENA GROUP S.A.	ROMANIA	10285	2017	01
RIVAROXABANUM	RUNAPLAX 10 mg	film-coated tablets	10mg	SANDOZ S.R.L.	ROMANIA	10473	2017	01
RIVAROXABANUM	RUNAPLAX 15 mg	film-coated tablets	15mg	SANDOZ S.R.L.	ROMANIA	10474	2017	01
RIVAROXABANUM	RUNAPLAX 20 mg	film-coated tablets	20mg	SANDOZ S.R.L.	ROMANIA	10475	2017	01
ROPINIROLUM	ROPINIROL ACTAVIS 2 mg	tablets with prolonged release	2mg	ACTAVIS GROUP PTC EHF.	ICELAND	10277	2017	01
ROPINIROLUM	ROPINIROL ACTAVIS 4 mg	tablets with prolonged release	4mg	ACTAVIS GROUP PTC EHF.	ICELAND	10278	2017	01
ROPINIROLUM	ROPINIROL ACTAVIS 8 mg	tablets with prolonged release	8mg	ACTAVIS GROUP PTC EHF.	ICELAND	10279	2017	01
SALBUTAMOLUM	VENTOLIN 5 mg/ml	sol. for inhalation by nebulise	5mg/ml	GLAXO WELLCOME UK LIMITED	GREAT BRITAIN	10302	2017	01
SITAGLIPTINUM	JIMANDIN 25 mg	film-coated tablets	25mg	MEDOCHEMIE LTD.	CYPRUS	10363	2017	01
SITAGLIPTINUM	JIMANDIN 50 mg	film-coated tablets	50mg	MEDOCHEMIE LTD.	CYPRUS	10364	2017	01

INN	Trade Name	Pharmaceutical Form	Strength	MAH	Holding country	MA no.		
SITAGLIPTINUM	JIMANDIN 100 mg	film-coated tablets	100mg	MEDOCHEMIE LTD.	CYPRUS	10365	2017	01
SOLIFENACINUM SUCCINATE	VESICARE 5 mg	film-coated tablets	5mg	ASTELLAS PHARMA EUROPE B.V.	THE NETHERLANDS	10444	2017	01
SOLIFENACINUM SUCCINATE	VESICARE 10 mg	film-coated tablets	10mg	ASTELLAS PHARMA EUROPE B.V.	THE NETHERLANDS	10445	2017	01
SOLIFENACINUM SUCCINATE	SOLIFENACIN MYLAN 5 mg	film-coated tablets	5mg	MYLAN S.A.S.	FRANCE	10469	2017	01
SOLIFENACINUM SUCCINATE	SOLIFENACIN MYLAN 10 mg	film-coated tablets	10mg	MYLAN S.A.S.	FRANCE	10470	2017	01
TAMSULOSINUM	TAMSULOSIN AUROBINDO 400 micrograms	caps. with prolonged release	400 micrograms	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	10359	2017	01
TELMISARTANUM	TELMARK 40 mg	film-coated tablets	40mg	GLENMARK PHARMACEUTICALS S.R.O.	CZECH REPUBLIC	10320	2017	01
TELMISARTANUM	TELMARK 80 mg	film-coated tablets	80mg	GLENMARK PHARMACEUTICALS S.R.O.	CZECH REPUBLIC	10321	2017	01
TIANEPTINUM	NOBIXAL 12,5 mg	film-coated tablets	12,5mg	ANTIBIOTICE S.A.	ROMANIA	10296	2017	01
TIAPRIDUM	TIAPRIDA PMCS 100 mg	tablets	100mg	PRO. MED. CS PRAHA A.S.	CZECH REPUBLIC	10442	2017	01

INN	Trade Name	Pharmaceutical Form	Strength	MAH	Holding country	MA no.		
TIGECYCLINUM	TIGECICLINA MYLAN 50 mg	powd. for sol. for inf.	50mg	MYLAN S.A.S.	FRANCE	10264	2017	01
TIGECYCLINUM	TIGECICLINA ATB 50 mg	powd. for sol. for inf.	50mg	ANTIBIOTICE S.A.	ROMANIA	10280	2017	01
TIGECYCLINUM	TIGECICLINA SANDOZ 50 mg	powd. for sol. for inf.	50mg	SANDOZ S.R.L.	ROMANIA	10335	2017	01
TRAMADOLUM	TRAMADOL 100 mg	suppositories.	100mg	KRKA, D.D., NOVO MESTO	SLOVENIA	10410	2017	01
TRAMADOLUM	TRAMADOL 50 mg/1 ml	sol. for inj.	50mg/1ml	KRKA D.D.	SLOVENIA	10411	2017	01
TRAMADOLUM	TRAMADOL 100 mg/2 ml	sol. for inj.	100mg/2ml	KRKA D.D.	SLOVENIA	10412	2017	01
TRAMADOLUM	TRAMADOL 50 mg	caps.	50mg	KRKA, D.D., NOVO MESTO	SLOVENIA	10413	2017	01
TRAMADOLUM	TRAMAG 50 mg	tablets	50mg	MAGISTRA C&C S.R.L.	ROMANIA	10415	2017	01
TRAMADOLUM	TRAMADOL KALCEKS	sol inj./perf.		AS KALCEKS	LATVIA	10308	2017	01
VACCIN GRIPAL INACTIVAT	INFLUVAC TETRA	susp. for inj. in pre-filled syringe		BCP PRODUCTS B.V.	THE NETHERLANDS	10276	2017	01
VALSARTANUM	WAROTA 40 mg	film-coated tablets	40mg	ALKALOID - INT D.O.O.	SLOVENIA	10446	2017	01
VALSARTANUM	WAROTA 80 mg	film-coated	80mg	ALKALOID - INT	SLOVENIA	10447	2017	01

INN	Trade Name	Pharmaceutical Form	Strength	MAH	Holding country	MA no.		
		tablets		D.O.O.				
VALSARTANUM	WAROTA 160 mg	film-coated tablets	160mg	ALKALOID - INT D.O.O.	SLOVENIA	10448	2017	01
VARDENAFILUM	VARDENAFIL SANDOZ 5 mg	film-coated tablets	5mg	SANDOZ S.R.L.	ROMANIA	10297	2017	01
VARDENAFILUM	VARDENAFIL SANDOZ 10 mg	film-coated tablets	10mg	SANDOZ S.R.L.	ROMANIA	10298	2017	01
VARDENAFILUM	VARDENAFIL SANDOZ 20 mg	film-coated tablets	20mg	SANDOZ S.R.L.	ROMANIA	10299	2017	01
VILDAGLIPTINUM	DALMEVIN 50 mg	tablets	50mg	MEDOCHEMIE LTD	CYPRUS	10344	2017	01

Centrally authorised medicinal products notified for marketing in Romania during the 4th quarter of 2017

INN	Trade name	Pharm. form	Strength	MAH	Holding company	MA no.		
FLUTICASONUM FUROATUM+ UMECLIDINIUM+ VILANTEROL)	TRELEGY ELLIPTA 92 micrograms/55 micrograms/ 22 micrograms	single dose powd. for inhal.	92micrograme/ 55micrograme/ 22micrograme	GSK TRADING SERVICES LTD.	IRELAND	1236	2017	01
FLUTICASONUM FUROATUM+ UMECLIDINIUM+ VILANTEROL)	ELEBRATO ELLIPTA 92 micrograms/55 micrograms/ 22 micrograms	single dose powd. for inhal.	92micrograme/ 55micrograme/ 22micrograme	GSK TRADING SERVICES LTD.	IRELAND	1237	2017	01
FULVESTRANTUM	FULVESTRANT MYLAN 250 mg/5ml	sol inj. in pre-filled syringe	250 mg/ml	MYLAN S.A.S.	FRANCE	1253	2017	01
MIGLUSTATUM	MIGLUSTAT GEN.ORPH 100 mg	caps.	100 mg	GEN.ORPH	FRANCE	1232	2017	01
RITONAVIRUM	RITONAVIR MYLAN 100 mg	film-coated tablets	100 mg	MYLAN S.A.S.	FRANCE	1242	2017	01