ROMANIA

Newsletter

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National Agency for Medicines and Medical Devices

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Order of the Minister of Health no. 131 on approval of Rules on authorisation of human medicinal product wholesalers, Good Distribution Practice certification and registration of brokers of medicinal products for human use

ISSUED BY: THE MINISTRY OF HEALTH
PUBLISHED IN: THE OFFICIAL GAZETTE OF ROMANIA, Part I no. 108 of 11 February 2016.

On seeing Approval Report no. A.C.P. 997/2016 of the Directorate for Policies on Medicinal Product and Medical Devices of the Ministry of Health and notification no. 59.619E of the National Agency for Medicines and Medical Devices, registered with the Minister of Health under no. 75.695/2014,

Taking into account provisions of Articles 800-803, of Articles 809 and 810, as well as of Article 857 of Law no. 95/2006 on healthcare reform, republished as amended,

Having regard to provisions of Article 12(9) of Government Decision No. 734/2010 on the organisation and operation of the National Agency for Medicines and Medical Devices, as amended,

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

the Minister of Health hereby issues the following Order:

Article 1. – The Rules on authorisation of human medicinal product wholesalers, Good Distribution Practice certification and registration of brokers of medicinal products for human use are hereby approved, as provided in the Annex which is integral part of this order.

Article 2. – On request, without additional inspection and within no longer than 2 years, before the date of this order entry into force, the National Agency for Medicines and Medical Devices shall grant wholesalers inspected pursuant to provisions of the Guideline for Good Distribution Practice in wholesale of medicinal products, approved through Order of the Minister of Health no. 761/2015, the Good Distribution Practice certificate and the Wholesale Distribution Authorisation in line with the updated format, based on the inspection conducted in the previously mentioned period.

Article 3. – On the date of this order entry into force, order of the Minister of Health no. 1.964/2008 on approval of Rules for setup, organisation and operation of wholesale sites for medicinal products for human use,

published in the Official Gazette of Romania, Part I, no. 855 of 19 December 2008.

Article 4. - This Order shall be published in the Official Gazette of Romania, Part I

p. Minister of Health,
Victor Dan Eugen Strâmbu,
Secretary of State

Bucharest, 04 February 2016
No. 131.

ANNEX
to the Rules

Rules on authorisation of human medicinal product wholesalers, Good Distribution Practice certification and registration of brokers of medicinal products for human use of 04.02.2016

In force as of February 2016
Published in the Official Gazette of Romania, Part I no. 108 of 11 February 2016.

CHAPTER I
Definitions

Article 1. – For the purpose of these Rules, the terms and concepts used herein shall mean as follows:

a) *broker* - legal person established in the European Economic Area (EEA), involved in activities in relation to the sale or purchase of medicinal products, except for wholesale distribution, that do not include physical handling and that consist of negotiating independently and on behalf of another legal or natural person;

b) *wholesaler of medicinal products for human use* - legal person established in the EEA, conducting, in line with legal provisions, of activities consisting of procuring, holding, supplying or exporting medicinal products, as defined in Title XVIII "The Medicinal Product" of Law no. 95/2006 on healthcare reform, republished as amended, apart from supplying medicinal products to the public;

c) *responsible person* - person referred to in Article 802 b) of Law no. 95/2006, republished as amended, whose qualification requirements are described in the Guidelines on Good Distribution Practice of medicinal products for human use Guideline, approved through Order of the Minister of Health no. 761/2015;

d) *falsified medicinal product* - any medicinal product with a false representation of:

(i) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients;

(ii) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or

(iii) its history, including the records and documents relating to the distribution channels used.

This definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights;

e) *distribution site* – site for medicinal product wholesaler conduct of one or several activities provided under b);

f) *traceability* - the ability to verify the history, location, or application of a medicinal product by means of documented recorded identification;

g) *healthcare products* – products other than medicinal products that may be held and supplied to the public in pharmacies;

h) *critical deficiencies*:

- A deficiency which may result in or lead to a significant risk during medicinal product distribution, potentially harmful to the public;

- a combination of several "major" deficiencies, none of which on their own may be "critical", but which may together represent a critical deficiency and should be explained and reported as such;

i) *major deficiencies*:

- deficiencies that may affect medicinal product quality during distribution, however not critically; or

- a combination of several "other deficiencies", none of which on their own may be" major", but which may together represent a major deficiency and should be explained and reported as such;

j) *other deficiencies* – deficiencies which cannot be classified as either critical or major, but which indicate a deviation from good distribution practices.

A deficiency may be "other" either because it is judged as minor, or because there is insufficient information to classify it as a major or critical;

k) *transportation hub* – location on the transport route where unloading/loading/transit storage (under 24 hrs.) may be performed;

l) *inspection of wholesale distribution authorisation* – inspection conducted for grant of wholesale distribution authorisation or modification thereof;

m) *routine inspection for assessment of compliance with good distribution practices (GDP)* – monitoring inspection conducted repeatedly to ensure GDP compliance by the authorised wholesaler, their premises and equipment.

CHAPTER II
Authorisation for wholesale of medicinal products for human use

Article 2. - (1) According to Article 800(1) of Law no. 95/2006, republished as amended, for wholesale distribution of medicinal products inside Romania, the applicants must own a wholesale distribution authorisation granted by the National Agency for Medicines and Medical Devices (NAMMD).

(2) Wholesale distribution authorisation is mandatory for each wholesale operator in the wholesale distribution chain, including free zones and free warehouses conducting such human medicines-related activities as:

a) procurement and delivery transactions;
b) holding (storing) and handling;
c) export.

Article 3. - (1) On Romanian territory, medicinal product wholesalers shall distribute medicinal products only that have been authorised for marketing pursuant to Law no. 95/2006, republished as amended, or by centralised procedure.

(2) By way of exception from provisions under (1), wholesalers may distribute medicinal products not authorised for marketing as provided in Articles 703(1) and (2) of Law no. 95/2006, republished as amended, based on authorisation for supply of medicinal products for special needs, granted by the NAMMD.

(3) Medicinal product wholesalers may hold and distribute other healthcare products as well, in compliance with legislation specific to their respective scope of work, which shall be stored in distinct areas.

(4) Wholesalers may supply medicinal products to such persons only that, in their turn, hold a wholesale distribution authorisation or are authorised for supply of medicines to the Romanian public.

Article 4. - (1) The wholesale distribution authorisation are authorised is granted on request of the legal representative of the applicant wholesaler; in the case of medicinal product manufacturers and importers, according to Article 800(4) of Law no. 95/2006, republished as amended, wholesale distribution is included into the manufacturing/import authorisation for the medicinal products included in the respective authorisation.

(2) A single medicinal product wholesaler may only hold a single or several wholesale site(s), each authorised pursuant to these Rules.

(3) Wholesale distribution authorisations are granted based on favourable inspection report prepared by NAMMD inspectors.

(4) Wholesale distribution authorisations may also be granted conditioned by compliance with obligations imposed on authorisation, to be met on the deadlines established in the preventive and corrective measures plan prepared for resolution of deficiencies by the inspectee after conduct of the inspection.

(5) For grant of the wholesale distribution authorisation applicants submit an application to the NAMMD requesting schedule of an inspection, in accordance with the form stipulated in Annex I and the form filled in as shown in Annex no. 2, accompanied by the following documents:

a) administrative documents:

a1) certified copy of the statutes of the company;

a2) certified copy of the closure/resolution for company authorisation and registration;

a3) certified copy of the registration certificate granted and issued by the Registry of Commerce, annexes included;

a4) fact-finding certificate issued 30 days prior to application submission;

a5) certified copy of the of proof of location ownership, wholesale sites included;

a6) for distributors who do not have their own holding areas, certified copy of the contract for collaboration with an authorised medicinal product wholesaler

b) technical documents:

b1) master file established for each manufacturing site, in line with Annex no. 3; form no. 2 is to be filled in individually for each distribution site;

b2) plan of the premise(s), their description;

b3) labour contract or proof of liberal conduct of profession, full-time with 8 working hours for the responsible person in each distribution site and the membership certificate in professional colleges granted under the law;

b4) labour contract or proof of liberal conduct of profession and the membership certificate for the College of Pharmacists in Romania granted under the law, for pharmacists employed;

b5) labour contract or proof of liberal conduct of profession the membership certificate for the College of Physicians in Romania granted under the law, for physicians employed;

b6) labour contract and the membership certificate for the Order of Nurses, Midwives and Medical Assistants in Romania, for pharmacy assistants;

b7) commitment concerning monthly submission to the NAMMD of the status of trade operations, parallel import included or, respectively, medicinal product distribution outside Romania to other EEA countries conducted with medicinal products for human use in their own portfolio.

Article 5. – The Responsible person referred to in Article 802 b) of Law no. 95/2006, republished as amended, shall meet the following requirements:

a) be a pharmacist/physician with at least one year work experience in operations of medicinal product handling, storage and distribution or transactions related to medicinal product procurement or sales;

b) be cognizant of Law no. 95/2006, republished as amended, concerning provisions of the Guidelines on Good Distribution Practice of medicinal products for human use, approved through Order of the Minister of Health no. 761/2015, as well as any other regulatory provisions related to distribution work.

Article 6. - Ten days as of registration of the application, the National Agency for Medicines and Medical Devices notifies the applicant on status of documents submitted for conduct of the inspections:

a) For documentation compliant with provisions of Article 4(5), the applicant is informed on acceptance of the respective application for inspection as well as on inspection fee, as approved through Order of the Minister of Health, payable within 10 days as of receipt of the NAMMD notification; the inspection is conducted 10 days as of fee payment confirmation, on an agreed date;

b) For incomplete documentation, the applicant is notified as to further information to be submitted to the National Agency for Medicines and Medical Devices; in such cases, timeframes provided in Article 801 of Law no. 95/2006, republished as amended, are suspended until submission of complete documentation.

Article 7. - The inspection is conducted in line with an inspection plan established by an inspector/inspectors nominated by the NAMMD; the respective plan is notified to the applicant site prior to the date set for inspection.

Article 8. - (1) The inspection for authorisation of wholesale distribution assesses compliance with Guidelines on Good Distribution Practice of Medicinal Products for Human Use, approved through Order of the Minister of Health no. 761/2015.

(2) Medicinal product wholesalers conducting either division-packaging operations or (re)packaging, (re)labelling operations for medicinal products, investigational medicinal products included, shall hold a manufacturing authorisation for the respective medicines, such operations being constitutive part of the manufacturing process.

Article 9. - (1) No later than 20 days as of the inspection date, the NAMMD provides to the applicant the list of deficiencies/inspection report, as appropriate.

(2) For the list of deficiencies, the applicant is required to submit the proposed corrective and preventive action plan within 15 days.

(3) In case of inadequate corrective and preventive plan proposed or of non-compliance with legal timeframe, before completion of the final inspection report, the applicant may only be notified once on supplementation/revision of the plan.

(4) Where inspection reports are unfavourable (concluding on GDP non-compliance), in the shortest time possible, the NAMMD issues a GDP Non-compliance Statement in the European format approved by the European Commission; in such cases, after resolution of deficiencies found, the inspectee may apply for a new inspection.

(5) Where inspection reports are favourable (concluding on GDP non-compliance), the National Agency for Medicines and Medical Devices grants the manufacturing authorisation within 90 days as of the registration date of the full documentation submitted by the applicant.

(6) Follow-up of resolution of potential deficiencies found, other than critical, is performed after issue of the wholesale distribution authorisation, based on documentation submitted by the applicant or by means of a new inspection.

Article 10. - (1) The wholesale distribution authorisation is issued in the format approved by the European Commission, in two original copies, one of which is handed to the applicant, while the other remains with the National Agency for Medicines and Medical Devices.

(2) Wholesale distribution authorisations issued by the NAMMD shall remain valid indeterminately.

(3) NAMMD inspectors conduct routine inspections for assessment of GDP compliance to authorised wholesale distribution sites according to the Annual Inspection Plan prepared pursuant to risk assessment results for each wholesale distributor; frequency of follow-up inspections is noted in the inspection report and shall not exceed 5 years.

(4) Routine inspections for assessment of GDP compliance may also be conducted without prior notification, any time there is reason to suspect wholesaler GDP non-compliance.

Article 11. - For announced inspection for assessment of GDP compliance, provided under Article 10(3), 90 days prior to the date of the next inspection specified in the previous inspection report, the wholesale distribution authorisation holder shall submit an application for inspection scheduling (as per Annex no. 1), accompanied by the Master File (according to Annex no. 3), the updated version of administrative documents mentioned in Article 4(5), in case of changes, and the status of corrective and preventive measures implemented after the previous inspection.

Article 12. - Changes subsequent to grant of the wholesale distribution authorisation, including inclusion/elimination of a transportation hub, are notified to the National Agency for Medicines and Medical Devices in advance, at the same time with an application for new authorisation/annexes; depending on the nature of the change, the, wholesale distribution authorisation/annex is granted based on an updated dossier submitted (for administrative changes) or a new favourable inspection report (for technical changes).

Article 13. - For wholesale distribution of medicinal products containing psychoactive or psychotropic substances, provisions of Law no. 339/2005 shall apply on the legal regime of psychoactive or psychotropic plants, substances and preparations, as amended.

Article 14. - Loss of the wholesale distribution authorisation leads to its cancellation and a copy may be issued based on the following documents:

a) application submitted in the format mentioned in Annex no. 4;

b) proof of published notification of the loss in a widely circulated daily;

c) copies of documents originally submitted in view of the initial authorisation;

d) a statutory declaration mentioning that no changes have been implemented to data initially allowing grant of wholesale distribution authorisation.

Article 15. - (1) Should non-compliance with GDP be found on any inspection with, the NAMMD shall in the shortest time possible proceed to issue the GDP Non-compliance Statement in the European format approved by the European Commission; in such cases, after resolution of deficiencies found, the inspectee may apply for a new inspection.

(2) In line with provisions of Article 800(7) of Law no. 95/2006, republished as amended, should one or several conditions for conditional

authorisation be found, or in cases of issuance of a GDP non-compliance statement, the National Agency for Medicines and Medical Devices shall suspend, in part or in whole, all non-complaint activities/operations until remedy of deficiencies found or revoke the wholesale distribution authorisation in case deficiencies found are beyond remedy; NAMMD shall notify the other Member States and the European Commission thereof.

(3) Suspension of the wholesale distribution authorisation may also be decided upon under the following circumstances:

a) the finding of contraventions established in Article 875(1) g), h) and n) of Law no. 95/2006, republished as amended;

b) on reasoned written request by the authorisation holder, for no longer than 6 months. Activities may only be resumed after submission to the NAMMD of a notification of recommencement of activities, accompanied by a mentioning that no changes have been implemented to data initially allowing grant of wholesale distribution authorisation. Should the holder submit no such request for cancellation of suspension within 6 months, the authorisation shall be revoked permanently.

(4) In cases of suspension/revocation, the wholesale distribution authorisation shall be handed over to the NAMMD 3 days as of NAMMD decision for suspension/revocation or at the same time with submission of the holder's application for suspension/revocation; the authorisation shall be accompanied information on the medicinal product stocks in place and the archiving site for documents provided for in Article 803 f) of Law no. 95/2006, republished as amended, which have to be made available to the NAMMD, for inspection purposes, for a 5-year period. In case of partial suspension of the wholesale distribution authorisation, involving certain activities/operations only, the NAMMD shall issue a new wholesale distribution authorisation only containing activities it is valid for.

(5) The NAMMD may revoke the wholesale distribution authorisation for medicinal products either as a result of GDP non-compliance or on holder's request, based on written application; the authorisation shall be accompanied information on the medicinal product stocks in place and the archiving site for documents provided for in Article 803 f) of Law no. 95/2006, republished as amended, which have to be made available to the NAMMD, for inspection purposes, for a 5-year period.

(6) For suspensions of authorisation triggered by GDP non-compliance, activities may only be resumed based on a favourable inspection report.

Article 16. - (1) Holders of wholesale distribution authorisations for medicinal products may appeal the decision for suspension/revocation within 48 working hours since receipt of the decision.

(2) NAMMD review of the appeal is mandatory within 48 working hours; pending resolution of the appeal, submission of the application for appeal shall

not suspend the NAMMD decision on suspension/revocation of the wholesale distribution authorisation for medicinal products.

Article 17. - (1) Authorisation for medicinal product wholesale activities includes the distributor's public service obligation provided under Article 699 pct. 19 and Article 804(2) of Law no. 95/2006, republished as amended, as well as obligations stipulated in Article 800(10) and Article 803 of Law no. 95/2006, republished as amended.

(2) The geographic area specified in Article 699 pct. 19 of Law no. 95/2006, republished as amended, refers to Romania.

Article 18. - Pharmacists and physicians working at the wholesale distribution site shall meet requirements established for conduct of their profession pursuant to Law no. 95/2006, republished as amended.

Article 19. - (1) Pharmacists, physicians and other staff may only conduct their profession at a medicinal product wholesale distribution site as proper employees and/or independently, as appropriate, in compliance with legal provisions in force and based on a job description providing a detailed description of their tasks and duties according to their respective qualification in the field.

(2) When absent, the responsible person may be replaced by a different person of the same qualification and meeting the same requirements only.

(3) The position as responsible person may be held in one distribution site only..

Article 20. - (1) In order to meet their functions, responsible persons shall:

a) be directly subordinated to the representative of the top management of the wholesale distribution authorisation holder for medicinal products;

b) hold the authority as defined in the organisational chart;

c) have well-defined responsibilities;

d) have access to all areas, spaces and documents (contract with third-parties included) sand records related to activities conducted by the wholesalers;

e) provide for conduct of authorised activities in compliance with good distribution practice, the accuracy and quality of records, in line with standard procedures established for each type of activity;

f) prepare and maintain records of responsibility delegation;

g) have knowledge of medicinal products distributed (e.g., medicinal product classes, their marketing authorisation status, storage conditions, other specific conditions to be complied with on the market for their distribution, as appropriate) or any other non-medicinal product distributes (and related activities), able to influence medicinal product quality;

h) have knowledge of principles for quality management;

i) ensure implementation and maintenance of a quality management system;

j) hold quality and provenance documents for each medicinal product batch as well as records required to ensure traceability of distribution to the retailer.

Article 21. – Wholesalers of medicines must hold all documents, information and records of transactions with suppliers, subcontractors and other operators in the distribution chain, including written contracts required to ensure traceability of the distribution chain, of the internal transfer between its wholesale sites and distribution of each product to the retailer.

Article 22. – In order to prevent and fight counterfeiting of medicines, the wholesale authorisation holder has the following obligations:

a) establish a functional mechanism to ensure that it can act effectively in cases of suspected tampering;

b) report without delay to the competent authorities (e.g., the NAMMD, investigation bodies, customs authorities, as appropriate) all information in their possession concerning a possible falsification of medicines;

c) cooperate with all parties involved, i.e. healthcare authorities, customs authorities, investigation bodies, the prosecutor's office, healthcare professionals etc., to detect falsified medicines, investigate cases and indictment of persons responsible for the manufacture or distribution of falsified medicines.

CHAPTER III
Good Distribution Practice Certificate

Article 23. - (1) Pursuant to Article 857(13) of Law no. 95/2006, republished as amended, in case of inspections concerning authorisation of medicinal product wholesalers or for any inspection for assessment of GDP compliance, in line with regulatory provisions, the National Agency for Medicines and Medical Devices grants the Good Distribution Certificate within 90 days as of the inspection date, on condition the inspection report confirms compliance with Good Distribution Practice Rules.

(2) The Good Distribution Certificate shall be valid for no longer than 5 years as of the date of inspection.

(3) Within 6 months prior to the expiry date stipulated under (2), applicants shall submit an application to the NAMMD requesting schedule of an inspection in accordance with the form stipulated in Annex I, accompanied by the Master File provided for in Annex no. 3, the updated version of administrative documents mentioned in Article 4 (5) (in case of changes) and the status of corrective and preventive measures implemented after the previous inspection.

Article 24. – Twenty days as of registration of the application, the National Agency for Medicines and Medical Devices shall notify the applicant on status of documents submitted for conduct of the inspections, as follows:

a) For full and compliant documentation, with provisions of Article 4 (3), the applicant is notified on acceptance of the respective application for

inspection as well as on inspection fee; except otherwise justified, the inspection is conducted 30 days as of fee payment confirmation, on an agreed date;

b) For incomplete documentation, the applicant is notified as to further information to be submitted to the National Agency for Medicines and Medical Devices.

Article 25. - The inspection is conducted in line with an inspection plan established by an inspector/inspectors nominated by the NAMMD; the respective plan is notified to the applicant site prior to the date of inspection.

Article 26. - The inspection for grant of the Good Distribution Certificate assesses compliance with Guidelines on Good Distribution Practice of medicinal products for human use, approved through Order of the Minister of Health no. 761/2015.

Article 27. - The inspection results in a list of deficiencies or an inspection report, as appropriate, to be provided to the applicant within 30 days as of the date of inspection.

a) for the list of deficiencies, within 15 days, the applicant is required to submit the proposed corrective and preventive action plan;

b) in case of inadequate corrective and preventive plan proposed or of non-compliance with legal timeframe, before completion of the final inspection report, the applicant may only be notified once on supplementation/revision of the plan;

c) In case of unfavourable inspection reports (concluding on GDP non-compliance), the NAMMD issues a GDP Non-compliance Statement in the European format approved by the European Commission, revokes the Good Distribution Certificate and operates the relevant changes in the wholesale distribution authorisation, as appropriate; in such circumstances, after resolution of deficiencies found, the inspectee may apply for a new inspection;

d) In case of favourable inspection reports, the National Agency for Medicines and Medical Devices grants the manufacturing authorisation within 90 days as of the date of inspection.

Article 28. - The Good Distribution Certificate is issued bilingually, in the format approved by the European Commission, in two original copies, one of which is handed to the applicant unit, while the other remains with the National Agency for Medicines and Medical Devices.

Article 29. - Loss of the Good Distribution Certificate results in cancellation thereof; grant of a duplicate manufacturing authorisation is done based on the following documents:

a) application as per the form mentioned in Annex 4;

b) proof of publication of the loss in a widely circulated daily;

c) statutory declaration that no changes have been made to information allowing for initial grant of wholesale authorisation.

Article 30. - (1) Should one or several conditions for grant of the Good Distribution Certificate be found, except for the situation stipulated under 27 a),

that had not been met, the National Agency for Medicines and Medical Devices shall suspend the manufacturing authorisation granted, in part or in whole, until remedy of deficiencies found or revoke the manufacturing authorisation in case deficiencies found are beyond remedy.

(2) Should the company cease its activity, Good Distribution Certificates owned shall be returned to the National Agency for Medicines and Medical Devices for cancellation and withdrawal from the EudraGMP European database.

Article 31. - (1) Wholesalers already authorised at the date of these rules entry into force shall obtain Good Distribution Certificates within 2 years.

(2) At the same time with the Good Distribution Certificate, the NAMMD issues a new wholesale authorisation according to the updated format.

CHAPTER IV
Provisions on brokers of medicinal products for human use

Article 32. - In line with Article 810(2) of Law no. 95/2006, republished as amended, brokers of medicinal products for human use shall be registered with the NAMMD.

Article 33. - (1) For registration with the NAMMD, prior to the date anticipated for start of activities, brokers shall submit to the NAMMD the form stipulated in Annex no. 5.

(2) Brokers who, on the date of these Rules entry into force, were already conducting brokering activities shall submit the application form to the NAMMD no later than 30 days as of this date.

Article 34. - The form for application for registration shall be submitted at least 30 days prior to start of activities and shall be accompanied by the following documents:

a) administrative documents:

a1) certified copy of statutes of the company (statutory act, statutes, company contract, as appropriate);

a2) certified copy of closure/resolution for company authorisation and registration;

a3) a certified copy of the registration certificate granted and issued by the Registry of Commerce, annexes included;

a4) fact-finding certificate issued 30 days prior to application submission;

a5) payment form for fee payment in two copies, filled in according to Annex no. 6;

b) technical documents:

b1) procedure on contingency plan ensuring full implementation of any medicinal product recall/withdrawal from the market;

b2) procedure on records of all brokering transactions according to Article 803 f) of Law no. 95/2006, republished as amended;

b3) procedure on resolution of complaints;

b4) procedure on notification of the NAMMD marketing authorisation holders on medicinal products found/suspected to be falsified;

b5) procedure on verification of wholesale authorisation held by the wholesaler supplying medicinal products, of the manufacturing authorisation of manufacturers/importers supplying medicinal products, of customers' wholesale/ retail distribution authorisation.

Article 35. - (1) Should the documentation submitted be found incomplete or non-compliant with provisions of Article 34, the applicant shall be notified on information to be further submitted to the NAMMD.

(2) Within 10 days as of acceptance of documentation and fee payment, the NAMMD shall enter broker's data in a public register to be made available on the NAMMD website. The NAMMD informs the broker in writing on the respective entry into the Public register of brokers of medicinal products for human use, according to the form provided in Annex no. 7.

Article 36. - (1) Further to start of operation, the NAMMD may at any time conduct announced or unannounced inspections, in line with provisions of Article 857 of Law no. 95/2006, republished as amended.

(2) Conduct of inspections at brokering sites for medicinal products is established based on risk evaluation.

(3) Inspection at brokering sites pursues assessment of compliance with Guidelines on Good Distribution Practice of Medicinal Products for Human Use, approved through Order of the Minister of Health no. 761/2015.

(4) The inspection is conducted in line with NAMMD procedures for medicinal product wholesale operations.

Article 37. - (1) The inspection results in a list of deficiencies or an inspection report, as appropriate, to be provided to the applicant within 20 days as of the date of inspection.

(2) For the list of deficiencies, within 15 days, the applicant is required to submit the proposed corrective and preventive action plan.

(3) In case of inadequate corrective and preventive plan proposed or of non-compliance with legal timeframe, before completion of the final inspection report, the applicant may only be notified once on supplementation/revision of the plan; where corrective and preventive plans are not submitted within 15 days, the deadline may be extended only once, with a similar duration.

(4) Where the corrective and preventive plan is inadequate or not submitted within 15 days, pursuant to provisions above, the NAMMD shall eliminate the respective broker from the Public register, to be re-entered only following inspection ending in favourable results.

(5) In case of unfavourable inspection reports (concluding on GDP non-compliance), after remedy of deficiencies found, the broker may apply for re-entry into the Public register, possible only following inspection ending in favourable results.

Article 38. - (1) Within 30 days, brokers shall notify the NAMMD on any changes to data published in the Public register of brokers of medicinal products for human use; no later than 10 days as of notification receipt, the NAMMD operates the respective changes accordingly.

(2) Within 30 days as of voluntary discontinuation of operations, brokers shall notify the NAMMD and submit information on the archiving site for documents provided for in Article 803 f) of Law no. 95/2006, republished as amended, which have to be made available to the NAMMD, for inspection purposes, for a 5-year period.

Article 39. – Annexes no. 1-7 are integral part of these rules.

ANNEX no. 1
to the Rules

To

THE NATIONAL AGENCY FOR MEDICINES
AND MEDICAL DEVICES
The Pharmaceutical Inspection Department

I, the undersigned, ... (Name and Surname), job ....., representative of …....., city……., address……., telephone/fax number ……, hereby apply for schedule of an inspection at the wholesale distribution site from…… in view of wholesale distribution authorisation/Good Manufacturing Practice certification.

Please find attached to the present application*) the documentation required under Order of Minister of Health no. 131/2016 on approval of Rules on authorisation of human medicinal product wholesalers Good Distribution Practice certification and registration of brokers of medicinal products for human use.

***)** The application and documentation can be forwarded to the National Agency for Medicines and Medical Devices (NAMMD) either directly, by post or by express delivery, at the NAMMD address: 48 Aviator Sănătescu, sector 1, Bucharest 011478.

Signature, stamp
. . . . . .

ANNEX no. 2
to the Rules

Application form for wholesale distribution authorisation for medicinal products for human use

(Please complete all relevant sections in this form in block capitals legibly, using black ink)

Section 1
Application form: administrative data

1.1. Applicant's details

Authorisation number (if previously authorised):		
Name of the company:		
Name of the representative*):		
Address:		
Postal code:	Telephone no.:	
Mobile no.:	Fax no.:	
E-mail address:		

***)** Please attach the original document attesting the quality of representative.

ATTENTION! ALL INFORMATION SPECIFIED IN THE AFOREMENTIONED SECTION MUST BE FILLED IN

1.2. Information concerning the contact person (if different from above)

Contact name:	
Name of represented company:	
Address:	

Postal code: Telephone no.:

Mobile no.: Fax no.:

E-mail address:

1.3. Information on invoicing address (if other than that of the authorisation holder)

Contact name:

Company:

Address:

Postal code: Telephone no.:

Mobile no.: Fax no.:

E-mail address:

Section 2

Information regarding the wholesale site

2.1. Information regarding the wholesale site

Sections 2 and 3 have to be filled in for each distribution site to be included in the authorisation

Name of the distribution site:

Address:

Postal code:

Contact name:

Telephone no.: Fax no.:

Mobile no.: ☐ ☐

E-mail address: ☐ ☐

2.2. Types of operations

□ Procurement
□ Holding
□ Delivery
□ Export
□ Other*): < please specify >
***)** If „Others", please specify:

Name of the distribution site: . . . . . Postal code: . . . . . .

2.3. Categories of products handled at the distribution site

Please indicate, by checking the appropriate box, what categories of products are handled at this site

1.1 □ with authorisation for marketing in member states of the European Economic Area

1.2 □ without authorisation for marketing in member states of the European Economic Area and which are intended to be marketed in the European Economic Area**)

1.3. □ without authorisation for marketing in member states of the European Economic Area and which are intended for exportation

2. □ Products compliant with Article 806 of Law 95/2006 - Title XVIII[1]

2.1 □ Drugs and psychotropic products

2.2 □ Blood-derived medicinal products

2.3 □ Immunologicals

2.4 □ Radiopharmaceuticals (radionuclide kits included)

3. □ Medicinal gases

4. □ Products distributed within the „cold chain" (which require handling at low temperatures)

5. □ Other products: < specify here >

[1] Without prejudice to any other authorisation required in accordance with the legislation in force.

****)** Article 699 of Law no. 95/2006 - Title VIII or Article 83 of Regulation (EC) no. 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

2.4. Classes of medicinal products

Sterile forms

Dosage forms - large volume liquids	yes	no
Dosage forms - small volume liquids (e.g. eye drops)	yes	no
Dosage forms - semisolids (e.g. sterile creams and ointments)	yes	no
Other sterile products	yes	no

If „Others”, please specify:

Non-sterile forms

Dosage forms - liquids (e.g. solutions, syrups, suspensions)	yes	no
Dosage forms - semi-solids (e.g. non-sterile creams and ointments)	yes	no
Dosage forms - solids (e.g. tablets, capsules, suppositories and powders)	yes	no
Other non-sterile products	yes	no

If „Others”, please specify:

2.5. Activities specific to the distribution site

Please answer the questions below to indicate the types of activities you intend to conduct at the distribution site

Are there unauthorised medicinal products from the European Economic Area (EEA) imported at this site?	yes	no

Are you handling products from parallel imports at this site?	yes	no

Name of the distribution site: . . . . . Postal code: . . . . . .

2.6. Other information

The inspectorate requires the following information, but it shall not be included in the authorisation.

Are there animal products available on the distribution site?	yes	no

Are the premises ready to be inspected?	yes	no

Do you intend to operate according to a quality ensurance system?	yes	no

Are you familiar with provisions of the Guideline on Good Distribution Practice as regards the required documentation and quality control?	yes	no

Are Standard Operating Procedures (SOPs) available, as shown in the Guideline for Good Distribution Practice? Please attach a copy of these documents on paper or electronically.	yes	no

Are the contracts you hold available for inspection?	yes	no

Distribution method

Post office	yes	no

Express services	yes	no

Your personal shipment service	yes	no

By client takeover	yes	no

Do you take the appropriate measures for products requiring	yes	no

shipment at low temperatures?		

Others	yes	no

If „Others”, please specify:

2.7. Equipment/facilities on distribution site

On a separate sheet, please write a brief description (of about 500 words) of the facilities available for storage and distribution of medicinal products.

Section 3
Appointed persons

Please specify the staff categories working at the distribution site.

Staff	Number
Responsible person (RP)	
Alternate of the responsible person	

For each staff category listed above, fill in one of the following pages.
Name of the distribution site: . . . . . Postal code: . . . . . .

3.1. Responsible person

Please attach a relevant CV for the responsible person; the appointment of the responsible person must be signed by both the nominee and the applicant..

Family name:

First name

Job address:

Postal code: Telephone no.:

Fax no.: Mobile no.:

E-mail

Qualifications (relevant for authorisation):

Experience (brief outline of jobs and responsibilities relevant for authorisation purposes)

Professional bodies:

I hereby confirm that all above details are accurate and true according to my knowledge and opinions. I agree with my assignment as Responsible Person

Signature (of the appointed person): . . . . . .
Date: . . . . . .
Name in full: . . . . . .
Signature of the applicant: . . . . . .
Date: . . . . . .

Name of the distribution site: . . . . . Postal code: . . . . . .

3.2. Alternate of the responsible person

Please attach a relevant CV for the alternate of the proposed responsible person; nomination of the responsible person must be signed by both the nominee and the applicant.

Family name:

First name

Job address:

Postal code: Telephone no.:

Fax no.:		Mobile no.:	
E-mail			

Are you a pharmacist?	yes	no
Are you a physician?	yes	no

Qualifications (relevant for authorisation)

Experience (brief outline of jobs and responsibilities relevant for authorisation purposes)

Professional bodies:

To the best of my knowledge and belief, the particulars I have given in this form are correct, truthful and complete. I agree to be assigned as a responsible person.

Signature (of the appointed person): . . . . . .
Date: . . . . . .
Name in full: . . . . . .
Signature of the applicant: . . . . . .
Date: . . . . . .
Name in full: . . . . . .

Name of the distribution site: . . . . . Postal code: . . . . . .

Section 4
Comments

Please provide any other information that may support your application. You can also detail any changes to addresses, appointed persons etc.

Section 5
Declaration

I hereby apply for grant of a Wholesale Distribution Authorisation to the proposed holder named in this application form in respect of the activities to which the application refers.

5.1. The activities are to be in accordance with the information set out in the application or furnished in connection with it.

5.2. To the best of my knowledge and belief, the particulars I have given in this form are correct and complete.

Signature of the applicant: . . . .
. . . . . .
Date: . . . . . .
Name in full: . . . . . .
Quality of the signatory: . . . . . .
. . . .

ANNEX no. 3
to the Rules

STANDARD DOSSIER
of the wholesale unit

This form is conceived so as to provide, after being filled in by the applicant, information on procurement, holding, delivery and/or export operations carried out at the distribution site to be inspected. If any of the operations previously mentioned is not conducted at the distribution site, the dossier shall only be filled in with these operations, e.g. only storage.

FORM no. 1: INFORMATION REGARDING THE COMPANY

1. GENERAL INFORMATION

1.1. Brief notification concerning the company

1.1.1. Company name, as registered by the legal authority

1.1.2. Post office address.

1.1.3. Telephone and fax numbers (24/24) and permanent e-mail address for contact of the responsible person or his/her alternate in case of withdrawal of a batch

1.1.4. Number and date of the latest wholesale authorisation

1.1.5. Other authorisations owned. Please specify the number, date and name of issuing authority for each authorisation.

2. RELEVANT ACTIVITIES FOR THE COMPETENT AUTHORITY

Please tick where appropriate:

Products distributed	Percentage of commercial units distributed		Division of distribution depending on the type of beneficiaries (%)	
	In Romania	In other countries	Pharmacies	Wholesalers
Medicinal products for human use				
Other products*)				

***)** If "Other products", please specify.

3. THE COMPANY'S DISTRIBUTION SITES

Please fill in the table below:

Name of the distribution site	Address	Telephone/fax number	Authorised activities

FORM no. 2: INFORMATION CONCERNING THE DISTRIBUTION SITE

Note:
Please fill in a Form no. 2 for each distribution site.

CHAPTER 1
GENERAL INFORMATION

1.1. Brief notification on the distribution site

1.1.1. Name of the distribution site, address and post office address (if different from the address of the distribution site)

1.1.2. Telephone and fax number of the contact person

1.1.3. Permanent contact telephone number

1.2. Authorised distribution operations

1.2.1. Specify whether the distribution site has been authorised by the National Agency for Medicines and Medical Devices or by other authorities (in the latter case, specify the authority and scope of authorisation, indicating whether it is the same or different from the one described in the application).

1.2.2. Please specify the number and validity of the authorisation issued by the competent authority. Any conditions and/or restrictions should be declared.

1.3. Any other type of operations conducted at the distribution site

Both pharmaceutical and non-pharmaceutical activities should be described.

1.4. Type of products handled at the distribution site and information on the handled medicinal products containing toxic and dangerous substances, specifying the manner of handling and the cautions taken

1.4.1. Specify the type of medicinal products handled, specifying whether these are handled based on a contractual agreement with a contract provider (e.g. radiopharmaceuticals).

1.4.2. Note any toxic, dangerous, highly sensitizing substances handled, e.g. antibiotics, hormones, cytostatics. Specify whether special cautions are taken for such products.

1.5. Brief description of the distribution site (size, city and immediate surroundings and other activities performed)

(No more than 250 words on an A4 sheet)

1.5.1. Provide a map of the site and surrounding areas. Please label the site, describe the surrounding area and activities conducted in the neighbourhood.

1.5.2. Size of the distribution site, type of buildings and their age

1.5.3. Other activities performed at the distribution site

1.6. Number of employees involved in administration, storage, distribution and shipment

Note:

Include both part-time and full-time employees

1.6.1. Administration

1.6.2. Storage

1.6.3. Distribution

1.6.4. Shipment

1.6.5. Technical support services

1.6.6. Total number of employees

1.7. Contract-based activities, contract-based operations (if any, see Chapter 8 for more details)

For each contract beneficiary (including shipment companies, if required), please specify:

1.7.1. Name, address, telephone and fax number of the contract beneficiary

1.7.2. Brief description of the activity conducted (in less than 100 words or half of an A4 sheet)

1.8. Brief description of the company's quality management system

(No more than 750 words or 3 A4 sheets)

1.8.1. Description of the company's quality policy.

1.8.2. Describe the elements of quality management, e.g. organisational structure, responsibilities, procedures, processes.

1.8.3. Describe the audit programme (self-inspections or audits performed by external bodies).

1.8.4. Please describe: how are outcomes analysed in order to demonstrate that the quality system is adequate in relation to its objectives, e.g. product quality and integrity (see also Chapter 7).

1.8.5. Please specify whether standards such as ISO 9000 are employed by the company.

CHAPTER 2
STAFF

2.1. Organisational chart including key-persons

The organisational chart for key-functions, as approved. Please mention the heads and supervisors only.

2.2. Competences, experience and responsibilities of the key-staff

2.2.1. Brief description of higher education competences, specialisations for the activity performed and years of experience in the field of persons appointed in the organisational chart

2.2.2. Job descriptions of the key-staff

2.3. Training of the staff and relevant documents concerning the training programme

Provide brief details concerning the training programme and include the training received upon hiring as well as the ongoing training, as follows:

2.3.1. Describe the manner of how training requirements are identified and by whom.

2.3.2. Provide details concerning specific Good Distribution Practice training.

2.3.3. Please declare the manner of training, e.g. internal, external, type of practical training and staff involved.

2.3.4. Please explain the manner of assessment of the training efficacy, e.g. via questionnaires.

2.3.5. Explain how retraining needs are identified.

2.3.6. Specify whether you hold records of performed trainings.

CHAPTER 3
SITES AND FACILITIES

3.1. Simple plans of the site and description of the storage area

3.1.1. Forward a plan of the site, indicating all storage areas and other operational areas.

3.1.2. Describe the measures taken in order to prevent unauthorised access.

3.1.3. Forward a simple plan for each area, indicating the scale. Specify the destination for each area (e.g. reception, storage, recalled products, expedition, for medicinal products with special storage conditions).

Note:

The plans should be legible on an A4 sheet. If deemed necessary, plans can be sent on an A3 sheet.

3.2. Brief description of ventilation systems (maximum 500 words on two A4 sheets). Please provide more details for critical areas where special storage conditions are ensured.

Note:

Schematic diagrams should be used in order to reduce the text.

3.2.1. Projection criteria. E.g. specifications for the provided air, temperature, humidity

3.3. Special areas for handling extremely toxic, dangerous and sensitising materials

Use the same plan as the one under point 3.1 above in order to describe the special areas for handling extremely toxic, dangerous and sensitising materials.

3.4. Maintenance (description of preventive maintenance and registration system programmes)

3.4.1. Describe the planned preventive maintenance programme.

3.4.2. Who is responsible for maintenance? (contract beneficiaries included).

3.4.3. Are there available written procedures and detailed contracts for the contracted activities?

3.4.4. Are there written procedures and adequate registration forms for maintenance (contract beneficiaries included) available? Do those documents specify the type/frequency of checks, details of the activity, rehabilitation and changes?

3.4.5. Are there routine maintenance activities which could affect the product's quality identified?

3.4.6. Are reports sent to users?

3.5. Existence of written specifications and procedures for cleaning the areas

3.5.1. Are there written procedures for cleaning and specifications for the cleaning agents and their strength for the cleaning method and frequency?

3.5.2. Which are the cleaning methods (and their frequency) for vehicles?

3.6. Policy for storage of materials

3.6.1. How are materials with different status (e.g. quarantine, refused, approved etc.) separated and controlled (e.g. computer, labels)?

3.6.2. How are materials stored, e.g. on pallets?

3.6.3. Please describe the storage conditions for stupefying substances and psychotropes, if required.

3.6.4. Describe the prevention programme of access of insects and other pests.

CHAPTER 4
STOCK HANDLING AND CONTROL

4.1. Registration systems for distribution activities

4.1.1. Please describe the receipt, handling and storage of materials:

- types of checks performed with materials
- is the delivery order compliant with the "first in - first out" (FIFO) principle and does it identify the batch number?
- which are the methods of distribution to the clients?

4.1.2. Distribution records

Do records kept ensure full traceability from plant to client as regards date of marketing, client details and delivered amounts?

4.1.3. Stock inventory procedure. Please provide information on the manner of performing the inventory and its frequency.

4.2. Delivery and shipment

4.2.1. Describe how security, storage and safety conditions are ensured in order to maintain material quality during shipment.

4.2.2. Describe your vehicles:

a) number of vehicles and their capacity

b) are these dedicated vehicles?

c) are these vehicles adapted for shipment of medicinal products or other special products (e.g. products requiring low temperatures, radioactive products)?

d) how are transportation routes planned?

CHAPTER 5
DOCUMENTATION

5.1. The set-up, revision and distribution of the required documentation as well as maintenance of starting documents

5.1.1. Is there a description of the documentation system?

5.1.2. Who is responsible for preparation, revision and distribution of documents?

5.1.3. Where are starting documents stored?

5.1.4. Are there any instructions and standard formats for document set-up?

5.1.5. How is the documentation controlled?

5.1.6. How long are documents stored?

5.1.7. Please provide details on the manners of registration in electronic format or microfilm.

5.2. Any other documents related to the product's quality which are not mentioned elsewhere

Are the following documents available and used?

5.2.1. Training procedures

5.2.2. Specifications for softs:

a) access to the system (internet, intranet) and authorisation for grant of access

b) monitoring of all entries and amendments ("audit trail") and frequency of verifications

c) data saving procedures

5.2.3. Control of the documentation

5.2.4. Calibrating of used tools

5.2.5. List and briefly explain the use of any other standard documentation usually employed.

CHAPTER 6
COMPLAINTS AND PRODUCT RECALL

6.1. Measures for handling complaints and product recalls

6.1.1. Complaints

6.1.1.1. Is there a written procedure on product complaints?

6.1.1.2. Who is responsible for:

a) registration

b) classification

c) investigation of complaints

6.1.1.3. Are written reports drafted?

6.1.1.4. Who checks these reports?

6.1.1.5. How long are the records of complaints kept?

6.1.2. Product recall

6.1.2.1. Is there a written procedure describing the sequence of actions to be conducted, including:

a) the list of distribution of the concerned product

b) notification of clients

c) reception/dissociation/inspection of returned goods

d) investigation/reporting of the cause

e) the reporting of corrective actions

6.1.2.2. Who is responsible for recalls?

6.1.2.3. Who informs the competent authority (NAMMD) about complaints and recalls?

6.1.2.4. Is the NAMMD involved in making the decision for recall?

6.1.2.5. Can retail be performed up to the level of retail distributor?

6.1.3. Falsified products

6.1.3.1. Is there a procedure for detection, reporting (to the NAMMD) and quarantine of falsified products?

CHAPTER 7
SELF INSPECTIONS

7.1. Brief description of the self-inspection system (see point 1.8.4.)

7.1.1. Describe the manner of assessing the activities impacting the product's quality through self-inspection.

7.1.2. Is there a documented procedure for the system of self-inspection and follow-up actions?

7.1.3. Are self-inspection results documented, brought to the attention of the staff responsible for the inspected area/activities?

7.1.4. Do the responsible persons for the area/activity manage to timely implement the proposed corrective actions for deficiencies found?

CHAPTER 8
CONTRACT ACTIVITIES

8.1. Describe the manner of assessing compliance of the contract beneficiary with the GDP or other adequate standards

8.1.1. Briefly describe details of technical contracts between the supplier and the contract beneficiary and the manner of assessing compliance of the contract beneficiary with the GDP or other adequate standards. Selected standards should be assessed as regards their applicability. The types of activities conducted by the contract beneficiary must be specified.

ANNEX no. 4
to the Rules

To

THE NATIONAL AGENCY FOR MEDICINES
AND MEDICAL DEVICES
The Pharmaceutical Inspection Department

I, the undersigned, ... (Name and Surname), legal representative of …....., site ……., address ……., telephone/fax number ……..., registered with the National Trade Register Office . . . . , fiscal code ……, in accordance with Order of the Minister of Health no. 131/2016 on approval of Rules on authorisation of human medicinal product wholesalers, Good Distribution Practice certification and registration of brokers of medicinal products for human use, hereby apply for release of a new wholesale distribution authorisation/a new Good Distribution Certificate. We hereby attach the announcement concerning the loss of the wholesale distribution authorisation/ the Good Distribution Certificate in . . . . . .

Signature,
stamp
. . . . . .

ANNEX no. 5
to the Rules

Form for request of registration of brokers of medicinal products for human use

(Please complete all relevant sections in this form in block capitals legibly, using black ink)

1. Applicant's details:
Name of the company:
Registration no. with the Registry of Commerce:
Permanent legal address of the applicant:
Telephone number:
Fax number:
E-mail address:
Contact person:
Address of the site where brokerage activities are performed:
Telephone number:
Fax number:
E-mail address:
Contact person:

2. Declaration

I hereby request the registration of the aforementioned broker.

2.1. I hereby confirm that medicinal products are subject to a marketing authorisation granted through the centralised procedure or by the National Agency for Medicines and Medical Devices in accordance with provisions of Law 95/2006 on healthcare reform, republished as amended.

2.2. I hereby confirm having set up an emergency plan to ensure effective implementation of any withdrawal from the market, ordinated by the National Agency for Medicines and Medical Devices or conducted in cooperation with the manufacturer or, as appropriate, with the wholesale distributor or with the product's Marketing Authorisation Holder.

2.3. I hereby confirm holding a system which allows storage of evidence either as purchase invoices, electronic format or any other format, providing for any brokerage transaction at least the following information: date, product name, name and country of origin of the manufacturer, manner of presentation, pharmaceutical form, concentration of active substances, packaging size, batch and sate of expiry, quality certificate and analysis bulletin, as appropriate, quantity received, supplied or subject to brokerage, name and address of the supplier/beneficiary, as appropriate, as well as the product batch.

2.4. I hereby confirm that the evidence mentioned in point 2.3 shall be kept for at least 5 years.

2.5. I hereby confirm that I observe the requirements for brokers mentioned in the Guidelines on Good Distribution Practice of medicinal products for human use, approved through Order of the Minister of Health no. 761/2015.

2.6. I hereby confirm that I have implemented and hold a quality system which involves the responsibilities, processes and risk management measures related to performed activities.

2.7. I am aware of the requirement of the National Agency for Medicines and Medical Devices concerning its immediate notification and, as appropriate, of the Marketing Authorisation Holder concerning medicinal products which are offered to me and which I discover/suspect of being falsified.

2.8. To the best of my knowledge, the particulars I have given in this form are correct and complete.

I shall notify any amendment of the aforementioned information to the National Agency for Medicines and Medical Devices.

Signature of the applicant:. . . . . .
. . . . .
Name in full:. . . . . Date:. . . .
Quality of the signatory:

ANNEX no. 6
to the Rules

FORM FOR PAYMENT OF THE TARIFF FOR REGISTRATION IN THE REGISTRY OF BROKERS OF MEDICINAL PRODUCTS FOR HUMAN USE

Name of the broker

Address of the broker	
Address:	
City:	
Country:	
Telephone no.:	
Fax no.:	
E-mail address:	

Name of the paying company	
Name:	
Address:	
City:	
Country:	
Telephone no.:	
Fax no.:	
E-mail address:	
Fiscal code:	
Number introduced at the Registry of commerce	
IBAN account:	
Bank:	

Tariffed service: registration in the Registry of brokers of medicinal products for human use

Person de contact

Name:	
Address:	
City:	
Country:	
Telephone no.:	
Fax no.:	
E-mail address:	

Fiscal code:

According to the signatories, the particulars given in this form are correct.
Date. . . . . .

Broker
Name, signature, stamp

ANNEX no. 7
to the Rules

Public Registry of brokers of medicinal products for human use

No.	Registration no.	Date of registration	Broker	Permanent legal address

Medicinal product batches recalled during the 1st quarter of 2016

No.	Product recalled	Pharmaceutical form	Strength	INN	Manufacturer/MAH	Batch	Grounds for recall	Proposed action	Date for recall
1	VOLTAREN EMULGEL	gel	11,6 mg/g x 50 g	diclofenac	Novartis Consumer Health GmbH, Germany	W7368, W7369, W7370, W7371, W7372, W7373, W7374, W7375, W7376, W7377, W7378, W7379, W7380, W7381, W7382, W7383, W7384, W7385, W7386, W7387, W7388, W7389, W7390, W7391	Product whose shelf life has expired 2 years ago (as shown in Order of the Minister of Health no. 279/2005) following NAMMD approval of changes to MA no. 5428/2005/04-05 on 10.09.2013 (change of primary packaging), namely the one of 10.02.2014 (update of information from Annexes 1.2,3 to the product's MA)	Voluntary recall and destruction	07.01.2016
2	VOLTAREN EMULGEL	gel	11,6 mg/g x 100 g	diclofenac	Novartis Consumer Health GmbH, Germany	W0022, W0023, W0024, W0025, W0026, W0027, W0028, W0029, W0030, W0031, W0032, W0033	Product whose shelf life has expired 2 years ago (as shown in Order of the Minister of Health no. 279/2005) following NAMMD approval of changes to MA no. 5428/2005/04-05 on 10.09.2013 (change of primary packaging), namely the one of 10.02.2014 (update of information from Annexes 1,2,3 to the product's MA)	Voluntary recall and destruction	07.01.2016

3	EFFERALGAN	oral solution	30mg/ ml	paracetamol	Bristol-Myers Squib Kft., HUNGARY/ Bristol-Myers Squib Kft.,France	P1449, P1450, P3499, P3745, P4103, P8290, R3426	Identification of a risk of contamination with particles from a packaging equipment.	Voluntary recall and destruction	13.01.2016
4	AREIDA	powder and solvent for solution for infusion	15mg	acid pamidronic	Novartis Pharma GmbH, GERMANY/Novartis Pharma Services Romania SRL	All batches cu APP 5291/2005/01	Discontinuation by the holder of the procedure for renewal of the marketing authorisation and decision on discontinuation of the marketing of the respective product	Voluntary recall and destruction	18.01.2016
5	SOLPADEINE	effervescent tablets		combinations	GSK dungarvan Ltd., Ireland	135021, 135066, 145012	Product whose shelf life has expired 2 years ago (as shown in Order of the Minister of Health no. 279/2005) following NAMMD approval of changes to MA no.: 3400/2011/03	Voluntary recall and destruction	19.02.2016
6	SOLPADEINE	tablets		combinations	GSK dungarvan Ltd., Ireland	130483, 130647, 130754, 5K9T	Product whose shelf life has expired 2 years ago (as shown in Order of the Minister of Health no. 279/2005) following NAMMD approval of changes to MA no. 5545/2005/01	Voluntary recall and destruction	19.02.2016
7	BETALOC	iv solution for injection/infusion	5mg/ 5ml	metoprolol	Cenexi, FRANCE/AstraZeneca AB, Sweden	F0094-1	Wrong imprinting of the label applied on the vial in terms of strength (the 5mg/ml strength was erroneously imprinted near the correct strength of 5mg/5ml)	Voluntary recall and destruction	29.02.2016

8	OMERAN	gastroresistant capsules	20mg	omeprazol	GSK	LC13550, LC13560, LC13561, LC14233, LC14247, LC14274, LC14281, LC14290, LC14291, LC14292, LC14770, LC14779, LC14780, LC14796, LC14761, LC15392, LC15423, LC15428, LC15446, LC15454, LC16309, LC16310, LC16345, LC18016, LC18035, LC18221, LC19010, LC18958, LC19011, LC19033, LC19207, LC19208, LC19209, LC19543, LC19552, LC19993	Product whose shelf life has expired one year ago (as shown in Order of the Minister of Health no. 1810/2006) following NAMMD approval of transfer of Marketing Authorisation (MA) no. 7785/2006/02 from S.C. Europharm S.A. to S.C. GlaxoSmithKline (GSK) S.R.L.	Voluntary recall and destruction	01.03.2016
9	ALZEPIL	film-coated tablets	10mg	donepezil	Egis Pharmaceuticals PLC, Hungary	All batches	Voluntary withdrawal initiated by the Marketing Authorisation Holder since the medicinal product does not have an updated price agreed by the Ministry of Health	Voluntary recall and destruction	04.03.2016
10	EGITROMB	film-coated tablets	75mg	clopidogrel	Egis Pharmaceuticals PLC, Hungary	All batches	Voluntary withdrawal initiated by the Marketing Authorisation Holder since the medicinal product does not have an updated price agreed by the Ministry of Health	Voluntary recall and destruction	04.03.2016
11	MEMIGMIN	film-coated tablets	10mg	memantin	Egis Pharmaceuticals PLC, Hungary	All batches	Voluntary withdrawal initiated by the Marketing Authorisation Holder since the medicinal product does not have an updated price agreed by the Ministry of Health	Voluntary recall and destruction	04.03.2016

12	PULMEX BABY	ointment		combinations	Novartis Cons. Helth GmbH, Germany	L02988A, M03077A	Product whose shelf life has expired 2 years ago (as shown in Order of the Minister of Health no. 279/2005) following NAMMD approval of discontinuation of renewal of MA no. 5339/2005/01 of 07.05.2015	Voluntary recall and destruction	21.03.2016
13	PENTOXI RETARD	film-coated tablets	400mg	pentoxifilin	Terapia S.A.	02135739, 02135742, 02135743, 02135744, 01147676	Results outside specification throughout stability studies (insufficient protection of the PVC/Alu packaging)	Voluntary recall and destruction	24.03.2016

Applications for marketing authorisation/marketing authorisation renewal submitted to the NAMMD during the 4th quarter of 2015

During the 4th quarter of 2015, **263** marketing authorisation/renewal applications for medicinal products corresponding to the following therapeutic groups have been received:

A02 - DRUGS FOR ACID RELATED DISORDERS
A04 – ANTIEMETICS AND ANTINAUSEANTS
B01 – ANTITHROMBOTIC AGENTS
C03 - DIURETICS
C05 - VASOPROTECTOARE
C07 – BETA BLOCKING AGENTS
C08 - CALCIUM CHANNEL BLOCKERS
C09 - AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
C10 - LIPID MODIFYING AGENTS
D01 - ANTIFUNGALS FOR DERMATOLOGICAL USE
G03 - SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM
G04 - UROLOGICALS
H05 – CALCIUM HOMEOSTASIS
J01 - ANTIBACTERIALS FOR SYSTEMIC USE
J02 - ANTIMYCOTICS FOR SYSTEMIC USE
J05 - ANTIVIRALS FOR SYSTEMIC USE
J07 - VACCINES
L01 - ANTINEOPLASTIC AGENTS
L04 - IMMUNOSUPPRESSANTS
M01 - ANTI-INFLAMMATORY AND ANTIRHEUMATIC PRODUCTS
M05 - DRUGS FOR TREATMENT OF BONE DISEASES
N01 - ANESTHETICS
N02 - ANALGESICS
N03 - ANTIEPILEPTICS
N04 – ANTI-PARKINSON DRUGS
N05 - PSYCHOLEPTICS
N06 - PSYCHOANALEPTICS
N07 – OTHER NERVOUS SYSTEM DRUGS
R01 – NASAL PREPARATIONS
R03 - DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES
R05 - COUGH AND COLD PREPARATIONS
R06 – ANTIHISTAMINES FOR SYSTEMIC USE
S01 - OPHTHALMOLOGICALS

Medicinal products authorised for marketing during the 4th quarter of 2015

INN	Invented name	Pharmaceutical form	Strength	MAH	Country	MA number		
ACECLOFENACUM	ACOFAX 100mg	FILM-COATED TABLETS	100mg	ACTAVIS GROUP PTC EHF.	ICELAND	8448	2015	01
ACIDUM ACETYLSALICYLICUM	ASAPRIN 500mg	TABLETS	500mg	AC HELCOR S.R.L.	ROMANIA	8405	2015	01
ACIDUM ALENDRONICUM	ALENDRONAT SANDOZ 70mg	FILM-COATED TABLETS	70mg	SANDOZ S.R.L.	ROMANIA	8465	2015	01
ACIDUM CLODRONICUM	BONEFOS 800mg	FILM-COATED TABLETS	800mg	BAYER OY	FINLAND	8458	2015	01
ACIDUM IBANDRONICUM	ACID IBANDRONIC TEVA 6mg	CONCENTRATE FOR SOLUTION FOR INFUSION	6mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	8440	2015	01
ALBENDAZOLUM	VERMIGAL NOVO 200mg	FILM-COATED TABLETS	200mg	BIOFARM S.A.	ROMANIA	8174	2015	01
AMANTADINUM	NEOMIDANTAN 100mg	CAPSULES	100mg	IENZIMED INTERNATIONAL GROUP LTD.	ROMANIA	8382	2015	01
AMBROXOLUM	AMBROMED 30mg	TABLETS	30mg	ARENA GROUP S.A.	ROMANIA	8178	2015	01
AMBROXOLUM	AMBROXOL ARENA 30mg	TABLETS	30mg	ARENA GROUP S.A.	ROMANIA	8198	2015	01
AMBROXOLUM	AMBROXOL EGIS 3mg/ml	SYRUP	3mg/ml	EGIS PHARMACEUTICALS PLC.	HUNGARY	8200	2015	01
AMBROXOLUM	AMBROXOL EGIS 30mg	TABLETS	30mg	EGIS PHARMACEUTICALS PLC.	HUNGARY	8199	2015	01
AMBROXOLUM	AMBROXOL ROMPHARM 15mg/5ml	SYRUP	15mg/ 5ml	ROMPHARM COMPANY S.R.L.	ROMANIA	8376	2015	01

AMISULPRIDUM	AKTIPROL 200 mg	TABLETS	200mg	MEDOCHEM IE LTD.	CYPRUS	8186	2015	01
AMISULPRIDUM	AKTIPROL 400mg	TABLETS	400mg	MEDOCHEM IE LTD.	CYPRUS	8187	2015	01
AMOXICILLINUM + ACIDUM CLAVULANICUM	AMOXICILINA/ ACID CLAVULANIC DSM-SINOCHEM 500mg/125mg	FILM-COATED TABLETS	500mg/125 mg	DSM SINOCHEM PHARMACEUTICALS NETHERLANDS B.V.	HOLLAND	8238	2015	01
AMOXICILLINUM + ACIDUM CLAVULANICUM	AMOXICILINA/ ACID CLAVULANIC DSM-SINOCHEM 875 mg/125 mg	FILM-COATED TABLETS	875mg/125 mg	DSM SINOCHEM PHARMACEUTICALS NETHERLANDS B.V.	HOLLAND	8239	2015	01
AMOXICILLINUM + ACIDUM CLAVULANICUM	AUGMENTIN 500mg/125mg	FILM-COATED TABLETS	500mg/125 mg	BEECHAM GROUP PLC	GREAT BRITAIN	8395	2015	01
ARIPIPRAZOLUM	ARICOGAN 10mg	TABLETS	10mg	G.L. PHARMA GMBH	AUSTRIA	8225	2015	01
ARIPIPRAZOLUM	ARICOGAN 15mg	TABLETS	15mg	G.L. PHARMA GMBH	AUSTRIA	8226	2015	01
ARIPIPRAZOLUM	ARIPIPRAZOL AMNEAL 10mg	TABLETS	10mg	AMNEAL PHARMA EUROPE LIMITED	IRELAND	8438	2015	01
ARIPIPRAZOLUM	ARIPIPRAZOL AMNEAL 15mg	TABLETS	15mg	AMNEAL PHARMA EUROPE LIMITED	IRELAND	8439	2015	01
ARIPIPRAZOLUM	ARIPIPRAZOL STADA 10mg	TABLETS	10mg	STADA M&D SRL	ROMANIA	8263	2015	01
ARIPIPRAZOLUM	ARIPIPRAZOL STADA 15mg	TABLETS	15mg	STADA M&D SRL	ROMANIA	8264	2015	01
ARIPIPRAZOLUM	ZYKALOR 10mg	TABLETS	10mg	MEDOCHEM IE LTD.	CYPRUS	8251	2015	01
ARIPIPRAZOLUM	ZYKALOR 15mg	TABLETS	15mg	MEDOCHEM IE LTD.	CYPRUS	8252	2015	01

ARIPIPRAZOLUM	ZYKALOR 20mg	TABLETS	20mg	MEDOCHEM IE LTD.	CYPRUS	8253	2015	01
ARIPIPRAZOLUM	ZYKALOR 30mg	TABLETS	30mg	MEDOCHEM IE LTD.	CYPRUS	8254	2015	01
ARIPIPRAZOLUM	ZYKALOR 5mg	TABLETS	5mg	MEDOCHEM IE LTD.	CYPRUS	8250	2015	01
ATOMOXETINUM	STRATTERA 4mg/ml	ORAL SOLUTION	4mg/ml	ELI LILLY HOLDINGS LIMITED	GREAT BRITAIN	8298	2015	01
ATORVASTATINUM	SORTIS 10mg	FILM-COATED TABLETS	10mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	8192	2015	01
ATORVASTATINUM	SORTIS 10mg	CHEWABLE TABLETS	10mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	8189	2015	01
ATORVASTATINUM	SORTIS 20mg	FILM-COATED TABLETS	20mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	8193	2015	01
ATORVASTATINUM	SORTIS 20mg	CHEWABLE TABLETS	20mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	8190	2015	01
ATORVASTATINUM	SORTIS 40mg	FILM-COATED TABLETS	40mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	8194	2015	01
ATORVASTATINUM	SORTIS 40mg	CHEWABLE TABLETS	40mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	8191	2015	01
ATORVASTATINUM	SORTIS 5mg	CHEWABLE TABLETS	5mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	8188	2015	01
ATORVASTATINUM	SORTIS 80mg	FILM-COATED TABLETS	80mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	8195	2015	01
BIMATOPROSTUM	STURIBAN 0.1mg/ml	EYE DROPS, SOLUTION	0.1mg/ml	ACTAVIS GROUP PTC EHF.	ICELAND	8256	2015	01

BIMATOPROSTUM	STURIBAN 0.3mg/ml	EYE DROPS, SOLUTION	0.3mg/ml	ACTAVIS GROUP PTC EHF.	ICELAND	8257	2015	01
BISMUTHI OXIDE	ULCAMED 120mg	FILM-COATED TABLETS	120mg	KRKA, D.D., NOVO MESTO	SLOVENIA	8437	2015	01
CANDESARTANUM CILEXETIL	TANDESAR 16mg	TABLETS	16mg	TERAPIA SA	ROMANIA	8447	2015	01
CANDESARTANUM CILEXETIL	TANDESAR 8mg	TABLETS	8mg	TERAPIA SA	ROMANIA	8446	2015	01
CARBAMAZEPINUM	CARBAMAZEPINA FARMEX 200mg	TABLETS	200mg	FARMEX COMPANY S.R.L.	ROMANIA	8381	2015	01
CARBAZOCHROMI SALICYLAS	ADRENOSTAZIN 1.5mg	SOLUTION FOR INJECTION/INFUSION	1.5mg	TERAPIA S.A.	ROMANIA	8232	2015	01
CARBOPLATINUM	CARBOPLATIN CIPLA 10mg/ml	CONCENTRATE FOR SOLUTION FOR INFUSION	10mg/ml	CIPLA EUROPE NV	BELGIUM	8402	2015	01
CARVEDILOLUM	CORYOL 3.125mg	TABLETS	3.125 mg	KRKA, D.D., NOVO MESTO	SLOVENIA	8342	2015	01
CARVEDILOLUM	CORYOL 6.25mg	TABLETS	6.25mg	KRKA, D.D., NOVO MESTO	SLOVENIA	8343	2015	01
CEFEPIMUM	CEFEPIME KABI 1g	POWDER FOR SOLUTION FOR INJECTION/INFUSION	1g	FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	8400	2015	01
CEFTAZIDIMUM	CEFTAZIDIMA HOSPIRA 1g	POWDER FOR SOLUTION FOR INJECTION/INFUSION	1g	HOSPIRA UK LIMITED	GREAT BRITAIN	8333	2015	01
CEFTAZIDIMUM	CEFTAZIDIMA HOSPIRA 2g	POWDER FOR SOLUTION FOR INJECTION/INFUSION	2g	HOSPIRA UK LIMITED	GREAT BRITAIN	8334	2015	01

CEFUROXIMUM	CEFUROXIMA AUROBINDO 125mg	TABLETS	125mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	8302	2015	01
CEFUROXIMUM	CEFUROXIMA AUROBINDO 250mg	TABLETS	250mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	8303	2015	01
CEFUROXIMUM	CEFUROXIMA AUROBINDO 250mg	FILM-COATED TABLETS	250mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	8261	2015	01
CEFUROXIMUM	CEFUROXIMA AUROBINDO 500mg	TABLETS	500mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	8304	2015	01
CEFUROXIMUM	CEFUROXIMA AUROBINDO 500mg	FILM-COATED TABLETS	500mg	AUROBINDO PHARMA ROMANIA S.R.L.	ROMANIA	8262	2015	01
CINACALCETUM	CINACALCET HELM 30mg	FILM-COATED TABLETS	30mg	HELM AG	GERMANY	8276	2015	01
CINACALCETUM	CINACALCET HELM 60mg	FILM-COATED TABLETS	60mg	HELM AG	GERMANY	8277	2015	01
CINACALCETUM	CINACALCET HELM 90mg	FILM-COATED TABLETS	90mg	HELM AG	GERMANY	8278	2015	01
CISPLATINUM	CISPLATIN EBEWE 10 mg/ 20ml	CONCENTRATE FOR SOLUTION FOR INFUSION	10mg/ 20ml	EBEWE PHARMA GES.M.B.H. NFG. KG	AUSTRIA	8370	2015	01
CISPLATINUM	CISPLATIN EBEWE 25mg/ 50ml	CONCENTRATE FOR SOLUTION FOR INFUSION	25mg/ 50ml	EBEWE PHARMA GES.M.B.H. NFG. KG	AUSTRIA	8371	2015	01
CISPLATINUM	CISPLATIN EBEWE 50mg/100 ml	CONCENTRATE FOR SOLUTION FOR INFUSION	50mg/ 100ml	EBEWE PHARMA GES.M.B.H. NFG. KG	AUSTRIA	8372	2015	01
CLARITHROMYCINUM	KLACID 125mg/5ml	GRANULES FOR ORAL SUSPENSION	125mg/5ml	BGP PRODUCTS S.R.L.	ITALY	8386	2015	01

CLARITHROMYCINUM	KLACID 250mg	FILM-COATED TABLETS	250mg	BGP PRODUCTS S.R.L.	ITALY	8383	2015	01
CLARITHROMYCINUM	KLACID I.V. 500mg	POWDER FOR SOLUTION FOR INFUSION	500mg	MYLAN MEDICAL SAS	FRANCE	8385	2015	01
CLARITHROMYCINUM	KLACID SR 500mg	PROLONGED-RELEASE TABLETS	500mg	BGP PRODUCTS LTD.	GREAT BRITAIN	8384	2015	01
CODEINUM	CODEINA FOSFAT MCC 15mg	TABLETS	15mg	MAGISTRA C&C S.R.L.	ROMANIA	8344	2015	01
COLECALCIFEROLUM	VIGANTOL OIL 0.5 mg/ml	ORAL DROPS, SOLUTION	0.5mg/ml	MERCK KGAA	GERMANY	8275	2015	01
COMBINATIONS	AGIOLAX	GRANULES		MADAUS GMBH	GERMANY	8408	2015	01
COMBINATIONS	COLDREX MAXGRIP FRUCTE DE PADURE & MENTOL	POWDER FORORAL SUSPENSION		GLAXOSMITHKLINE CONSUMER HEALTHCARE	GREAT BRITAIN	8378	2015	01
COMBINATIONS	EUCARBON	TABLETS		F.TRENKA CHEMISCH-PHARM. FABRIK GES.M.B.H	AUSTRIA	8426	2015	01
COMBINATIONS	IONOLYTE	SOLUTION FOR INFUSION		FRESENIUS KABI ROMANIA SR.L.	FRANCE	8314	2015	01
COMBINATIONS	KALCIPOS - D FORTE 500mg/800 IU	CHEWABLE TABLETS	500mg/800 IU	MEDA AB	SWEDEN	8441	2015	01
COMBINATIONS	METEOSPASMYL 60 mg/300 mg	SOFT CAPSULES	60mg/ 300mg	LABORATOIRES MAYOLY SPINDLER	FRANCE	8347	2015	01

COMBINATIONS	PICOPREP	POWDER FOR ORAL SOLUTION		FERRING GMBH	GERMANY	8454	2015	01
COMBINATIONS	POLYGYNAX	SOFT VAGINAL CAPSULES		LABORATOIRE INNOTECH INTERNATIONAL	FRANCE	8321	2015	01
COMBINATIONS	REVIGRIP HOT LEMON 500 mg/200mg/10mg	POWDER FOR ORAL SOLUTION	500mg/200 mg/10mg	WRAFTON LABORATORIES LIMITED	GREAT BRITAIN	8300	2015	01
COMBINATIONS	REVIGRIP HOT LEMON MAX 1000mg/200mg/ 12.2mg	POWDER FOR ORAL SOLUTION	1000 mg/ 200mg/ 12.2mg	WRAFTON LABORATORIES LIMITED	GREAT BRITAIN	8301	2015	01
COMBINATIONS	STREPSILS CU AROMA DE PRUNE 0.6mg/1.2mg	LOZENGES	0.6mg/1.2mg	RECKITT BENCKISER HEALTHCARE LTD.	GREAT BRITAIN	8356	2015	01
COMBINATIONS	STREPSILS EUCALIPT 0.6mg/1.2mg	LOZENGES	0.6mg/1.2mg	RECKITT BENCKISER HEALTHCARE LTD.	GREAT BRITAIN	8355	2015	01
COMBINATIONS	VITALIPID N ADULT	CONCENTRATE FOR EMULSION FOR INFUSION		FRESENIUS KABI AB	SWEDEN	8308	2015	01
COMBINATIONS	VITALIPID N INFANT	CONCENTRATE FOR EMULSION FOR INFUSION		FRESENIUS KABI AB	SWEDEN	8309	2015	01
COMBINATIONS	VITAMINA B COMPLEX EIPICO	SYRUP		E.I.P.I.CO. MED S.R.L.	ROMANIA	8367	2015	01
COMBINATIONS (ETINILESTRADIOLUM + DROSPIRENONUM)	DAYLETTE 0.02mg/3mg	FILM-COATED TABLETS	0.02mg/3mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	8393	2015	01

COMBINATIONS (ETINILESTRADIOLUM + DROSPIRENONUM)	DAYLLA 0.02mg/3mg	FILM-COATED TABLETS	0.02mg/3mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	8392	2015	01
COMBINATIONS (ROSUVASTATINUM+ AMLODIPINUM)	ROSUDAPIN 10 g/10mg	FILM-COATED TABLETS	10mg/ 10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	8266	2015	01
COMBINATIONS (ROSUVASTATINUM+ AMLODIPINUM)	ROSUDAPIN 10mg/5mg	FILM-COATED TABLETS	10mg/ 5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	8265	2015	01
COMBINATIONS (ROSUVASTATINUM+ AMLODIPINUM)	ROSUDAPIN 15mg/10mg	FILM-COATED TABLETS	15mg/ 10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	8268	2015	01
COMBINATIONS (ROSUVASTATINUM+ AMLODIPINUM)	ROSUDAPIN 15mg/5mg	FILM-COATED TABLETS	15mg/ 5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	8267	2015	01
COMBINATIONS (ROSUVASTATINUM+ AMLODIPINUM)	ROSUDAPIN 20mg/10mg	FILM-COATED TABLETS	20mg/ 10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	8270	2015	01
COMBINATIONS (ROSUVASTATINUM+ AMLODIPINUM)	ROSUDAPIN 20mg/5mg	FILM-COATED TABLETS	20mg/ 5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	8269	2015	01
COMBINATIONS (ARTICAINUM+ ADRENALINUM)	ARTIDENTAL 40mg/0.005mg/ml	SOLUTION FOR INJECTION	40mg/ 0.005 mg/ml	INIBSA DENTAL S.L.U	SPAIN	8234	2015	01

COMBINATIONS (ARTICAINUM+ ADRENALINUM)	ARTIDENTAL 40mg/0.01mg/ml	SOLUTION FOR INJECTION	40mg 0.01mg/ml	INIBSA DENTAL S.L.U	SPAIN	8234	2015	01
COMBINATIONS (ETINILESTRADIOLUM + DROSPIRENONUM)	BELUSHA 0.02mg/3mg	FILM-COATED TABLETS	0.02mg/3mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	8394	2015	01
COMBINATIONS (ETINILESTRADIOLUM + DROSPIRENONUM)	XANTHADU 0.02mg/3mg	FILM-COATED TABLETS	00,2mg/3mg	LABORATORIOS LICONSA, S.A.	SPAIN	8397	2015	01
COMBINATIONS (FACTORI DE COAGULARE)	PRONATIV 1000 IU	POWDER AND SOLVENT FOR SOLUTION FOR INFUSION	1000 IU	OCTAPHARMA (IP) LTD.	GREAT BRITAIN	8245	2015	01
COMBINATIONS (FACTORI DE COAGULARE)	PROTHROMPLEX TOTAL 600 IU	POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	600 IU	BAXTER AG	AUSTRIA	8401	2015	01
COMBINATIONS (IBUPROFENUM+ CODEINUM)	IBUVALEN DUO 200mg/12.8mg	FILM-COATED TABLETS	200mg/12.8 mg	POLISANO PHARMACEUTICALS S.R.L.	ROMANIA	8177	2015	01
COMBINATIONS (RAMIPRILUM + AMLODIPINUM)	VIVACE PLUS 10mg/10mg	CAPSULES	10mg/ 10mg	ACTAVIS GROUP PTC EHF.	ICELAND	8210	2015	01
COMBINATIONS (RAMIPRILUM + AMLODIPINUM)	VIVACE PLUS 10mg/5mg	CAPSULES	10mg/ 5mg	ACTAVIS GROUP PTC EHF.	ICELAND	8209	2015	01
COMBINATIONS (RAMIPRILUM + AMLODIPINUM)	VIVACE PLUS 5mg/10mg	CAPSULES	5mg/ 10mg	ACTAVIS GROUP PTC EHF.	ICELAND	8208	2015	01
COMBINATIONS (RAMIPRILUM + AMLODIPINUM)	VIVACE PLUS 5mg/5mg	CAPSULES	5mg/ 5mg	ACTAVIS GROUP PTC EHF.	ICELAND	8207	2015	01

COMPLEX DE ANTIINHIBITORI AI COAGULARII	FEIBA 25U/ml	POWDER AND SOLVENT FOR SOLUTION FOR INFUSION	25U/ml	BAXALTA INNOVATIONS GMBH	AUSTRIA	8463	2015	01
COMPLEX DE ANTIINHIBITORI AI COAGULARII	FEIBA 50U/ml	POWDER AND SOLVENT FOR SOLUTION FOR INFUSION	50U/ml	BAXALTA INNOVATIONS GMBH	AUSTRIA	8464	2015	01
DICLOFENACUM	DICLOREUM 150mg	PROLONGED-RELEASE CAPSULES	150mg	ALFA WASSERMANN S.P.A.	ITALY	8293	2015	01
DICLOFENACUM	TRATUL 30mg/ml	SOLUTION FOR INJECTION	30mg/ml	GEROT PHARMAZEUTIKA GES.M.B.H	AUSTRIA	8345	2015	01
DIVERSE	QUINAX 0.15mg/ml	EYE DROPS, SOLUTION	0.15mg/ml	ALCON-COUVREUR N.V.	BELGIUM	8407	2015	01
DOXAZOSINUM	KAMIREN XL 4mg (see C02CA04)	PROLONGED-RELEASE TABLETS	4mg	KRKA D.D., NOVO MESTO	SLOVENIA	8445	2015	01
DOXAZOSINUM	KAMIREN XL 4mg (see G04CAN1)	PROLONGED-RELEASE TABLETS	4mg	KRKA D.D., NOVO MESTO	SLOVENIA	8445	2015	01
DULOXETINUM	DULASOLAN 30mg	GASTRORESISTANT CAPSULES	30mg	G.L. PHARMA GMBH	AUSTRIA	8240	2015	01
DULOXETINUM	DULASOLAN 60mg	GASTRORESISTANT CAPSULES	60mg	G.L. PHARMA GMBH	AUSTRIA	8241	2015	01
DULOXETINUM	DULOXETINA AUROBINDO 30mg	GASTRORESISTANT CAPSULES	30mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	8242	2015	01
DULOXETINUM	DULOXETINA AUROBINDO 60mg	GASTRORESISTANT CAPSULES	60mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	8243	2015	01

DULOXETINUM	DULOXETINA STADA 30mg	GASTRORESISTANT CAPSULES	30mg	STADA M&D SRL	ROMANIA	8235	2015	01
DULOXETINUM	DULOXETINA STADA 60mg	GASTRORESISTANT CAPSULES	60mg	STADA M&D SRL	ROMANIA	8236	2015	01
DULOXETINUM	DUTOR 20mg	GASTRORESISTANT CAPSULES	20mg	DR. EBELING & ASSOC. GMBH	GERMANY	8335	2015	01
DULOXETINUM	DUTOR 30mg	GASTRORESISTANT CAPSULES	30mg	DR. EBELING & ASSOC. GMBH	GERMANY	8336	2015	01
DULOXETINUM	DUTOR 40mg	GASTRORESISTANT CAPSULES	40mg	DR. EBELING & ASSOC. GMBH	GERMANY	8337	2015	01
DULOXETINUM	DUTOR 60mg	GASTRORESISTANT CAPSULES	60mg	DR. EBELING & ASSOC. GMBH	GERMANY	8338	2015	01
DUTASTERIDUM	DUTASTERIDA ACTAVIS 0.5mg	SOFT CAPSULES	0.5mg	ACTAVIS GROUP PTC EHF.	ICELAND	8260	2015	01
ESCITALOPRAMUM	CIPRALEX MELTZ 20mg	ORODISPERSIBLE TABLETS	20mg	H. LUNDBECK A/S	DENMARK	8285	2015	02
ESCITALOPRAMUM	CIPRALEX MELTZ 10mg	ORODISPERSIBLE TABLETS	10mg	H. LUNDBECK A/S	DENMARK	8284	2015	02
ESOMEPRAZOLUM	NEXIUM 20mg	GASTRORESISTANT TABLETS	20mg	ASTRAZENECA AB	SWEDEN	8423	2015	01

ESOMEPRAZOLUM	NEXIUM 40mg	GASTRORESISTANT TABLETS	40mg	ASTRAZENECA AB	SWEDEN	8424	2015	01
EXEMESTANUM	AROSTANIL 25mg	FILM-COATED TABLETS	25mg	SANDOZ S.R.L.	ROMANIA	8299	2015	01
EXEMESTANUM	ESCEPRAN 25mg	FILM-COATED TABLETS	25mg	KRKA, D.D., NOVO MESTO	SLOVENIA	8286	2015	01
EXEMESTANUM	EXEMESTAN GLENMARK 25mg	FILM-COATED TABLETS	25mg	GLENMARK PHARMACEUTICALS S.R.O.	THE CZECH REPUBLIC	8255	2015	01
EXEMESTANUM	NATERAN 25mg	FILM-COATED TABLETS	25mg	SYNTHON BV	HOLLAND	8290	2015	01
FEXOFENADINUM	TELFAST 120mg	FILM-COATED TABLETS	120mg	SANOFI - AVENTIS ROMANIA S.R.L.	ROMANIA	8315	2015	01
FLUCONAZOLUM	FLUCONAZOL 150mg	CAPSULES	150mg	SLAVIA PHARMA S.R.L.	ROMANIA	8461	2015	01
FLUCONAZOLUM	FLUCONAZOL 50mg	CAPSULES	50mg	SLAVIA PHARMA S.R.L.	ROMANIA	8460	2015	01
FLUMAZENILUM	ANEXATE 0.1mg/ml	SOLUTION FOR INJECTION	0.1mg/ml	ROCHE ROMANIA S.R.L.	ROMANIA	8409	2015	01
GLICLAZIDUM	GLICLAZIDA LUPIN 60mg	PROLONGED-RELEASE TABLETS	60mg	LUPIN (EUROPE) LTD.	GREAT BRITAIN	8292	2015	01
GOSERELINUM	RESELIGO 10.8mg	IMPLANT IN SERINGA PREUMPLUTA	10.8mg	ALVOGEN IPCO S.AR.L.	LUXEMBOURG	8396	2015	01
GOSERELINUM	RESELIGO 3.6mg	IMPLANT IN SERINGA PREUMPLUTA	3.6mg	ALVOGEN IPCO S.AR.L.	LUXEMBOURG	8436	2015	01

HALOPERIDOLUM	HALOPERIDOL-RICHTER 2mg/ml	PIC. ORALE-SOL.	2mg/ml	GEDEON RICHTER ROMANIA S.A.	ROMANIA	8349	2015	01
HOMEOPATE	CICADERMA	OINTMENT		BOIRON	FRANCE	8459	2015	01
IBUPROFENUM	ADVIL ULTRA 200mg	SOFT CAPSULES	200mg	PFIZER CORPORATION AUSTRIA GMBH	AUSTRIA	8319	2015	01
IBUPROFENUM	IBUFEN 200mg	FILM-COATED TABLETS	200mg	ANTIBIOTICE SA	ROMANIA	8318	2015	01
IMATINIBUM	IMATINIB ACTAVIS GROUP 100mg	FILM-COATED TABLETS	100mg	ACTAVIS GROUP PTC EHF.	ICELAND	8416	2015	01
IMATINIBUM	IMATINIB ACTAVIS GROUP 400mg	FILM-COATED TABLETS	400mg	ACTAVIS GROUP PTC EHF.	ICELAND	8417	2015	01
IMATINIBUM	IMATINIB STADA 100mg	FILM-COATED TABLETS	100mg	STADA HEMOFARM S.R.L.	ROMANIA	8289	2015	01
INDAPAMIDUM	INDAPAMID SR ZENTIVA 1.5mg	PROLONGED-RELEASE TABLETS	1.5mg	ZENTIVA S.A.	ROMANIA	8307	2015	01
INDAPAMIDUM	INDAPAMIDA ATB 1.5 mg	PROLONGED-RELEASE TABLETS	1.5mg	ANTIBIOTICE S.A.	ROMANIA	8176	2015	01
IOVERSOLUM	OPTIRAY 240	SOLUTION FOR INJECTION/INFUSION	509mg/ml	MALLINCKRODT DEUTSCHLAND GMBH	GERMANY	8363	2015	01
IOVERSOLUM	OPTIRAY 300	SOLUTION FOR INJECTION/INFUSION	636mg/ml	MALLINCKRODT DEUTSCHLAND GMBH	GERMANY	8364	2015	01
IOVERSOLUM	OPTIRAY 320	SOLUTION FOR INJECTION/INFUSION	678mg/ml	MALLINCKRODT DEUTSCHLAND GMBH	GERMANY	8365	2015	01

IOVERSOLUM	OPTIRAY 350	SOLUTION FOR INJECTION/INFUSION	741mg/ml	MALLINCKRODT DEUTSCHLAND GMBH	GERMANY	8366	2015	01
IRINOTECANUM	IRINOTECAN KABI 20mg/ml	CONCENTRATE FOR SOLUTION FOR INFUSION	20mg/ml	FRESENIUS KABI ONCOLOGY PLC.	GREAT BRITAIN	8422	2015	01
LACTULOSUM	DUPHALAC FRUIT 667mg/ml	ORAL SOLUTION	667mg/ml	MYLAN HEALTHCARE GMBH	GERMANY	8291	2015	01
LEVOFLOXACINUM	LEVOTOR 250mg	FILM-COATED TABLETS	250mg	TORRENT PHARMA S.R.L.	ROMANIA	8196	2015	01
LEVOFLOXACINUM	LEVOTOR 500 mg	FILM-COATED TABLETS	500mg	TORRENT PHARMA S.R.L.	ROMANIA	8197	2015	01
LEVONORGESTRELUM	POSTINOR-2 750micrograms	TABLETS	750 micro-grams	GEDEON RICHTER PLC.	HUNGARY	8348	2015	01
LINEZOLIDUM	LINEZOLID KRKA 600mg	FILM-COATED TABLETS	600mg	KRKA, D.D., NOVO MESTO	SLOVENIA	8462	2015	01
LISINOPRILUM	LISINOPRIL SANDOZ 10mg	TABLETS	10mg	HEXAL AG	GERMANY	8443	2015	01
LISINOPRILUM	LISINOPRIL SANDOZ 20mg	TABLETS	20mg	HEXAL AG	GERMANY	8444	2015	01
MANNITOLUM	OSMOFUNDIN 150 mg/ml	SOLUTION FOR INFUSION	150mg/ml	B. BRAUN MELSUNGEN AG	GERMANY	8247	2015	01
MEROPENEMUM	MEROPENEM ARENA 1g	POWDER FORSOLUTION FOR INJECTION/INFUSION	1g	ARENA GROUP S.A.	ROMANIA	8380	2015	01
MEROPENEMUM	MEROPENEM ARENA 500mg	POWDER FORSOLUTION FOR INJECTION/INFUSION	500mg	ARENA GROUP S.A.	ROMANIA	8379	2015	01

MEROPENEMUM	MEROPENEM ZENTIVA 1000mg	POWDER FOR SOLUTION FOR INJECTION/INFUSION	1000 mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	8259	2015	01
MEROPENEMUM	MEROPENEM ZENTIVA 500mg	POWDER FOR SOLUTION FOR INJECTION/INFUSION	500 mg	ZENTIVA, K.S.	THE CZECH REPUBLIC	8258	2015	01
METAMIZOLUM NATRIUM	MIMETANAL 500mg	TABLETS	500mg	MIDAS PHARMA GMBH	GERMANY	8359	2015	01
METHADONUM	METADON BIOEEL 20mg	TABLETS	20mg	BIO EEL SRL	ROMANIA	8411	2015	01
METHADONUM	METADON BIOEEL 5mg	TABLETS	5mg	BIO EEL SRL	ROMANIA	8410	2015	01
METHOTREXATUM	NAMAXIR 10mg	SOLUTION FOR INJECTION IN SERINGA PREUMPLUTA	10mg	ACTAVIS GROUP PTC EHF.	ICELAND	8213	2015	01
METHOTREXATUM	NAMAXIR 12.5mg	SOLUTION FOR INJECTION IN SERINGA PREUMPLUTA	12.5mg	ACTAVIS GROUP PTC EHF.	ICELAND	8214	2015	01
METHOTREXATUM	NAMAXIR 15mg	SOLUTION FOR INJECTION IN SERINGA PREUMPLUTA	15mg	ACTAVIS GROUP PTC EHF.	ICELAND	8215	2015	01
METHOTREXATUM	NAMAXIR 17.5mg	SOLUTION FOR INJECTION IN SERINGA PREUMPLUTA	17.5mg	ACTAVIS GROUP PTC EHF.	ICELAND	8216	2015	01
METHOTREXATUM	NAMAXIR 2.5mg	SOLUTION FOR INJECTION IN SERINGA PREUMPLUTA	2.5mg	ACTAVIS GROUP PTC EHF.	ICELAND	8211	2015	01
METHOTREXATUM	NAMAXIR 20mg	SOLUTION FOR INJECTION IN SERINGA PREUMPLUTA	20mg	ACTAVIS GROUP PTC EHF.	ICELAND	8217	2015	01

METHOTREXATUM	NAMAXIR 22.5mg	SOLUTION FOR INJECTION IN SERINGA PREUMPLUTA	22.5mg	ACTAVIS GROUP PTC EHF.	ICELAND	8218	2015	01
METHOTREXATUM	NAMAXIR 25mg	SOLUTION FOR INJECTION IN SERINGA PREUMPLUTA	25mg	ACTAVIS GROUP PTC EHF.	ICELAND	8219	2015	01
METHOTREXATUM	NAMAXIR 27.5mg	SOLUTION FOR INJECTION IN SERINGA PREUMPLUTA	27.5mg	ACTAVIS GROUP PTC EHF.	ICELAND	8220	2015	01
METHOTREXATUM	NAMAXIR 30mg	SOLUTION FOR INJECTION IN SERINGA PREUMPLUTA	30mg	ACTAVIS GROUP PTC EHF.	ICELAND	8221	2015	01
METHOTREXATUM	NAMAXIR 7.5mg	SOLUTION FOR INJECTION IN SERINGA PREUMPLUTA	7.5mg	ACTAVIS GROUP PTC EHF.	ICELAND	8212	2015	01
METOPROLOLUM	METOPROLOL TERAPIA 100mg	TABLETS	100mg	TERAPIA SA	ROMANIA	8317	2015	01
METOPROLOLUM	METOPROLOL TERAPIA 50mg	TABLETS	50mg	TERAPIA SA	ROMANIA	8316	2015	01
MINOXIDILUM	ALOPEXY 20mg/ml	SOL. CUT.	20mg/ml	PIERRE FABRE DERMATOLOGIE	FRANCE	8246	2015	01
MONTELUKASTUM	MONTELUKAST ACTAVIS 10mg	FILM-COATED TABLETS	10mg	ACTAVIS GROUP PTC EHF	ICELAND	8421	2015	01
MONTELUKASTUM	MONTELUKAST ACTAVIS 4mg	CHEWABLE TABLETS	4mg	ACTAVIS GROUP PTC EHF	ICELAND	8419	2015	01

MONTELUKASTUM	MONTELUKAST ACTAVIS 5mg	CHEWABLE TABLETS	5mg	ACTAVIS GROUP PTC EHF	ICELAND	8420	2015	01
NEBIVOLOLUM	NEBIVOLOL ACTAVIS 5mg	TABLETS	5mg	ACTAVIS S.R.L.	ROMANIA	8457	2015	01
NORFLOXACINUM	NORFLOXACIN LAROPHARM 400mg	FILM-COATED TABLETS	400mg	LAROPHARM S.R.L.	ROMANIA	8249	2015	01
OFLOXACINUM	FLOXAL 3mg/ml	PICATURI OFT., SOL.	3mg/ml	DR. GERHARD MANN CHEM-PHARM. FABRIK GMBH	GERMANY	8455	2015	01
OFLOXACINUM	FLOXAL3mg/ml	UNG. OFT.	3mg/ml	DR. GERHARD MANN CHEM-PHARM. FABRIK GMBH	GERMANY	8456	2015	01
OLANZAPINUM	OLANZAPINA ACTAVIS 10mg	FILM-COATED TABLETS	10mg	ACTAVIS GROUP PTC EHF.	ICELAND	8206	2015	01
OLANZAPINUM	OLANZAPINA ACTAVIS 5mg	FILM-COATED TABLETS	5mg	ACTAVIS GROUP PTC EHF.	ICELAND	8205	2015	01
OLANZAPINUM	OLANZAPINA TERAPIA 10mg	ORODISPERSIBLE TABLETS	10mg	TERAPIA S.A.	ROMANIA	8295	2015	01
OLANZAPINUM	OLANZAPINA TERAPIA 15mg	ORODISPERSIBLE TABLETS	15mg	TERAPIA S.A.	ROMANIA	8296	2015	01

OLANZAPINUM	OLANZAPINA TERAPIA 20mg	ORODISPERSIBLE TABLETS	20mg	TERAPIA S.A.	ROMANIA	8297	2015	01
OLANZAPINUM	OLANZAPINA TERAPIA 5mg	ORODISPERSIBLE TABLETS	5mg	TERAPIA S.A.	ROMANIA	8294	2015	01
OLOPATADINUM	OLOPATADINA ABDI 1mg/ml	EYE DROPS, SOLUTION	1mg/ml	ABDI FARMA, UNIPESSOAL LDA.	PORTUGAL	8204	2015	01
OXACILLINUM	OXACILINA FORTE 500mg	CAPSULES	500mg	FARMEX COMPANY S.R.L.	ROMANIA	8406	2015	01
PANTOPRAZOLUM	GESOFLUX 20mg	GASTRORESISTANT TABLETS	20mg	G.L. PHARMA GMBH	AUSTRIA	8452	2015	01
PANTOPRAZOLUM	GESOFLUX 40mg	GASTRORESISTANT TABLETS	40mg	G.L. PHARMA GMBH	AUSTRIA	8453	2015	01
PARACETAMOLUM	PARACETAMOL KABI 10mg/ml	SOLUTION FOR INFUSION	10mg/ml	FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	8237	2015	01
PARACETAMOLUM	PARAFIZZ 1000mg	EFFERVESCENT TABLETS	1000 mg	CIPLA EUROPE NV	BELGIUM	8283	2015	01
PARACETAMOLUM	PARAFIZZ 500mg	EFFERVESCENT TABLETS	500mg	CIPLA EUROPE NV	BELGIUM	8282	2015	01
PARICALCITOLUM	PARICALCITOL MEDICE 2 micrograms/ml	SOLUTION FOR INJECTION	2micrograms /ml	MEDICE ARZNEIMITTEL PUTTER GMBH & CO. KG	GERMANY	8339	2015	01

PARICALCITOLUM	PARICALCITOL MEDICE 5 micrograms/ml	SOLUTION FOR INJECTION	5micrograms /ml	MEDICE ARZNEIMITTEL PUTTER GMBH & CO. KG	GERMANY	8340	2015	01
PIRACETAMUM	PIRACETAM FARMEX 400mg	TABLETS	400mg	FARMEX COMPANY S.R.L.	ROMANIA	8369	2015	01
PIRACETAMUM	PIRACETAM SINTOFARM 400mg	TABLETS	400mg	SINTOFARM S.A.	ROMANIA	8368	2015	01
PLANTE (SUNATOARE)	REMOTIV 250mg	FILM-COATED TABLETS	250mg	EWOPHARMA INTERNATIONAL, S.R.O.	SLOVAKIA	8271	2015	01
PREGABALINUM	BRIEKA 150mg	CAPSULES	150mg	ACTAVIS GROUP PTC EHF.	ICELAND	8361	2015	01
PREGABALINUM	BRIEKA 300mg	CAPSULES	300mg	ACTAVIS GROUP PTC EHF.	ICELAND	8362	2015	01
PREGABALINUM	BRIEKA 75mg	CAPSULES	75mg	ACTAVIS GROUP PTC EHF.	ICELAND	8360	2015	01
PREGABALINUM	PREGABALINA AUROBINDO 150mg	CAPSULES	150mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	8280	2015	01
PREGABALINUM	PREGABALINA AUROBINDO 300mg	CAPSULES	300mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	8281	2015	01
PREGABALINUM	PREGABALINA AUROBINDO 75mg	CAPSULES	75mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	8279	2015	01

PREGABALINUM	PREGABALINA TEVA 20mg/ml	ORAL SOLUTION	20mg/ml	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	8341	2015	01
PREGABALINUM	PREGABALINA TORRENT 150mg	CAPSULES	150mg	TORRENT PHARMA SRL	ROMANIA	8450	2015	01
PREGABALINUM	PREGABALINA TORRENT 300mg	CAPSULES	300mg	TORRENT PHARMA SRL	ROMANIA	8451	2015	01
PREGABALINUM	PREGABALINA TORRENT 75mg	CAPSULES	75mg	TORRENT PHARMA SRL	ROMANIA	8449	2015	01
PREGABALINUM	PREGAMID 100mg	CAPSULES	100mg	G.L. PHARMA GMBH	AUSTRIA	8325	2015	01
PREGABALINUM	PREGAMID 150mg	CAPSULES	150mg	G.L. PHARMA GMBH	AUSTRIA	8326	2015	01
PREGABALINUM	PREGAMID 200mg	CAPSULES	200mg	G.L. PHARMA GMBH	AUSTRIA	8327	2015	01
PREGABALINUM	PREGAMID 25mg	CAPSULES	25mg	G.L. PHARMA GMBH	AUSTRIA	8322	2015	01
PREGABALINUM	PREGAMID 300mg	CAPSULES	300mg	G.L. PHARMA GMBH	AUSTRIA	8328	2015	01
PREGABALINUM	PREGAMID 50mg	CAPSULES	50mg	G.L. PHARMA GMBH	AUSTRIA	8323	2015	01
PREGABALINUM	PREGAMID 75mg	CAPSULES	75mg	G.L. PHARMA GMBH	AUSTRIA	8324	2015	01
PREGABALINUM	RABAKIR 100 mg	CAPSULES	100mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	8432	2015	01

PREGABALINUM	RABAKIR 150mg	CAPSULES	150mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	8433	2015	01
PREGABALINUM	RABAKIR 200mg	CAPSULES	200mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	8434	2015	01
PREGABALINUM	RABAKIR 25 mg	CAPSULES	25mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	8429	2015	01
PREGABALINUM	RABAKIR 300mg	CAPSULES	300mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	8435	2015	01
PREGABALINUM	RABAKIR 50mg	CAPSULES	50mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	8430	2015	01
PREGABALINUM	RABAKIR 75mg	CAPSULES	75mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	8431	2015	01
PROTEINE PLASMATICE UMANE DE GRUP SANGUIN A,B,AB,0	OCTAPLASLG 45-70mg/ml	SOLUTION FOR INFUSION	45-70 mg/ml	OCTAPHARMA (IP) LIMITED	GREAT BRITAIN	8288	2015	01
PROTIONAMIDUM	PETEHA 250mg	FILM-COATED TABLETS	250 mg	PHARMA S.A.	ROMANIA	179	2015	01
QUETIAPINUM	Q MIND 100mg	FILM-COATED TABLETS	100mg	TORRENT PHARMA S.R.L.	ROMANIA	8351	2015	01
QUETIAPINUM	Q MIND 150mg	FILM-COATED TABLETS	150mg	TORRENT PHARMA S.R.L.	ROMANIA	8352	2015	01
QUETIAPINUM	Q MIND 200mg	FILM-COATED TABLETS	200mg	TORRENT PHARMA S.R.L.	ROMANIA	8353	2015	01

QUETIAPINUM	Q MIND 25mg	FILM-COATED TABLETS	25mg	TORRENT PHARMA S.R.L.	ROMANIA	8350	2015	01
QUETIAPINUM	Q MIND 300mg	FILM-COATED TABLETS	300mg	TORRENT PHARMA S.R.L.	ROMANIA	8354	2015	01
RADIOFARMACEUTICE (CLORURA DE FLUOROCOLINA 18 F)	IASOCHOLINE 1GBq/ml	SOLUTION FOR INJECTION	1GBq/ml	IASON GMBH	AUSTRIA	8391	2015	01
RASAGILINUM	RALAGO 1mg	TABLETS	1mg	KRKA, D.D., NOVO MESTO	SLOVENIA	8287	2015	01
RISPERIDONUM	RISPERIDONE TEVA 1mg	FILM-COATED TABLETS	1mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	8387	2015	01
RISPERIDONUM	RISPERIDONE TEVA 2mg	FILM-COATED TABLETS	2mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	8388	2015	01
RISPERIDONUM	RISPERIDONE TEVA 3mg	FILM-COATED TABLETS	3mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	8389	2015	01
RISPERIDONUM	RISPERIDONE TEVA 4mg	FILM-COATED TABLETS	4mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	8390	2015	01
RIVASTIGMINUM	RIVASTIGMINA AMW 4.6 mg/24 h	TRANSDERMAL PATCH	4.6mg/24h	AMW GMBH ARZNEIMITTELWERK WARNGAU	GERMANY	8398	2015	01
RIVASTIGMINUM	RIVASTIGMINA AMW 9.5mg/24 h	TRANSDERMAL PATCH	9.5mg/24h	AMW GMBH ARZNEIMITTELWERK WARNGAU	GERMANY	8399	2015	01
ROSUVASTATINUM	ROSUVASTATINA RATIOPHARM 10mg	FILM-COATED TABLETS	10mg	RATIOPHARM GMBH	GERMANY	8414	2015	01

ROSUVASTATINUM	ROSUVASTATINA RATIOPHARM 20mg	FILM-COATED TABLETS	20mg	RATIOPHARM GMBH	GERMANY	8415	2015	01
SERENOA REPENS	PROSTA URGENIN UNO 320 mg	SOFT CAPSULES	320mg	MADAUS GMBH	GERMANY	8248	2015	01
SERENOA REPENS	PROSTAMOL UNO	SOFT CAPSULES	320mg	BERLIN-CHEMIE AG (MENARINI GROUP)	GERMANY	8272	2015	01
SERTRALINUM	SERLIFT 100mg	FILM-COATED TABLETS	100mg	TERAPIA SA	ROMANIA	8404	2015	01
SERTRALINUM	SERLIFT 50mg	FILM-COATED TABLETS	50mg	TERAPIA SA	ROMANIA	8403	2015	01
SERTRALINUM	ZOLOFT 100mg	FILM-COATED TABLETS	100mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	8228	2015	01
SERTRALINUM	ZOLOFT 20mg/ml	CONCENTRATE FOR ORAL SOLUTION	20mg/ml	PFIZER EUROPE MA EEIG	GREAT BRITAIN	8229	2015	01
SERTRALINUM	ZOLOFT 50mg	FILM-COATED TABLETS	50mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	8227	2015	01
SEVOFLURANUM	SOJOURN	INHALATION VAPOUR, LIQUID		PIRAMAL HEALTHCARE UK LIMITED	GREAT BRITAIN	8418	2015	01
SILDENAFILUM	TAXIER 100mg	FILM-COATED TABLETS	100mg	ZENTIVA A.S.	SLOVAKIA	8358	2015	01
SILDENAFILUM	TAXIER 50mg	FILM-COATED TABLETS	50mg	ZENTIVA A.S.	SLOVAKIA	8357	2015	01
SILIBINUM	SILIBINA ARENA 35mg	TABLETS	35mg	ARENA GROUP S.A.	ROMANIA	8320	2015	01
SIMVASTATINUM	SIMVAHEXAL 20mg	FILM-COATED TABLETS	20mg	HEXAL AG	GERMANY	8374	2015	01
SIMVASTATINUM	SIMVAHEXAL 40mg	FILM-COATED TABLETS	40mg	HEXAL AG	GERMANY	8375	2015	01

SOLIFENACINUM SUCCINATE	VESICARE 1mg/ml	ORAL SUSPENSION	1mg/ml	ASTELLAS PHARMA EUROPE B.V.	HOLLAND	8442	2015	01
SUCRALFATUM	VENTER 1g	TABLETS	1g	KRKA D.D. NOVO MESTO	SLOVENIA	8373	2015	01
SULTAMICILLINUM	UNASYN 250mg/ml	POWDER FOR ORAL SUSPENSION	250mg/5ml	PFIZER EUROPE MA EEIG	GREAT BRITAIN	8274	2015	01
SULTAMICILLINUM	UNASYN 375mg	FILM-COATED TABLETS	375mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	8273	2015	01
TADALAFILUM	TADALAFIL TEVA 10mg	FILM-COATED TABLETS	10mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	8331	2015	01
TADALAFILUM	TADALAFIL TEVA 2.5mg	FILM-COATED TABLETS	2.5mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	8329	2015	01
TADALAFILUM	TADALAFIL TEVA 20mg	FILM-COATED TABLETS	20mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	8332	2015	01
TADALAFILUM	TADALAFIL TEVA 5mg	FILM-COATED TABLETS	5mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	8330	2015	01
TEICOPLANINUM	TEICOPLANINA SANDOZ 100mg	POWDER AND SOLVENT FOR SOLUTION FOR INJECTION/INFUSION OR ORAL SOLUTION	100mg	SANDOZ S.R.L.	ROMANIA	8222	2015	01

TEICOPLANINUM	TEICOPLANINA SANDOZ 200mg	POWDER AND SOLVENT FOR SOLUTION FOR INJECTION/INFUSION OR ORAL SOLUTION	200mg	SANDOZ S.R.L.	ROMANIA	8223	2015	01
TEICOPLANINUM	TEICOPLANINA SANDOZ 400mg	POWDER AND SOLVENT FOR SOLUTION FOR INJECTION/INFUSION OR ORAL SOLUTION	400mg	SANDOZ S.R.L.	ROMANIA	8224	2015	01
TELMISARTANUM	TELMISARTAN FAIR-MED 20mg	TABLETS	20mg	FAIR-MED HEALTHCARE GMBH	GERMANY	8201	2015	01
TELMISARTANUM	TELMISARTAN FAIR-MED 40mg	TABLETS	40mg	FAIR-MED HEALTHCARE GMBH	GERMANY	8202	2015	01
TELMISARTANUM	TELMISARTAN FAIR-MED 80mg	TABLETS	80mg	FAIR-MED HEALTHCARE GMBH	GERMANY	8203	2015	01
TESTOSTERONUM	ANDROGEL 50mg	GEL	50mg	LABORATOIRES BESINS INTERNATIONAL	FRANCE	8425	2015	01
TETRACYCLINUM	TETRACICLINA ATB 30 mg/g	OINTMENT	30mg/g	ANTIBIOTICE S.A.	ROMANIA	8346	2015	01
TIOTROPIUM	FAVYND 18 micrograms	INHALATION POWDER, CAPSULES	18micrograms	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	GERMANY	8231	2015	01
TIOTROPIUM	SRIVASSO 18 micrograms	INHALATION POWDER, CAPSULES	18micrograms	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	GERMANY	8230	2015	01

TOBRAMYCINUM	TOBI 300mg/5ml	SOLUTION FOR INHALATION VIA A NEBULISER	300mg/5ml	NOVARTIS PHARMA GMBH	GERMANY	8377	2015	01
TOBRAMYCINUM	TOBREX 2 X 3mg/ml	EYE DROPS, SOLUTION	3mg/ml	ALCON-COUVREUR N.V.	BELGIUM	8413	2015	01
TOBRAMYCINUM	TOBREX 3mg/ml	EYE DROPS, SOLUTION	3mg/ml	ALCON COUVREUR NV	BELGIUM	8412	2015	01
TOXINA BOTULINICA DE TIP A	BOTOX 100 UNITATS ALLERGAN	POWDER FOR SOLUTION FOR INJECTION	100 units	ALLERGAN PHARMACEUTICALS IRELAND	IRELAND	8184	2015	01
TOXINA BOTULINICA DE TIP A	BOTOX 200 UNITATI ALLERGAN	POWDER FOR SOLUTION FOR INJECTION	200 units	ALLERGAN PHARMACEUTICALS IRELAND	IRELAND	8185	2015	01
TOXINA BOTULINICA DE TIP A	BOTOX 50 UNITATS ALLERGAN	POWDER FOR SOLUTION FOR INJECTION	50 units	ALLERGAN PHARMACEUTICALS IRELAND	IRELAND	8183	2015	01
VACCIN GRIPAL INACTIVAT	FLUARIX	SUSPECTION FOR INJECTION IN PRE-FILLED SYRINGE		GLAXO-SMITHKLINE BIOLOGICALS S.A.	BELGIUM	8244	2015	01
VERAPAMILUM	VERAPAMIL 40mg	LOZENGES	40mg	SANOFI ROMANIA S.R.L.	ROMANIA	8427	2015	01
VERAPAMILUM	VERAPAMIL 80mg	LOZENGES	80mg	SANOFI ROMANIA S.R.L.	ROMANIA	8428	2015	01
VINPOCETINUM	CAVINTON 5mg	TABLETS	5mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	8305	2015	01

VINPOCETINUM	CAVINTON FORTE 10mg	TABLETS	10mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	8306	2015	01

Medicinal products authorised through centralised procedure by the EMA, notified for marketing in Romania during the 4th quarter of 2015

INN	Invented name	Pharmaceutical form	Strength	MAH	Country	MA number		
ARIPIPRAZOLUM	ARIPIPRAZOLE ACCORD 5mg	TABLETS	5mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	1045	2015	02
ARIPIPRAZOLUM	ARIPIPRAZOLE ACCORD 10mg	TABLETS	10mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	1045	2015	08
ARIPIPRAZOLUM	ARIPIPRAZOLE ACCORD 15mg	TABLETS	15mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	1045	2015	13
ARIPIPRAZOLUM	ARIPIPRAZOLE ACCORD 30mg	TABLETS	30mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	1045	2015	20
BLINATUMOMABUM	BLINCYTO 38.5 micrograms	POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	38.5micrograms	AMGEN EUROPE B.V.	HOLLAND	1047	2015	01
CARFILZOMIBUM	KYPROLIS 60mg	POWDER FOR SOLUTION FOR INFUSION	60mg	AMGEN EUROPE B.V.	HOLLAND	1060	2015	01
COMBINATIONS (SACUBITRILUM+ VALSARTANUM)	ENTRESTO 24 mg/26mg	FILM-COATED TABLETS	24mg/ 26mg	NOVARTIS EUROPHARM LIMITED	GREAT BRITAIN	1058	2015	01
COMBINATIONS (SACUBITRILUM+ VALSARTANUM)	ENTRESTO 49mg/51mg	FILM-COATED TABLETS	49mg/ 51mg	NOVARTIS EUROPHARM LIMITED	GREAT BRITAIN	1058	2015	03
COMBINATIONS (SACUBITRILUM+ VALSARTANUM)	ENTRESTO 97mg/103mg	FILM-COATED TABLETS	97mg/ 103mg	NOVARTIS EUROPHARM LIMITED	GREAT BRITAIN	1058	2015	06
EFMOROCTOCOG ALFA	ELOCTA 250 IU	POWDER AND SOLVENT FOR	250 IU	BIOGEN IDEC LTD	GREAT BRITAIN	1046	2015	01

		SOLUTION FOR INJECTION						
EFMOROCTOCOG ALFA	ELOCTA 500 IU	POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	500 IU	BIOGEN IDEC LTD	GREAT BRITAIN	1046	2015	02
EFMOROCTOCOG ALFA	ELOCTA 750 IU	POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	750 IU	BIOGEN IDEC LTD	GREAT BRITAIN	1046	2015	03
EFMOROCTOCOG ALFA	ELOCTA 1000 IU	POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	1000 IU	BIOGEN IDEC LTD	GREAT BRITAIN	1046	2015	04
EFMOROCTOCOG ALFA	ELOCTA 1500 IU	POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	1500 IU	BIOGEN IDEC LTD	GREAT BRITAIN	1046	2015	05
EFMOROCTOCOG ALFA	ELOCTA 2000 IU	POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	2000 IU	BIOGEN IDEC LTD	GREAT BRITAIN	1046	2015	06
EFMOROCTOCOG ALFA	ELOCTA 3000 IU	POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	3000 IU	BIOGEN IDEC LTD	GREAT BRITAIN	1046	2015	07
IDARUCIZUMABUM	PRAXBIND 2.5g/50ml	SOLUTION FOR INJECTION/INFUSION	2.5g/ 50ml	BOEHRINGER INGELHEIM GMBH	GERMANY	1056	2015	01