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National Agency for Medicines and Medical Devices

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LAW 132
of 9 October 2014
on approval of Emergency Government Ordinance no. 2/2014 on amendment of Law 95/2006 on healthcare reform and of certain regulatory acts

ISSUED BY: THE PARLIAMENT
PUBLISHED IN: THE OFFICIAL GAZETTE OF ROMANIA No 739 of 10 October 2014

The Parliament of Romania hereby adopts this Law.

ARTICLE I

Emergency Government Ordinance no. 2 of 29 January 2014 on amendment of Law 95/2006 on healthcare reform and of certain regulatory acts, published in the Official Gazette of Romania, Part I, no. 104 of 11 February 2014, is approved as amended:

1. Under Article I point 3, paragraph (2) of Article 4 is amended as follows:

"(2) In line with provisions of this Law, ministries and institutions provided with healthcare networks of their own are authorities and institutions with subordinated healthcare facilities, other than the Ministry of Health, namely the Ministry of National Defence, the Ministry of Internal Affairs, the Ministry of Justice, the Ministry of Transport, the Romanian Intelligence Service, the Foreign Intelligence Service, the Special Telecommunication Service, the Romanian Academy, local public administration authorities, accredited medicine and pharmacy universities and universities with accredited medicine and pharmacy faculties."

2. Under Article I, points 7, 13, 18, 19, 23, 25, 26, 28, 30, 52, 54, 86 and 91 shall be repealed.

3. Under Article I point 11, Article 16 (1^1) is amended as follows:

"(1^1) In conduct of its duties and responsibilities mentioned under (1), the Ministry of Health and its special structures shall have full access to and make use of data of the Health Insurance Information Platform, in line with provisions of Law no. 677/2001 on the protection of individuals with regard to personal data processing and free movement, as amended. The National Health Insurance House (NHIH) and the provider of the Health Insurance Information Platform shall grant the Ministry of Health the same access rights and privileges to information data as granted to the NHIH."

4. Under Article I, a new point, 12^1, is introduced after point 12, which reads as follows:

"12^1. Under Article 16(1), a new point, j), is introduced after point i), which reads as follows:

«j) funding, according to the budget available in this respect, scientific research activities in the medical field, as included in the sectoral plan, as approved through Order of the Minister of Health.»"

5. Under Article I (20), paragraphs (1), (2) and (4) of Article 47 are amended as follows:

"ARTICLE 47

(1) National healthcare programmes are set up by the Ministry of Health through a specialised structure, established through Government Decision.

(2) For set up of national healthcare programs, the specialised structure collaborates with the NHIH and authorities, institutions and non-governmental organisations.

.....

(4) In case of epidemiological risk, beneficiaries of national healthcare programmes, whose purpose is to prevent, monitor and control communicable diseases, are persons mentioned under (3), as well as transients in Romania."

6. Under Article I, point 21 is amended as follows:

"21. On 1 August 2014, paragraph (4) of Article 48 shall be repealed."

7. Under Article I, point 22 shall be repealed.

8. Under Article I, point 24 shall be repealed.

9. Under Article I, point 27 shall be repealed.

10. Under Article I, point 29 shall be repealed.

11. Under Article I, point 31 shall be repealed.

12. Under Article I, a new point, 36^1, is introduced after point 36, which reads as follows:

"36^1. Under Article 93, paragraph (4) is amended as follows:

«(4) Amounts required for management of critical cases whose costs cannot be covered from funds obtained from contracts with health insurance houses shall be covered from Ministry of Health funds, state budget funds and personal revenues."

13. Under Article I point 39, Title V^1, "Special outpatient medical assistance" Chapter I, Article 128^1 paragraph (1), point e) is amended as follows:

"e) outpatient medical facilities of accredited medicine and pharmacy universities with accredited medicine and pharmacy faculties."

14. Under Article I, after point 40, two new points are added, points 40^1 and 40^2, which read as follows:

"40^1. Under Article 148, paragraph (16) is amended as follows:

«(16) The health inspection structure of the Ministry of Health and public health control structures on county level and Bucharest health directorates coordinate and organise the vigilance system mentioned under (15) for notification of severe adverse events and severe adverse reactions in human cells and tissues used for therapeutic purposes.»

40^2. Under Article 148, a new paragraph, (16^1), is introduced after paragraph (16), which reads as follows:

«(16^1) The National Transplant Agency coordinates and organises the vigilance system mentioned under (15) for notification of severe adverse events and severe adverse reactions in human organs used for therapeutic purposes.»"

15. Under Article I point 44, paragraph (3) of Article 170 is amended as follows:

"(3) Expenses of hospital facilities, in the cases mentioned under (2), are reimbursed from the state budget, through budgets of the ministries, of management structures, as well as through the budget of administrative-territorial structures, the budgets of universities of medicine and pharmacy, as required, through Government Decision, within maximum 30 days as of date of cessation of the underlying cause."

16. Under Article I point 45, paragraphs (2^1) and (2^2) of Article 174 are amended as follows:

"(2^1) Management of medical care provided in public hospitals may be transferred to local public administration authorities, accredited state medicine and pharmacy universities, universities with accredited state medicine and pharmacy universities, through Government Decision, initiated by the Ministry of Health, on proposal by local public administration authorities, accredited state medicine and pharmacy universities, universities with accredited medicine and pharmacy faculties, as required.

(2^2) Buildings of public hospitals mentioned under (2^1) may be given for administration to local public administration authorities, accredited state universities for medicine and pharmacy, universities with accredited medicine and pharmacy faculties, in accordance with the law."

17. Under Article I, a new point, 45^1, is introduced after point 45, which reads as follows:

"45^1. Under Article 178 paragraph (2), the introductory paragraph is amended as follows:

«(2) The manager (natural entity) or the representative appointed by the manager (legal entity) is a graduate from medical/economic-financial/legal upper education institutions and shall meet one of the following conditions:»".

18. Under Article I point 46 a) of paragraph (2) of Article 178 is amended as follows:

"a) to have specialised training in management/healthcare management, approved by the Ministry of Health and established through Order of the Minister of Health;".

19. Under Article I point 47, paragraph (3) of Article 178 is amended as follows:

"(3) The manager, physical or legal entity, signs management contracts with the Ministry of Health, ministries or institutions with healthcare networks of their own, represented by the Minister of Health, the head of the Ministry or institution, dean of the university of medicine/pharmacy, as required, for maximum 3 years. The management contract may be terminated in advance following annual assessment or whenever needed. Assessment is performed according to overall performance criteria established through Order of the

Minister of Health, as well as according to specific criteria and averages established and approved through administrative action of the heads of ministries or institutions with healthcare networks of their own, of the head of the territorial-administrative unit, the Mayor of Bucharest or the President of the County Council or by decision of the Senate of the university of medicine and pharmacy, as required. Following evaluation, the administration board shall contact external experts/auditors responsible for verification of accomplishment of general and specific criteria specified in the management contract, by approval of the credit officer and in accordance with legal provisions in force. According to the external audit, the administration board may require the manager to implement corrective measures or may decide upon termination of the management contract. When the mandate is suspended, the management contract may be prolonged for a 3-month period, not more than two times, for the period required for organisation of the employment competition, or public auction, as required. The minister of health, the representative minister or the mayor of the administrative-territorial unit, the mayor of Bucharest, the President of the County Council or the Dean of the University of Medicine and Pharmacy, as required, issue an administrative act assigning an interim manager until employment of a new manager or organisation of the public auction, as required. Implementation rules on auditing and legal advice are issued by the Ministry of Health and approved through Order of the Minister of Health."

20. Under Article I point 48, paragraph (1) of Article 179 is amended as follows:

"ARTICLE 179

(1) The Administration board organises a competition or public auction, as required, in order to select the manager/legal person able to ensure the management of the healthcare unit, in accordance with the norms approved through Order of the Minister of Health or, as required, through Order of the Minister from ministries provided with their own healthcare networks and through administrative act of the mayor of the administrative-territorial unit, the mayor of Bucharest or the President of the county council, the dean of the university of medicine and pharmacy, as required. The Administration board must contract external experts for proper performance of the competition/auction, assessment of the management plan and manner of accomplishment (through management plan) of general and specific performance criteria, in accordance with the chief credit accountant and legal provisions in force."

21. Under Article I, two new points, 53^1 and 53^2, are introduced after point 53, which read as follows:

"53^1. Under Article 190 paragraph (3), point a) is amended as follows:

«a) from the state budget, as regards the situation mentioned under (2) b), d) and e) through budget of the Romanian Academy and, by exemption from provisions of Article 47 (6) of Law 500/2002 on public finances, as amended, through budget transfer from the Ministry of Health to the Romanian Academy, based on signed contract between chief credit accountants;».

53^2. Under Article 190, a new paragraph, (3^1), is introduced after (3), which reads as follows:

«(3^1) Financing of the Elias Emergency University Hospital, as stipulated under (3) a), may also be ensured from local budgets, according to budget credits approved for this purpose in the frame of local budgets.»"

22. Under Article I point 55, paragraph (2) of Article 190^3 is amended as follows:

"(2) Amounts required to perform agreements mentioned under Article 190^1 a) and e) are ensured from state budget funds and from personal revenues, through budget of the Ministry of Health."

23. Under Article I point 56, Article 190^5 is amended as follows:

"ARTICLE 190^5

(1) Public hospitals from the network of local public administration authorities can be paid from the state budget and the revenues of the Ministry of Health, allocated through transfer based on contracts signed between public health directorates and health directorate of Bucharest and local public administration authorities to whom the respective facilities subordinate, for:

a) finalisation of new investment objectives, ongoing investments, investments financed, prior to the date of transfer of public hospital management, through yearly investment programs of the Ministry of Health;

b) supply with medical equipment, taking into account that local public administration authorities participate to this purchase with funds amounting to minimum 10% of their value;

c) major hospital rehabilitation, taking into account that local public administration authorities participate to this purchase with funds amounting to minimum 5% of their value;

d) funding of objectives related to refurbishment, transformation and extension of existing buildings and of inspection, design and consolidation of buildings, if local public administration authorities cooperate in payment with funds of minimum 10% of their value.

(2) Amounts allocated from the budget of the Ministry of Health mentioned under (1) b), c) and d), as well as the list of beneficiary public hospitals are submitted to yearly approval through Government Decision, after publication of the State Budget Law.

(3) The Orders mentioned under (2) are approved according to proposals of special structures of the Ministry of Health following requests from local public administration authorities."

24. Under Article I, a new point, 59^1, is introduced after point 59, which reads as follows:

"59^1. Under Article 210 paragraph (1), a new point, k), is introduced after point j), which reads as follows:

«k) reimbursement price – price paid from the Single national fund for social health insurance for medicinal products, health materials, medical devices and such released through closed circuit pharmacies for insured persons included

in national healthcare programs. Their List and reimbursement price are approved through joint Order of the Minister of Health and of the NHIH president.»"

25. Under Article I point 65, paragraphs (2) and (4) of Article 217 are amended as follows:

(2) Rights mentioned under (1) are stablished based on a multiannual framework contract, elaborated by the NHIH following consultation with the Romanian College of Physicians, hereinafter RCP, the Romanian College of Dentists, hereinafter RCD, the Romanian College of Pharmacists, hereinafter RCP, the Romanian Order of Medical Assistants, Nurses and Midwives, hereinafter ROMANM, the Romanian Order of Healthcare Biochemists, Biologists and Chemists, hereinafter ROHBBC, as well as with representative patronal, union and professional healthcare organisations. The project is approved by the Ministry of Health through Government Decision, within 60 days as of approval of the State Budget Law for the year awaiting approval of a new framework agreement.

.....

(4) The NHIH prepares implementation rules for application of the framework agreement, in collaboration with the RCP, RCD, ROMANM, ROHBBC, RCP, as well as with representative patronal, union and professional healthcare organisations, approved through Order of the Minister of Health and through Order of the NHIH president, within 30 days as of publication of the Government Decision mentioned under (2)."

26. Under Article I point 84, point c) of Article 238 is amended as follows:

"c) supplier compliance with quality criteria for medical and dental assistance, elaborated by the Ministry of health and the CNA."

27. Under Article I, a new point, 84^1, is introduced after point 84, which reads as follows:

"84^1. A new Article, 239, is introduced after Article 239^1, which reads as follows:

«ARTICLE 239^1

The NHIH and health insurance houses organise the control of healthcare activities in order to maintain the quality of medical services provided for insured persons, according to the criteria mentioned under Article 238 c) and Article 239.»"

28. Under Article I point 87, Article 242 is amended as follows:

"ARTICLE 242

Medicinal products granted by outpatient facilities within the national healthcare programs (national therapeutic healthcare programs) are ensured through pharmacies belonging to healthcare facilities where provided or through other pharmacies, as the case may be."

29. Under Article I point 89, Article 244 is amended as follows:

"ARTICLE 244

(1) Providers of healthcare services, medicinal products and medical devices, meeting the assessment criteria established by the NHIH and the

Ministry of Health, may enter a contractual relationship with health insurance houses.

(2) The assessment process involves medical cabinets, special outpatient facilities, hospitals, pharmacies, providers of medical care at home, providers of medical devices, private providers of emergency consultations at home and unassisted health transportation, as well as other physical or legal persons authorised in this respect by the Ministry of Health.

(3) The assessment of medical service providers, medicinal products and medical devices mentioned under (2), is performed at national/county level.

(4) Assessment commissions of providers of medical services, medical devices and medicinal products at national level are made of representatives of the Ministry of Health and of the NHIH; at county level, assessment commissions are made of county and Bucharest representatives of public health directorates and representatives of health insurance houses and, as required, of ministries and institutions with their own health networks.

(5) The regulation for operation of commissions assessing providers of medical services, medical devices and medicinal products, as specified under paragraph (2), is set up by national commissions and approved through Order of the Minister of Health and Order of the NHIH president. Assessment standards issued by national assessment commissions are approved through Order of the Minister of Health and Order of the NHIH president.

(6) The methodology and level of assessment of providers of medical services, medical devices and medicinal products, as specified under paragraph (2), are set up and established by commissions organized at national level and approved through Order of the Minister of Health and Order of the NHIH president.

(7) In view of performing the assessment process, providers of medical services, medicinal products and medical devices are required to pay an assessment tax whose quantum is approved through the Order mentioned under (6).

Venues obtained after assessment activities become own revenues to the fund."

(8) Termination of the assessment activity is supported from venues obtained in line with paragraph (7)."

30. Under Article I, a new point, 91^1, is introduced after point 91, which reads as follows:

"91^1. A new Article, 253^1, is introduced after Article 253, which reads as follows:

«ARTICLE 253^1

Medical assistance and medical care at the residence of the insured person are contracted by health insurance houses with authorised suppliers according to the Law.»"

31. Under Article I point 106, paragraph (2) of Article 262^1 shall be repealed.

32. Under Article I point 107, paragraph (2^1) of Article 265 shall be repealed.

33. Under Article I, a new point, 110^1, is introduced after point 110, which reads as follows:

"110^1. Under Article 275, point a) shall be repealed."

34. Under Article I, a new point, 111^1, is introduced after point 111, which reads as follows:

"111^1. Under Article 279 paragraph (1), point g) is amended as follows:

«g) approves the individual status of the NHIH, as approved through Government decision, and the frame status of insurance houses, upon request of the steering committee;»".

35. Under Article I, a new point, 117^1, is introduced after point 117, which reads as follows:

"117^1. Under Article 313, paragraph (1) is amended as follows:

«ARTICLE 313

(1) Persons whose deeds are detrimental to other person's health, as well as to their own, are legally liable and shall repair harm done to the medical service supplier by covering actual costs incurred by medical care provided. Amounts representing actual costs are recovered by medical service suppliers. As regards litigations for recovery of such amounts, medical service suppliers may substitute as concerns all procedural rights and obligations of health insurance houses and gain their procedural quality in all trials and requests related to courts of jurisdiction, regardless of trial stage.»"

36. Under Article I, a new point, 120^1, is introduced after point 120, which reads as follows:

"120^1. Under Article 362, point a) is amended as follows:

«a) investments in infrastructure and subsidies for public facilities in the network of the Ministry of Health and public hospitals in the network of the local public administration authority, in line with conditions established in Article 190^5 (1);»".

37. Under Article I, a new point, 121^1, is introduced after point 121, which reads as follows:

"121^1. Under Article 370, paragraph (2) is amended as follows:

«(2) By exemption from provisions of Article 371 (1), (3) d) and Article 372, physicians who are citizens of a third state may perform professional activities in Romania for educational purpose and occasionally by permission of the Romanian College of Physicians. In such cases, professional activities may be conducted over a 3-month duration, with possibility of extension to no longer than 3 months per year. The methodology for approval is adopted through Decision of the National Council of the Romanian College of Physicians and is published in the Official Gazette of Romania, Part I.»"

38. Under Article I, a new point, 121^2, is introduced after point 121^1, which reads as follows:

"121^2. Under Article 375, paragraph (2) is amended as follows:

«(2) Considering the nature of the physician status and the physician's main duties toward patients, the physician is not a civil servant and may not be assimilated to civil servant status.»"

39. Under Article I, point 122 shall be repealed.

40. Under Article I, 5 new points, 122^1, 122^2, 122^3, 122^4 and 122^5, are introduced after point 122, which read as follows:

"122^1. Under Article 392, paragraph (2) is amended as follows:

«(2) On a case-by-case basis, the Romanian College of Physicians decides on the temporary or occasional character of provision of physician-related activities, depending on their duration, frequency, periodicity and continuity.»

122^2. Under Article 393, paragraph (2) is amended as follows:

«(2) They are automatically registered with the Romanian National College of Physicians during conduct of the respective services, based on documents mentioned under Article 396, submitted by the provider.»

122^3. Under Article 396, paragraphs (1) and (2) are amended as follows:

«ARTICLE 396

(1) Requests of physicians who are citizens of a EU member state/the EEA/the Swiss Confederacy residing in one of these states, on temporary/occasional provision of services in Romania, are processed by the Romanian College of Physicians.

(2) If, for temporary provision of medical services, this is the applicant's first visit to Romania or in case of documented material changes in the applicant's status, the applicant shall submit the following to the College of Physicians:

a) a preliminary written declaration, stating the applicant's field of insurance or other means of personal/collective protection for professional liability in their member state of residence;

b) a copy of the citizenship document;

c) a declaration attesting knowledge of the Romanian language, required for work in Romania;

d) proof of attestation by competent authorities of the member state of residence that the holder has not been subject to temporary or final suspension from conduct of their profession or to criminal convictions ;

e) the diplomas, certificates or other medical titles as stipulated by the law or by European Union norms for conduct of activities concerned;

f) certified translation into Romanian of documents mentioned under c), d) and e).»

122^4. A new Article, 396^1, is introduced after Article 396, which reads as follows:

«ARTICLE 396^1

(1) As regards first provision of services, for physicians educated in a Member State of the European Union, whose professional training does not meet the criteria for automatic recognition established by the Rules for recognition of diplomas, certificates and titles of physician, dentist, pharmacist, general medical

assistant and midwife, released by a Member State of the European Union, by a state of the European Economic Area or by the Swiss Confederacy, the Romanian College of Physicians may perform an assessment of the provider's professional qualifications.

(2) Preliminary check is possible, only for avoidance of potential serious harm to the patient's health resulting from providing physician's lack of professional qualification and as long as it does not exceed necessities in that respect.

(3) Within 1 month after receipt of the declaration and attached documents, the Romanian College of Physicians informs the providing physician about:

a) its decision not to check the provider's qualifications; or

b) following assessment of professional qualifications, to require a passing score from the providing physician in a capability test or inform him/her on its decision to allow provision of the respective services.

In case of difficulties possibly resulting in delayed response, in advance of the end of the first month after receipt of the declaration and its attached documents, the Romanian College of Physicians informs the providing physician, on the grounds for delay, as well as on the time required to make a decision. Difficulties are solved within one month after notification and the decision is made within two months after resolution of the difficulty.

(4) In case of major differences between providing physician's professional qualifications and specific training required in Romania for supply of the respective medical services, to the extent to which such difference may adversely impact public safety or health and cannot be compensated by the providing physician's professional experience or the knowledge, abilities and competences acquired through lifelong learning, officially validated in this respect by a relevant body, the Romanian College of Physicians provides the applicant an opportunity to demonstrate, by taking a capability test, as mentioned under (3) b), the acquisition of required knowledge, abilities and competences.

(5) After the capability test, the Romanian College of Physicians decides whether the providing physician may perform the medical service in question.

(6) Supply of services must be feasible within one month after adoption of the Decision in accordance with provisions of par. (5).

(7) The Romanian College of Physicians failing to respond, as established under paragraphs (3) and (4), the respective services may be performed.»

122^5. A new Article, 396^2, is introduced after Article 396^1, which reads as follows:

«ARTICLE 396^2

Every six months, the Romanian College of Physicians reports the number of physicians beneficiary of provisions of Articles 396 and 396^1 to the Ministry of Health.»"

41. Under Article I, five new points, 123^1, 123^2, 123^3, 123^4 and 123^5, are introduced after point 123, which read as follows:

"123^1. Under Article 488, paragraph (2) is amended as follows:

«(2) On a case-by-case basis, the Romanian College of Dentists decides on the temporary or occasional character of provision of dentist activities, depending on their duration, frequency, periodicity and continuity.»

123^2. Under Article 492, paragraphs (1) and (2) are amended as follows:

«ARTICLE 492

(1) Requests of dentists who are citizens of a EU member state/the EEA/the Swiss Confederacy residing in one of these states, on temporary/occasional provision of services in Romania, are processed by the Romanian College of Dentists.

(2) If, for temporary provision of medical services, this is the applicant's first visit to Romania or in case of documented material changes in the applicant's status, the applicant shall submit the following to the Romanian College of Dentists:

a) a preliminary written declaration, stating the applicant's field of insurance or other means of personal/collective protection for professional liability in their member state of residence;

b) a copy of the citizenship document;

c) a declaration attesting knowledge of the Romanian language, required for work in Romania;

d) proof of attestation by competent authorities of the member state of residence that the holder has not been subject to temporary or final suspension from conduct of their profession or to criminal convictions;

e) the diplomas, certificates or other medical titles as stipulated by the law or by European Union norms for conduct of activities concerned;

f) certified translation into Romanian of documents mentioned under c), d) and e).»

123^3. A new Article, 492^1, is introduced after Article 492, which reads as follows:

«ARTICLE 492^1

(1) As regards first provision of services, for physicians educated in a Member State of the European Union, whose professional training does not meet the criteria for automatic recognition established by the Rules for recognition of diplomas, certificates and titles of physician, dentist, pharmacist, general medical assistant and midwife, released by a Member State of the European Union, by a state of the European Economic Area or by the Swiss Confederacy, the Romanian College of Dentists may perform an assessment of the provider's professional qualifications.

(2) Preliminary check is possible, only for avoidance of potential serious harm to the patient's health resulting from providing physician's lack of professional qualification and as long as it does not exceed necessities in that respect.

(3) Within 1 month after receipt of the declaration and attached documents, the Romanian College of Dentists informs the providing physician about:

a) its decision not to check the provider's qualifications; or

b) following assessment of professional qualifications, to require a passing score from the providing physician in a capability test or inform him/her on its decision to allow provision of the respective services.

In case of difficulties possibly resulting in delayed response, in advance of the end of the first month after receipt of the declaration and its attached documents, the Romanian College of Dentists informs the providing physician, on the grounds for delay, as well as on the time required to make a decision. Difficulties are solved within one month after notification and the decision is made within two months after resolution of the difficulty.

(4) In case of major differences between providing physician's professional qualifications and specific training required in Romania for supply of the respective medical services, to the extent to which such difference may adversely impact public safety or health and cannot be compensated by the providing physician's professional experience or the knowledge, abilities and competences acquired through lifelong learning, officially validated in this respect by a relevant body, the Romanian College of Dentists provides the applicant an opportunity to demonstrate, by taking a capability test, as mentioned under (3) b), the acquisition of required knowledge, abilities and competences.

(5) After the capability test, the Romanian College of Dentists decides whether the providing physician may perform the medical service in question.

(6) Supply of services must be feasible within one month after adoption of the Decision in accordance with provisions of par (5).

(7) The Romanian College of Dentists failing to respond, as established under paragraphs (3) and (4), the respective services may be performed. Supply of services is performed according to professional title, as stipulated by the law.»

123^4. A new Article, 492^2, is introduced after Article 492^1, which reads as follows:

«ARTICLE 492^2

Every six months, the Romanian College of Dentists reports the number of physicians beneficiary of provisions of Articles 492 and 492^1 to the Ministry of Health.»

123^5. Under Article 683, paragraph (1^1) is amended as follows:

«(1^1) The SNSPMPDSB is a Romanian public legal entity, entirely self-funded, under coordination of the Ministry of Health; academic coordination is established through Government decision. The SNSPMPDSB operates according to economic administration and financial autonomy; it calculates depreciations and conducts economic management of accounts.»"

42. Under Article I point 124, point 17 of Article 695 is amended as follows:

"17. *Public service obligation*: the obligation placed on marketing authorisation holders/representatives marketing authorisation holders and wholesale authorisation holders to permanently ensure an adequate range of medicinal products properly meeting requirements of a specific geographical area, as established and justified by the Ministry of Health, and deliver supplies

requested over the entire area in question within the shortest time possible after order.”

43. Under Article I, a new point, 126^1, is introduced after point 126, which reads as follows:

"126^1. Under Article 750, paragraph (1) is amended as follows:

«ARTICLE 750

(1) The National Medicines Agency only grants the manufacturing authorisation after ascertaining the accuracy of the information supplied pursuant to Article 749, by means of an inspections carried out by its inspectors."

44. Under Article I point 127, paragraph (6) of Article 787 is amended as follows:

"(6) For medicinal products reimbursed in the frame of the national healthcare insurance system, the marketing authorisation holder or their representative in Romania shall take all measures required for wholesale distribution of these medicinal products through at least three authorised wholesale distributors, except for medicinal products supplied in accordance with Order of the Minister of Health."

45. Under Article I, five new points, 127^1, 127^2, 127^3, 127^4 and 127^5, are introduced after point 127, which read as follows:

"127^1. Under Article 788, paragraph (2) is amended as follows:

«(2) Under national law, legal persons authorised to supply medicinal products to the public may not engage in wholesale distribution business as well.»

127^2. Under Article 791, point b) is amended as follows:

«b) only set up their medicinal product supply stocks from persons themselves in possession of the distribution authorisation or who are exempt from obtaining such authorisation under the terms of Article 788, paragraph (4);

127^3. Under Article 791, a new point, j), is introduced after point i), which reads as follows:

«j) to monthly report to the National Agency for Medicines and Medical Devices the record mentioned under e), under conditions established through Order of the Minister of Health.».

127^4. Under Article 792, paragraph (2) is amended as follows:

« (2) Marketing authorisation holders /their representative and wholesale distributors of the said medicinal product actually placed on the market in Romania shall ensure, within their responsibilities, appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products, so as to cover needs of patients in Romania in accordance with provisions of the Order of the Minister of Health; ».

127^5. Article 795 is amended as follows:

«ARTICLE 795

(1) The National Agency for Medicines and Medical Devices shall monitor the application of guidelines on good distribution practice, which are published by the European Commission.

(2) It is the duty of the Ministry of Health to monitor application of Good Pharmaceutical Practice Guidelines stipulated by the law.»"

46. Under Article I point 129, paragraph (1) of Article 799^1 is amended as follows:

"ARTICLE 799^1

(1) Manufacturers, marketing authorisation holders or their representatives to Romania and wholesale and retail distributors of medicinal products, medical devices and healthcare material shall notify the Ministry of Health and the National Agency for Medicines and Medical Devices, as required, on all sponsoring activities as well as on any other expenses covered for physicians, nurses, professional organisations, patient organisations and any other types of organisations in the healthcare system, in accordance with provisions of the Order of the Minister of Health."

47. Under Article I, a new point, 131^1, is introduced after point 131, which reads as follows:

"131^1. Under Article 836 paragraph (1), points c), f), g), h), i), j) and m) are amended as follows:

«c) 5,000 RON to 10,000 RON penalty shall be applied to wholesale manufacturer/importer/distributor, as appropriate, in case of: conduct, within their premises, of activities other than authorised; distribution of medicinal products from the manufacturer or wholesale distributors to units not authorised UNDER the law; distribution to drugstores of medicinal products other than released without medical prescription, participation of staff not appropriately qualified in technical operations requiring specialised training, in the manufacturing and distribution process, as well as violation of provisions on medicinal product labelling and package leaflet, reporting of changes in manufacturing/import or distribution, infringement of good practice in pharmacovigilance activity carried out by the marketing authorisation holder, non-compliance with storage conditions, non-compliance with legislation on export, subsidies and provision of medicinal product samples;

.....

f) 5,000 RON to 10,000 RON penalty shall be applied for absence of the chief pharmacist or their alternate from the distribution site premises during unit operation time; the same penalty applies for absence of the quality responsible person or their alternate from wholesale distribution site during working hours;

g) 10,000 RON to 30,000 RON penalty and one year suspension of the operation authorisation for manufacturers/importers/distribution units shall be applied in case one of the violations referred to under c), e), j) and m) is repeated within 3 months.

h) 5,000 RON to 20,000 RON penalty and suspension of wholesale distribution authorisation, in case of non-compliance with the Guideline on Good Wholesale Distribution Practice, until remedy of the reported deficiencies; the same penalty and exclusion from the registry of brokers apply for brokers not compliant with specific provisions of the Guideline for Good Wholesale Distribution Practice;

i) 10,000 RON to 30,000 RON penalty, for marketing authorisation holders' failure to:

- comply with conditions/restrictions included in the marketing authorisation, related to medicinal product release/use, as well as with those concerning medicinal product safe and effective use;

- report adverse reactions to the National Agency for Medicines and Medical Devices, do not submit Periodic Safety Update Reports to the National Agency for Medicines and Medical Devices,

- submit changes (variations) to marketing authorisation terms,

- notify the National Agency for Medicines and Medical Devices on the date of actual marketing,

- provide the Ministry of Health or, as required, the National Agency for Medicines and Medical Devices, data on the volume of sales and prescriptions of the medicinal product, in accordance with the provisions of this title;

j) 2,000 to 5,000 RON penalty shall be applied for importers' failure to report the status of each import to the National Agency for Medicines and Medical Devices, in accordance with legislation in force, or if the respective reporting is inaccurate or incomplete;

.....

m) 10,000 RON to 30,000 RON penalty shall be applied for manufacturers'/ importers'/wholesale distributors' failure to report to the National Agency for Medicines and Medical Devices, in accordance with the legislation in force, the status of each medicinal product supplied or if the respective reporting is inaccurate or incomplete;

48. Under Article I point 132, point m^1) of paragraph (1) of Article 836 is amended as follows:

"m^1) 50,000 to 100,000 RON penalty, for non-compliance with requirements mentioned under Article 695 (17) and Article 792 (2), as well as with requirements established in accordance with Article 787 (6)."

49. Under Article I, a new point, 132^1, is introduced after point 132, which reads as follows:

"132^1. Under Article 836 paragraph (1), a new point, m^2), is introduced after point m^1), which reads as follows:

«m^2) 50,000 to 100,000 RON penalty, for non-compliance of the marketing authorisation holders or their representatives with requirements mentioned under Article 695 (17) and Article 792 (2), as well as with requirements established in accordance with Article 787 (6)."

50. Under Article I, a new point, 133^1, is introduced after point 133, which reads as follows:

"133^1. Under Article 836 paragraph (1), two new points, x) and y), are introduced after point v), which read as follows:

«x) 5,000 to 10,000 RON penalty, for non-compliance with Article 787 (4) of distributors other than marketing authorisation holders."

y) 5,000 to 10,000 RON penalty, for manufacturer's/importer's/wholesale distributor's/retail distributor's/ marketing authorisation holder's non-

compliance, as required, with provisions related to medicinal product advertisement."

51. Under Article I point 136, a new point, f), is introduced after point e) of paragraph (1) of Article 868, which reads as follows:

"f) provision of information to patients related to items with mandatory inclusion in medical prescription issued in Romania, released in a different Member State."

52. Under Article I point 136 Title XVIII "Cross-border medical assistance", Chapter III, Article 870, paragraph (2) is amended as follows:

"(2) The Ministry of Health publishes on its website the information mentioned under (1), in accordance with norms approved through joint Order of the Minister of Health and of the President of the National Health Insurance House."

53. Under Article I point 136, paragraph (3) of Article 887 is amended as follows:

"(3) In line with this Title, a specialised structure is the Medical Devices Department of the National Agency for Medicines and Medical Devices, with specific assignments in the field of medical devices."

54. Under Article I point 136, paragraphs (1) and (3) of Article 888 are amended as follows:

"ARTICLE 888

(1) Activities related to the marketing, distribution and supply of services in the field of medical devices are performed in accordance with provisions of this Title and of implementation rules, approved through Order of the Minister of Health.

.....

(3) The approval mentioned under (2) is granted by the National Agency for Medicines and Medical Devices, in accordance with applicable implementation rules, based on assessment of the expertise and ability of natural or legal persons, as required, to perform activities requiring approval. "

55. Under Article I point 136, Articles 890 - 895, 898 - 901 and 903 are amended as follows:

"ARTICLE 890

Commissioned and in-use medical devices shall comply, according to the terms established through instructions approved through Order of the Minister of Health, with the following types of control:

a) periodic check-up;

b) unannounced inspection and testing;

c) in-use surveillance.

ARTICLE 891

Assessment activities mentioned under Article 888 (3) and control activities stipulated under Article 890 are performed by the National Agency for Medicines and Medical Devices.

ARTICLE 892

(1) In line with provisions of this Title, the National Agency for Medicines and Medical Devices has the following main duties:

a) to elaborate specific technical procedures for medical devices;

b) to assess and/or audit, upon request, natural or legal entities applying for approval as mentioned under Article 888 (3);

c) to ensure, by examination and testing, control of medical devices in use, in accordance with implementation norms approved through Order of the Minister of Health;

d) to ensure assessment of the performance of medical devices, under conditions mentioned in this Title;

e) periodically inform the Ministry of Health about activities conducted in the respective field of competence.

(2) The National Agency for Medicines and Medical Devices performs other activities as well, in accordance with the law.

ARTICLE 893

(1) Second-hand medical devices, provided free of charge or purchased, shall only be marketed, commissioned and used after assessment by the National Agency for Medicines and Medical Devices and based on grant of approval.

(2) Second-hand medical devices mentioned under (1), marketed and/or commissioned, must be labelled with the EC marking, on condition of assessment of compliance prior to placement on the market, in accordance with European rules on medical devices.

ARTICLE 894

(1) The National Agency for Medicines and Medical Devices is the competent, decision-making authority for medical devices.

(2) The National Agency for Medicines and Medical Devices performs the duties of a competent authority, as mentioned in the legislation, and proposes the Minister of Health regulatory acts for transposition of European directives or implementation of the legal framework of EU regulations in the field of medical devices, as required.

(3) The policy related to medical devices is established by the Ministry of Health.

(4) The Commission for Medical Devices and the Medical Devices Department of the National Agency for Medicines and Medical Devices organise clinical investigation of medical devices on human subjects, in accordance with provisions of regulations in force.

(5) The constituents, organisation and assignments of the Commission for Medical Devices are approved through Order of the Minister of Health.

ARTICLE 895

(1) To ensure appropriate safety and performance suitable to the intended purpose of the medical device and to avoid incidents, users are required:

a) to use medical devices for their intended purpose only;

b) to ascertain that medical devices are used during their period of validity only, when required, and that no deviations exist from operational performance and applicable safety requirements;

c) to enforce a programme for surveillance of medical devices, taking into account the risk posed to the patient, their intended use and complexity, in accordance with implementation rules in force;

d) to ensure periodic check-up, maintenance and repair of medical devices in collaboration with facilities specialised in delivery of such services;

e) to notify manufacturers and the specialised structure about any incident during use;

f) to report to the National Agency for Medicines and Medical Devices all medical devices in the unit, recorded as fixed assets in the accounting records, irrespective of their manner of acquisition, in accordance with the implementation rules approved through Order of the Minister of Health;

g) to ensure a documented inventory system for medical devices in use, repaired and checked, in accordance with implementation rules in force.

(2) medical devices in use for clinical investigation or assessment of performance for certification purposes, compliant with regulations or, as required, with the procedure for assessment of compliance stipulated in the applicable technical regulation are exempt from provisions of par. (1).

(3) Users of medical devices shall ensure spare parts for used and commissioned medical devices as well as units able to perform the respective servicing.

.....

ARTICLE 898

(1) The offence notice and application of civil penalties are performed by staff of the National Agency for Medicines and Medical Devices, assigned in this respect.

(2) The legal or natural entity may file a complaint against the offence notice, within 15 days after notification, to the courthouse in whose territorial area the offence has taken place.

(3) The court decision is subject to means of appeal as stipulated by the law.

(4) Decisions on civil liability mentioned in Title XIX are supplemented with those of Government Ordinance no. 2/2001 on the legal regime of civil liability, approved as amended through Law 180/2002, as amended.

ARTICLE 899

Data recorded in accordance with this Title are stored into a database organised and coordinated by the National Agency for Medicines and Medical Devices.

ARTICLE 900

The implementation rules and instructions approved through Order of the Minister of Health are published in accordance with provisions of this Title.

ARTICLE 901

As regards examinations mentioned under Article 892 (1) b) - d), the National Agency for Medicines and Medical Devices establishes and collects fees for fee-based services, as established through Order of the Minister of Health.

.....

ARTICLE 903

Within 3 months as of entry into force of this Title, the medical devices specialised structure within the National Agency for Medicines and Medical Devices shall issue implementation rules, as approved through Order of the Minister of Health."

56. Articles II - V shall be repealed.

57. Under Article VII, paragraphs (1), (5), (6) and (7) shall be repealed.

58. Under Article VII, paragraph (2) is amended as follows:

"(2) Provisions of Article 54 (1) and (4), Article 220 to 262^1 of Law no. 95/2006, as amended, as amended through this Emergency Ordinance, shall come into force on 1 January 2015. "

59. Articles VIII and X shall be repealed.

60. Under Article XII, point 1 shall be repealed.

61. Under Article XII, a new point, 3, is introduced after 2, which reads as follows:

"3. Article 4 is amended as follows:

«ARTICLE 4

By exemption, before nationwide completion of implementation of the centralised system for acquisition of medicinal products, health materials, medical equipment, protection equipment, services, fuel and lubricants for the auto park, the Ministry of Health may approve acquisitions performed by public health units.»"

62. Article XV shall be repealed.

ARTICLE II

Government Decisions mentioned under Article 872 (3) and (4), Article 873 (1) d) and (5), Article 874 (3) b) and (4), Article 876 (1) a) (i) and (2), Article 877 (1) and Article 880 (2) and (4) of Law 95/2006 on healthcare reform, as amended, including those incurred by this Law, shall be set up in 30 days as of publication of this Law in the Official Gazette of Romania, Part I.

This Law has been adopted by the Romanian Parliament, in accordance with Article 77 (2), in line with provisions of Article 75 and Article 76 (2) of the Romanian Constitution, republished.

On behalf of the PRESIDENT OF THE CHAMBER OF DEPUTIES,
VIOREL HREBENCIUC

PRESIDENT OF THE SENATE,
CĂLIN-CONSTANTIN-ANTON POPESCU-TĂRICEANU

Bucharest, 9 October 2014.
No. 132.

ORDER no. 1575
of 22 December 2014
on amendment of Order of the Minister of Health no. 456/2013 on approval of the List of International Non-proprietary Names of medicinal products at high unavailability risk, as provided to insurants in the health insurance system and agreement on a measure to ensure their market availability in Romania

ISSUED BY: THE MINISTRY OF HEALTH
PUBLISHED IN: THE OFFICIAL GAZETTE OF ROMANIA, PART I, No. 946 of 23 December 2014

On seeing Approval report no. N.B. 11.520/2014 of the Medicinal Product and Medical Devices Directorate and NAMMD notifications no. N.B. 7.288, 71.247/2014 and 77.894/2014,

taking into account provisions of Article 695 (17) and Article 792 of Law 95/2006 on healthcare reform, as amended,

based on provisions of 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 I

Order of the Minister of Health no. 456/2013 on approval of the List of International Non-proprietary Names of medicinal products at high unavailability risk, as provided to insurants in the health insurance system and agreement on a measure to ensure their market availability in Romania, published in the Official Gazette of Romania, Part I, no. 197 of 8 April 2013, as amended, is amended as follows:

1. Under Article 1, paragraph (2) is amended as follows:

"(2) Distribution outside Romania of medicinal products included in the List specified in (1) is temporarily suspended as of the date of this Order coming into force to 30 June 2015."

2. The Annex is replaced with the Annex which is integral part of this Order.

ARTICLE II

This Order is to be published in the Official Gazette of Romania, Part I.

On behalf of the Minister of Health,
Dorel Săndesc,
State Secretary

Bucharest, 22 December 2014.
No. 1.575.

ANNEX 1
(Annex to Order no. 456/2013)

No.	International Non-proprietary Name
1.	ASPARAGINAZUM
2.	BLEOMYCINUM SULFAS
3.	BUSULFANUM
4.	CARMUSTINA
5.	CHLORAMBUCILUM
6.	CISPLATINUM
7.	CYCLOPHOSPHAMIDUM
8.	CYTARABINUM
9.	DACARBAZINUM
10.	DACTINOMICINUM
11.	DAUNORUBICINUM
12.	DEXAMETHASONUM
13.	ETOPOSIDE
14.	FLUOROURACILUM
15.	LOMUSTINUM
16.	MELPHALANUM
17.	MERCAPTOPURINUM
18.	METHOTREXATUM
19.	PROCARBAZINA
20.	TENIPOSIDE
21.	TIOGUANINA
22.	VINBLASTINUM
23.	PEGINTERFERON alfa-2a
24.	SUNITINIBUM
25.	ENOXAPARINUM
26.	NADROPARINUM
27.	DALTEPARINUM

28.	TINZAPARINUM
29.	BEMIPARINUM
30.	HEPARINUM
31.	RITUXIMABUM
32.	BEVACIZUMABUM
33.	ERLOTINIBUM
34.	OCTREOTIDUM LAR
35.	VORICONAZOLUM
36.	GOSERELINUM
37.	FULVESTRANTUM
38.	INSULINUM GLARGINUM
39.	INSULINUM GLULIZINUM
40.	HUMAN INSULINS
41.	DEFERASIROXUM

Medicinal product batches recalled during the 4th quarter of 2014

No.	Product recalled	Pharmaceutical form	Strength	INN	Manufacturer/ MAH	Batch	Grounds for recall	Action proposed	Date of recall
1	EFFERALGAN PEDIATRIC	oral solution	3%	paracetamolum	Bristol-Myers Squibb, France/ Bristol-Myers Squibb, Hungary	P3499	Detection of a deviation in the product's repackaging stage (vial leaflet not containing all information included in Annex 3 to IP/2013/01)	Recall	23.10. 2014
2	AZALIA	film-coated tablets	75 µg	desogestrelum	Gedeon Richter PLC, Hungary/ Gedeon Richter Romania S.R.L., RO	T37501C	out-of-specification result (OOS) for impurity 3-keto-desogestrel during the continued stability study (6 months) and during testing of the product's counter-samples,	Recall and destruction	23.10. 2014
3	ZOVIRAX	eye ointment	30 mg/g	aciclovirum	Glaxo Operations UK/ The Welcome Foundation Ltd UK		Identification of metal particles in 3 batches of active substance from Mylan Laboratories, India	Recall and return to manufacturer/ destruction	05.11. 2014
5	ORFIRIL LONG	prolonged-release capsules	150 mg	sodium valproate	Destin Arzneimittel GmbH, GERMANY	14003529	Medicinal product with potential risk of humidity absorption and change in release effect, because of improperly closed packaging	Recall and destruction	05.11. 2014
6	LEKOKLAR	film-coated tablets	250 mg	claritromicinum	Lek Pharmaceuticals DD, Slovenia/Sandoz România S.R.L., RO	CA8141, DE4587	Medicinal product whose 1-year validity has expired on discontinuation of the 2 MAs granted through national procedure	Voluntary recall and destruction	17.11. 2014
7	LEKOKLAR	film-coated tablets	500 mg	claritromicinum	Lek Pharmaceuticals DD, Slovenia/Sandoz România S.R.L., RO	BZ0698, BZ0699, BZ0700, CF8900, DB5809, DB5810, DK0634	Medicinal product whose 1-year validity has expired on discontinuation of the MA granted through national procedure	Voluntary recall and destruction	17.11. 2014
8	TORISEL	concentrate and	25 mg/ml	temsirolimusum	Wyeth Lederle	AIIM/14,	Presence in solvent vials of	Recall and	02.12.

No.	Product recalled	Pharmaceutical form	Strength	INN	Manufacturer/ MAH	Batch	Grounds for recall	Action proposed	Date of recall
		solvent for solution for infusion			(Pfizer), Italy/Pfizer Ltd. UK	AIIM/97	impurities derived from a starting material used in the manufacturing of the specified product	destruction	2014
9	PRAMIPEXOL TORRENT	tablets	0.18 mg	pramipexolum	Heumann Pharma GmbH, GERMANY/Torrent Pharma S.R.L., RO	BM85A006	Product found noncompliant after reanalysis in Romania of the product batch imported from India	Recall and destruction	08.12. 2014
10	HUMAGRIP	tablets and capsules		combinations	Lab. Urgo, France	66613	Lack of printing of the manufacturing batch number on some of the product's secondary packaging	Recall and destruction/ return to manufacturer	08.12. 2014
11	EBIXA	oral drops, solution	5 mg/ dose	memantinum	H. Lundebeck A/S, Denmark	364383, 365771, 369092, 370327, 471990, 473830	Potential flawed functioning of the product's dosing pump	Recall and destruction	12.12. 2014

Applications for marketing authorisation/marketing authorisation renewal submitted to the NAMMD during the 3rd quarter of 2014

During the 3rd quarter of 2014, 326 marketing authorisation/renewal applications for medicinal products corresponding to the following therapeutic groups have been received:

A02 - Drugs for acid related disorders
A03 – Drugs for functional gastrointestinal disorders
A06 – Drugs for constipation
A07 – Antidiarrheals, intestinal anti-inflammatory/anti-infective agents
B01 – Antithrombotic agents
B02 – Antihemorrhagics
B05 – Blood substitutes and perfusion solutions
C01 – Cardiac therapy
C02 – Antihypertensives
C03 – Diuretics
C07 – Beta blocking agents
C08 – Calcium channel blockers
C09 – Agents acting on the renin-angiotensin system
C10 – Lipid modifying agents
G03 – Sex hormones and modulators of the genital system
G04 - Urologicals
H01 – Pituitary and hypothalamic hormones and analogues
H02 – Corticosteroids for systemic use
J01 – Antibacterial for systemic use
J02 – Antimycotics for systemic use
J05 – Antivirals for systemic use
J07 - Vaccines
L01 – Antineoplastic agents
L02 – Endocrine therapy
L03 – Immunomodulating agents
L04 – Immunosuppressants
M01 – Anti-inflammatory and antirheumatic products
M03 – Muscle relaxants
M05 – Drugs for treatment of bone diseases
N01 - Anesthetics
N02 - Analgezics
N03 - Antiepileptics
N04 – Anti-parkinson drugs
N05 - Psycholeptics
N06 - Psychoanaleptics

N07 – Other nervous system drugs
P02 – Anthelmintics
R01 – Nasal preparations
R03 – Drugs for obstructive airway diseases
R05 – Cough and cold preparations
R06 – Antihistamines for systemic use
S01 - Ophthalmologicals
V03 – All other therapeutic products
V09 – Diagnostic radiopharmaceuticals

Medicinal products authorised for marketing during the 2nd quarter of 2014

INN	Invented name	Pharm.	Strength	Country	MA number	INN		
ABCIXIMABUM	REOPRO 2mg/ml	solution for injection/infusion	2mg/ml	CENTOCOR B.V.	HOLLAND	6943	2014	01
ACETYLCYSTEINUM	ACC 100 mg	effervescent tablets	100mg	SANDOZ S.R.L.	ROMANIA	6612	2014	01
ACETYLCYSTEINUM	ACC 200 mg	effervescent tablets	200mg	SANDOZ S.R.L.	ROMANIA	6613	2014	01
ACETYLCYSTEINUM	ACC 600 mg	effervescent tablets	600mg	SANDOZ S.R.L.	ROMANIA	6614	2014	01
ACETYLCYSTEINUM	REVIFEN 200 mg	capsules	200mg	SOLACIUM PHARMA S.R.L.	ROMANIA	6922	2014	01
ACIDUM ACETYLSALICYLICUM	ASPIRIN CARDIO 300 mg	gastroresistant tablets	300mg	BAYER S.R.L.	ROMANIA	6755	2014	01
ACIDUM ACETYLSALICYLICUM	ASPIRIN CARDIO 100mg	gastroresistant tablets	100mg	BAYER S.R.L.	ROMANIA	6754	2014	01
ACIDUM ACETYLSALICYLICUM	ASPIMAX 500 mg	tablets	500mg	LAROPHARM S.R.L.	ROMANIA	6880	2014	01
ACIDUM ACETYLSALICYLICUM	TROMALYT 150 mg	prolonged-release capsules	150mg	MADAUS GMBH	AUSTRIA	6756	2014	01
ACIDUM ALENDRONICUM	ACID ALENDRONIC/ COLECALCIFEROL TEVA 70 mg/2800 UI	tablets	70mg/ 2800UI	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	6622	2014	01
ACIDUM ALENDRONICUM	ACID ALENDRONIC/ COLECALCIFEROL TEVA 7mg/5600 UI	tablets	70mg/ 5600IU	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	6623	2014	01
ACIDUM HIALURONICUM	HYALGAN 20 mg/2 ml	solution for injection in pre-filled syringe	20mg/2ml	CSC PHARMACEUTICALS HANDELS GMBH	AUSTRIA	6669	2014	01
ACIDUM HIALURONICUM	HYALGAN 20 mg/2 ml	solution for injection	20mg/2ml	CSC PHARMACEUTICALS HANDELS GMBH	AUSTRIA	6670	2014	01

ACIDUM RISEDRONICUM	NORIFAZ 75 mg	film-coated tablets	75mg	ZAKLAD FARMACEUTYCZNY ADAMED PHARMA S.A.	POLAND	6962	2014	01
ACIDUM ZOLEDRONICUM	ACID ZOLEDRONIC DR. REDDY'S 4mg/100 ml	solution for infusion	4mg/100ml	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	6678	2014	01
ALBUMINUM HUMANUM	ALBUMINA UMANA BEHRING 200g/l	solution for infusion	200g/l	CSL BEHRING GMBH	GERMANY	6918	2014	01
AMBAZONUM	FARINGOSEPT SCORTISOARA 10 mg	orodispersible tablets	10mg	TERAPIA S.A.	ROMANIA	6615	2014	01
AMBAZONUM	FARINGOSEPT MENTA 10 mg	orodispersible tablets	10mg	TERAPIA S.A.	ROMANIA	6616	2014	01
AMBAZONUM	FARINGOSEPT ROM 10 mg	orodispersible tablets	10mg	TERAPIA S.A.	ROMANIA	6617	2014	01
AMIODARONUM	SEDACORON 200 mg	tablets	200mg	EBEWE PHARMA GES.M.B.H. NFG. KG	AUSTRIA	6713	2014	01
AMISULPRIDUM	MIDORA 400 mg	film-coated tablets	400mg	TERAPIA SA	ROMANIA	6641	2014	01
AMPICILLINUM	EPICOCILLIN 250 mg	powder for solution for injection/infusion	250mg	EIPICO MED SRL	ROMANIA	6726	2014	01
AMPICILLINUM	EPICOCILLIN 1 g	powder for solution for injection/infusion	1g	EIPICO MED SRL	ROMANIA	6727	2014	01
ANASTROZOLUM	OZOLAN 1 mg	film-coated tablets	1mg	ALVOGEN IPCO S.A.R.L.	LUXEMBOURG	6925	2014	01
ATENOLOLUM	ATENOLOL ARENA 50 mg	tablets	50mg	ARENA GROUP S.A.	ROMANIA	6728	2014	01
ATENOLOLUM	ATENOLOL ARENA 100 mg	tablets	100mg	ARENA GROUP S.A.	ROMANIA	6729	2014	01
ATOMOXETINUM	ATOMOXETINA ZENTIVA 10 mg	capsules	10mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	6888	2014	01
ATOMOXETINUM	ATOMOXETINA ZENTIVA 18 mg	capsules	18mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	6889	2014	01
ATOMOXETINUM	ATOMOXETINA ZENTIVA 25 mg	capsules	25mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	6890	2014	01
ATOMOXETINUM	ATOMOXETINA ZENTIVA 40 mg	capsules	40mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	6891	2014	01

ATOMOXETINUM	ATOMOXETINA ZENTIVA 60 mg	capsules	60mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	6892	2014	01
ATOMOXETINUM	ATOMOXETINA ZENTIVA 80 mg	capsules	80mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	6893	2014	01
ATOMOXETINUM	ATOMOXETINA ZENTIVA 100 mg	capsules	100mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	6894	2014	01
ATORVASTATINUM	ATORGAMMA 10 mg	film-coated tablets	10mg	WORWAG PHARMA GMBH & CO. KG	GERMANY	6848	2014	01
ATORVASTATINUM	ATORGAMMA 20 mg	film-coated tablets	20mg	WORWAG PHARMA GMBH & CO. KG	GERMANY	6849	2014	01
ATORVASTATINUM	ATORGAMMA 40 mg	film-coated tablets	40mg	WORWAG PHARMA GMBH & CO. KG	GERMANY	6850	2014	01
ATORVASTATINUM	TULIP 10 mg	film-coated tablets	10mg	SANDOZ S.R.L.	ROMANIA	6944	2014	01
ATORVASTATINUM	TULIP 20 mg	film-coated tablets	20mg	SANDOZ S.R.L.	ROMANIA	6945	2014	01
ATORVASTATINUM	TULIP 40 mg	film-coated tablets	40mg	SANDOZ S.R.L.	ROMANIA	6946	2014	01
ATORVASTATINUM	TULIP 80 mg	film-coated tablets	80mg	SANDOZ S.R.L.	ROMANIA	6947	2014	01
ATORVASTATINUM	TULIP 30 mg	film-coated tablets	30mg	SANDOZ S.R.L.	ROMANIA	6948	2014	01
ATORVASTATINUM	GLETOR 10 mg	film-coated tablets	10mg	GLENMARK PHARMACEUTICALS S.R.O.	THE CZECH REPUBLIC	6831	2014	01
ATORVASTATINUM	GLETOR 20 mg	film-coated tablets	20mg	GLENMARK PHARMACEUTICALS S.R.O.	THE CZECH REPUBLIC	6832	2014	01
ATORVASTATINUM	GLETOR 40 mg	film-coated tablets	40mg	GLENMARK PHARMACEUTICALS S.R.O.	THE CZECH REPUBLIC	6833	2014	01
AZITHROMYCINUM	AZIBIOT 250 mg	film-coated tablets	250mg	KRKA ,D.D., NOVO MESTO	SLOVENIA	6917	2014	01
BENFOTIAMINUM	BENFOTIAMINA BIOMEDIAL 300 mg	film-coated tablets	300mg	BIOMEDIAL PHARMA S.R.L.	ROMANIA	6861	2014	01
BENZYDAMINUM	TANTUM GEL 50 mg/g	gel	50mg/g	CSC PHARMACEUTICALS HANDELS GMBH	AUSTRIA	6874	2014	01
BETAHISTINUM	BETAHISTINA DICLORHIDRAT AUROBINDO 8 mg	tablets	8mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	6907	2014	01

BETAHISTINUM	BETAHISTINA DICLORHIDRAT AUROBINDO 16 mg	tablets	16mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	6908	2014	01
BETAHISTINUM	BETAHISTINA DICLORHIDRAT AUROBINDO 24 mg	tablets	24mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	6909	2014	01
BISACODYLUM	BISACODIL ARENA 5 mg	gastroresistant coated tablets	5mg	ARENA GROUP S.A.	ROMANIA	6673	2014	01
BROMAZEPAMUM	BROMAZEPAM LPH 1.5 mg	tablets	1.5mg	LABORMED PHARMA S.A.	ROMANIA	6881	2014	01
BROMAZEPAMUM	BROMAZEPAM LPH 3 mg	tablets	3mg	LABORMED PHARMA S.A.	ROMANIA	6882	2014	01
BUDESONIDUM	BUDENOFALK 3 mg	capsules with gastro-resistant pellets	3mg	DR. FALK PHARMA GMBH	GERMANY	6934	2014	01
CAPECITABINUM	CITAMED 500 mg	film-coated tablets	500mg	MEDISON PHARMA SRL	ROMANIA	6906	2014	01
CAPECITABINUM	CITAMED 150 mg	film-coated tablets	150mg	MEDISON PHARMA SRL	ROMANIA	6905	2014	01
CARVEDILOLUM	CARVEHEAL 3.125 mg	tablets	3.125mg	ALAPIS ROMANIA S.R.L.	ROMANIA	6911	2014	01
CARVEDILOLUM	CARVEHEAL 6.25 mg	tablets	6.25mg	ALAPIS ROMANIA S.R.L.	ROMANIA	6912	2014	01
CARVEDILOLUM	CARVEHEAL 12.5 mg	tablets	12.5mg	ALAPIS ROMANIA S.R.L.	ROMANIA	6913	2014	01
CARVEDILOLUM	CARVEHEAL 25 mg	tablets	25mg	ALAPIS ROMANIA S.R.L.	ROMANIA	6914	2014	01
CELECOXIBUM	ZELSIGLAT 100 mg	capsules	100mg	SIGILLATA LIMITED	UK	6636	2014	01
CELECOXIBUM	ZELSIGLAT 200 mg	capsules	200mg	SIGILLATA LIMITED	UK	6637	2014	01
CELECOXIBUM	CELECOXIB TERAPIA 100 mg	capsules	100mg	TERAPIA SA	ROMANIA	6810	2014	01
CELECOXIBUM	CELECOXIB TERAPIA 200 mg	capsules	200mg	TERAPIA SA	ROMANIA	6811	2014	01
CLARITHROMYCINUM	CLARITROMICINA HEC PHARM 250 mg	film-coated tablets	250mg	HEC PHARM GMBH	GERMANY	6752	2014	01
CLARITHROMYCINUM	CLARITROMICINA HEC PHARM 500 mg	film-coated tablets	500mg	HEC PHARM GMBH	GERMANY	6753	2014	01

CODEINUM	CODEINA FOSFAT LPH 15 mg	tablets	15mg	LABORMED PHARMA S.A.	ROMANIA	6872	2014	01
COMBINATIONS	COLPOSEPTINE 10 mg/200 mg	vaginal tablets	10mg/ 200mg	LABORATOIRE THERAMEX	MONACO	6709	2014	01
COMBINATIONS	ESSENTIALE FORTE 300 mg	capsules	300mg	SANOFI-AVENTIS ROMANIA S.R.L.	ROMANIA	6779	2014	01
COMBINATIONS	CALCIU D3 MASTICABIL 500 mg/200 UI	chewable tablets	500mg/ 200IU	TAKEDA NYCOMED AS	NORWAY	6674	2014	01
COMBINATIONS	EXCEDRINIL 250 mg/250 mg/65 mg	film-coated tablets	250mg/ 250mg/65mg	NOVARTIS CONSUMER HEALTH GMBH	GERMANY	6774	2014	01
COMBINATIONS (ETINILESTRADIOLUM + DROSPIRENONUM)	FELICITY 0.02 mg/3 mg 28	film-coated tablets	0.02mg/3mg	SANDOZ S.R.L.	ROMANIA	6819	2014	01
COMBINATIONS (ETINILESTRADIOLUM + DROSPIRENONUM)	FELICITY 0.03 mg/3 mg 28	film-coated tablets	0.03mg/3mg	SANDOZ S.R.L.	ROMANIA	6820	2014	01
COMBINATIONS (ATORVASTATINUM+ AMLODIPINUM)	ATORDAPIN 5 mg/10 mg	film-coated tablets	5 mg/10 mg	KRKA, D.D., NOVO MESTO	SLOVENIA	6694	2014	01
COMBINATIONS (ATORVASTATINUM+ AMLODIPINUM)	AMLODIPINA/ATORVASTATINA POLPHARMA	film-coated tablets	10mg/5mg	PHARMACEUTICAL WORKS POLPHARMA SA	POLAND	6680	2014	01
COMBINATIONS (ATORVASTATINUM+ AMLODIPINUM)	AMLODIPINA/ATORVASTATINA POLPHARMA	film-coated tablets	10mg/10mg	PHARMACEUTICAL WORKS POLPHARMA SA	POLAND	6681	2014	01
COMBINATIONS (ATORVASTATINUM+ AMLODIPINUM)	AMLODIPINA/ATORVASTATINA KRKA 5 mg/10 mg	film-coated tablets	5mg/ 10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	6695	2014	01
COMBINATIONS (CALCIPOTRIOLUM+ BETAMETHASONUM)	XAMIOL 50 µgr./ 0.5 mg/g	gel	50µgr./ 0.5mg/g	LEO PHARMA A/S	DENMARK	6926	2014	01
COMBINATIONS (CANDESARTANUM CILEXETIL+ AMLODIPINUM)	CARAMLO 8 mg/5 mg	tablets	8 mg/5 mg	ZENTIVA K.S.	THE CZECH REPUBLIC	6634	2014	01

COMBINATIONS (CANDESARTANUM CILEXETIL+ AMLODIPINUM)	CARAMLO 16 mg/10 mg	tablets	16 mg/10 mg	ZENIVA K.S.	THE CZECH REPUBLIC	6635	2014	01
COMBINATIONS (CHLORHEXIDINUM+ BENZOCAINUM)	HEXORALETTEN N 5 mg+1.5 mg	drops	5mg+1.5mg	MCNEIL PRODUCTS LIMITED C/O JOHNSON&JOHNSON LTD.	UK	6735	2014	01
COMBINATIONS (DIENOGESTUM+ ETINILESTRADIOLUM)	DIENILLE	film-coated tablets		PHARMASWISS CESKA REPUBLIKA S.R.O.	THE CZECH REPUBLIC	6904	2014	01
COMBINATIONS (DORZOLAMIDUM+ TIMOLOLUM)	COSOPT 20 mg/l + 5 mg/ml	eye drops, solution	20mg/ml+ 5mg/ml	MERCK SHARP & DOHME ROMANIA S.R.L.	ROMANIA	6829	2014	01
COMBINATIONS (ESTRADIOLUM + DROSPIRENONUM)	ANGELIQ 1 mg + 2 mg	film-coated tablets	1mg+2mg	BAYER PHARMA AG	GERMANY	6793	2014	01
COMBINATIONS (FERROSI SULFAS+ACIDUM FOLICUM)	FOLIFER BIOMEDIAL 37 mg+0.8 mg	gastroresistant tablets	37mg+0.8mg	BIOMEDIAL PHARMA SRL	ROMANIA	6777	2014	01
COMBINATIONS (IBUPROFENUM+ PSEUDOEFEDRINUM)	TEDOLFEN 200 mg/30 mg (see R01BA52)	film-coated tablets	200mg/30mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	6744	2014	01
COMBINATIONS (IBUPROFENUM+ PSEUDOEFEDRINUM)	TEDOLFEN 200 mg/30 mg (see R05X)	film-coated tablets	200mg/30mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	6744	2014	01
COMBINATIONS (IRBERSARTANUM+ HYDROCHLOROTHIAZIDUM)	LARTOKAZ 150 mg/12.5mg	tablets	150mg/ 12.5mg	LABORATORIOS LICONSA, S.A.	SPAIN	6696	2014	01
COMBINATIONS (IRBERSARTANUM+ HYDROCHLOROTHIAZIDUM)	LARTOKAZ 300 mg/12.5mg	tablets	300mg/12.5 mg	LABORATORIOS LICONSA, S.A.	SPAIN	6697	2014	01
COMBINATIONS (IRBERSARTANUM+ HYDROCHLOROTHIAZIDUM)	LARTOKAZ 300 mg/25mg	tablets	300mg/25mg	LABORATORIOS LICONSA, S.A.	SPAIN	6698	2014	01

COMBINATIONS (IRBERSARTANUM+ HYDROCHLOROTHIAZIDUM)	CONVERIDE 150 mg/12.5 mg	film-coated tablets	150mg/ 12.5mg	MEDOCHEMIE LTD	CYPRUS	6900	2014	01
COMBINATIONS (IRBERSARTANUM+ HYDROCHLOROTHIAZIDUM)	CONVERIDE 300 mg/12.5 mg	film-coated tablets	300mg/ 12.5mg	MEDOCHEMIE LTD	CYPRUS	6901	2014	01
COMBINATIONS (IRBERSARTANUM+ HYDROCHLOROTHIAZIDUM)	CONVERIDE 300 mg/25 mg	film-coated tablets	300mg/25mg	MEDOCHEMIE LTD	CYPRUS	6902	2014	01
COMBINATIONS (LEVODOPUM+ CARBIDOPUM+ ENTACAPONUM)	LEVODOPA/CARBIDOPA/ENTACAPONA TORRENT 50 mg/12.5 mg/200 mg	film-coated tablets	50mg/ 12.5mg/ 200mg	TORRENT PHARMA S.R.L.	ROMANIA	6853	2014	01
COMBINATIONS (LEVODOPUM+ CARBIDOPUM+ ENTACAPONUM)	LEVODOPA/CARBIDOPA/ENTACAPONA TORRENT 75 mg/18.75 mg/200 mg	film-coated tablets	75mg/ 18.75mg/ 200mg	TORRENT PHARMA S.R.L.	ROMANIA	6854	2014	01
COMBINATIONS (LEVODOPUM+ CARBIDOPUM+ ENTACAPONUM)	LEVODOPA/CARBIDOPA/ENTACAPONA TORRENT 100 mg/25 mg/200 mg	film-coated tablets	100mg/ 25mg/200mg	TORRENT PHARMA S.R.L.	ROMANIA	6855	2014	01
COMBINATIONS (LEVODOPUM+ CARBIDOPUM+ ENTACAPONUM)	LEVODOPA/CARBIDOPA/ENTACAPONA TORRENT 125 mg/31.25 mg/200 mg	film-coated tablets	125mg/ 31.25mg/ 200mg	TORRENT PHARMA S.R.L.	ROMANIA	6856	2014	01
COMBINATIONS (LEVODOPUM+ CARBIDOPUM+ ENTACAPONUM)	LEVODOPA/CARBIDOPA/ENTACAPONA TORRENT 150 mg/37.5mg/200 mg	film-coated tablets	150mg/ 37.5mg/ 200mg	TORRENT PHARMA S.R.L.	ROMANIA	6857	2014	01
COMBINATIONS (LEVODOPUM+ CARBIDOPUM+ ENTACAPONUM)	LEVODOPA/CARBIDOPA/ENTACAPONA TORRENT 200 mg/50 mg/200 mg	film-coated tablets	200mg/ 50mg/ 200mg	TORRENT PHARMA S.R.L.	ROMANIA	6858	2014	01
COMBINATIONS (LEVONOGESTRELUM+ ETINILESTRADIOLUM)	SYLVINA 150 µgr./30 µgr.	film-coated tablets	150µgr./ 30µgr.	LABORATORIOS LEON FARMA, S.A.	SPAIN	6844	2014	01

COMBINATIONS (LOPERAMIDUM+ SIMETHICONUM)	LOPEDIUM DUO 2 mg/125 mg	tablets	2mg/125mg	SANDOZ S.R.L.	ROMANIA	6898	2014	01
COMBINATIONS (LOSARTANUM+ HYDROCHLOROTHIAZIDUM)	LORZITIN 50 mg/12.5 mg	film-coated tablets	50mg/ 12.5mg	GENERICS (UK) LIMITED	UK	6638	2014	01
COMBINATIONS (LOSARTANUM+ HYDROCHLOROTHIAZIDUM)	LORZITIN 100 mg/12.5 mg	film-coated tablets	100mg/ 12.5mg	GENERICS (UK) LIMITED	UK	6639	2014	01
COMBINATIONS (LOSARTANUM+ HYDROCHLOROTHIAZIDUM)	LORZITIN 100 mg/25 mg	film-coated tablets	100mg/ 25mg	GENERICS (UK) LIMITED	UK	6640	2014	01
COMBINATIONS (PARACETAMOLUM+ PHENYLEPHRINUM)	INFLUBENE 1000 mg/12.2 mg	powder for oral solution	1000mg/ 12.2mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	6667	2014	01
COMBINATIONS (PERINDOPRILUM+ AMLODIPINUM)	PERINDOPRIL TOSILAT/AMLODIPINA TEVA 5 mg/5 mg	tablets	5mg/5mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	6797	2014	01
COMBINATIONS (PERINDOPRILUM+ AMLODIPINUM)	PERINDOPRIL TOSILAT/AMLODIPINA TEVA 5 mg/10 mg	tablets	5mg/ 10mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	6798	2014	01
COMBINATIONS (PERINDOPRILUM+ AMLODIPINUM)	PERINDOPRIL TOSILAT/AMLODIPINA TEVA 10 mg/5 mg	tablets	10mg/ 5mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	6799	2014	01
COMBINATIONS (PERINDOPRILUM+ AMLODIPINUM)	PERINDOPRIL TOSILAT/AMLODIPINA TEVA 10 mg/10 mg	tablets	10mg/ 10mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	6800	2014	01
COMBINATIONS (RAMIPRILUM + AMLODIPINUM)	PRYLAR 2.5 mg/5 mg	capsules	2.5 mg/5mg	SANDOZ S.R.L.	ROMANIA	6801	2014	01
COMBINATIONS (RAMIPRILUM + AMLODIPINUM)	PRYLAR 5 mg/5 mg	capsules	5mg/5mg	SANDOZ S.R.L.	ROMANIA	6802	2014	01

COMBINATIONS (RAMIPRILUM + AMLODIPINUM)	PRYLAR 10 mg/5 mg	capsules	10mg/5mg	SANDOZ S.R.L.	ROMANIA	6803	2014	01
COMBINATIONS (RAMIPRILUM + AMLODIPINUM)	PRYLAR 5 mg/10 mg	capsules	5mg/10mg	SANDOZ S.R.L.	ROMANIA	6804	2014	01
COMBINATIONS (RAMIPRILUM + AMLODIPINUM)	PRYLAR 10 mg/10 mg	capsules	10mg/10mg	SANDOZ S.R.L.	ROMANIA	6805	2014	01
COMBINATIONS (SOLIFENACINUM SUCCINATE+ TAMSULOSINUM)	VESOMNI 6 mg/0.4 mg	modified-release tablets	6mg/0.4mg	ASTELLAS PHARMA D.O.O.	SLOVENIA	6661	2014	01
COMBINATIONS (GLIBENCLAMIDUM+ METFORMINUM)	GLUCOVANCE® 500 mg/5 mg	film-coated tablets	500mg/5mg	MERCK SANTE S.A.S	FRANCE	6742	2014	01
COMBINATIONS (GLIBENCLAMIDUM+ METFORMINUM)	GLUCOVANCE® 500 mg/2.5 mg	film-coated tablets	500mg/ 2.5 mg	MERCK SANTE S.A.S	FRANCE	6741	2014	01
CYPROHEPTADINUM	PERITOL 4 mg	tablets	4mg	EGIS PHARMACEUTICALS PLC.	HUNGARY	6767	2014	01
CYPROHEPTADINUM	PERITOL 2 mg/5 ml	syrup	2mg/5ml	EGIS PHARMACEUTICAL PLC.	HUNGARY	6768	2014	01
DESMOPRESSINUM	DESMOPRESINA TEVA 0.2 mg	tablets	0.2mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	6657	2014	01
DEXKETOPROFENUM	DEXKETOPROFEN ROMPHARM 50 mg/2 ml	solution for injection/concentrate for solution for infusion	50mg/ 2ml	ROMPHARM COMPANY S.R.L.	ROMANIA	6903	2014	01
DIOSMECTITA	SMECTA 3 g/sachet	powder for oral suspension	3g/sachet	IPSEN PHARMA	FRANCE	6706	2014	01

DOCETAXELUM	DOCETAXEL TEVA 20 mg/ml	concentrate for solution for infusion	20mg/ml	TEVA PHARMACEUTICAL S.R.L.	ROMANIA	6743	2014	01
DOCOSANOLUM	ERAZABAN 100 mg/g	cream	100mg/g	MAXIMA HEALTHCARE LTD.	UK	6940	2014	01
DONEPEZILUM	ALZEPIL S-Tab 5 mg	orodispersible tablets	5mg	EGIS PHARMACEUTICALS PLC	HUNGARY	6618	2014	01
DONEPEZILUM	ALZEPIL S-Tab 10 mg	orodispersible tablets	10mg	EGIS PHARMACEUTICALS PLC	HUNGARY	6619	2014	01
DONEPEZILUM	ALZEPIL 10 mg	film-coated tablets	10mg	EGIS PHARMACEUTICALS PLC	HUNGARY	6621	2014	01
DONEPEZILUM	ALZEPIL 5 mg	film-coated tablets	5mg	EGIS PHARMACEUTICALS PLC	HUNGARY	6620	2014	01
DONEPEZILUM	ALTZER 5 mg	film-coated tablets	5mg	HIKMA FARMACEUTICA (PORTUGAL) S.A.	PORTUGAL	6846	2014	01
DONEPEZILUM	ALTZER 10 mg	film-coated tablets	10mg	HIKMA FARMACEUTICA (PORTUGAL) S.A.	PORTUGAL	6847	2014	01
DORZOLAMIDUM	DUOKOPT 20mg/ml+5 mg/ml	eye drops, solution	20mg/ml+5 mg/ml	LABORATOIRES THEA	FRANCE	6783	2014	01
EPIRUBICINUM	EPIRUBICINA TEVA 2 mg/ml	solution for injection/infusion	2mg/ml	TEVA PHARMACEUTICAL S.R.L.	ROMANIA	6834	2014	01
EPLERENONUM	INSPRA 25 mg	film-coated tablets	25mg	PFIZER EUROPE MA EEIG	UK	6919	2014	01
EPLERENONUM	INSPRA 50 mg	film-coated tablets	50mg	PFIZER EUROPE MA EEIG	UK	6920	2014	01
EPLERENONUM	EPLOHART 25 mg	film-coated tablets	25mg	STADA HEMOFARM SRL	ROMANIA	6931	2014	01
EPLERENONUM	EPLOHART 50 mg	film-coated tablets	50mg	STADA HEMOFARM SRL	ROMANIA	6932	2014	01

ESCITALOPRAMUM	DEPRESINAL 5 mg	film-coated tablets	5mg	LANNACHER HEILMITTEL GES.M.B.H.	AUSTRIA	6648	2014	01
ESCITALOPRAMUM	DEPRESINAL 10 mg	film-coated tablets	10mg	LANNACHER HEILMITTEL GES.M.B.H.	AUSTRIA	6649	2014	01
ESCITALOPRAMUM	DEPRESINAL 15 mg	film-coated tablets	15mg	LANNACHER HEILMITTEL GES.M.B.H.	AUSTRIA	6650	2014	01
ESCITALOPRAMUM	DEPRESINAL 20 mg	film-coated tablets	20mg	LANNACHER HEILMITTEL GES.M.B.H.	AUSTRIA	6651	2014	01
ESCITALOPRAMUM	ESCITIL 5 mg	film-coated tablets	5mg	EGIS PHARMACEUTICALS PLC.	HUNGARY	6839	2014	01
ESCITALOPRAMUM	ESCITIL 10 mg	film-coated tablets	10mg	EGIS PHARMACEUTICALS PLC.	HUNGARY	6840	2014	01
ESCITALOPRAMUM	ESCITIL 15 mg	film-coated tablets	15mg	EGIS PHARMACEUTICALS PLC.	HUNGARY	6841	2014	01
ESCITALOPRAMUM	ESCITIL 20 mg	film-coated tablets	20mg	EGIS PHARMACEUTICALS PLC.	HUNGARY	6842	2014	01
EVEROLIMUS	CERTICAN 0.5 mg	tablets	0.5mg	NOVARTIS PHARMA GMBH	GERMANY	6762	2014	01
EVEROLIMUS	CERTICAN 0.75 mg	tablets	0.75mg	NOVARTIS PHARMA GMBH	GERMANY	6763	2014	01
EVEROLIMUS	CERTICAN 1 mg	tablets	1mg	NOVARTIS PHARMA GMBH	GERMANY	6764	2014	01
EVEROLIMUS	CERTICAN 0.25 mg	tablets	0.25mg	NOVARTIS PHARMA GMBH	GERMANY	6761	2014	01
EVEROLIMUS	CERTICAN 0.25 mg	orodispersible tablets	0.25mg	NOVARTIS PHARMA GMBH	GERMANY	6760	2014	01
EVEROLIMUS	CERTICAN 0.1 mg	orodispersible tablets	0.1mg	NOVARTIS PHARMA GMBH	GERMANY	6759	2014	01
EZETIMIBUM	COLTOWAN 10 mg	tablets	10mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	6725	2014	01

FENTANYLUM	FENTANYL PFIZER 12 µgr./h	transdermal patch	12µgr./h	LAVIPHARM S.A.	UK	6883	2014	01
FENTANYLUM	FENTANYL PFIZER 25 µgr./h	transdermal patch	25µgr./h	LAVIPHARM S.A.	UK	6884	2014	01
FENTANYLUM	FENTANYL PFIZER 50 µgr./h	transdermal patch	50µgr./h	LAVIPHARM S.A.	UK	6885	2014	01
FENTANYLUM	FENTANYL PFIZER 75 µgr./h	transdermal patch	75µgr./h	LAVIPHARM S.A.	UK	6886	2014	01
FENTANYLUM	FENTANYL PFIZER 100 µgr./h	transdermal patch	100µgr./h	LAVIPHARM S.A.	UK	6887	2014	01
FEXOFENADINUM	EWOFEX 120 mg	film-coated tablets	120mg	EWOPHARMA INTERNATIONAL S.R.O.	SLOVAKIA	6835	2014	01
FEXOFENADINUM	EWOFEX 180 mg	film-coated tablets	180mg	EWOPHARMA INTERNATIONAL S.R.O.	SLOVAKIA	6836	2014	01
FLUDEOXIGLUCOZA (18F)	FLUDEOXYGLUCOSE BIONT 200-1300 MBQ/ml	solution for injection	200-1300mbq/ml	BIONT A.S.	SLOVAKIA	6665	2014	01
FLUDEOXIGLUCOZA (18F)	FLUDEOXIGLUCOZA (18F) MONROL 200-2200 MBq/ml	solution for injection	200-2200MBq/ml	MONROL EUROPE SRL	ROMANIA	6642	2014	01
FLUMAZENILUM	FLUMAZENIL PHARMASELECT 0.1mg/ml	solution for injection/concentrate for solution for infusion	0.1mg/ml	PHARMASELECT INTERNATIONAL BETEILIGUNGS GMBH	AUSTRIA	6660	2014	01
GEMCITABINUM	GITRABIN 38 mg/ml	powder for solution for infusion	38mg/ml	ACTAVIS GROUP PTC EHF.	ICELAND	6941	2014	01
GEMCITABINUM	GEMCITABINA ACCORD 100 mg/ml	concentrate for solution for infusion	100mg/ml	ACCORD HEALTHCARE LIMITED	UK	6658	2014	01
GLICLAZIDUM	ZODEDIAB 30 mg	modified-release tablets	30mg	ALVOGEN IPCO S.ÀR.L	LUXEMBURG	6784	2014	01
GLICLAZIDUM	ZODEDIAB 60 mg	modified-release tablets	60mg	ALVOGEN IPCO S.ÀR.L	LUXEMBURG	6785	2014	01
GLICLAZIDUM	GLICLAZIDA ZENTIVA 60 mg	modified-release tablets	60mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	6788	2014	01
GLICLAZIDUM	GLICLAZIDA GENERICS 30 mg	modified-release tablets	30mg	GENERICS [UK] LTD.	UK	6910	2014	01
GLUCOSUM	GLUCOSE B. BRAUN 50 mg/ml	solution for infusion	50mg/ml	B. BRAUN MELSUNGEN AG	GERMANY	6791	2014	01

GLUCOSUM	GLUCOSE B. BRAUN 100 mg/ml	solution for infusion	100mg/ml	B. BRAUN MELSUNGEN AG	GERMANY	6792	2014	01
GRANISETRONUM	GRANISETRON ACTAVIS 1 mg	film-coated tablets	1mg	ACTAVIS GROUP PTC EHF.	ICELAND	6699	2014	01
GRANISETRONUM	GRANISETRON ACTAVIS 2 mg	film-coated tablets	2mg	ACTAVIS GROUP PTC EHF.	ICELAND	6700	2014	01
GUAIFENESINUM	VICKS EXPECTORANT MIERE&GHIMBIR 200 mg/15 ml	syrup	200mg/15ml	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	6786	2014	01
HOMEOPATE	MEDITONSINMED	oral drops, solution		PROMOMED SRL	ROMANIA	6740	2014	01
IBUPROFENUM	CALMOLIN ARENA 400 mg	capsules	400mg	ARENA GROUP S.A.	ROMANIA	6710	2014	01
IBUPROFENUM	PADUDEN RAPID 200 mg	film-coated tablets	200mg	TERAPIA S.A.	ROMANIA	6964	2014	01
IMATINIBUM	IMATINIB GENTHON 100 mg	capsules	100mg	GENTHON BV	HOLLAND	6942	2014	01
IMATINIBUM	IMATINIB SYNTHON 100 mg	capsules	100mg	SYNTHON BV	HOLLAND	6927	2014	01
IMIPENEMUM + CILASTATINUM	IMIPENEM/CILASTATIN ATB 500 mg/500 mg	powder for solution for infusion	500mg/ 500mg	ANTIBIOTICE S.A.	ROMANIA	6879	2014	01
IRBESARTANUM	IRBEGAMMA 75 mg	film-coated tablets	75mg	WORWAG PHARMA GMBH & CO. KG	GERMANY	6895	2014	01
IRBESARTANUM	IRBEGAMMA 150 mg	film-coated tablets	150mg	WORWAG PHARMA GMBH & CO. KG	GERMANY	6896	2014	01
IRBESARTANUM	IRBEGAMMA 300 mg	film-coated tablets	300mg	WORWAG PHARMA GMBH & CO. KG	GERMANY	6897	2014	01
IRINOTECANUM	IRINOTECAN STRIDES ARCOLAB INTERNATIONAL 20 mg/ml	concentrate for solution for infusion	20mg/ml	STRIDES ARCOLAB INTERNATIONAL LIMITED	UK	6666	2014	01
ISONIAZIDUM	ISONIAZIDA ARENA 100 mg	tablets	100mg	ARENA GROUP S.A.	ROMANIA	6950	2014	01
ISONIAZIDUM	ISONIAZIDA ARENA 300 mg	tablets	300mg	ARENA GROUP S.A.	ROMANIA	6951	2014	01
ISOTRETINOINUM	SOTRET 10 mg	soft capsules	10mg	TERAPIA S.A.	ROMANIA	6765	2014	01
ISOTRETINOINUM	SOTRET 20 mg	soft capsules	20mg	TERAPIA S.A.	ROMANIA	6766	2014	01
LACTULOSUM	LACTULOSE-MIP 650 mg/ml	syrup	650mg/ ml	MIP PHARMA GMBH	GERMANY	6675	2014	01
LERCANIDIPINUM	LERCANIDIPINA ZENTIVA 10 mg	film-coated tablets	10mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	6937	2014	01

LETROZOLUM	ZEQUIPRA 2.5 mg	film-coated tablets	2.5 mg	ROMASTRU TRADING S.R.L.	ROMANIA	6664	2014	01
LETROZOLUM	LOOSYN 2.5 mg	film-coated tablets	2.5 mg	SYNTHON BV	HOLLAND	6961	2014	01
LEVOBUPIVACAINUM	LEVOBUPIVACAINA KABI 2.5 mg/ml	solution for injection/infusion	2.5 mg/ml	FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	6745	2014	01
LEVOBUPIVACAINUM	LEVOBUPIVACAINA KABI 5 mg/ml	solution for injection/infusion	5mg/ml	FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	6746	2014	01
LEVOBUPIVACAINUM	LEVOBUPIVACAINA KABI 7,5 mg/ml	solution for injection/infusion	7,5mg/ml	FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	6747	2014	01
LEVOMEPROMAZINUM	LEVOMEPROMAZIN TERAPIA 25 mg	tablets	25mg	TERAPIA SA	ROMANIA	6676	2014	01
LEVOTHYROXINUM	ACCU-THYROX 25 µgr./5 ml	oral solution	25µgr./5ml	GALENICA S.A.	GREECE	6825	2014	01
LEVOTHYROXINUM	ACCU-THYROX 50 µgr./5 ml	oral solution	50µgr./5ml	GALENICA S.A.	GREECE	6826	2014	01
LEVOTHYROXINUM	ACCU-THYROX 100 µgr./ 5 ml	oral solution	100µgr./ 5ml	GALENICA S.A.	GREECE	6827	2014	01
LINEZOLIDUM	LINEZOLID SANDOZ 600 mg	film-coated tablets	600mg	SANDOZ SRL	ROMANIA	6812	2014	01
LOPERAMIDUM	TAMMEX AKUT 2 mg	capsules	2mg	DH-NORM S.R.O.	THE CZECH REPUBLIC	6960	2014	01
LORATADINUM	LORATADIN VIM SPECTRUM 10 mg	tablets	10mg	VIM SPECTRUM S.R.L.	ROMANIA	6671	2014	01
LORATADINUM	LORATADINÃ LEK 5mg/5ml	oral suspension	5mg/5ml	LEK PHARMACEUTICALS D.D.	SLOVENIA	6721	2014	01
LOSARTANUM	LOSARTAN ARENA 25 mg	film-coated tablets	25mg	ARENA GROUP S.A.	ROMANIA	6711	2014	01
LOSARTANUM	LOSARTAN ARENA 100 mg	film-coated tablets	100mg	ARENA GROUP S.A.	ROMANIA	6712	2014	01
MELOXICAMUM	RECOXA 15 mg/1.5 ml	solution for injection	15mg/1.5 ml	ZENTIVA, K.S.	THE CZECH REPUBLIC	6688	2014	01
MEMANTINUM	MELUTRIN 5 mg	orodispersible tablets	5mg	NEOLA PHARMA S.R.L.	ROMANIA	6821	2014	01
MEMANTINUM	MELUTRIN 10 mg	orodispersible tablets	10mg	NEOLA PHARMA S.R.L.	ROMANIA	6822	2014	01

MEMANTINUM	MELUTRIN 15 mg	orodispersible tablets	15mg	NEOLA PHARMA S.R.L.	ROMANIA	6823	2014	01
MEMANTINUM	MELUTRIN 20 mg	orodispersible tablets	20mg	NEOLA PHARMA S.R.L.	ROMANIA	6824	2014	01
MEMANTINUM	MEMANTINA PHARMASCOPE 10 mg	film-coated tablets	10mg	PHARMASCOPE LIMITED	IRELAND	6851	2014	01
MEMANTINUM	MEMANTINA PHARMASCOPE 20 mg	film-coated tablets	20mg	PHARMASCOPE LIMITED	IRELAND	6852	2014	01
MEPIVACAINUM	MEPIDENTAL 30 mg/ml	solution for injection	30mg/ml	DENTOTAL PROTECT	ROMANIA	6780	2014	01
MEROPENEMUM	ARCHIFAR 500 mg	powder for solution for injection/infusion	500mg	MEDOCHEMIE ROMANIA SRL	ROMANIA	6859	2014	01
MEROPENEMUM	ARCHIFAR 1000 mg	powder for solution for injection/infusion	1000mg	MEDOCHEMIE ROMANIA SRL	ROMANIA	6860	2014	01
METRONIDAZOLUM	METROGENE 4,5 mg	dental sponge	4,5mg	SEPTODONT	FRANCE	6778	2014	01
MINOXIDILUM	MINOXIDIL LAVINELI 20 mg/ml	cutaneous solution	20mg/ml	LAVINELI FARMACEUTICA, LDA.	PORTUGAL	6662	2014	01
MINOXIDILUM	MINOXIDIL LAVINELI 50 mg/ml	cutaneous solution	50mg/ml	LAVINELI FARMACEUTICA, LDA.	PORTUGAL	6663	2014	01
MINOXIDILUM	REGAINE 50 mg/g	cutaneous foam	50mg/g	MCNEIL PRODUCTS LIMITED C/O JOHNSON&JOHNSON	UK	6724	2014	01
MOMETASONUM	NASONEX 50 µgr./dose	nasal spray, suspension	50µgr./dose	MERCK SHARP & DOHME ROMANIA S.R.L.	ROMANIA	6787	2014	01
MOMETASONUM	BLOCTIMO 50 µgr./dose	nasal spray, solution	50µg/dose	ACTAVIS GROUP PTC EHF	ICELAND	6809	2014	01
MOMETASONUM	FUROAT DE MOMETAZONA JELFA 1 mg/g	cutaneous solution	1mg/g	PRZEDSIEBIORSTWO FARMACEUTYCZNE JELFA S.A.	POLAND	6923	2014	01
MONTELUKASTUM	MONTELUKAST POLIPHARMA 10 mg	film-coated tablets	10mg	POLIPHARMA INDUSTRIES S.R.L.	ROMANIA	6684	2014	01
MONTELUKASTUM	MONTELUKAST POLIPHARMA 4 mg	chewable tablets	4mg	POLIPHARMA INDUSTRIES S.R.L.	ROMANIA	6682	2014	01
MONTELUKASTUM	MONTELUKAST POLIPHARMA 5 mg	chewable tablets	5mg	POLIPHARMA INDUSTRIES S.R.L.	ROMANIA	6683	2014	01
MOXIFLOXACINUM	VIGAMOX 5 mg/ml	eye drops, solution	5mg/ml	ALCON PHARMA GMBH	GERMANY	6924	2014	01

MYCOPHENOLATUM MOFETILUM	MOMETIL 500 mg	film-coated tablets	500mg	PHAROS PHARMACEUTICAL ORIENTED SERVICES LTD	GREECE	6843	2014	01
NEOSTIGMINI BROMIDUM	NEOSTIGMINA LPH 15 mg	tablets	15mg	LABORMED PHARMA S.A.	ROMANIA	6677	2014	01
NIMESULIDUM	AULIN 100 mg	tablets	100mg	CSC PHARMACEUTICALS HANDELS GMBH	AUSTRIA	6646	2014	01
NIMESULIDUM	AULIN 100 mg	granules for oral suspension	100mg/ sachet	CSC PHARMACEUTICALS HANDELS GMBH	AUSTRIA	6647	2014	01
OCTREOTIDUM	SANDOSTATIN LAR 10 mg	powder and solvent for solution for injection	10mg	NOVARTIS PHARMA GMBH	GERMANY	6869	2014	01
OCTREOTIDUM	SANDOSTATIN LAR 20 mg	powder and solvent for solution for injection	20mg	NOVARTIS PHARMA GMBH	GERMANY	6870	2014	01
OCTREOTIDUM	SANDOSTATIN LAR 30 mg	powder and solvent for solution for injection	30mg	NOVARTIS PHARMA GMBH	GERMANY	6871	2014	01
OLANZAPINUM	OLANZAPINA AUROBINDO 5 mg	orodispersible tablets	5mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	6736	2014	01
OLANZAPINUM	OLANZAPINA AUROBINDO 10 mg	orodispersible tablets	10mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	6737	2014	01
OLANZAPINUM	OLANZAPINA AUROBINDO 15 mg	orodispersible tablets	15mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	6738	2014	01
OLANZAPINUM	OLANZAPINA AUROBINDO 20 mg	orodispersible tablets	20mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	6739	2014	01
OMEPRAZOLUM	OMEDAR 20 mg	gastroresistant tablets	20mg	DAR AL DAWA PHARMA S.R.L	ROMANIA	6828	2014	01
OMEPRAZOLUM	OMEPLIS 10 mg	gastroresistant capsules	10mg	DISTRIQUIMICA, S.A.	SPAIN	6954	2014	01
OMEPRAZOLUM	OMEPLIS 20 mg	gastroresistant capsules	20mg	DISTRIQUIMICA, S.A.	SPAIN	6955	2014	01
OMEPRAZOLUM	OMEPLIS 40 mg	gastroresistant capsules	40mg	DISTRIQUIMICA, S.A.	SPAIN	6956	2014	01
OMEPRAZOLUM	PRENOME 10 mg	gastroresistant capsules	10mg	DISTRIQUIMICA, S.A.	SPAIN	6957	2014	01
OMEPRAZOLUM	PRENOME 20 mg	gastroresistant capsules	20mg	DISTRIQUIMICA, S.A.	SPAIN	6958	2014	01
OMEPRAZOLUM	PRENOME 40 mg	gastroresistant capsules	40mg	DISTRIQUIMICA, S.A.	SPAIN	6959	2014	01
OXYMETAZOLINUM	VICKS SINEX 0.5 mg/ml	nasal spray, solution	0.5mg/ml	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	6899	2014	01
PANCREATINUM	TRIFERMENT FORTE 325 mg	gastroresistant tablets	325mg	BIOFARM S.A.	ROMANIA	6769	2014	01

PANTOPRAZOLUM	CONTROLOC 40mg	powder for solution for injection	40mg	NYCOMED GMBH	GERMANY	6873	2014	01
PANTOPRAZOLUM	PANTOPRAZOL KRKA 20 mg	gastroresistant tablets	20mg	KRKA ,D.D., NOVO MESTO	SLOVENIA	6915	2014	01
PANTOPRAZOLUM	PANTOPRAZOL KRKA 40 mg	gastroresistant tablets	40mg	KRKA ,D.D., NOVO MESTO	SLOVENIA	6916	2014	01
PARACETAMOLUM	PARACETAMOL PANPHARMA 10 mg/ml	solution for infusion	10 mg/ml	PANMEDICA	FRANCE	6679	2014	01
PARICALCITOLUM	ZEMPLAR 1 µgram	soft capsules	1µgr.	ABBVIE FARMACEUTICA S.L.U.	SPAIN	6703	2014	01
PARICALCITOLUM	ZEMPLAR 2 µgr.	soft capsules	2µgr.	ABBVIE FARMACEUTICA S.L.U.	SPAIN	6704	2014	01
PHENYTOINUM	PHENYTOIN HYKMA 50 mg/ml	solution for injection	50mg/ml	HIKMA FARMACEUTICA (PORTUGAL) S.A.	PORTUGAL	6845	2014	01
PIOGLITAZONUM	PIOGLIGAMMA 15 mg	tablets	15mg	WORWAG PHARMA GMBH & CO. KG	GERMANY	6685	2014	01
PIOGLITAZONUM	PIOGLIGAMMA 30 mg	tablets	30mg	WORWAG PHARMA GMBH & CO. KG	GERMANY	6686	2014	01
PIOGLITAZONUM	PIOGLIGAMMA 45 mg	tablets	45mg	WORWAG PHARMA GMBH & CO. KG	GERMANY	6687	2014	01
PIPERACILLINUM + TAZOBACTAMUM	PIPERACILINA/TAZOBACTAM MYLAN 2g/0.25 g	powder for solution for infusion	2g/0.25g	MYLAN S.A.S.	FRANCE	6938	2014	01
PIPERACILLINUM + TAZOBACTAMUM	PIPERACILINA/TAZOBACTAM MYLAN 4g/0.5 g	powder for solution for infusion	4g/0.5g	MYLAN S.A.S.	FRANCE	6939	2014	01
PLANTE	VENOPROTECT 180 mg	capsules	180mg	WALMARK, A.S.	THE CZECH REPUBLIC	6921	2014	01
PRAMIPEXOLUM	PRAMIPEXOL LAGEMAN 0.52 mg	prolonged-release tablets	0.52mg	FERRER INTERNACIONAL, S.A.	SPAIN	6749	2014	01
PRAMIPEXOLUM	PRAMIPEXOL LAGEMAN 2,1 mg	prolonged-release tablets	2,1mg	FERRER INTERNACIONAL, S.A.	SPAIN	6750	2014	01
PRAMIPEXOLUM	PRAMIPEXOL LAGEMAN 3.15 mg	prolonged-release tablets	3.15mg	FERRER INTERNACIONAL, S.A.	SPAIN	6751	2014	01
PREDNISONUM	LODOTRA 1 mg	modified-release tablets	1mg	MUNDIPHARMA GESELLSCHAFT M.B.H.	AUSTRIA	6928	2014	01

PREDNISONUM	LODOTRA 2 mg	modified-release tablets	2mg	MUNDIPHARMA GESELLSCHAFT M.B.H.	AUSTRIA	6929	2014	01
PREDNISONUM	LODOTRA 5 mg	modified-release tablets	5mg	MUNDIPHARMA GESELLSCHAFT M.B.H.	AUSTRIA	6930	2014	01
PYRANTELUM	HELMINTOX 125 mg/2.5 ml	oral suspension	125mg/ 2.5 ml	LABORATOIRE INNOTECH INTERNATIONAL	FRANCE	6668	2014	01
RALOXIFENUM	RALOXA 60 mg	film-coated tablets	60mg	SYNTHON BV	HOLLAND	6814	2014	01
REMIFENTANILUM	REMIFENTANIL KABI 1 mg	powder for concentrate for solution for injection/infusion	1mg	FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	6935	2014	01
REMIFENTANILUM	REMIFENTANIL KABI 2 mg	powder for concentrate for solution for injection/infusion	2mg	FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	6936	2014	01
REPAGLINIDUM	REPAGLINIDA HF 0.5mg	tablets	0.5mg	STADA HEMOFARM SRL	ROMANIA	6862	2014	01
REPAGLINIDUM	REPAGLINIDA HF 1 mg	tablets	1mg	STADA HEMOFARM SRL	ROMANIA	6863	2014	01
REPAGLINIDUM	REPAGLINIDA HF 2 mg	tablets	2mg	STADA HEMOFARM SRL	ROMANIA	6864	2014	01
REPAGLINIDUM	REPAGLINIDA HF 4 mg	tablets	4mg	STADA HEMOFARM SRL	ROMANIA	6865	2014	01
RETINOLUM	VITAMIN A 50000 UI	soft capsules	50000UI	PHARCO IMPEX 93 S.R.L.	ROMANIA	6708	2014	01
RISPERIDONUM	TORENDO Q-TAB 0.5 mg	orodispersible tablets	0.5mg	KRKA D.D. NOVO MESTO	SLOVENIA	6631	2014	01
RISPERIDONUM	TORENDO Q-TAB 1 mg	orodispersible tablets	1mg	KRKA D.D. NOVO MESTO	SLOVENIA	6632	2014	01
RISPERIDONUM	TORENDO Q-TAB 2 mg	orodispersible tablets	2mg	KRKA D.D. NOVO MESTO	SLOVENIA	6633	2014	01
RISPERIDONUM	TORENDO 1 mg	film-coated tablets	1mg	KRKA D.D. NOVO MESTO	SLOVENIA	6627	2014	01
RISPERIDONUM	TORENDO 2 mg	film-coated tablets	2mg	KRKA D.D. NOVO MESTO	SLOVENIA	6628	2014	01
RISPERIDONUM	TORENDO 3 mg	film-coated tablets	3mg	KRKA D.D. NOVO MESTO	SLOVENIA	6629	2014	01
RISPERIDONUM	TORENDO 4 mg	film-coated tablets	4mg	KRKA D.D. NOVO MESTO	SLOVENIA	6630	2014	01
RISPERIDONUM	RISPOLEPT 1mg/ml	oral solution	1mg/ml	JANSSEN PHARMACEUTICA NV	BELGIUM	6875	2014	01

RISPERIDONUM	RISPOLEPT CONSTA 25 mg	powder and solvent for prolonged-release suspension for injection	25mg	JANSSEN PHARMACEUTICA N.V.	BELGIUM	6876	2014	01
RISPERIDONUM	RISPOLEPT CONSTA 50 mg	powder and solvent for prolonged-release suspension for injection	50mg	JANSSEN PHARMACEUTICA N.V.	BELGIUM	6878	2014	01
RISPERIDONUM	RISPOLEPT CONSTA 37.5mg	powder and solvent for prolonged-release suspension for injection	37.5mg	JANSSEN PHARMACEUTICA N.V.	BELGIUM	6877	2014	01
ROSUVASTATINUM	ROSUVASTATINA TEVA 10 mg	film-coated tablets	10mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	6816	2014	01
ROSUVASTATINUM	ROSUVASTATINA TEVA 20 mg	film-coated tablets	20mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	6817	2014	01
ROSUVASTATINUM	ROSUVASTATINA TEVA 40 mg	film-coated tablets	40mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	6818	2014	01
ROSUVASTATINUM	ROSUVASTATINA ATB 5 mg	film-coated tablets	5mg	ANTIBIOTICE S.A.	ROMANIA	6714	2014	01
ROSUVASTATINUM	ROSUVASTATINA ATB 10 mg	film-coated tablets	10mg	ANTIBIOTICE S.A.	ROMANIA	6715	2014	01
ROSUVASTATINUM	ROSUVASTATINA ATB 20 mg	film-coated tablets	20mg	ANTIBIOTICE S.A.	ROMANIA	6716	2014	01
ROSUVASTATINUM	ROSUVASTATINA ATB 40 mg	film-coated tablets	40mg	ANTIBIOTICE S.A.	ROMANIA	6717	2014	01
SEVELAMER	CARBONAT DE SEVELAMER SYNTHON 800 mg	film-coated tablets	800mg	SYNTHON BV	HOLLAND	6781	2014	01
SEVELAMER	CARBONAT DE SEVELAMER KIRON PHARMACEUTICA 800 mg	film-coated tablets	800mg	KIRON PHARMACEUTICA B.V.	HOLLAND	6782	2014	01
SEVOFLURANUM	SEVOFLURAN BAXTER 100%	inhalation vapour, liquid	100%	BAXTER SA	BELGIUM	6808	2014	01
SILDENAFILUM	SILDENAFIL HEMOFARM 25 mg	film-coated tablets	25mg	STADA HEMOFARM S.R.L.	ROMANIA	6643	2014	01
SILDENAFILUM	SILDENAFIL HEMOFARM 50 mg	film-coated tablets	50mg	STADA HEMOFARM S.R.L.	ROMANIA	6644	2014	01

SILDENAFILUM	SILDENAFIL HEMOFARM 100 mg	film-coated tablets	100mg	STADA HEMOFARM S.R.L.	ROMANIA	6645	2014	01
SIMVASTATINUM	ZOCOR FORTE	film-coated tablets	40mg	MERCK SHARP & DOHME ROMANIA S.R.L.	ROMANIA	6796	2014	01
SIMVASTATINUM	ZOCOR 10 mg	film-coated tablets	10mg	MERCK SHARP & DOHME ROMANIA S.R.L.	ROMANIA	6794	2014	01
SIMVASTATINUM	ZOCOR 20 mg	film-coated tablets	20mg	MERCK SHARP & DOHME ROMANIA S.R.L.	ROMANIA	6795	2014	01
SIMVASTATINUM	SIMVASTATIN LPH 10 mg	film-coated tablets	10mg	LABORMED PHARMA S.A.	ROMANIA	6770	2014	01
SIMVASTATINUM	SIMVASTATIN LPH 20 mg	film-coated tablets	20mg	LABORMED PHARMA S.A.	ROMANIA	6771	2014	01
SIMVASTATINUM	SIMVASTATIN LPH 40 mg	film-coated tablets	40mg	LABORMED PHARMA S.A.	ROMANIA	6772	2014	01
SIMVASTATINUM	SIMVASTATIN LPH 80 mg	film-coated tablets	80mg	LABORMED PHARMA S.A.	ROMANIA	6773	2014	01
SOLIFENACINUM SUCCINATE	SOLIFENACIN ACTAVIS 5 mg	film-coated tablets	5mg	ACTAVIS GROUP PTC EHF.	ICELAND	6789	2014	01
SOLIFENACINUM SUCCINATE	SOLIFENACIN ACTAVIS 10 mg	film-coated tablets	10mg	ACTAVIS GROUP PTC EHF.	ICELAND	6790	2014	01
SOMATROPINUM	ZOMACTON 4 mg (12 UI)	powder and solvent for solution for injection	4mg (12UI)	FERRING GMBH	GERMANY	6933	2014	01
SOTALOLUM	DAROB 80 mg	tablets	80mg	ABBOTT GMBH&CO.KG	GERMANY	6672	2014	01
SULODEXIDUM	COREFLUX 600 ULS/2 ml	solution for injection	600ULS/2ml	SANIENCE S.R.L.	ROMANIA	6731	2014	01
SULODEXIDUM	COREFLUX 250 ULS	soft capsules	250ULS	SANIENCE S.R.L.	ROMANIA	6730	2014	01
TAMSULOSINUM	OMNIC TOCAS 0.4 mg	prolonged-release tablets	0.4mg	ASTELLAS PHARMA EUROPE B.V.	HOLLAND	6775	2014	01
TC 99 M - PERTECHNETATE	DRYTEC 2.5 - 100 GBq	radionuclide generator	2.5 -100GBq	GE HEALTHCARE LIMITED	UK	6953	2014	01
TERBINAFINUM	LAMISIL 250 mg	tablets	250mg	NOVARTIS PHARMA GMBH	GERMANY	6707	2014	01
TETRACOSACTIDUM	SYNACHTEN DEPOT 1 mg/ml	suspension for injection	1mg/ml	NOVARTIS PHARMA GMBH	GERMANY	6748	2014	01
TINIDAZOLUM	TIPROGYN 500 mg (see J01XD02)	film-coated tablets	500mg	AC HELCOR SRL	ROMANIA	6830	2014	01

TINIDAZOLUM	TIPROGYN 500 mg (see P01AB02)	film-coated tablets	500mg	AC HELCOR SRL	ROMANIA	6830	2014	01
TOPIRAMATUM	TOPIRAMAT EGIS 25 mg	film-coated tablets	25mg	EGIS PHARMACEUTICALS PLC	HUNGARY	6652	2014	01
TOPIRAMATUM	TOPIRAMAT EGIS 50 mg	film-coated tablets	50mg	EGIS PHARMACEUTICALS PLC	HUNGARY	6653	2014	01
TOPIRAMATUM	TOPIRAMAT EGIS 100 mg	film-coated tablets	100mg	EGIS PHARMACEUTICALS PLC	HUNGARY	6654	2014	01
TOPIRAMATUM	TOPIRAMAT EGIS 200 mg	film-coated tablets	200mg	EGIS PHARMACEUTICALS PLC	HUNGARY	6655	2014	01
TRAVOPROSTUM	TRAVOPROST ZENTIVA 40 µgr./ml	eye drops, solution	40µgr./ml	ZENTIVA, K.S.	THE CZECH REPUBLIC	6689	2014	01
TRAVOPROSTUM	BONDULC 40 µgr./ml	eye drops, solution	40 µgr./ml	ACTAVIS GROUP PTC EHF.	ICELAND	6705	2014	01
TRAVOPROSTUM	TRAVOPROST TEVA 40 µgr./ml	eye drops, solution	40µg/ml	TEVA PHARMACEUTICAL S.R.L.	ROMANIA	6813	2014	01
TRIPTORELINUM	DIPHERELINE 0.1 mg	powder and solvent for solution for injection	0.1mg	IPSEN PHARMA	FRANCE	6776	2014	01
VACCIN GRIPAL INACTIVAT	INFLUVAC	suspension for injection in pre-filled syringe	minimum 15µg of each influenza vaccine	ABBOTT BIOLOGICALS B.V.	HOLLAND	6963	2014	01
VALSARTANUM	VASOPENTOL 40 mg	film-coated tablets	40mg	EGIS PHARMACEUTICALS PLC.	HUNGARY	6718	2014	01
VALSARTANUM	VASOPENTOL 80 mg	film-coated tablets	80mg	EGIS PHARMACEUTICALS PLC.	HUNGARY	6719	2014	01
VALSARTANUM	VASOPENTOL 160 mg	film-coated tablets	160mg	EGIS PHARMACEUTICALS PLC.	HUNGARY	6720	2014	01
VALSARTANUM	VAMADRID 40 mg	film-coated tablets	40mg	LABORATORIOS LICONSA, S.A.	SPAIN	6690	2014	01
VALSARTANUM	VAMADRID 80 mg	film-coated tablets	80mg	LABORATORIOS LICONSA, S.A.	SPAIN	6691	2014	01
VALSARTANUM	VAMADRID 160 mg	film-coated tablets	160mg	LABORATORIOS LICONSA, S.A.	SPAIN	6692	2014	01
VALSARTANUM	VAMADRID 320 mg	film-coated tablets	320mg	LABORATORIOS LICONSA, S.A.	SPAIN	6693	2014	01

VENLAFAXINUM	VENLAGAMMA 37.5mg	prolonged-release capsules	37.5mg	WORWAG PHARMA GMBH & CO. KG	GERMANY	6624	2014	01
VENLAFAXINUM	VENLAGAMMA 75 mg	prolonged-release capsules	75mg	WORWAG PHARMA GMBH & CO. KG	GERMANY	6625	2014	01
VENLAFAXINUM	VENLAGAMMA 150 mg	prolonged-release capsules	150mg	WORWAG PHARMA GMBH & CO. KG	GERMANY	6626	2014	01
VINORELBINUM	VINORELBINA STRIDES ARCOLAB INTERNATIONAL 10 mg/ml	concentrate for solution for infusion	10mg/ml	STRIDES ARCOLAB INTERNATIONAL LIMITED	UK	6659	2014	01
XYLOMETAZOLINUM	OLYNTH 0.5 mg/ml	nasal spray, solution	0.5mg/ml	MCNEIL PRODUCTS LIMITED C/O JOHNSON & JOHNSON LTD	UK	6837	2014	01
XYLOMETAZOLINUM	OLYNTH 1 mg/ml	nasal spray, solution	1mg/ml	MCNEIL PRODUCTS LIMITED C/O JOHNSON & JOHNSON LTD	UK	6838	2014	01
ZOLMITRIPTANUM	ZOLMITRIPTAN SANOFI-AVENTIS 2.5 mg	film-coated tablets	2.5 mg	SANOFI - AVENTIS ROMANIA S.R.L.	ROMANIA	6701	2014	01
ZOLMITRIPTANUM	ZOLMITRIPTAN SANOFI-AVENTIS 2.5 mg	orodispersible tablets	2.5 mg	SANOFI - AVENTIS ROMANIA S.R.L.	ROMANIA	6702	2014	01

Medicinal products authorised through centralised procedure by the EMA for which a marketing price was established in Romania during the 3rd quarter of 2014

INN	Invented name	Pharmaceutical form	Strength	Manufacturer	Country	MA number		
COMBINATIONS (BRINZOLAMIDUM + BRIMONIDINUM)	SIMBRINZA 10 mg/ml + 2 mg/ml	ye drops, suspension	10 mg/ml + 2 mg/ml	ALCON LABORATORIES (UK) LTD.	UK	933	2014	01
DACLATASVIRUM	DAKLINZA 30 mg	film-coated tablets	30mg	BRISTOL-MYERS SQUIBB PHARMA EEIG	UK	939	2014	01
DACLATASVIRUM	DAKLINZA 60 mg	film-coated tablets	60mg	BRISTOL-MYERS SQUIBB PHARMA EEIG	UK	939	2014	03
PROPRANOLOLUM	HEMANGIOL 3.75 mg/ml	oral solution	3.75 mg/ml	PIERRE FABRE DERMATOLOGIE	FRANCE	919	2014	01