

ROMANIA

Newsletter

Year 17, No. 2 (66), 2nd quarter of 2015

National Agency for

Medicines

and

Medical Devices

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The Ministry of Health – MoH – Order No. 761/17. 06. 2015

ORDER
No. 761/17. 06. 2015
for approval of the Guidelines on Good Distribution Practice
of medicinal products for human use

In force starting with 02 July 2015

PUBLISHED IN: THE OFFICIAL GAZETTE OF ROMANIA, PART I, NO. 483 of 02 July 2015. No amendments operated before 06 August 2015.

On seeing Approval Report No. N. B. 6. 528/2015 of the Directorate for Medicinal Product and Medical Devices Policies of the Ministry of Health and notification No. 41.381E/2015, of the National Agency for Medicines and Medical Devices, registered with the Minister of Health under No. 7.227/2015,

Taking into account provisions of Articles 748 – 762, 787 - 796² of Law 95/2006 on healthcare reform, as amended,

Having regard to provisions of Article 4(2), a) 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 Guidelines on Good Distribution Practice of medicinal products for human use are hereby approved, as provided in the Annex which is integral part of this Order.

Article 2. – On the date of this Order entry into force, Order of the Minister of Health No. 1.963/2008 for approval of the Guidelines on Good Distribution Practice of medicinal products for human use, as amended, published in the Official Gazette of Romania, Part I, No. 865/22.12.2008, shall be repealed

Article 3. – This Order shall be published in the Official Gazette of Romania, Part I.

p. **the Minister of Health,**
Gabriel Pușcău,
Secretary General

Bucharest, 17 June, 2015.
Nr. 761.

**Guidelines on Good Distribution Practice
of medicinal products for human use**

Note:

The Annex to this Order is a translation into Romanian and an adaptation of the European Commission document 2013/C 343/01 on Guidelines on Good Distribution Practice of medicinal products for human use, published in the Official Journal of the European Union, No. C 343 of 23.11.2013.

Adaptation consists in reference to respective Romanian healthcare regulatory provisions, transposing EU regulations.

Therefore, for the Annex to this Order, please see the Information from European Union institutions, bodies, offices and agencies, the European Commission. Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use (Text with EEA relevance) (2013/c 343/01), available at http://ec.europa.eu/health/files/eudralex/vol-1/2013_c343_01/2013_c343_01_en.pdf

Medicinal product batches recalled during the 2nd quarter of 2015

N	Product recalled	Pharm. form	Strength	INN	Manufacturer/ MAH	Batch No.	Grounds for recall	Action proposed	Date of recall
1	NISTATINA	film-coated tablets	500000 UI	nistatina	S.C. Antibiotice, Iași	T210181	MAH name and address not imprinted on secondary packaging	Recall and destruction	01.04.2015
2	TRAMAL RETARD	film-coated tablets with prolonged release	200 mg	tramadol	Grunental GmbH, Germany	928E03 932E08	Expiry of the 2-year term for maintenance in therapeutic use	Voluntary recall and destruction	03.04.2015
3	VENORUTON	gel, tube x 40 g	2%	troxerutin	Novartis Consumer Health GmbH, Germany	L01651A M01047A M02371B M02372B	Expiry of the 2-year term (as per MOH No. 279/2005) after NAMMD approval on 03.06.2013 of variation to MA No. 6017/2005/01-02 (change of trade name, pharmaceutical form, strength)	Recall and destruction	23.05.2015
4	VENORUTON	gel, tube x 100 g	2%	troxerutin	Novartis Consumer Health GmbH, Germany	J02226A M03965A	Expiry of the 2-year term (as per MOH No. 279/2005) after NAMMD approval on 03.06.2013 of variation to MA No. 6017/2005/01-02 (change	Recall and destruction	23.05.2015

N	Product recalled	Pharm. form	Strength	INN	Manufacturer/ MAH	Batch No.	Grounds for recall	Action proposed	Date of recall
							of trade name, pharmaceutical form, strength)		

Applications for marketing authorisation/marketing authorisation renewal submitted to the NAMMD during the 1st quarter 2015

During the 1st quarter of 2015, 266 applications for marketing authorisation/marketing authorisation renewal for medicinal products have been submitted, corresponding to the following therapeutic groups:

- A02 - Drugs for acid related disorders
- A09 – Digestives, including enzymes
- A10 – Drugs used in diabetes
- A11 – multivitamins, combinations
- B01 – Antithrombotic agents
- B02 – Antihemorrhagics
- C02 – Antihypertensives
- C04 – Peripheral vasodilators
- C05 – Vasoprotectives
- C09 – Agents acting on the renin-angiotensin system
- C10 – Lipid modifying agents
- D06 – Antibiotics and chemotherapeutics for dermatological use
- G02 – Other gynecologicals
- G03 – Sex hormones and modulators of the genital system
- G04 – Urologicals
- J01 – Antibacterial for systemic use
- J02 – Antimycotics for systemic use
- J04 – Antimycobacterials
- J05 – Antivirals for systemic use
- L01 – Antineoplastic agents
- L02 – Endocrine therapy
- M01 – Anti-inflammatory and antirheumatic products
- M03 – Miorelaxants
- M05 – Drugs for treatment of bone diseases
- N01 – Anaesthetics
- N02 – Analgezics
- 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
V09 – Diagnostic radiopharmaceuticals

Medicinal products authorised for marketing during the 1st quarter of 2015

INN	Invented name	Pharm. form	Strength	MAH	Country	MA number		
ACIDUM IBANDRONICUM	ACID IBANDRONIC STADA 150 mg	film-coated tabl.	150mg	STADA ARZNEIMITTEL AG	GERMANY	7494	2015	01
AMBROXOLUM	MUCOSOLVAN MAX 75 mg	caps. with. prol. release	75mg	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	GERMANY	7323	2015	01
AMOXICILLINUM + ACIDUM CLAVULANICUM	AMOXICILINA/ACID CLAVULANIC AUROBINDO 500 mg/125 mg	film-coated tabl.	500mg/ 125mg	AUROBINDO PHARMA LTD.	UK	7374	2015	01
AMOXICILLINUM + ACIDUM CLAVULANICUM	AMOXICILINA/ACID CLAVULANIC AUROBINDO 875 mg/125 mg	film-coated tabl.	875mg/ 125mg	AUROBINDO PHARMA LTD.	UK	7375	2015	01
ARIPIPRAZOLUM	ARYZALERA 5mg	tablets	5mg	KRKA, D.D., NOVO MESTO	SLOVENIA	7345	2015	01
ARIPIPRAZOLUM	ARYZALERA 10mg	tablets	10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	7346	2015	01
ARIPIPRAZOLUM	ARYZALERA 15mg	tablets	15mg	KRKA, D.D., NOVO MESTO	SLOVENIA	7347	2015	01
ARIPIPRAZOLUM	ARYZALERA 30mg	tablets	30mg	KRKA, D.D., NOVO MESTO	SLOVENIA	7348	2015	01
AZITHROMYCINUM	AZATRIL 250 mg	caps.	250mg	BALKANPHARMA RAZGRAD AD	BULGARIA	7420	2015	01
BETAHISTINUM	ACUVER 8 mg/dose	oral sol.	8mg/dose	CYATHUS EXQUIRERE PHARMAFORSCHUNGS GMBH	AUSTRIA	7475	2015	01
BISOPROLOLUM	BISOPROLOL LPH 5mg	tablets	5mg	LABORMED PHARMA S.A.	ROMANIA	7302	2015	01
BISOPROLOLUM	BISOPROLOL LPH 10mg	tablets	10mg	LABORMED PHARMA S.A.	ROMANIA	7303	2015	01
BUDESONIDUM	CORTIMENT 9mg	tablets with prol. release	9mg	FERING GMBH	GERMANY	7403	2015	01
BUTYLSCOPOLAMMON	SCOBUTIL 10 mg	tablets	10mg	TAKEDA GmbH	GERMANY	7400	2015	01

II BROMIDUM								
BUTYLSCOPOLAMMON II BROMIDUM	BUSCOPAN 10 mg	lozenges	10mg	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	GERMANY	7337	2015	01
CANDESARTANUM CILEXETIL	CANDESARTAN SANDOZ 16 mg	tablets	16mg	SANDOZ SRL	ROMANIA	7455	2015	01
CANDESARTANUM CILEXETIL	CANDESARTAN SANDOZ 8 mg	tablets	8mg	SANDOZ SRL	ROMANIA	7454	2015	01
CANDESARTANUM CILEXETIL	CANDESARTAN CILEXETIL MCC 8 mg	tablets	8mg	MAGISTRA C&C SRL	ROMANIA	7315	2015	01
CANDESARTANUM CILEXETIL	CANDESARTAN CILEXETIL MCC 16 mg	tablets	16mg	MAGISTRA C&C SRL	ROMANIA	7316	2015	01
CANDESARTANUM CILEXETIL	CANDESARTAN CILEXETIL MCC 32 mg	tablets	32mg	MAGISTRA C&C SRL	ROMANIA	7317	2015	01
CARTEOLOLUM	FORTINOL EP 2%	eye drops with prol. release	20mg/ml	DR. GERHARD MANN CHEM- PHARM. FABRIK GMBH	GERMANY	7497	2015	01
CEFEPIMUM	CEFEPIMA MIP 1 g	powder for sol. for inj./infus.	1g	MIP PHARMA GMBH	GERMANY	7422	2015	01
CEFEPIMUM	CEFEPIMA MIP 2 g	powder for sol. for inj./infus.	2g	MIP PHARMA GMBH	GERMANY	7423	2015	01
CEFUROXIMUM	CEFUROXIMA ATB 750mg	powder for susp. (i.m)/sol. for inj. (i.m.,i.v.)	750mg	ANTIBIOTICE S.A.	ROMANIA	7294	2015	01
CEFUROXIMUM	CEFUROXIMA ATB 1.5g	powder for susp. (i.m)/sol.	1.5g	ANTIBIOTICE S.A.	ROMANIA	7295	2015	01

		for inj. (i.m.,i.v.)						
CICLOPIROXUM	KITONAIL 80 mg/g	medicated nail lacquer	80mg/g	POLICHEM SA	LUXEMBOURG	7476	2015	01
CLOPIDOGRELUM	CLOPIDOGREL ACTAVIS 75 mg	film-coated tabl.	75mg	ACTAVIS GROUP PTC EHF.	ICELAND	7435	2015	01
CLOPIDOGRELUM	PLATEL 75 mg	film-coated tabl.	75mg	MEDOCHEMIE LTD.	CYPRUS	7397	2015	01
CLOPIDOGRELUM	TESSYRON 75 mg	film-coated tabl.	75mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	7396	2015	01
CLOPIDOGRELUM	TROGRAN 75 mg	film-coated tabl.	75mg	GLENMARK PHARMACEUTICALS S.R.O.	CZECH REP.	7457	2015	01
COLECALCIFEROLUM	VITAMINA D3 BIOFARM 18000UI/ml	eye drops, sol.	18000UI/ ml	BIOFARM SA	ROMANIA	7296	2015	01
COLISTINUM	COLISTINA ATB 1.000.000 UI	powder for sol. for inj./infus.	1.000.000 UI	ANTIBIOTICE SA	ROMANIA	7451	2015	01
COMBINATIONS	COLEBIL	lozenges		BIOFARM SA	ROMANIA	0	2015	01
COMBINATIONS	TRACHISAN	compressed lozenges		ENGELHARD ARZNEIMITTEL GMBH & CO. KG	GERMANY	7382	2015	01
COMBINATIONS	COLDREX NITE	syrup		GLAXOSMITHKLINE CONSUMER HEALTHCARE	UK	7297	2015	01
COMBINATIONS	PROCTO-GLYVENOL 400 mg+ 40 mg	suppos.	400mg+ 40mg	RECORDATI ROMANIA SRL	ROMANIA	7351	2015	01
COMBINATIONS	PROCTO-GLYVENOL 50 mg+20 mg/g	rectal cream	50mg+ 20mg/g	RECORDATI ROMANIA SRL	ROMANIA	7350	2015	01
COMBINATIONS	ZINERYT	powder + solv.	40mg/	ASTELLAS PHARMA EUROPE	THE	7452	2015	01

	40 mg/12 mg/ml	for cutan. sol.	12mg/ml	B.V.	NETHERLANDS			
COMBINATIONS	PARAREMIN	tablets		POLIPHARMA INDUSTRIES SRL	ROMANIA	7381	2015	01
COMBINATIONS (ATORVASTATINUM+ AMLODIPINUM)	AMLODIPINA/ATORVA STATINA TEVA 10 mg/5 mg	film-coated tabl.	10mg/5mg	TEVA PHARMACEUTICALS SRL	ROMANIA	7298	2015	01
COMBINATIONS (ATORVASTATINUM+ AMLODIPINUM)	AMLODIPINA/ATORVA STATINA TEVA 10 mg/10 mg	film-coated tabl.	10mg/ 10mg	TEVA PHARMACEUTICALS SRL	ROMANIA	7299	2015	01
COMBINATIONS (DICLOFENACUM+ OMEPRAZOLUM)	DICLOPRAM 75 mg/20 mg	caps. with modif. release	75mg/ 20mg	PHARMASWISS CESKA REPUBLIKA S.R.O.	CZECH REP.	7379	2015	01
COMBINATIONS (ENALAPRILUM+ LERCANIDIPINUM)	CORIPREN 20 mg /10 mg	film-coated tabl.	20mg/ 10mg	RECORDATI IRELAND LTD.	IRELAND	7434	2015	01
COMBINATIONS (ENALAPRILUM+ LERCANIDIPINUM)	CORIPREN 10 mg /10 mg	film-coated tabl.	10mg/ 10mg	RECORDATI IRELAND LTD.	IRELAND	7433	2015	01
COMBINATIONS (ENALAPRILUM+ LERCANIDIPINUM)	LERCARIL 20 mg /10 mg	film-coated tabl.	20mg/ 10mg	RECORDATI IRELAND LTD.	IRELAND	7428	2015	01
COMBINATIONS (ENALAPRILUM+ LERCANIDIPINUM)	LERCARIL 10 mg /10 mg	film-coated tabl.	10mg/ 10mg	RECORDATI IRELAND LTD.	IRELAND	7427	2015	01
COMBINATIONS (GESTODENUM+ ETINILESTRADIOLUM)	ARTIZIA 0.075 mg/0.020 mg	lozenges	0.075mg/ 0.020mg	ZENTIVA K.S.	CZECH REP.	7462	2015	01

COMBINATIONS (GESTODENUM+ ETINILESTRADIOLUM)	JULIPERLA 0.075 mg/ 0.020 mg	tablets	0.075mg/ 0.020mg	ACTAVIS GROUP PTC EHF.	ICELAND	7342	2015	01
COMBINATIONS (LATANOPROSTUM+ TIMOLOLUM)	XALCOM 50 µgr./ml+5 mg/ml	eye lotion	50 µgr./ml +5 mg/ml	PFIZER EUROPE MA EEIG	UK	7421	2015	01
COMBINATIONS (LEVODOPUM+ CARBIDOPUM+ ENTACAPONUM)	SASTRAVI 0 mg/12.5 mg/200 mg	film-coated tabl.	50mg/ 12.5mg/ 200mg	ACTAVIS GROUP PTC EHF.	ICELAND	7413	2015	01
COMBINATIONS (LEVODOPUM+ CARBIDOPUM+ ENTACAPONUM)	SASTRAVI 75 mg/18.75 mg/200 mg	film-coated tabl.	75mg/ 18.75mg/ 200mg	ACTAVIS GROUP PTC EHF.	ICELAND	7414	2015	01
COMBINATIONS (LEVODOPUM+ CARBIDOPUM+ ENTACAPONUM)	SASTRAVI 100 mg/25 mg/200 mg	film-coated tabl.	100mg/25 mg/200mg	ACTAVIS GROUP PTC EHF.	ICELAND	7415	2015	01
COMBINATIONS (LEVODOPUM+ CARBIDOPUM+ ENTACAPONUM)	SASTRAVI 125 mg/31.25 mg/200 mg	film-coated tabl.	125mg/ 31.25mg/ 200mg	ACTAVIS GROUP PTC EHF.	ICELAND	7416	2015	01
COMBINATIONS (LEVODOPUM+ CARBIDOPUM+ ENTACAPONUM)	SASTRAVI 150 mg/37.5 mg/200 mg	film-coated tabl.	150mg/ 37.5mg/ 200mg	ACTAVIS GROUP PTC EHF.	ICELAND	7417	2015	01

COMBINATIONS (LEVODOPUM+ CARBIDOPUM+ ENTACAPONUM)	SASTRAVI 175 mg/43.75 mg/200 mg	film-coated tabl.	175mg/ 43.75mg/ 200mg	ACTAVIS GROUP PTC EHF.	ICELAND	7418	2015	01
COMBINATIONS (LEVODOPUM+ CARBIDOPUM+ ENTACAPONUM)	SASTRAVI 200 mg/50 mg/200 mg	film-coated tabl.	200mg/50 mg/200mg	ACTAVIS GROUP PTC EHF.	ICELAND	7419	2015	01
COMBINATIONS (LEVODOPUM+ CARBIDOPUM+ ENTACAPONUM)	TADOGLEN 50 mg/12.5 mg/200 mg	film-coated tabl.	50mg/ 12.5 mg/ 200 mg	GLENMARK PHARMACEUTICALS S.R.O.	CZECH REP.	7436	2015	01
COMBINATIONS (LEVODOPUM+ CARBIDOPUM+ ENTACAPONUM)	TADOGLEN 100 mg/25 mg/200 mg	film-coated tabl.	100mg/ 25mg/ 200 mg	GLENMARK PHARMACEUTICALS S.R.O.	CZECH REP.	7437	2015	01
COMBINATIONS (LEVODOPUM+ CARBIDOPUM+ ENTACAPONUM)	TADOGLEN 150 mg/37.5 mg/200 mg	film-coated tabl.	150mg/ 37.5mg/ 200 mg	GLENMARK PHARMACEUTICALS S.R.O.	CZECH REP.	7438	2015	01
COMBINATIONS (LEVODOPUM+ CARBIDOPUM+ ENTACAPONUM)	TADOGLEN 200 mg/50 mg/200 mg	film-coated tabl.	200mg/ 50mg/ 200 mg	GLENMARK PHARMACEUTICALS S.R.O.	CZECH REP.	7439	2015	01
COMBINATIONS (PARACETAMOLUM+ PHENYLEPHRINUM)	PINEX RACEALA SI GRIPA 500 mg/12.2 mg	powder for oral susp.	500mg/ 12.2mg	ACTAVIS GROUP PTC EHF.	ICELAND	7398	2015	01

COMBINATIONS (PERINDOPRILUM+ INDAPAMIDUM)	DANURIT 4 mg/1.25mg	tablets	4mg/ 1.25mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	7395	2015	01
COMBINATIONS (PERINDOPRILUM+ INDAPAMIDUM)	DANURIT 2 mg/0.625 mg	tablets	2mg/ 0.625mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	7394	2015	01
COMBINATIONS (TOBRAMYCINUM +DEXAMETAZONUM)	TOMIDEXOFTA 3 mg/ml+1 mg/ml	eye drops, sol.	3mg/ml+ 1mg/ml	SOOFT ITALY S.P.A.	ITALY	7393	2015	01
COMBINATIONS (TRAMADOLUM+ PARACETAMOLUM)	PADOLTEN 37.5 mg/325 mg	film-coated tabl.	37.5mg/ 325mg	S.C.TEVA PHARMACEUTICALS SRL	ROMANIA	7432	2015	01
COMBINATIONS (TRAMADOLUM+ PARACETAMOLUM)	PALGOTAL 75 mg/650 mg	tablets	75mg/ 650mg	ZENTIVA, K.S.	CZECH REP.	7424	2015	01
DALTEPARINUM	FRAGMIN 2500 UI/0.2 ml	sol. for inj.	2500UI/ 0.2ml	PFIZER EUROPE MA EEIG	UK	7361	2015	01
DALTEPARINUM	FRAGMIN 5000 UI/0.2 ml	sol. for inj.	5000UI/ 0.2ml	PFIZER EUROPE MA EEIG	UK	7362	2015	01
DALTEPARINUM	FRAGMIN 7500 UI/0.3 ml	sol. for inj.	7500UI/ 0.3ml	PFIZER EUROPE MA EEIG	UK	7363	2015	01
DALTEPARINUM	FRAGMIN 10000 UI/ml	sol. for inj.	10000UI/ ml	PFIZER EUROPE MA EEIG	UK	7365	2015	01
DALTEPARINUM	FRAGMIN 15000 UI/0.6 ml	sol. for inj.	15000UI/ 0.6ml	PFIZER EUROPE MA EEIG	UK	7367	2015	01
DALTEPARINUM	FRAGMIN 10000 UI/0.4 ml	sol. for inj.	10000UI/ 0.4ml	PFIZER EUROPE MA EEIG	UK	7364	2015	01

DALTEPARINUM	FRAGMIN 12500 UI/0.5 ml	sol. for inj.	12500UI/ 0.5ml	PFIZER EUROPE MA EEIG	UK	7366	2015	01
DALTEPARINUM	FRAGMIN 18000 UI/0.72 ml	sol. for inj.	18000UI/ 0.72ml	PFIZER EUROPE MA EEIG	UK	7368	2015	01
DALTEPARINUM	FRAGMIN 25000 UI/ml	sol. for inj.	25000UI/ ml	PFIZER EUROPE MA EEIG	UK	7369	2015	01
DAPOXETINUM	PRILIGY 30 mg	film-coated tabl.	30mg	BERLIN-CHEMIE AG (MENARINI GROUP)	GERMANY	7473	2015	01
DAPOXETINUM	PRILIGY 60 mg	film-coated tabl.	60mg	BERLIN-CHEMIE AG (MENARINI GROUP)	GERMANY	7474	2015	01
DIENOGESTUM	VISANNE 2 mg	tablets	2mg	BAYER PHARMA AG	GERMANY	7329	2015	01
DIMENHYDRINATUM	DIMENHIDRINAT GALENICA 50 mg	subling. tablets	50mg	GALENICA S.A.	GREECE	7450	2015	01
DIVERSE	ACTOVEGIN 200 mg/5 ml	sol. for inj.	200mg/5ml	TAKEDA AUSTRIA GMBH	AUSTRIA	7336	2015	01
DIVERSE	ACTOVEGIN 200 mg	lozenges	200mg	TAKEDA AUSTRIA GMBH	AUSTRIA	7335	2015	01
DONEPEZILUM	DOSPELIN 5 mg	film-coated tabl.	5mg	MEDOCHEMIE LTD.	CYPRUS	7425	2015	01
DONEPEZILUM	DOSPELIN 10 mg	film-coated tabl.	10mg	MEDOCHEMIE LTD.	CYPRUS	7426	2015	01
ENALAPRILUM	RENITEC 5 mg	tablets	5mg	MERCK SHARP & DOHME ROMANIA SRL	ROMANIA	7498	2015	01
ENALAPRILUM	RENITEC 10 mg	tablets	10mg	MERCK SHARP & DOHME ROMANIA SRL	ROMANIA	7499	2015	01
ENALAPRILUM	RENITEC 20 mg	tablets	20mg	MERCK SHARP & DOHME ROMANIA SRL	ROMANIA	7500	2015	01
ENTACAPONUM	ENTACAPONA STADA 200 mg	film-coated tabl.	200mg	STADA HEMOFARM SRL	ROMANIA	7458	2015	01

ESCITALOPRAMUM	ESCITALOPRAM CIPLA 5 mg	film-coated tabl.	5mg	CIPLA EUROPE NV	BELGIUM	7447	2015	01
ESCITALOPRAMUM	ESCITALOPRAM CIPLA 10 mg	film-coated tabl.	10mg	CIPLA EUROPE NV	BELGIUM	7448	2015	01
ESCITALOPRAMUM	ESCITALOPRAM CIPLA 20 mg	film-coated tabl.	20mg	CIPLA EUROPE NV	BELGIUM	7449	2015	01
ESCITALOPRAMUM	ESCITALOPRAM SANDOZ 5 mg	orodispers. tablets	5mg	SANDOZ SRL	ROMANIA	7469	2015	01
ESCITALOPRAMUM	ESCITALOPRAM SANDOZ 10 mg	orodispers. tablets	10mg	SANDOZ SRL	ROMANIA	7470	2015	01
ESCITALOPRAMUM	ESCITALOPRAM SANDOZ 15 mg	orodispers. tablets	15mg	SANDOZ SRL	ROMANIA	7471	2015	01
ESCITALOPRAMUM	ESCITALOPRAM SANDOZ 20 mg	orodispers. tablets	20mg	SANDOZ SRL	ROMANIA	7472	2015	01
ESOMEPRAZOLUM	MESOPRAL 20 mg	caps. gastrorez.	20mg	PHARM.WORKS POLPHARMA S.A.	POLAND	7487	2015	01
ESOMEPRAZOLUM	MESOPRAL 40 mg	caps. gastrorez.	40mg	PHARM.WORKS POLPHARMA S.A.	POLAND	7488	2015	01
ETHAMBUTOLUM	ETAMBUTOL ATB 400 mg	film-coated tabl.	400mg	ANTIBIOTICE SA	ROMANIA	7402	2015	01
ETHAMBUTOLUM	ETAMBUTOL ATB 250 mg	film-coated tabl.	250mg	ANTIBIOTICE SA	ROMANIA	7401	2015	01
COAGULATION FACTOR IX	OCTANINE F 500 UI	powder + solv. for sol. for infus.	500 UI	OCTAPHARMA (IP) LTD.	UK	7370	2015	01
COAGULATION FACTOR IX	OCTANINE F 1000 UI	powder + solv. for sol. for	1000UI	OCTAPHARMA (IP) LTD.	UK	7371	2015	01

		infus.						
FELODIPINUM	PLENDIL 2.5 mg	tablets with prol. release	2.5mg	ASTRAZENECA AB	SWEDEN	7358	2015	01
FELODIPINUM	PLENDIL 5 mg	tablets with prol. release	5mg	ASTRAZENECA AB	SWEDEN	7359	2015	01
FELODIPINUM	PLENDIL 10 mg	tablets with prol. release	10mg	ASTRAZENECA AB	SWEDEN	7360	2015	01
FLUOROURACILUM	5 - FLUOROURACIL EBEWE 50mg/ml	conc. for sol. for inj./infus.	50mg/ml	EBEWE PHARMA GES.M.B.H. NFG. KG	AUSTRIA	7321	2015	01
GABAPENTINUM	GABAPENTINA TERAPIA 300 mg	caps.	300mg	TERAPIA SA	ROMANIA	7492	2015	01
GABAPENTINUM	GABAPENTINA TERAPIA 400 mg	caps.	400mg	TERAPIA SA	ROMANIA	7493	2015	01
GEMCITABINUM	GEMCITABINA KABI 38 mg/ml	conc. for sol. for infus.	38mg/ml	FRESENIUS KABI ONCOLOGY PLC.	UK	7404	2015	01
GLATIRAMER ACETAT	COPAXONE 20 mg/ml	sol for inj. in prefilled syringe	20mg/ml	TEVA PHARMACEUTICALS SRL	ROMANIA	7380	2015	01
GLIMEPIRIDUM	GLIMEPIRIDE 2 mg	tablets	2mg	ACTAVIS GROUP HF.	ICELAND	7325	2015	01
GLIMEPIRIDUM	GLIMEPIRIDE 3 mg	tablets	3mg	ACTAVIS GROUP HF.	ICELAND	7326	2015	01
GLYCEROFOSFATUM	GLYCOPHOS 216 mg/ml	conc. for sol. for infus.	216mg/ml	FRESENIUS KABI AB	SWEDEN	7324	2015	01
IBUPROFENUM	BRUFEN 20 mg/ml	oral susp.	20mg/ml	ABBOTT SCANDINAVIA AB	SWEDEN	7459	2015	01
IBUPROFENUM	BRUFEN RETARD 800 mg	tablets with prol. release	800mg	ABBOTT SCANDINAVIA AB	SWEDEN	7461	2015	01
IBUPROFENUM	BRUFEN 400 mg	film-coated tabl.	400mg	ABBOTT SCANDINAVIA AB	SWEDEN	7460	2015	01

IMUNOGLOBULINA ANTIHEPATITICA B	HEPATECT CP 50 UI/ml	sol. for infus.	50 UI/ ml	BIOTEST PHARMA GMBH	GERMANY	7349	2015	01
INDAPAMIDUM	INDAPEN SR 1.5 mg	tablets with prol. release	1.5mg	PHARM.WORKS POLPHARMA S.A.	POLAND	7391	2015	01
INDAPAMIDUM	INDAPAMIDA TEVA 1.5 mg	tablets with prol. release	1.5mg	TEVA PHARMACEUTICALS SRL	ROMANIA	7318	2015	01
IRBESARTANUM	IRBESARTAN GALENICA 75 mg	film-coated tabl.	75 mg	GALENICA S.A.	GREECE	7306	2015	01
IRBESARTANUM	IRBESARTAN GALENICA 150 mg	film-coated tabl.	150 mg	GALENICA S.A.	GREECE	7307	2015	01
IRBESARTANUM	IRBESARTAN GALENICA 300 mg	film-coated tabl.	300 mg	GALENICA S.A.	GREECE	7308	2015	01
LANTANUM	FOSRENOL 250 mg	chewable tabl.	250mg	SHIRE PHARM.CONTRACTS LTD.	UK	7352	2015	01
LANTANUM	FOSRENOL 500 mg	chewable tabl.	500mg	SHIRE PHARM.CONTRACTS LTD.	UK	7353	2015	01
LANTANUM	FOSRENOL 750 mg	chewable tabl.	750mg	SHIRE PHARM.CONTRACTS LTD.	UK	7354	2015	01
LANTANUM	FOSRENOL 1000 mg	chewable tabl.	1000mg	SHIRE PHARM.CONTRACTS LTD.	UK	7355	2015	01
LANTANUM	FOSRENOL 750 mg	oral powder	750mg	SHIRE PHARM.CONTRACTS LTD.	UK	7356	2015	01
LANTANUM	FOSRENOL 1000 mg	oral powder	1000mg	SHIRE PHARM.CONTRACTS LTD.	UK	7357	2015	01
LATANOPROSTUM	UNILAT 50 µgr./ml	eye drops, sol.	50µgr./ml	UNIMED PHARMA SPOL. S.R.O.	SLOVAKIA	7429	2015	01
LERCANIDIPINUM	LERCANIDIPIN ACTAVIS 10 mg	film-coated tabl.	10mg	ACTAVIS GROUP PTC EHF.	ICELAND	7343	2015	01

LERCANIDIPINUM	LERCANIDIPIN ACTAVIS 20 mg	film-coated tabl.	20mg	ACTAVIS GROUP PTC EHF.	ICELAND	7344	2015	01
LEVETIRACETAMUM	LEVETIRACETAM CIPLA 250 mg	film-coated tabl.	250mg	CIPLA EUROPE NV	BELGIUM	7331	2015	01
LEVETIRACETAMUM	LEVETIRACETAM CIPLA 500 mg	film-coated tabl.	500mg	CIPLA EUROPE NV	BELGIUM	7332	2015	01
LEVETIRACETAMUM	LEVETIRACETAM CIPLA 750 mg	film-coated tabl.	750mg	CIPLA EUROPE NV	BELGIUM	7333	2015	01
LEVETIRACETAMUM	LEVETIRACETAM CIPLA 1000 mg	film-coated tabl.	1000mg	CIPLA EUROPE NV	BELGIUM	7334	2015	01
LEVOFLOXACINUM	LEVALOX 250 mg	film-coated tabl.	250mg	KRKA, D.D., NOVO MESTO	SLOVENIA	7509	2015	01
LEVOFLOXACINUM	LEVALOX 500 mg	film-coated tabl.	500mg	KRKA, D.D., NOVO MESTO	SLOVENIA	7510	2015	01
LEVOFLOXACINUM	LEVALOX 5 mg/ml	sol. for infus.	5mg/ml	KRKA, D.D., NOVO MESTO	SLOVENIA	7511	2015	01
LINEZOLIDUM	LINEZOLID KABI 2 mg/ml	sol. for infus.	2mg/ml	FRESENIUS KABI ROMANIA SRL	ROMANIA	7392	2015	01
MEDROXY- PROGESTERONUM	SAYANAJECT 104 mg	susp. for inj.	104mg	PFIZER EUROPE MA EEIG	UK	7289	2015	01
METAMIZOLUM NATRIUM	LOCAMIN 500 mg/ml	eye drops, sol.	500mg/ml	STADA ARZNEIMITTEL AG	GERMANY	7491	2015	01
METHOTREXATUM	METHOTREXAT EBEWE 20 mg/ml	sol. for inj. in prefilled syringe	20mg/ml	EBEWE PHARMA GES.M.B.H. NFG. KG	AUSTRIA	7328	2015	01
METHYLII NICOTINAS	NICOTINAT DE METIL - RICHTER 30mg/g	ointment	30mg/g	GEDEON RICHTER ROMANIA S.A.	ROMANIA	7383	2015	01
MIDAZOLAMUM	DORMICUM 1 mg/ml	sol. for inj.	1mg/ml	ROCHE ROMANIA SRL	ROMANIA	7477	2015	01

MONTELUKASTUM	MONTELUKAST TEVA 4 mg	chewable tabl.	4mg	TEVA PHARMACEUTICALS SRL	ROMANIA	7478	2015	01
MONTELUKASTUM	MONTELUKAST TEVA 5 mg	chewable tabl.	5mg	TEVA PHARMACEUTICALS SRL	ROMANIA	7479	2015	01
MONTELUKASTUM	MONTELUKAST TEVA 10 mg	film-coated tabl.	10mg	TEVA PHARMACEUTICALS SRL	ROMANIA	7480	2015	01
MONTELUKASTUM	SINGULAIR 4 mg	granules	4mg	MERCK SHARP & DOHME ROMANIA SRL	ROMANIA	7309	2015	01
MONTELUKASTUM	MONTELUKAST CIPLA 10 mg	film-coated tabl.	10mg	CIPLA EUROPE NV	BELGIUM	7496	2015	01
MOXIFLOXACINUM	MOFINACIN 400 mg/250 ml	sol. for infus.	400mg/ 250ml	ALVOGEN IPCO S.AR.L.	LUXEMBOURG	7373	2015	01
NICOTINUM	NICORETTE CLEAR 10 mg/16 ore	transderm. patch	10mg/ 16 hrs	MCNEIL AB	SWEDEN	7286	2015	01
NICOTINUM	NICORETTE CLEAR 15 mg/16 ore	transderm. patch	15mg/ 16 hrs	MCNEIL AB	SWEDEN	7287	2015	01
NICOTINUM	NICORETTE CLEAR 25 mg/16 ore	transderm. patch	25mg/ 16hrs	MCNEIL AB	SWEDEN	7288	2015	01
NICOTINUM	NICORETTE FRESHFRUIT 2 mg	medicated gum	2mg	MCNEIL AB	SWEDEN	7291	2015	01
NICOTINUM	NICORETTE FRESHFRUIT 4 mg	medicated gum	4mg	MCNEIL AB	SWEDEN	7292	2015	01
PERINDOPRILUM	VIDOTIN 4 mg	tablets	4mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	7319	2015	01
PERINDOPRILUM	VIDOTIN 8 mg	tablets	8mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	7320	2015	01
PERINDOPRILUM	STOPRESS 4 mg	tablets	4mg	PHARM.WORKS POLPHARMA SA	POLAND	7300	2015	01

PERINDOPRILUM	STOPRESS 8 mg	tablets	8mg	PHARM.WORKS POLPHARMA SA	POLAND	7301	2015	01
HERBAL	SINUPRET ACUTE	lozenges		BIONORICA SE	GERMANY	7330	2015	01
HERBAL	SINUPRET FORTE	lozenges		BIONORICA SE	GERMANY	7338	2015	01
HERBAL (ST.JOHN'S WART)	DR. BÖHM SUNATOARE 425 mg	caps.	425mg	STRALLHOFER PHARMA GMBH	AUSTRIA	7453	2015	01
PRAMIPEXOLUM	GLEPARK 0.18 mg	tablets	0.18mg	GLENMARK PHARMACEUTICALS s.r.o.	CZECH REP.	7430	2015	01
PRAMIPEXOLUM	GLEPARK 0.7 mg	tablets	0.7mg	GLENMARK PHARMACEUTICALS s.r.o.	CZECH REP.	7431	2015	01
PRAMIPEXOLUM	PRAMIPEXOL TEVA 0.26 mg	tablets with prol. release	0.26mg	TEVA PHARMACEUTICALS SRL	ROMANIA	7440	2015	01
PRAMIPEXOLUM	PRAMIPEXOL TEVA 0.52 mg	tablets with prol. release	0.52mg	TEVA PHARMACEUTICALS SRL	ROMANIA	7441	2015	01
PRAMIPEXOLUM	PRAMIPEXOL TEVA 1.05 mg	tablets with prol. release	1.05mg	TEVA PHARMACEUTICALS SRL	ROMANIA	7442	2015	01
PRAMIPEXOLUM	PRAMIPEXOL TEVA 1.57 mg	tablets with prol. release	1.57mg	TEVA PHARMACEUTICALS SRL	ROMANIA	7443	2015	01
PRAMIPEXOLUM	PRAMIPEXOL TEVA 2.1 mg	tablets with prol. release	2.1mg	TEVA PHARMACEUTICALS SRL	ROMANIA	7444	2015	01
PRAMIPEXOLUM	PRAMIPEXOL TEVA 2.62 mg	tablets with prol. release	2.62mg	TEVA PHARMACEUTICALS SRL	ROMANIA	7445	2015	01
PRAMIPEXOLUM	PRAMIPEXOL TEVA 3.15 mg	tablets with prol. release	3.15mg	TEVA PHARMACEUTICALS SRL	ROMANIA	7446	2015	01
QUETIAPINUM	QUETIAPINE TEVA 100 mg	film-coated tabl.	100mg	TEVA PHARMACEUTICALS SRL	ROMANIA	7376	2015	01
QUETIAPINUM	QUETIAPINE TEVA 200 mg	film-coated tabl.	200mg	TEVA PHARMACEUTICALS SRL	ROMANIA	7377	2015	01

QUETIAPINUM	QUETIAPINE TEVA 300 mg	film-coated tabl.	300mg	TEVA PHARMACEUTICALS SRL	ROMANIA	7378	2015	01
QUETIAPINUM	KVENTIAX EP 150 mg	tablets with prol. release	150mg	KRKA, D.D., NOVO MESTO	SLOVENIA	7339	2015	01
QUETIAPINUM	KVENTIAX EP 200 mg	tablets with prol. release	200mg	KRKA, D.D., NOVO MESTO	SLOVENIA	7340	2015	01
QUETIAPINUM	KVENTIAX EP 300 mg	tablets with prol. release	300mg	KRKA, D.D., NOVO MESTO	SLOVENIA	7341	2015	01
QUETIAPINUM	QUETIAPINA MYLAN 25 mg	film-coated tabl.	25mg	GENERICS (UK) LTD.	UK	7310	2015	01
QUETIAPINUM	QUETIAPINA MYLAN 100 mg	film-coated tabl.	100mg	GENERICS (UK) LTD.	UK	7311	2015	01
QUETIAPINUM	QUETIAPINA MYLAN 150 mg	film-coated tabl.	150mg	GENERICS (UK) LTD.	UK	7312	2015	01
QUETIAPINUM	QUETIAPINA MYLAN 200 mg	film-coated tabl.	200mg	GENERICS (UK) LTD.	UK	7313	2015	01
QUETIAPINUM	QUETIAPINA MYLAN 300 mg	film-coated tabl.	300mg	GENERICS (UK) LTD.	UK	7314	2015	01
RIVASTIGMINUM	EMERPAND 4.6 mg/24 h	transderm. patch	4.6mg/24h	ACTAVIS GROUP PTC EHF.	ICELAND	7466	2015	01
RIVASTIGMINUM	EMERPAND 9.5 mg/24 h	transderm. patch	9.5mg/24h	ACTAVIS GROUP PTC EHF.	ICELAND	7467	2015	01
RIVASTIGMINUM	EMERPAND 13.3 mg/24 h	transderm. patch	13.3mg/24 h	ACTAVIS GROUP PTC EHF.	ICELAND	7468	2015	01
RIZATRIPTANUM	RIZATRIPTAN MYLAN 5 mg	orodispers. tablets	5mg	GENERICS (UK) LTD	UK	7481	2015	01

RIZATRIPTANUM	RIZATRIPTAN MYLAN 10 mg	orodispers. tablets	10mg	GENERICS (UK) LTD	UK	7482	2015	01
RIZATRIPTANUM	MAXALT 5 mg	tablets	5mg	MERCK SHARP & DOHME ROMANIA SRL	ROMANIA	7503	2015	01
RIZATRIPTANUM	MAXALT 10 mg	tablets	10mg	MERCK SHARP & DOHME ROMANIA SRL	ROMANIA	7504	2015	01
RIZATRIPTANUM	MAXALT 5 mg	oral lioph.	5mg	MERCK SHARP & DOHME ROMANIA SRL	ROMANIA	7505	2015	01
RIZATRIPTANUM	MAXALT 10 mg	oral lioph.	10mg	MERCK SHARP & DOHME ROMANIA SRL	ROMANIA	7506	2015	01
ROPINIROLUM	NERVAMAT 2 mg	tablets with prol. release	2mg	EGIS PHARMACEUTICALS PLC	HUNGARY	7483	2015	01
ROPINIROLUM	NERVAMAT 3 mg	tablets with prol. release	3mg	EGIS PHARMACEUTICALS PLC	HUNGARY	7484	2015	01
ROPINIROLUM	NERVAMAT 4 mg	tablets with prol. release	4mg	EGIS PHARMACEUTICALS PLC	HUNGARY	7485	2015	01
ROPINIROLUM	NERVAMAT 8 mg	tablets with prol. release	8mg	EGIS PHARMACEUTICALS PLC	HUNGARY	7486	2015	01
SILDENAFILUM	SILDENAFIL MEDANA 25 mg	film-coated tabl.	25mg	MEDANA PHARMA SA	POLAND	7388	2015	01
SILDENAFILUM	SILDENAFIL MEDANA 50 mg	film-coated tabl.	50mg	MEDANA PHARMA SA	POLAND	7389	2015	01
SILDENAFILUM	SILDENAFIL MEDANA 100 mg	film-coated tabl.	100mg	MEDANA PHARMA SA	POLAND	7390	2015	01
SILIBINUM	LAGOSA 150 mg	lozenges	150mg	WORWAG PHARMA GMBH & CO. KG	GERMANY	7322	2015	01
SOLIFENACINUM SUCCINATE	ZEVESIN 5 mg	film-coated tabl.	5 mg	ZENTIVA, K.S.	CZECH REP.	7489	2015	01

SOLIFENACINUM SUCCINATE	ZEVESIN 10 mg	film-coated tabl.	10 mg	ZENTIVA, K.S.	CZECH REP.	7490	2015	01
SULODEXIDUM	VESSEL DUE F 250 ULS	caps., soft	250ULS	ALFA WASSERMANN S.P.A.	ITALY	7293	2015	01
TEMOZOLOMIDUM	TEMOZOLOMIDA HF 5 mg	caps.	5mg	STADA HEMOFARM SRL	ROMANIA	7407	2015	01
TEMOZOLOMIDUM	TEMOZOLOMIDA HF 20 mg	caps.	20mg	STADA HEMOFARM SRL	ROMANIA	7408	2015	01
TEMOZOLOMIDUM	TEMOZOLOMIDA HF 100 mg	caps.	100mg	STADA HEMOFARM SRL	ROMANIA	7409	2015	01
TEMOZOLOMIDUM	TEMOZOLOMIDA HF 140 mg	caps.	140mg	STADA HEMOFARM SRL	ROMANIA	7410	2015	01
TEMOZOLOMIDUM	TEMOZOLOMIDA HF 180 mg	caps.	180mg	STADA HEMOFARM SRL	ROMANIA	7411	2015	01
TEMOZOLOMIDUM	TEMOZOLOMIDA HF 250 mg	caps.	250mg	STADA HEMOFARM SRL	ROMANIA	7412	2015	01
TERBINAFINUM	TERBINAFINE 250 mg	tablets	250mg	ACTAVIS GROUP HF.	ICELAND	7399	2015	01
TOPIRAMATUM	TOPIRAMAT AUROBINDO 25 mg	film-coated tabl.	25mg	AUROBINDO PHARMA (MALTA) LTD.	MALTA	7384	2015	01
TOPIRAMATUM	TOPIRAMAT AUROBINDO 50 mg	film-coated tabl.	50mg	AUROBINDO PHARMA (MALTA) LTD.	MALTA	7385	2015	01
TOPIRAMATUM	TOPIRAMAT AUROBINDO 100 mg	film-coated tabl.	100mg	AUROBINDO PHARMA (MALTA) LTD.	MALTA	7386	2015	01
TOPIRAMATUM	TOPIRAMAT AUROBINDO 200 mg	film-coated tabl.	200mg	AUROBINDO PHARMA (MALTA) LTD.	MALTA	7387	2015	01
TRAVOPROSTUM	TRAVOPROST PH&T 40 µgr./ml	eye drops, sol.	40µgr./ml	PH&T SPA	ITALY	7304	2015	01
TRAVOPROSTUM	TRAVAPRESS 40 µgr./ml	eye drops, sol.	40µgr./ml	ROMPHARM COMPANY SRL	ROMANIA	7495	2015	01

VALGANCICLOVIRUM	VALGANCICLOVIR AUROBINDO 450 mg	film-coated tabl.	450mg	AUROBINDO PHARMA (MALTA) LTD.	MALTA	7305	2015	01
VALGANCICLOVIRUM	VALGANCICLOVIR SANDOZ 450 mg	film-coated tabl.	450mg	SANDOZ SRL	ROMANIA	7327	2015	01
VALGANCICLOVIRUM	VALDAMIN 450 mg	film-coated tabl.	450mg	EGIS PHARMACEUTICALS PLC.	HUNGARY	7372	2015	01
VALGANCICLOVIRUM	ALVANOCYT 450 mg	film-coated tabl.	450mg	ALVOGEN IPCO S.AR.L.	LUXEMBOURG	7456	2015	01
VANCOMYCINUM	VANCOMYCIN-CNP 500 mg	powder for sol. for infus.	500mg	CNP PHARMA GMBH	GERMANY	7507	2015	01
VANCOMYCINUM	VANCOMYCIN-CNP 1000 mg	powder for sol. for infus.	1000mg	CNP PHARMA GMBH	GERMANY	7508	2015	01
VENLAFAXINUM	VENLAFAXINA AUROBINDO 37.5 mg	caps. with. prol. release	37.5mg	AUROBINDO PHARMA (MALTA) LTD.	MALTA	7463	2015	01
VENLAFAXINUM	VENLAFAXINA AUROBINDO 75 mg	caps. with. prol. release	75mg	AUROBINDO PHARMA (MALTA) LTD.	MALTA	7464	2015	01
VENLAFAXINUM	VENLAFAXINA AUROBINDO 150 mg	caps. with. prol. release	150mg	AUROBINDO PHARMA (MALTA) LTD.	MALTA	7465	2015	01
VORICONAZOLUM	VORICONAZOL ZENTIVA 50 mg	film-coated tabl.	50mg	ZENTIVA, K.S.	CZECH REP.	7501	2015	01
VORICONAZOLUM	VORICONAZOL ZENTIVA 200 mg	film-coated tabl.	200mg	ZENTIVA, K.S.	CZECH REP.	7502	2015	01
ZOLMITRIPTANUM	ZOLMITRIPTAN ACTAVIS 2.5 mg	orodispers. tablets	2.5mg	ACTAVIS GROUP PTC EHF.	ICELAND	7405	2015	01
ZOLMITRIPTANUM	ZOLMITRIPTAN ACTAVIS 5 mg	orodispers. tablets	5mg	ACTAVIS GROUP PTC EHF.	ICELAND	7406	2015	01

**Medicinal products authorised through centralised procedure by the EMA, notified for marketing in Romania
during the 1st quarter of 2015**

INN	Invented name	Pharm.form	Strength	MAH	country	MA no.		
DALBAVANCINUM	XYDALBA 500 mg	powder for conc. for sol. for infus.	500mg	DURATA THERAPEUTICS INTERNATIONAL B.V.	THE NETHERLANDS	986	2015	01
DASABUVIRUM	EXVIERA 250mg	film-coated tabl.	250 mg	ABBVIE LTD.	UK	983	2015	01
NINTEDANIBUM	OFEV 100 mg	caps., soft	100mg	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	GERMANY	979	2015	01
NINTEDANIBUM	OFEV 100 mg	caps., soft	100mg	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	GERMANY	979	2015	02
NINTEDANIBUM	OFEV 150 mg	caps., soft	150mg	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	GERMANY	979	2015	03
NINTEDANIBUM	OFEV 150 mg	caps., soft	150mg	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	GERMANY	979	2015	04