

*ROMANIA*

*Newsletter*

**Year 21, No. 1 (81), 1st Quarter 2019**

*National Agency  
for Medicines  
and Medical Devices*

**Medicinal product batches recalled/withdrawn in the 1st quarter 2019**

**Applications for marketing authorisation/marketing authorisation renewal submitted to the NAMMD in the 4th quarter 2018**

**Medicinal products authorised for marketing in the 4th quarter 2018**

**Centrally authorised medicinal products notified for marketing in Romania in the 4th quarter 2018**

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## Medicinal product batches recalled/withdrawn in the 1st quarter 2019

| No. | Product recalled/<br>withdrawn                | Pharm. form               | Strength             | INN                                      | Manufacturer/<br>MAH   | Batch   | Grounds for<br>recall/withdrawal  | Action<br>proposed                     | Recall/<br>Withdrawal<br>date |
|-----|---|---------------------------|----------------------|--|--|---|---|--|-------------------------------|
| 1   | HEPARINA<br>SODICA<br>PANPHARMA<br>5000 UI/ml | solution for<br>injection | 5000 UI/ml           | heparin                                  | Panpharma, France  | 502050000,<br>502570001,<br>602020000,<br>801130000 | recall triggered by launch of<br>a rapid alert by the<br>competent authority in<br>Germany, following<br>manufacturer finding of<br>manufacturing line<br>nonconformity   | Recall and<br>destruction              | 22.01.2019                    |
| 2   | VIBROCIL<br>2.5 mg/0.25 mg/g                  | nasal gel                 | 2.5 mg/<br>0.25 mg/g | dimetindene/<br>phenylephrine<br>maleate | Novartis Consumer<br>Health GmbH, Germany/<br>GSK Consumer<br>Healthcare SRL | T03642A,<br>U05167B                                 | recall triggered by expiry of<br>the 1-year period after<br>NAMMD approval of MA<br>discontinuation<br>(MA no. 6036/2005/01)  | Voluntary<br>recall and<br>destruction | 25.01.2019                    |
| 3   | PENTOXI RETARD<br>400 mg                      | prol. release<br>tabl.    | 400 mg               | pentoxifylline                           | Terapia SA   | 3186711   | recall triggered by out-of-<br>specification result for the<br>“Dissolution” parameter  | Recall and<br>destruction              | 04.02.2019                    |
| 4   | EURESPAL 80 mg                                | prol. release<br>tabl.    | 80 mg                | fenspiride                               | Les Lab. Servier Ind.<br>France/Les Laboratoires<br>Servier France           | all marketed<br>batches                             | recall triggered by launch of<br>an EU-wide emergency<br>procedure launched by the<br>French competent authority<br>(ANSM), discussed on the<br>PRAC February meeting,<br>concerning fenspiride<br>containing medicines | Voluntary<br>recall and<br>destruction | 11.02.2019                    |

| No. | Product recalled/<br>withdrawn | Pharm. form               | Strength        | INN           | Manufacturer/<br>MAH   | Batch                   | Grounds for<br>recall/withdrawal  | Action<br>proposed                     | Recall/<br>Withdrawal<br>date |
|-----|--------------------------------|---------------------------|-----------------|---------------|--|-------------------------|---|--|-------------------------------|
| 5   | EURESPAL<br>2 mg/2 ml          | syrup                     | 2 mg/<br>2 ml   | fenspiride    | Les Lab. Servier Ind.<br>France/Les Laboratoires<br>Servier France | all marketed<br>batches | recall triggered by launch of<br>an EU-wide emergency<br>procedure launched by the<br>French competent authority<br>(ANSM), discussed on the<br>PRAC February meeting,<br>concerning fenspiride<br>containing medicines | Voluntary<br>recall and<br>destruction | 11.02.2019                    |
| 6   | VITAMEDI-C<br>750 mg/5 ml      | solution for<br>injection | 750 mg/<br>5 ml | ascorbic acid | Pascoe Pharmazeutische<br>Preparate GmbH,<br>Germany               | 9368                    | recall triggered by launch of<br>a rapid alert by the<br>competent authority in<br>Germany, following<br>manufacturer finding of<br>manufacturing line<br>nonconformity   | Voluntary<br>recall and<br>destruction | 20.02.2019                    |
| 7   | EPISTAT 80 mg                  | prol. release<br>tabl.    | 80 mg           | fenspiride    | Gedeon Richter SA  | all marketed<br>batches | recall triggered by launch of<br>an EU-wide emergency<br>procedure launched by the<br>French competent authority<br>(ANSM), discussed on the<br>PRAC February meeting,<br>concerning fenspiride<br>containing medicines | Recall and<br>destruction              | 26.02.2019                    |
| 8   | SEROQUEL XR<br>200 mg          | prol. release<br>tabl.    | 200 mg          | quetiapine    | Astrazeneca UK Ltd/<br>Astrazeneca AB, Sweden                      | all marketed<br>batches | Permanent discontinuation<br>of marketing following<br>product removal from the<br>CaNaMed Index and the<br>Public Catalogue starting<br>with 01.01.2019  | Voluntary<br>recall and<br>destruction | 13.03.2019                    |
| 9   | SEROQUEL XR<br>300 mg          | prol. release<br>tabl.    | 300 mg          | quetiapine    | Astrazeneca UK Ltd/<br>Astrazeneca AB, Sweden                      | all marketed<br>batches | Permanent discontinuation<br>of marketing following<br>product removal from the<br>CaNaMed Index and the<br>Public Catalogue starting<br>with 01.01.2019  | Voluntary<br>recall and<br>destruction | 13.03.2019                    |

| No. | Product recalled/<br>withdrawn | Pharm. form                            | Strength      | INN         | Manufacturer/<br>MAH                                  | Batch                   | Grounds for<br>recall/withdrawal   | Action<br>proposed                     | Recall/<br>Withdrawal<br>date |
|-----|--------------------------------|--|---------------|-------------|---|-------------------------|--|--|-------------------------------|
| 10  | SEROQUEL XR<br>400 mg          | prol. release<br>tabl.                 | 400 mg        | quetiapine  | Astrazeneca UK Ltd/<br>Astrazeneca AB, Sweden         | all marketed<br>batches | Permanent discontinuation<br>of marketing following<br>product removal from the<br>CaNaMed Index and the<br>Public Catalogue starting<br>with 01.01.2019 | Voluntary<br>recall and<br>destruction | 13.03.2019                    |
| 11  | ALVESCO 80<br>INHALER          | pressurised<br>inhalation,<br>solution | 80µg/<br>doza | ciclesonide | Takeda GmbH,<br>Germany/Astrazeneca<br>AB, Sweden     | all marketed<br>batches | Permanent discontinuation<br>of marketing following<br>product removal from the<br>CaNaMed Index and the<br>Public Catalogue starting<br>with 01.01.2019 | Voluntary<br>recall and<br>destruction | 13.03.2019                    |
| 12  | PLENDIL 2.5 mg                 | prol. release<br>tabl.                 | 2.5 mg        | felodipine  | Astrazeneca AB,<br>Germany/ Astrazeneca<br>AB, Sweden | all marketed<br>batches | Permanent discontinuation<br>of marketing following<br>product removal from the<br>CaNaMed Index and the<br>Public Catalogue starting<br>with 01.01.2019 | Voluntary<br>recall and<br>destruction | 13.03.2019                    |

**Applications for marketing authorisation/marketing authorisation renewal submitted to the NAMMD  
in the 4th quarter 2018**

During the 4<sup>th</sup> quarter of 2018, 75 marketing authorisation/renewal applications for medicinal products corresponding to the following therapeutic groups have been submitted:

| INN  | Trade name                 | Pharm. form          | Strength | MAH                         | Country | Date of placement on the market | Procedure type | Status  | ATC Code   |
|--|----------------------------|----------------------|----------|-----------------------------|---------|---------------------------------|----------------|---------|--|
| LOPERAMIDUM  | LOPERAMID<br>LAROPHARM     | oral solution        | 1mg/5ml  | LAROPHARM S.R.L.            | ROMANIA | 02.10.2018                      | NAT<br>PROC    | Renewal | A07- Antidiarrheals,<br>intestinal<br>antiinflammatory/anti-<br>infective agents |
| BENFOTIAMINUM                                      | NEUROSEN                   | film coated<br>tabl. | 300mg    | AAA PHARMA GMBH             | GERMANY | 02.10.2018                      | NAT<br>PROC    | Renewal | A11- Vitamins  |
| ATORVASTATINUM                                     | ATORVASTATINA<br>AUROBINDO | film coated<br>tabl. | 10mg     | AUROBINDO PHARMA<br>LIMITED | MALTA   | 02.10.2018                      | MRP            | Renewal | C10- Lipid modifying<br>agents   |
| ATORVASTATINUM                                     | ATORVASTATINA<br>AUROBINDO | film coated<br>tabl. | 20mg     | AUROBINDO PHARMA<br>LIMITED | MALTA   | 02.10.2018                      | MRP            | Renewal |  |
| ATORVASTATINUM                                     | ATORVASTATINA<br>AUROBINDO | film coated<br>tabl. | 40mg     | AUROBINDO PHARMA<br>LIMITED | MALTA   | 02.10.2018                      | MRP            | Renewal |  |
| ATORVASTATINUM                                     | ATORVASTATINA<br>AUROBINDO | film coated<br>tabl. | 80mg     | AUROBINDO PHARMA<br>LIMITED | MALTA   | 02.10.2018                      | MRP            | Renewal |  |
| DORZOLAMIDUM<br>HYDROCHLORIDE +<br>TIMOLOL MALEATE | DUOKOPT                    | eye drops,<br>sol    | 20mg/5mg | LAB THEA S.A.S              | FRANCE  | 02.10.2018                      | MRP            | Renewal | S01-<br>Ophthalmologicals  |

| INN                      | Trade name              | Pharm. form      | Strength      | MAH              | Country | Date of placement on the market | Procedure type | Status  | ATC Code   |
|--------------------------|-------------------------|------------------|---------------|------------------|---------|---------------------------------|----------------|---------|--|
| DICLOFENACUM SODIUM      | DICLOFENAC ARENA        | gastrores. tabl. | 25mg          | ARENA GROUP S.A. | ROMANIA | 03.10.2018                      | NAT PROC       | Renewal | M01-<br>Antiinflammatory and<br>antirheumatic products |
| DICLOFENACUM SODIUM      | DICLOFENAC ARENA        | gastrores. tabl. | 50mg          | ARENA GROUP S.A. | ROMANIA | 03.10.2018                      | NAT PROC       | Renewal |  |
| BISOPROLOLUM/AMLOPIDINUM | ALOTENDIN               | tabl.            | 5mg/5mg       | EGIS PHARMA. PLC | HUNGARY | 03.10.2018                      | MRP            | Renewal | C07- Beta blocking<br>agents                           |
| BISOPROLOLUM/AMLOPIDINUM | ALOTENDIN               | tabl.            | 5mg/10mg      | EGIS PHARMA. PLC | HUNGARY | 03.10.2018                      | MRP            | Renewal |  |
| BISOPROLOLUM/AMLOPIDINUM | ALOTENDIN               | tabl.            | 10mg/5mg      | EGIS PHARMA. PLC | HUNGARY | 03.10.2018                      | MRP            | Renewal |  |
| BISOPROLOLUM/AMLOPIDINUM | ALOTENDIN               | tabl.            | 10mg/<br>10mg | EGIS PHARMA. PLC | HUNGARY | 03.10.2018                      | MRP            | Renewal |  |
| AMBAZONUM MONOHYDRATE    | FARINGOSEPT SCORTISOARA | lozenges         | 10mg          | TERAPIA S.A.     | ROMANIA | 04.10.2018                      | NAT PROC       | Renewal | R02- Throat<br>preparations                            |
| AMBAZONUM MONOHYDRATE    | FARINGOSEPT ROM         | lozenges         | 10mg          | TERAPIA S.A.     | ROMANIA | 04.10.2018                      | NAT PROC       | Renewal |  |
| AMBAZONUM MONOHYDRATE    | FARINGOSEPT MENTA       | lozenges         | 10mg          | TERAPIA S.A.     | ROMANIA | 04.10.2018                      | NAT PROC       | Renewal |  |



| INN                         | Trade name                       | Pharm. form                               | Strength        | MAH                       | Country  | Date of placement on the market | Procedure type | Status  | ATC Code   |
|-----------------------------|----------------------------------|---|-----------------|---------------------------|----------|---------------------------------|----------------|---------|--|
| LAMIVUDINUM/<br>ZIDOVUDINUM | LAMIVUDINA/ZIDO<br>VUDINA ACCORD | film coated<br>tabl.                      | 150mg/<br>300mg | ACCORD<br>HEALTHCARE LTD. | UK       | 05.10.2018                      | MRP            | Renewal | J05- Antivirals for<br>systemic use                    |
| IBUPROFENUM<br>LYSINE       | PADUDEN RAPID                    | film coated<br>tabl.                      | 200mg           | INN-FARM d.o.o.           | SLOVENIA | 08.10.2018                      | MRP            | Renewal | M01-<br>Antiinflammatory and<br>antirheumatic products |
| INSULINE UMANE              | HUMULIN M3                       | susp. for inj.<br>cartridge               | 100UI/ml        | LILLY FRANCE S.A.S        | FRANCE   | 16.10.2018                      | MRP            | Renewal | A10- Drugs used in<br>diabetes                         |
| INSULINE UMANE              | HUMULIN M3<br>KIWKPEN            | susp. for inj.                            | 100IU/ml        | LILLY FRANCE S.A.S        | FRANCE   | 16.10.2018                      | MRP            | Renewal |  |
| INSULINE UMANE              | HUMULIN R                        | sol. for inj.<br>(vial)                   | 100 IU/ml       | LILLY FRANCE S.A.S        | FRANCE   | 16.10.2018                      | MRP            | Renewal |  |
| INSULINE UMANE              | HUMULIN R                        | sol. for inj.<br>(cartridge)              | 100 IU/ml       | LILLY FRANCE S.A.S        | FRANCE   | 16.10.2018                      | MRP            | Renewal |  |
| INSULINE UMANE              | HUMULIN R<br>KWIKPEN             | sol. for inj.<br>(pre-filled<br>syringes) | 100 IU/ml       | LILLY FRANCE S.A.S        | FRANCE   | 16.10.2018                      | MRP            | Renewal |  |
| INSULINE UMANE              | HUMULIN N                        | sol. for inj.<br>(cartridge)              | 100 IU/ml       | LILLY FRANCE S.A.S        | FRANCE   | 16.10.2018                      | MRP            | Renewal |  |
| INSULINE UMANE              | HUMULIN N<br>KWIKPEN             | sol. for inj.<br>(multidose<br>ampoules)  | 100mg/ml        | LILLY FRANCE S.A.S        | FRANCE   | 16.10.2018                      | MRP            | Renewal |  |

| INN                           | Trade name               | Pharm. form                    | Strength  | MAH  | Country | Date of placement on the market | Procedure type | Status    | ATC Code   |
|-------------------------------|--------------------------|--------------------------------|-----------|--|---------|---------------------------------|----------------|-----------|--|
| BETAHISTINUM DIHYDROCHLORIDE  | BETAHISTINA DICLORHIDRAT | tabl.                          | 8mg       | AUROBINDO PHARMA LIMITED                   | MALTA   | 16.10.2018                      | MRP            | Renewal   | N07- Other nervous system drugs                  |
| BETAHISTINUM DIHYDROCHLORIDE  | BETAHISTINA DICLORHIDRAT | tabl.                          | 16mg      | AUROBINDO PHARMA LIMITED                   | MALTA   | 16.10.2018                      | MRP            | Renewal   |  |
| BETAHISTINUM DIHYDROCHLORIDE  | BETAHISTINA DICLORHIDRAT | tabl.                          | 24mg      | AUROBINDO PHARMA LIMITED                   | MALTA   | 16.10.2018                      | MRP            | Renewal   |  |
| DESKETOPROFENUM TROMETAMOL    | DEXKETOPROFEN ROMPHARM   | sol. for inj. /inf.            | 50mg/2ml  | ROMPHARM COMPANY S.R.L.                    | ROMANIA | 17.10.2018                      | MRP            | Renewal   | M01- Antiinflammatory and antirheumatic products |
| BENDAMUSTINUM                 | BENDAMUSTINA ACCORD      | conc. powder for sol. for inf. | 2.5mg/ml  | ACCORD HEALTHCARE LIMITED                  | UK      | 19.10.2018                      | MRP            | Renewal   | L01- Antineoplastic agents                       |
| XILOMETAZOLINUM HYDROCHLORIDE | OLYNTH                   | nasal spray                    | 0.5 mg/ml | MCNEIL PRODUCTS LTD. c/o JOHNSON & JOHNSON | UK      | 22.10.2018                      | MRP            | Renewal   | R01- Nasal preparations                          |
| XILOMETAZOLINUM HYDROCHLORIDE | OLYNTH                   | nasal spray                    | 1mg/ml    | MCNEIL PRODUCTS LTD. c/o JOHNSON & JOHNSON | UK      | 22.10.2018                      | MRP            | Renewal   |  |
| AMISULPRIDUM                  | MIDORA                   | film coated tabl.              | 400mg     | TERAPIA S.A                                | ROMANIA | 23.10.2018                      | NAT PROC       | Renewal   | N05- Psycholeptics                               |
| COMBINATII                    | GRIPOFF                  | gran. for oral susp.           |           | SLAVIA PHARM S.R.L.                        | ROMANIA | 23.10.2018                      | NAT PROC       | Authoris. | N02- Analgesics                                  |

| INN               | Trade name                   | Pharm. form    | Strength     | MAH                      | Country | Date of placement on the market | Procedure type | Status    | ATC Code   |
|-------------------|------------------------------|----------------|--------------|--------------------------|---------|---------------------------------|----------------|-----------|--|
| FLUODEOXIGLUCOSUM | FLUDEXIGLUCOZA (18F) MONROL  | sol. for inj.  | 200/2200/MBq | MONROL EUROPE S.R.L.     | ROMANIA | 23.10.2018                      | MRP            | Renewal   | V09- Diagnostic radiopharmaceuticals                   |
| SOMATROPINUM      | SAIZEN                       | sol. for inj.  | 5.83mg/ml    | MERCK ROMANIA SRL        | ROMANIA | 24.10.2018                      | MRP            | Authoris. | H01- Pituitary and hypothalamic hormones and analogues |
| SOMATROPINUM      | SAIZEN                       | sol. for inj.  | 8mg/ml       | MERCK ROMANIA SRL        | ROMANIA | 24.10.2018                      | MRP            | Authoris. |  |
| COMBINATII        | GAVISCON CU AROMA DE CAPSUNI | chewable tabl. |              | RECKITT BECKISER IRELAND | IRELAND | 25.10.2018                      | MRP            | Renewal   | A02- Drugs for acid related disorders                  |
| ATOMOXETINUM      | ATOMOXETINA ZENTIVA          | caps.          | 10mg         | ZENTIVA S.A.             | ROMANIA | 29.10.2018                      | MRP            | Renewal   | N06- Psychoanaleptics                                  |
| ATOMOXETINUM      | ATOMOXETINA ZENTIVA          | caps.          | 18mg         | ZENTIVA S.A.             | ROMANIA | 29.10.2018                      | MRP            | Renewal   |  |
| ATOMOXETINUM      | ATOMOXETINA ZENTIVA          | caps.          | 25mg         | ZENTIVA S.A.             | ROMANIA | 29.10.2018                      | MRP            | Renewal   |  |
| ATOMOXETINUM      | ATOMOXETINA ZENTIVA          | caps.          | 40mg         | ZENTIVA S.A.             | ROMANIA | 29.10.2018                      | MRP            | Renewal   |  |
| ATOMOXETINUM      | ATOMOXETINA ZENTIVA          | caps.          | 60mg         | ZENTIVA S.A.             | ROMANIA | 29.10.2018                      | MRP            | Renewal   |  |
| ATOMOXETINUM      | ATOMOXETINA ZENTIVA          | caps.          | 100mg        | ZENTIVA S.A.             | ROMANIA | 29.10.2018                      | MRP            | Renewal   |  |

| INN                                     | Trade name                            | Pharm. form                    | Strength        | MAH                       | Country | Date of placement on the market | Procedure type | Status    | ATC Code   |
|---|---------------------------------------|--------------------------------|-----------------|---------------------------|---------|---------------------------------|----------------|-----------|--|
| LEVODOPUM + CARBIDOPUM                  | DUODOPA                               | intestinal gel                 | 20mg/ml+5 mg/ml | ABBVIE AB                 | SWEDEN  | 30.10.2018                      | MRP            | Renewal   | N04- Anti-Parkinson drugs                        |
| AMPICILLINUM                            | EPICOCILLIN 250 mg                    | powder for sol. for inj.       | 250 mg          | EIPICO MED SRL            | ROMANIA | 01.11.2018                      | NAT PROC       | Renewal   | J01- Antibacterials for systemic use             |
| AMPICILLINUM                            | EPICOCILLIN 1g                        | powder for sol. for inj. /inf. | 1g              | EIPICO MED SRL            | ROMANIA | 01.11.2018                      | NAT PROC       | Renewal   |  |
| FLUDARABINUM PHOSPHATUM                 | FLUDARABINA ACCORD                    | conc. for sol. for inf.        | 25mg/ml         | ACCORD HEALTHCARE LIMITED | UK      | 01.11.2018                      | MRP            | Renewal   | L01- Antineoplastic agents                       |
| CELECOXIBUM                             | CELECOXIB TERAPIA                     | caps.                          | 100mg           | RANBAXY ITALY SPA         | ITALY   | 01.11.2018                      | MRP            | Renewal   | M01- Antiinflammatory and antirheumatic products |
| CELECOXIBUM                             | CELECOXIB TERAPIA                     | caps.                          | 200mg           | RANBAXY ITALY SPA         | ITALY   | 01.11.2018                      | MRP            | Renewal   |  |
| IBUPROFENUM /PSEUDOEFEDRINUM CLORHIDRAT | IBUPROFEN CU PSEUDOEFEDRINA LAROPHARM | film coated tabl.              | 200mg/ 30mg     | LAROPHARM S.R.L.          | ROMANIA | 08.11.2018                      | NAT PROC       | Authoris. | R01- Nasal preparations                          |
| PARACETAMOLUM + PHENYLEPHRINE HCL       | LEKADOL                               | powder for oral solution       | 500mg/ 12.2mg   | SALUTAS PHARMA GmbH       | GERMANY | 09.11.2018                      | MRP            | Renewal   | N02- Analgesics                                  |
| PARACETAMOLUM + PHENYLEPHRINE HCL       | LEKADOL                               | powder for oral solution       | 1000mg/ 12.2mg  | SALUTAS PHARMA GmbH       | GERMANY | 09.11.2018                      | MRP            | Renewal   |  |

| INN                             | Trade name        | Pharm. form                    | Strength  | MAH                                       | Country | Date of placement on the market | Procedure type | Status    | ATC Code                             |
|---------------------------------|-------------------|--------------------------------|-----------|---|---------|---------------------------------|----------------|-----------|--------------------------------------|
| TRIMETAZIDINUM DIHYDROCHLORIDUM | MODUXIN MR        | prol. release tabl.            | 35mg      | GEDEON RICHTER PLC                        | HUNGARY | 21.11.2018                      | MRP            | Renewal   | C01- Cardiac therapy                 |
| TROSPIUM                        | INKONTAN          | film coated tabl.              | 45mg      | PHARMAZEUTISCHE FABRIK MONTAVIT Ges.m.B.H | AUSTRIA | 27.11.2018                      | NAT PROC       | Authoris. | G04- Urologicals                     |
| DORZOLAMIDUM                    | DORZOLAMIDA ARENA | eye sol.                       | 20mg/ml   | ARENA GROUP S.A.                          | ROMANIA | 04.12.2018                      | NAT PROC       | Renewal   | S01- Ophthalmologicals               |
| MEROPENEMUM                     | ARCHIFAR          | powder for sol. for inj. /inf. | 500mg     | MEDOCHEMIE ROMANIA S.R.L.                 | ROMANIA | 04.12.2018                      | NAT PROC       | Renewal   | J01- Antibacterials for systemic use |
| MEROPENEMUM                     | ARCHIFAR          | powder for sol. for inj. /inf. | 1000mg    | MEDOCHEMIE ROMANIA S.R.L.                 | ROMANIA | 04.12.2018                      | NAT PROC       | Renewal   |                                      |
| EZETIMIBUM/ATORVASTATINUM       | ATOZET            | film coated tabl.              | 10mg/10mg | MERCK SHARP & DOHME ROMANIA SRL           | ROMANIA | 04.12.2018                      | MRP            | Renewal   | C10- Lipid modifying agents          |
| EZETIMIBUM/ATORVASTATINUM       | ATOZET            | film coated tabl.              | 10mg/20mg | MERCK SHARP & DOHME ROMANIA SRL           | ROMANIA | 04.12.2018                      | MRP            | Renewal   |                                      |
| EZETIMIBUM/ATORVASTATINUM       | ATOZET            | film coated tabl.              | 10mg/40mg | MERCK SHARP & DOHME ROMANIA SRL           | ROMANIA | 04.12.2018                      | MRP            | Renewal   |                                      |
| EZETIMIBUM/ATORVASTATINUM       | ATOZET            | film coated tabl.              | 10mg/80mg | MERCK SHARP & DOHME ROMANIA SRL           | ROMANIA | 04.12.2018                      | MRP            | Renewal   |                                      |

| INN                                       | Trade name                  | Pharm. form                        | Strength         | MAH                                | Country | Date of placement on the market | Procedure type | Status    | ATC Code   |
|---|-----------------------------|------------------------------------|------------------|------------------------------------|---------|---------------------------------|----------------|-----------|--|
| PARACETAMOLUM                             | PARACETAMOL POLISANO        | tabl.                              | 500mg            | POLISANO PHARMACEUTICALS           | ROMANIA | 06.12.2018                      | NAT PROC       | Renewal   | N02- Analgesics  |
| DICLOFENACUM SODIUM/ OMEORAZOLUM          | DICLOPRAM                   | caps.                              | 75mg/ 20mg       | PHARMASWISS CESKA REPUBLIKA s.r.o. | CEHIA   | 06.12.2018                      | MRP            | Renewal   | M01- Antiinflammatory and antirheumatic products       |
| IPATROPIUM BROMIDE/ SALBUTAMOLUM SULPHATE | IPRATROPIU/ SALBUTMOL CIPLA | nebuliser sol.                     | 0.5/2.5mg/ 2.5ml | CIPLA EUROPE                       | BELGIUM | 10.12.2018                      | MRP            | Renewal   | R03- Drugs for obstructive airway diseases             |
| EXTRACT USCAT DE IEDERA                   | MUCOPLANT                   | syrup                              | 1.54mg/ml        | DR THEISS NATURWAREN GMBH          | GERMANY | 11.12.2018                      | MRP            | Renewal   | R05- Cough and cold preparations                       |
| BROMHEXINUM HYDROCHLORIDE                 | BROMHEXIN BIOFARM           | tabl.                              | 8 mg             | BIOFARM S.A.                       | ROMANIA | 13.12.2018                      | NAT PROC       | Renewal   |  |
| BROMHEXINUM HYDROCHLORIDE                 | BROMHEXIN BIOFARM           | tabl.                              | 12 mg            | BIOFARM S.A.                       | ROMANIA | 13.12.2018                      | NAT PROC       | Renewal   |  |
| HOMEOPATE                                 | CORYZALIA                   | tabl.                              |                  | BOIRON S.A.                        | FRANCE  | 13.12.2018                      | NAT PROC       | Authoris. | XRNIT  |
| CHORIONIC GONADOTROPIN                    | CHORIOMON                   | powder and solv. for sol. for inj. | 5000IU           | MLD-V LIMITED                      | ROMANIA | 17.12.2018                      | NAT PROC       | Authoris. | G03- Sex hormones and modulators of the genital system |
| IMIPENEM/ CILASTATIN                      | IMIPENEM/ CILASTATINA ATB   | powder for sol. for inf.           | 500 mg/ 500 mg   | ANTIBIOTICE S.A.                   | ROMANIA | 21.12.2018                      | NAT PROC       | Renewal   | J01- Antibacterials for systemic use                   |

| INN             | Trade name          | Pharm. form            | Strength     | MAH                                       | Country | Date of placement on the market | Procedure type | Status    | ATC Code                               |
|-----------------|---------------------|------------------------|--------------|---|---------|---------------------------------|----------------|-----------|--|
| FLURBIPROFEN    | STREPFEB            | oromucosal spray, sol. | 8.75 mg/DOSE | RECKITT BENCKISER HEALTHCARE LTD          | UK      | 27.12.2018                      | MRP            | Renewal   | R02- Throat preparations               |
| PLANTE          | TAVIPEC FORTE       | gastrores. caps.       | 300 mg       | PHARMAZEUTISCHE FABRIK MONTAVIT Ges.m.B.H | AUSTRIA | 27.12.2018                      | NAT PROC       | Authoris. | R07- Other respiratory system products |
| ACETYLCYSTEINUM | REVITUS EXPECTORANT | caps.                  | 200 mg       | SOLACIUM PHARMA                           | ROMANIA | 27.12.2018                      | NAT PROC       | Renewal   | R05- Cough and cold preparations       |
| ATOMOXETINUM    | ATOMOXETINA ZENTIVA | caps.                  | 80mg         | ZENTIVA S.A.                              | ROMANIA | 29.10.2018                      | MRP            | Renewal   | N06- Psychoanaleptics                  |

### Medicinal products authorised for marketing in the 4<sup>th</sup> quarter 2018

| INN             | Trade name                  | Pharm. form       | Strength | MAH                                 | Country    | ATC Code | MA No. | MA Date    |
|-----------------|-----------------------------|-------------------|----------|-------------------------------------|------------|----------|--------|------------|
| ACETYLCYSTEINUM | MUCOFORTIN 600 mg           | efferv. tabl.     | 600mg    | NATUR PRODUKT ZDROVIT SP. Z O.O.    | POLAND     | R05CB01  | 11144  | 29.11.2018 |
| ACICLOVIRUM     | VIRANTI 50 mg/g             | cutaneous stick   | 50mg/g   | ALVOGEN MALTA OPERATIONS (ROW) LTD. | MALTA      | D06BB03  | 11255  | 18.12.2018 |
| AGOMELATINUM    | ZILBEA 25 mg                | film coated tabl. | 25mg     | ZENTIVA, K.S.                       | CZECH REP. | N06AX22  | 11173  | 29.11.2018 |
| ALLOPURINOLUM   | ALOPURINOL AUROBINDO 100 mg | tabl.             | 100mg    | AUROBINDO PHARMA ROMANIA S.R.L.     | ROMANIA    | M04AA01  | 11183  | 29.11.2018 |
| ALLOPURINOLUM   | ALOPURINOL AUROBINDO 300 mg | tabl.             | 300mg    | AUROBINDO PHARMA ROMANIA S.R.L.     | ROMANIA    | M04AA01  | 11184  | 29.11.2018 |
| ALLOPURINOLUM   | MILURIT 150 mg              | tabl.             | 150mg    | EGIS PHARMACEUTICALS PLC.           | HUNGARY    | M04AA01  | 11091  | 16.11.2018 |
| ALLOPURINOLUM   | MILURIT 200 mg              | tabl.             | 200mg    | EGIS PHARMACEUTICALS PLC.           | HUNGARY    | M04AA01  | 11092  | 16.11.2018 |
| ANAGRELIDUM     | ANAGRELIDA AUROBINDO 0.5 mg | caps.             | 0.5mg    | AUROBINDO PHARMA ROMANIA S.R.L.     | ROMANIA    | L01XX35  | 11142  | 29.11.2018 |



| INN          | Trade name                     | Pharm. form | Strength       | MAH                                | Country | ATC Code | MA No. | MA Date    |
|--------------|--------------------------------|-------------|----------------|------------------------------------|---------|----------|--------|------------|
| APREPITANTUM | TIPERANT 125 mg                | caps.       | 125mg          | ETHYPHARM                          | FRANCE  | A04AD12  | 11048  | 24.10.2018 |
| APREPITANTUM | TIPERANT 125 mg/80 mg          | caps.       | 125mg/<br>80mg | ETHYPHARM                          | FRANCE  | A04AD12  | 11049  | 24.10.2018 |
| APREPITANTUM | TIPERANT 80 mg                 | caps.       | 80mg           | ETHYPHARM                          | FRANCE  | A04AD12  | 11047  | 24.10.2018 |
| ATAZANAVIRUM | ATAZANAVIR SANDOZ<br>100 mg    | caps.       | 100mg          | SANDOZ S.R.L.                      | ROMANIA | J05AE08  | 11278  | 27.12.2018 |
| ATAZANAVIRUM | ATAZANAVIR SANDOZ<br>150 mg    | caps.       | 150mg          | SANDOZ S.R.L.                      | ROMANIA | J05AE08  | 11279  | 27.12.2018 |
| ATAZANAVIRUM | ATAZANAVIR SANDOZ<br>200 mg    | caps.       | 200mg          | SANDOZ S.R.L.                      | ROMANIA | J05AE08  | 11280  | 27.12.2018 |
| ATAZANAVIRUM | ATAZANAVIR SANDOZ<br>300 mg    | caps.       | 300mg          | SANDOZ S.R.L.                      | ROMANIA | J05AE08  | 11281  | 27.12.2018 |
| ATOMOXETINUM | ATOMOXETINA<br>AUROBINDO 10 mg | caps.       | 10mg           | AUROBINDO PHARMA<br>ROMANIA S.R.L. | ROMANIA | N06BA09  | 11103  | 16.11.2018 |
| ATOMOXETINUM | ATOMOXETINA<br>AUROBINDO 18 mg | caps.       | 18mg           | AUROBINDO PHARMA<br>ROMANIA S.R.L. | ROMANIA | N06BA09  | 11104  | 16.11.2018 |

| INN            | Trade name  | Pharm. form | Strength | MAH                                | Country | ATC Code | MA No. | MA Date    |
|----------------|---|-------------|----------|------------------------------------|---------|----------|--------|------------|
| ATOMOXETINUM   | ATOMOXETINA<br>AUROBINDO 25 mg                    | caps.       | 25mg     | AUROBINDO PHARMA<br>ROMANIA S.R.L. | ROMANIA | N06BA09  | 11105  | 16.11.2018 |
| ATOMOXETINUM   | ATOMOXETINA<br>AUROBINDO 40 mg                    | caps.       | 40mg     | AUROBINDO PHARMA<br>ROMANIA S.R.L. | ROMANIA | N06BA09  | 11106  | 16.11.2018 |
| ATOMOXETINUM   | ATOMOXETINA<br>AUROBINDO 60 mg                    | caps.       | 60mg     | AUROBINDO PHARMA<br>ROMANIA S.R.L. | ROMANIA | N06BA09  | 11107  | 16.11.2018 |
| ATOMOXETINUM   | ATOMOXETINA<br>AUROBINDO 80 mg                    | caps.       | 80mg     | AUROBINDO PHARMA<br>ROMANIA S.R.L. | ROMANIA | N06BA09  | 11108  | 16.11.2018 |
| ATORVASTATINUM | ATORVASTATINA ARENA<br>10 mg                      | tabl.       | 10mg     | ARENA GROUP S.A.                   | ROMANIA | C10AA05  | 11235  | 14.12.2018 |
| ATORVASTATINUM | ATORVASTATINA ARENA<br>20 mg                      | tabl.       | 20mg     | ARENA GROUP S.A.                   | ROMANIA | C10AA05  | 11236  | 14.12.2018 |
| ATORVASTATINUM | ATORVASTATINA ARENA<br>40 mg                      | tabl.       | 40mg     | ARENA GROUP S.A.                   | ROMANIA | C10AA05  | 11237  | 14.12.2018 |
| ATORVASTATINUM | ATORVASTATINA ARENA<br>80 mg                      | tabl.       | 80mg     | ARENA GROUP S.A.                   | ROMANIA | C10AA05  | 11238  | 14.12.2018 |
| BENZYDAMINUM   | BENZIDAMINA ZENTIVA<br>CU AROMA DE LAMAIE<br>3 mg | lozenges    | 3mg      | ZENTIVA S.A.                       | ROMANIA | R02AX03  | 11286  | 27.12.2018 |

| INN           | Trade name  | Pharm. form                              | Strength | MAH                                    | Country | ATC Code | MA No. | MA Date    |
|---------------|---|--|----------|--|---------|----------|--------|------------|
| BENZYDAMINUM  | BENZIDAMINA ZENTIVA<br>CU AROMA DE<br>PORTOCALA and MIERE<br>3 mg | lozenges                                 | 3mg      | ZENTIVA S.A.                           | ROMANIA | R02AX03  | 11285  | 27.12.2018 |
| BENZYDAMINUM  | FARINGO LAMAIE 3 mg   | lozenges                                 | 3mg      | TERAPIA SA                             | ROMANIA | R02AX03  | 11219  | 07.12.2018 |
| BENZYDAMINUM  | FARINGO MIERE and<br>PORTOCALA 3 mg                               | lozenges                                 | 3mg      | TERAPIA SA                             | ROMANIA | R02AX03  | 11220  | 07.12.2018 |
| BUPROPIONUM   | BUPROPIONA ACCORD<br>300 mg                                       | modif. release<br>tabl.                  | 300mg    | ACCORD HEALTHCARE<br>POLSKA SP. Z O.O. | POLAND  | N06AX12  | 11309  | 28.12.2018 |
| CARMUSTINUM   | CARMUSTINE 100 mg   | powd+solv.<br>for sol. for<br>inf.       | 100mg    | CN UNIFARM S.A.                        | ROMANIA | L01AD01  | 386    | 10.10.2018 |
| CASPOFUNGINUM | CASPOFUNGINA SANDOZ<br>50 mg                                      | powder for<br>conc. for sol.<br>for inf. | 50mg     | SANDOZ S.R.L.                          | ROMANIA | J02AX04  | 11161  | 29.11.2018 |
| CASPOFUNGINUM | CASPOFUNGINA SANDOZ<br>70 mg                                      | powder for<br>conc. for sol.<br>for inf. | 70mg     | SANDOZ S.R.L.                          | ROMANIA | J02AX04  | 11162  | 29.11.2018 |
| CEFAZOLINUM   | CEFAZOLIN 1 g   | powder for<br>sol. for inj.<br>i.v./i.m. | 1g       | CN UNIFARM S.A.                        | ROMANIA | J01DB04  | 385    | 10.10.2018 |
| CEFAZOLINUM   | ZOLINEF 1 g   | powder for<br>sol. for inj.<br>/inf.     | 1g       | MEDOCHEMIE<br>ROMANIA S.R.L.           | ROMANIA | J01DB04  | 11299  | 28.12.2018 |

| INN  | Trade name  | Pharm. form  | Strength                  | MAH                                | Country | ATC Code | MA No. | MA Date    |
|--|---|--|---------------------------|------------------------------------|---------|----------|--------|------------|
| CINACALCETUM   | CINACALCET FLOMI<br>30 mg                             | film coated<br>tabl.                               | 30mg                      | FLOMI FARMA SRL                    | ROMANIA | H05BX01  | 11295  | 28.12.2018 |
| CINACALCETUM   | CINACALCET FLOMI<br>60 mg                             | film coated<br>tabl.                               | 60mg                      | FLOMI FARMA SRL                    | ROMANIA | H05BX01  | 11296  | 28.12.2018 |
| CINACALCETUM   | CINACALCET FLOMI<br>90 mg                             | film coated<br>tabl.                               | 90mg                      | FLOMI FARMA SRL                    | ROMANIA | H05BX01  | 11297  | 28.12.2018 |
| CLOPIDOGRELUM  | CLOPIDOGREL ARENA<br>75 mg                            | film coated<br>tabl.                               | 75mg                      | ARENA GROUP S.A.                   | ROMANIA | B01AC04  | 11109  | 16.11.2018 |
| COMBINATIONS<br>(BISOPROLOLUM+<br>PERINDOPRILUM)       | SCALIAN 5 mg/5 mg                                     | film coated<br>tabl.                               | 5mg/5mg                   | EGIS<br>PHARMACEUTICALS<br>PLC     | HUNGARY | C09BX02  | 11206  | 07.12.2018 |
| COMBINATIONS<br>(DORZOLAMIDUM+<br>TIMOLOLUM)           | COSOPT FARA<br>CONSERVANT<br>20 mg/ml+5 mg/ml         | eye drops<br>susp.                                 | 20mg/ml+<br>5mg/ml        | SANTEN OY                          | FINLAND | S01ED51  | 11102  | 16.11.2018 |
| COMBINATIONS<br>(DUTASTERIDUM+<br>TAMSULOSINUM)        | AVATERID DUO<br>0.5 mg/0.4 mg                         | caps.  | 0.5mg/<br>0,4mg           | SANDOZ S.R.L.                      | ROMANIA | G04CA52  | 11101  | 16.11.2018 |
| COMBINATIONS<br>(ETINILESTRADIOLUM +<br>DROSPIRENONUM) | DROSPIRENONA/<br>ETINILESTRADIOL VALE<br>3 mg/0.03 mg | tabl.  | 3mg/0.03mg                | VALE<br>PHARMACEUTICALS<br>LIMITED | IRELAND | G03AA12  | 11298  | 28.12.2018 |
| COMBINATIONS<br>(LATANOPROSTUM+<br>TIMOLOLUM)          | FIXANPOST<br>50 micrograms/ml+5 mg/ml                 | eye drops<br>sol., in single-<br>dose<br>container | 50micrograme<br>ml+5mg/ml | LABORATOIRES THEA                  | FRANCE  | S01ED51  | 11012  | 10.10.2018 |

| INN  | Trade name                                       | Pharm. form             | Strength         | MAH   | Country  | ATC Code | MA No. | MA Date    |
|--|--|-------------------------|------------------|---|----------|----------|--------|------------|
| COMBINATIONS<br>(PERINDOPRILUM+<br>AMLODIPINUM)                  | PREAMLESSA<br>2.85 mg/2.5 mg                     | tabl.                   | 2,85mg/<br>2.5mg | KRKA, D.D., NOVO<br>MESTO                                 | SLOVENIA | C09BB04  | 11127  | 20.11.2018 |
| COMBINATIONS<br>(PERINDOPRILUM+<br>AMLODIPINUM)                  | PREAMLESSA<br>5.7 mg/5 mg                        | tabl.                   | 5.7mg/5mg        | KRKA, D.D., NOVO<br>MESTO                                 | SLOVENIA | C09BB04  | 11128  | 20.11.2018 |
| COMBINATIONS<br>(ROSUVASTATINUM+<br>EZETIMIBUM)                  | TWICOR 10 mg/10 mg                               | film coated<br>tabl.    | 10mg/10mg        | MYLAN HEALTHCARE<br>GMBH                                  | GERMANY  | C10BA06  | 11316  | 28.12.2018 |
| COMBINATIONS<br>(ROSUVASTATINUM+<br>EZETIMIBUM)                  | TWICOR 20 mg/10 mg                               | film coated<br>tabl.    | 20mg/10mg        | MYLAN HEALTHCARE<br>GMBH                                  | GERMANY  | C10BA06  | 11317  | 28.12.2018 |
| COMBINATIONS<br>(ACIDUM<br>ACETYLSALICYLICUM+<br>PSEUDOEFEDRINA) | ASPIRIN COMPLEX<br>500 mg/30 mg<br>(see N02BA01) | gran. for oral<br>susp. | 500mg/<br>30mg   | BAYER S.R.L.  | ROMANIA  | R01BA02  | 11096  | 16.11.2018 |
| COMBINATIONS<br>(ACIDUM<br>ACETYLSALICYLICUM+<br>PSEUDOEFEDRINA) | ASPIRIN COMPLEX<br>500 mg/30 mg<br>(see R01BA02) | gran. for oral<br>susp. | 500mg/<br>30mg   | BAYER S.R.L.  | ROMANIA  | N02BA01  | 11096  | 16.11.2018 |
| CYTARABINUM  | CITARABINA ACCORD<br>20 mg/ml                    | sol for<br>inj./inf.    | 20mg/ml          | ACCORD HEALTHCARE<br>LIMITED                              | UK       | L01BC01  | 11051  | 26.10.2018 |
| DAPSONUM   | DISULONE 100 mg                                  | scored tablets          | 100mg            | CN UNIFARM S.A.   | ROMANIA  | J04BA02  | 398    | 29.11.2018 |
| DASATINIBUM  | DASATINIB PHAROS<br>100 mg                       | film coated<br>tabl.    | 100mg            | PHAROS LTD-<br>PHARMACEUTICAL<br>ORIENTED SERVICES<br>LTD | GREECE   | L01XE06  | 11218  | 07.12.2018 |

| INN           | Trade name                  | Pharm. form                              | Strength   | MAH   | Country  | ATC Code | MA No. | MA Date    |
|---------------|-----------------------------|--|------------|---|----------|----------|--------|------------|
| DASATINIBUM   | DASATINIB PHAROS<br>20 mg   | film coated<br>tabl.                     | 20mg       | PHAROS LTD-<br>PHARMACEUTICAL<br>ORIENTED SERVICES<br>LTD | GREECE   | L01XE06  | 11215  | 07.12.2018 |
| DASATINIBUM   | DASATINIB PHAROS<br>50 mg   | film coated<br>tabl.                     | 50mg       | PHAROS LTD-<br>PHARMACEUTICAL<br>ORIENTED SERVICES<br>LTD | GREECE   | L01XE06  | 11216  | 07.12.2018 |
| DASATINIBUM   | DASATINIB PHAROS<br>70 mg   | film coated<br>tabl.                     | 70mg       | PHAROS LTD-<br>PHARMACEUTICAL<br>ORIENTED SERVICES<br>LTD | GREECE   | L01XE06  | 11217  | 07.12.2018 |
| DINOPROSTONUM | PROPESS 10 mg/24 ore        | vaginal<br>delivery<br>system            | 10mg/24ore | FERRING GMBH  | GERMANY  | G02AD02  | 11129  | 20.11.2018 |
| DOXYLAMINUM   | DORNITE 25 mg               | film coated<br>tabl.                     | 25 mg      | KRKA, D.D., NOVO<br>MESTO                                 | SLOVENIA | R06AA09  | 11287  | 27.12.2018 |
| ENTECAVIRUM   | ENTECAVIR TERAPIA<br>0.5 mg | film coated<br>tabl.                     | 0.5mg      | S.C. TERAPIA S.A.   | ROMANIA  | J05AF10  | 11307  | 28.12.2018 |
| ENTECAVIRUM   | ENTECAVIR TERAPIA<br>1 mg   | film coated<br>tabl.                     | 1mg        | S.C. TERAPIA S.A.   | ROMANIA  | J05AF10  | 11308  | 28.12.2018 |
| ERTAPENEMUM   | ERTAPENEM AUROBINDO<br>1 g  | powder for<br>conc. for sol.<br>for inf. | 1g         | AUROBINDO PHARMA<br>ROMANIA S.R.L.                        | ROMANIA  | J01DH03  | 11099  | 16.11.2018 |
| ETORICOXIBUM  | XALEBA 120 mg               | film coated<br>tabl.                     | 120mg      | ACCORD HEALTHCARE<br>LIMITED                              | UK       | M01AH05  | 11233  | 13.12.2018 |

| INN          | Trade name                   | Pharm. form       | Strength | MAH                       | Country  | ATC Code | MA No. | MA Date    |
|--------------|------------------------------|-------------------|----------|---------------------------|----------|----------|--------|------------|
| ETORICOXIBUM | XALEBA 30 mg                 | film coated tabl. | 30mg     | ACCORD HEALTHCARE LIMITED | UK       | M01AH05  | 11230  | 13.12.2018 |
| ETORICOXIBUM | XALEBA 60 mg                 | film coated tabl. | 60mg     | ACCORD HEALTHCARE LIMITED | UK       | M01AH05  | 11231  | 13.12.2018 |
| ETORICOXIBUM | XALEBA 90 mg                 | film coated tabl. | 90mg     | ACCORD HEALTHCARE LIMITED | UK       | M01AH05  | 11232  | 13.12.2018 |
| EVEROLIMUS   | EVEROLIMUS KRKA<br>10 mg     | tabl.             | 10mg     | KRKA, D.D. NOVO MESTO     | SLOVENIA | L01XE10  | 11033  | 16.10.2018 |
| EVEROLIMUS   | EVEROLIMUS KRKA<br>2.5 mg    | tabl.             | 2.5mg    | KRKA, D.D. NOVO MESTO     | SLOVENIA | L01XE10  | 11031  | 16.10.2018 |
| EVEROLIMUS   | EVEROLIMUS KRKA<br>5 mg      | tabl.             | 5mg      | KRKA, D.D. NOVO MESTO     | SLOVENIA | L01XE10  | 11032  | 16.10.2018 |
| EVEROLIMUS   | EVEROLIMUS SANDOZ<br>0.25 mg | tabl.             | 0.25mg   | SANDOZ S.R.L.             | ROMANIA  | L04AA18  | 11265  | 20.12.2018 |
| EVEROLIMUS   | EVEROLIMUS SANDOZ 0.5<br>mg  | tabl.             | 0.5mg    | SANDOZ S.R.L.             | ROMANIA  | L04AA18  | 11266  | 20.12.2018 |
| EVEROLIMUS   | EVEROLIMUS SANDOZ<br>0.75 mg | tabl.             | 0.75mg   | SANDOZ S.R.L.             | ROMANIA  | L04AA18  | 11267  | 20.12.2018 |

| INN            | Trade name  | Pharm. form                              | Strength | MAH                                       | Country    | ATC Code | MA No. | MA Date    |
|----------------|---|--|----------|---|------------|----------|--------|------------|
| EVEROLIMUS     | EVEROLIMUS SANDOZ<br>1 mg                             | tabl.                                    | 1mg      | SANDOZ S.R.L.                             | ROMANIA    | L04AA18  | 11268  | 20.12.2018 |
| FLUDARABINUM   | FLUDARABINA ACCORD<br>25 mg/ml                        | conc. for sol.<br>for inj./inf.          | 25mg/ml  | ACCORD HEALTHCARE<br>LIMITED              | UK         | L01BB05  | 11310  | 28.12.2018 |
| FLURBIPROFENUM | STREPSILS INTENSIV<br>PORTOCALE FARA<br>ZAHAR 8.75 mg | lozenges                                 | 8.75mg   | RECKITT BENCKISER<br>(ROMANIA) S.R.L.     | ROMANIA    | R07AXN1  | 11124  | 19.11.2018 |
| FULVESTRANTUM  | FULVESTRANT<br>ROMPHARM 250 mg                        | sol for inj. in<br>pre-filled<br>syringe | 250mg    | ROMPHARM COMPANY<br>S.R.L.                | ROMANIA    | L02BA03  | 11138  | 29.11.2018 |
| FUROSEMIDUM    | FUROSEMID HAMELN<br>10 mg/ml                          | sol for inj.                             | 10mg/ml  | HAMELN PHARMA PLUS<br>GMBH                | GERMANY    | C03CA01  | 11130  | 20.11.2018 |
| GEFITINIBUM    | GEFITINIB ALVOGEN 250<br>mg                           | film coated<br>tabl.                     | 250mg    | ALVOGEN MALTA<br>OPERATIONS (ROW)<br>LTD. | MALTA      | L01XE02  | 11302  | 28.12.2018 |
| GEFITINIBUM    | GEFITINIB GLENMARK<br>250 mg                          | film coated<br>tabl.                     | 250mg    | GLENMARK<br>PHARMACEUTICALS<br>S.R.O.     | CZECH REP. | L01XE02  | 11222  | 13.12.2018 |
| GEFITINIBUM    | GEFITINIB SANDOZ<br>250 mg                            | film coated<br>tabl.                     | 250mg    | S.C. SANDOZ SRL                           | ROMANIA    | L01XE02  | 11288  | 27.12.2018 |
| GINKGO BILOBA  | FRUNZA DE GINKGO<br>QUEISSER 120 mg                   | film coated<br>tabl.                     | 120mg    | QUEISSER PHARMA<br>GMBH CO. KG            | GERMANY    | N06DX02  | 11082  | 14.11.2018 |



| INN                              | Trade name   | Pharm. form                        | Strength        | MAH                                 | Country  | ATC Code | MA No. | MA Date    |
|----------------------------------|--|------------------------------------|-----------------|-------------------------------------|----------|----------|--------|------------|
| GINKGO BILOBA                    | FRUNZA DE GINKGO<br>QUEISSER 240 mg                | film coated<br>tabl.               | 240mg           | QUEISSER PHARMA<br>GMBH CO. KG      | GERMANY  | N06DX02  | 11083  | 14.11.2018 |
| GINKGO BILOBA                    | GINKGO BILOBA SLAVIA<br>120 mg                     | caps.                              | 120mg           | SLAVIA PHARM S.R.L.                 | ROMANIA  | N06DX02  | 11117  | 19.11.2018 |
| GINKGO BILOBA                    | GINKGO BILOBA SLAVIA<br>80 mg                      | caps.                              | 80mg            | SLAVIA PHARM S.R.L.                 | ROMANIA  | N06DX02  | 11116  | 19.11.2018 |
| GLUCOSAMINUM                     | GATMYN 1500 mg                                     | powder for<br>oral solution        | 1500mg          | NEOLA PHARMA S.R.L.                 | ROMANIA  | M01AX05  | 11115  | 19.11.2018 |
| HYDROCORTISONUM                  | HYDROCORTISONE<br>ROUSSEL                          | scored tablets                     | 10mg            | CN UNIFARM S.A.                     | ROMANIA  | H02AB09  | 390    | 19.10.2018 |
| IBUPROFENUM                      | NUROFEN 200 mg                                     | medicated<br>plaster               | 200mg           | RECKITT BENCKISER<br>(ROMÂNIA) SRL  | ROMANIA  | M02AA13  | 11221  | 13.12.2018 |
| IMIPENEMUM +<br>CILASTATINUM     | IMIPENEM/CILASTATIN<br>APTAPHARMA<br>500 mg/500 mg | powder for<br>sol. for inf.        | 500mg/<br>500mg | APTA MEDICA<br>INTERNACIONAL D.O.O. | SLOVENIA | J01DH51  | 11137  | 29.11.2018 |
| RABIES IMMUNE<br>GLOBULIN, HUMAN | IMOGAM RAGE 150 IU/ml                              | sol for inj.                       | 150UI/ml        | CN UNIFARM S.A.                     | ROMANIA  | J06BB05  | 397    | 19.11.2018 |
| C1-ESTERASE<br>INHIBITOR, HUMAN  | BERINERT 2000 2000 IU                              | powd+solv.<br>for sol. for<br>inj. | 2000UI          | CSL BEHRING GMBH                    | GERMANY  | B06AC01  | 11243  | 14.12.2018 |

| INN                          | Trade name                     | Pharm. form                          | Strength | MAH               | Country     | ATC Code | MA No. | MA Date    |
|------------------------------|--------------------------------|--------------------------------------|----------|-------------------|-------------|----------|--------|------------|
| C1-ESTERASE INHIBITOR, HUMAN | BERINERT 3000 3000 IU          | powd+solv. for sol. for inj.         | 3000UI   | CSL BEHRING GMBH  | GERMANY     | B06AC01  | 11244  | 14.12.2018 |
| KETOPROFENUM                 | KETOPROFEN MIDAS 50 mg         | granules for oral solution in sachet | 50mg     | MIDAS PHARMA GMBH | GERMANY     | M01AE03  | 11311  | 28.12.2018 |
| LENALIDOMIDUM                | LENALIDOMIDA BIOORGANICS 10 mg | caps.                                | 10mg     | BIOORGANICS       | NETHERLANDS | L04AX04  | 11240  | 14.12.2018 |
| LENALIDOMIDUM                | LENALIDOMIDA BIOORGANICS 15 mg | caps.                                | 15mg     | BIOORGANICS       | NETHERLANDS | L04AX04  | 11241  | 14.12.2018 |
| LENALIDOMIDUM                | LENALIDOMIDA BIOORGANICS 25 mg | caps.                                | 25mg     | BIOORGANICS       | NETHERLANDS | L04AX04  | 11242  | 14.12.2018 |
| LENALIDOMIDUM                | LENALIDOMIDA BIOORGANICS 5 mg  | caps.                                | 5mg      | BIOORGANICS       | NETHERLANDS | L04AX04  | 11239  | 14.12.2018 |
| LENALIDOMIDUM                | LENALIDOMIDA GENTHON 10 mg     | caps.                                | 10mg     | GENTHON BV        | NETHERLANDS | L04AX04  | 11270  | 20.12.2018 |
| LENALIDOMIDUM                | LENALIDOMIDA GENTHON 15 mg     | caps.                                | 15mg     | GENTHON BV        | NETHERLANDS | L04AX04  | 11271  | 20.12.2018 |
| LENALIDOMIDUM                | LENALIDOMIDA GENTHON 25 mg     | caps.                                | 25mg     | GENTHON BV        | NETHERLANDS | L04AX04  | 11272  | 20.12.2018 |

| INN             | Trade name                  | Pharm. form       | Strength | MAH              | Country     | ATC Code | MA No. | MA Date    |
|-----------------|-----------------------------|-------------------|----------|------------------|-------------|----------|--------|------------|
| LENALIDOMIDUM   | LENALIDOMIDA GENTHON 5 mg   | caps.             | 5mg      | GENTHON BV       | NETHERLANDS | L04AX04  | 11269  | 20.12.2018 |
| LENALIDOMIDUM   | LENALIDOMIDA SANDOZ 10 mg   | caps.             | 10mg     | SANDOZ SRL       | ROMANIA     | L04AX04  | 11202  | 05.12.2018 |
| LENALIDOMIDUM   | LENALIDOMIDA SANDOZ 15 mg   | caps.             | 15mg     | SANDOZ SRL       | ROMANIA     | L04AX04  | 11203  | 05.12.2018 |
| LENALIDOMIDUM   | LENALIDOMIDA SANDOZ 2.5 mg  | caps.             | 2.5mg    | SANDOZ SRL       | ROMANIA     | L04AX04  | 11199  | 05.12.2018 |
| LENALIDOMIDUM   | LENALIDOMIDA SANDOZ 20 mg   | caps.             | 20mg     | SANDOZ SRL       | ROMANIA     | L04AX04  | 11204  | 05.12.2018 |
| LENALIDOMIDUM   | LENALIDOMIDA SANDOZ 25 mg   | caps.             | 25mg     | SANDOZ SRL       | ROMANIA     | L04AX04  | 11205  | 05.12.2018 |
| LENALIDOMIDUM   | LENALIDOMIDA SANDOZ 5 mg    | caps.             | 5mg      | SANDOZ SRL       | ROMANIA     | L04AX04  | 11200  | 05.12.2018 |
| LENALIDOMIDUM   | LENALIDOMIDA SANDOZ 7.5 mg  | caps.             | 7.5mg    | SANDOZ SRL       | ROMANIA     | L04AX04  | 11201  | 05.12.2018 |
| LEVETIRACETAMUM | LEVETIRACETAM ARENA 1000 mg | film coated tabl. | 1000mg   | ARENA GROUP S. A | ROMANIA     | N03AX14  | 11119  | 19.11.2018 |

| INN             | Trade name                    | Pharm. form                              | Strength               | MAH                                | Country | ATC Code | MA No. | MA Date    |
|-----------------|-------------------------------|--|------------------------|------------------------------------|---------|----------|--------|------------|
| LEVETIRACETAMUM | LEVETIRACETAM ARENA<br>500 mg | film coated<br>tabl.                     | 500mg                  | ARENA GROUP S. A                   | ROMANIA | N03AX14  | 11118  | 19.11.2018 |
| LIDOCAINUM      | LIDOCAINA KABI<br>10 mg/ml    | sol for inj.                             | 10mg/ml                | FRESENIUS KABI<br>ROMANIA S.R.L.   | ROMANIA | N01BB02  | 11185  | 29.11.2018 |
| LIDOCAINUM      | LIDOCAINA KABI<br>20 mg/ml    | sol for inj.                             | 20mg/ml                | FRESENIUS KABI<br>ROMANIA S.R.L.   | ROMANIA | N01BB02  | 11186  | 29.11.2018 |
| LINEZOLIDUM     | ZOXILID 600 mg                | film coated<br>tabl.                     | 600mg                  | MEDOCHEMIE LTD                     | CIPRU   | J01XX08  | 11304  | 28.12.2018 |
| LOPERAMIDUM     | LOPERAMID AUROBINDO<br>2 mg   | caps.                                    | 2mg                    | AUROBINDO PHARMA<br>ROMANIA S.R.L. | ROMANIA | A07DA03  | 11143  | 29.11.2018 |
| MELPHALANUM     | MELPHALAN<br>RATIOPHARM       | powd+solv.<br>for sol. for<br>inj. /inf. | 50mg                   | CN UNIFARM S.A.                    | ROMANIA | L01AA03  | 400    | 03.12.2018 |
| METHOTREXATUM   | METHOTREXATE 2.5 mg           | film coated<br>tabl.                     | 2.5mg                  | CN UNIFARM S.A.                    | ROMANIA | L01BA01  | 392    | 05.11.2018 |
| MOMETASONUM     | RINAMET<br>50 micrograms/dose | nasal spray<br>susp.                     | 50microgra-<br>me/doza | SANDOZ S.R.L.                      | ROMANIA | R01AD09  | 11009  | 10.10.2018 |
| MOXIFLOXACINUM  | ERELAN 400 mg                 | film coated<br>tabl.                     | 400mg                  | MEDOCHEMIE LTD.                    | CIPRU   | J01MA14  | 11293  | 28.12.2018 |

| INN          | Trade name                  | Pharm. form            | Strength | MAH              | Country | ATC Code | MA No. | MA Date    |
|--------------|-----------------------------|------------------------|----------|------------------|---------|----------|--------|------------|
| NEBIVOLOLUM  | NOLET 5 mg                  | tabl.                  | 5mg      | ANTIBIOTICE S.A. | ROMANIA | C07AB12  | 11289  | 27.12.2018 |
| OLANZAPINUM  | OLANZAPINA ARENA<br>10 mg   | film coated<br>tabl.   | 10mg     | ARENA GROUP S.A. | ROMANIA | N05AH03  | 11228  | 13.12.2018 |
| OLANZAPINUM  | OLANZAPINA ARENA<br>15 mg   | film coated<br>tabl.   | 15mg     | ARENA GROUP S.A. | ROMANIA | N05AH03  | 11229  | 13.12.2018 |
| OLANZAPINUM  | OLANZAPINA ARENA<br>2.5 mg  | film coated<br>tabl.   | 2.5mg    | ARENA GROUP S.A. | ROMANIA | N05AH03  | 11226  | 13.12.2018 |
| OLANZAPINUM  | OLANZAPINA ARENA<br>5 mg    | film coated<br>tabl.   | 5mg      | ARENA GROUP S.A. | ROMANIA | N05AH03  | 11227  | 13.12.2018 |
| PRAMIPEXOLUM | PRAMIPEXOL MYLAN<br>0.26 mg | prol. release<br>tabl. | 0.26mg   | MYLAN S.A.S.     | FRANCE  | N04BC05  | 11084  | 14.11.2018 |
| PRAMIPEXOLUM | PRAMIPEXOL MYLAN 0.52<br>mg | prol. release<br>tabl. | 0.52mg   | MYLAN S.A.S.     | FRANCE  | N04BC05  | 11085  | 14.11.2018 |
| PRAMIPEXOLUM | PRAMIPEXOL MYLAN<br>1.05 mg | prol. release<br>tabl. | 1.05mg   | MYLAN S.A.S.     | FRANCE  | N04BC05  | 11086  | 14.11.2018 |
| PRAMIPEXOLUM | PRAMIPEXOL MYLAN<br>1.57 mg | prol. release<br>tabl. | 1.57mg   | MYLAN S.A.S.     | FRANCE  | N04BC05  | 11087  | 14.11.2018 |

| INN              | Trade name  | Pharm. form            | Strength | MAH                                | Country  | ATC Code | MA No. | MA Date    |
|------------------|---|------------------------|----------|------------------------------------|----------|----------|--------|------------|
| PRAMIPEXOLUM     | PRAMIPEXOL MYLAN<br>2.1 mg                                    | prol. release<br>tabl. | 2.1mg    | MYLAN S.A.S.                       | FRANCE   | N04BC05  | 11088  | 14.11.2018 |
| PRAMIPEXOLUM     | PRAMIPEXOL MYLAN<br>2.62 mg                                   | prol. release<br>tabl. | 2,62mg   | MYLAN S.A.S.                       | FRANCE   | N04BC05  | 11089  | 14.11.2018 |
| PRAMIPEXOLUM     | PRAMIPEXOL MYLAN<br>3.15 mg                                   | prol. release<br>tabl. | 3.15mg   | MYLAN S.A.S.                       | FRANCE   | N04BC05  | 11090  | 14.11.2018 |
| PRASUGREL        | BEWIM 10 mg   | film coated<br>tabl.   | 10mg     | GEDEON RICHTER<br>ROMANIA S.A.     | ROMANIA  | B01AC22  | 11172  | 29.11.2018 |
| PRASUGREL        | ELISKARDIA 10 mg  | film coated<br>tabl.   | 10mg     | KRKA, D.D., NOVO<br>MESTO          | SLOVENIA | B01AC22  | 11164  | 29.11.2018 |
| PRASUGREL        | ELISKARDIA 5 mg   | film coated<br>tabl.   | 5mg      | KRKA, D.D., NOVO<br>MESTO          | SLOVENIA | B01AC22  | 11163  | 29.11.2018 |
| PROTAMINI SULFAS | PROTAMINSULFAT LEO<br>PHARMA 1400 HEPARIN-<br>ANTIDOT I.E./ml | sol for inj.si<br>inf. | 10mg/ml  | CN UNIFARM S.A.                    | ROMANIA  | V03AB14  | 399    | 29.11.2018 |
| QUETIAPINUM      | KVENTIAX EP 400 mg  | prol. release<br>tabl. | 400mg    | KRKA, D.D., NOVO<br>MESTO          | SLOVENIA | N05AH04  | 11100  | 16.11.2018 |
| RIVAROXABANUM    | RIVAROXABAN<br>AUROBINDO 10 mg                                | film coated<br>tabl.   | 10mg     | AUROBINDO PHARMA<br>ROMANIA S.R.L. | ROMANIA  | B01AF01  | 11169  | 29.11.2018 |

| INN  | Trade name                     | Pharm. form         | Strength            | MAH                             | Country  | ATC Code | MA No. | MA Date    |
|--|--------------------------------|---------------------|---------------------|---------------------------------|----------|----------|--------|------------|
| RIVAROXABANUM                                    | RIVAROXABAN AUROBINDO 15 mg    | film coated tabl.   | 15mg                | AUROBINDO PHARMA ROMANIA S.R.L. | ROMANIA  | B01AF01  | 11170  | 29.11.2018 |
| RIVAROXABANUM                                    | RIVAROXABAN AUROBINDO 20 mg    | film coated tabl.   | 20mg                | AUROBINDO PHARMA ROMANIA S.R.L. | ROMANIA  | B01AF01  | 11171  | 29.11.2018 |
| ROPINIROLUM                                      | ROPINIROL RUAL 2 mg            | prol. release tabl. | 2mg                 | RUAL FARM SRL                   | ROMANIA  | N04BC04  | 11151  | 29.11.2018 |
| ROPINIROLUM                                      | ROPINIROL RUAL 4 mg            | prol. release tabl. | 4mg                 | RUAL FARM SRL                   | ROMANIA  | N04BC04  | 11152  | 29.11.2018 |
| ROPINIROLUM                                      | ROPINIROL RUAL 8 mg            | prol. release tabl. | 8mg                 | RUAL FARM SRL                   | ROMANIA  | N04BC04  | 11153  | 29.11.2018 |
| ROSUVASTATINUM+<br>PERINDOPRILUM+<br>INDAPAMIDUM | ROXIPER 10 mg/4 mg/<br>1.25 mg | film coated tabl.   | 10mg/4mg/<br>1.25mg | KRKA D.D., NOVO MESTO           | SLOVENIA | C10BX13  | 11165  | 29.11.2018 |
| ROSUVASTATINUM+<br>PERINDOPRILUM+<br>INDAPAMIDUM | ROXIPER 10 mg/8 mg/<br>2.5 mg  | film coated tabl.   | 10mg/8mg/<br>2.5mg  | KRKA D.D., NOVO MESTO           | SLOVENIA | C10BX13  | 11167  | 29.11.2018 |
| ROSUVASTATINUM+<br>PERINDOPRILUM+<br>INDAPAMIDUM | ROXIPER 20 mg/4 mg/<br>1.25 mg | film coated tabl.   | 20mg/4mg/<br>1.25mg | KRKA D.D., NOVO MESTO           | SLOVENIA | C10BX13  | 11166  | 29.11.2018 |
| ROSUVASTATINUM+<br>PERINDOPRILUM+<br>INDAPAMIDUM | ROXIPER 20 mg/8 mg/<br>2.5 mg  | film coated tabl.   | 20mg/8mg/<br>2.5mg  | KRKA D.D., NOVO MESTO           | SLOVENIA | C10BX13  | 11168  | 29.11.2018 |

| INN                    | Trade name                           | Pharm. form                        | Strength    | MAH                             | Country    | ATC Code | MA No. | MA Date    |
|------------------------|--------------------------------------|------------------------------------|-------------|---------------------------------|------------|----------|--------|------------|
| SIMETHICONUM           | NONFLATIN 80 mg                      | soft caps.                         | 80mg        | BIOFARM S.A.                    | ROMANIA    | A03AX13  | 11066  | 13.11.2018 |
| SITAGLIPTINUM          | ZINZIBET 100 mg                      | film coated tabl.                  | 100mg       | EGIS PHARMACEUTICALS PLC        | HUNGARY    | A10BH01  | 11065  | 30.10.2018 |
| SITAGLIPTINUM          | ZINZIBET 25 mg                       | film coated tabl.                  | 25mg        | EGIS PHARMACEUTICALS PLC        | HUNGARY    | A10BH01  | 11063  | 30.10.2018 |
| SITAGLIPTINUM          | ZINZIBET 50 mg                       | film coated tabl.                  | 50mg        | EGIS PHARMACEUTICALS PLC        | HUNGARY    | A10BH01  | 11064  | 30.10.2018 |
| TENOFOVIRUM DISOPROXIL | TENOFOVIR DISOPROXIL GLENMARK 245 mg | film coated tabl.                  | 245mg       | GLENMARK PHARMACEUTICALS S.R.O. | CZECH REP. | J05AF07  | 11057  | 26.10.2018 |
| THIOTEPUM              | TEPADINA 15 mg                       | powder for conc. for sol. for inf. | 15mg        | CN UNIFARM S.A.                 | ROMANIA    | L01AC01  | 391    | 25.10.2018 |
| TRAMADOLUM             | TRAMADOL KRKA 100 mg/ml              | oral drops, sol.                   | 100mg/ml    | KRKA D.D., NOVO MESTO           | SLOVENIA   | N02AX02  | 11210  | 07.12.2018 |
| VACCIN BCG             | BCG VACCINE                          | powd+solv. for. susp. for inj.     | 0.05mg/dose | CN UNIFARM S.A.                 | ROMANIA    | J07AN01  | 388    | 10.10.2018 |
| XYLOMETAZOLINUM        | RHINXYL HA 0.5 mg/ml                 | nas. spray sol.                    | 0.5mg/ml    | TERAPIA S.A.                    | ROMANIA    | R01AA07  | 11016  | 11.10.2018 |



| INN                                | Trade name                                       | Pharm. form     | Strength               | MAH  | Country | ATC Code | MA No. | MA Date    |
|------------------------------------|--|-----------------|------------------------|--|---------|----------|--------|------------|
| XYLOMETAZOLINUM                    | RHINXYL HA 1 mg/ml                               | nas. spray sol. | 1mg/ml                 | TERAPIA S.A.                                     | ROMANIA | R01AA07  | 11017  | 11.10.2018 |
| XYLOMETAZOLINUM+D<br>EXPANTHENOLUM | VIBROCIL ACTILONG<br>PLUS 1.0mg/ml+<br>50.0mg/ml | nas. spray sol. | 1.0mg/ml+<br>50.0mg/ml | GLAXOSMITHKLINE<br>CONSUMER<br>HEALTHCARE S.R.L. | ROMANIA | R01AB06  | 11039  | 23.10.2018 |

### Centrally authorised medicinal products notified for marketing in Romania in the 4th quarter 2018

| INN           | Trade name           | Pharm. form                           | Strength | MAH                                  | COUNTRY     | MA No. | MA date    | ATC Code |
|---------------|----------------------|---------------------------------------|----------|--------------------------------------|-------------|--------|------------|----------|
| MARAVIROCUM   | CESENTRI<br>150 mg   | film coated tabl.                     | 150mg    | VIIV HEALTHCARE BV                   | NETHERLANDS | 418    | 18.09.2007 | J05AX09  |
| MARAVIROCUM   | CESENTRI<br>300 mg   | film coated tabl.                     | 300mg    | VIIV HEALTHCARE BV                   | NETHERLANDS | 418    | 18.09.2007 | J05AX09  |
| BELIMUMABUM   | BENLYSTA             | powder for conc.<br>for sol. for inf. | 120 mg   | GLAXOSMITHKLINE<br>(IRELAND) LIMITED | IRELAND     | 700    | 13.07.2011 | L04AA26  |
| MARAVIROCUM   | CESENTRI<br>25 mg    | film coated tabl.                     | 25mg     | VIIV HEALTHCARE BV                   | NETHERLANDS | 418    | 18.09.2007 | J05AX09  |
| MARAVIROCUM   | CESENTRI<br>75 mg    | film coated tabl.                     | 75mg     | VIIV HEALTHCARE BV                   | NETHERLANDS | 418    | 18.09.2007 | J05AX09  |
| MARAVIROCUM   | CESENTRI<br>20 mg/ml | oral solution                         | 20mg/ml  | VIIV HEALTHCARE BV                   | NETHERLANDS | 418    | 18.09.2007 | J05AX09  |
| POMALIDOMIDUM | IMNOVID 1 mg         | caps.                                 | 1mg      | CELGENE EUROPE B.V.                  | NETHERLANDS | 850    | 05.08.2013 | L04AX06  |
| POMALIDOMIDUM | IMNOVID 2 mg         | caps.                                 | 2mg      | CELGENE EUROPE B.V.                  | NETHERLANDS | 850    | 05.08.2013 | L04AX06  |

| INN              | Trade name        | Pharm. form                    | Strength   | MAH                        | COUNTRY     | MA No. | MA date    | ATC Code |
|------------------|-------------------|--------------------------------|------------|----------------------------|-------------|--------|------------|----------|
| POMALIDOMIDUM    | IMNOVID 3 mg      | caps.                          | 3mg        | CELGENE EUROPE B.V.        | NETHERLANDS | 850    | 05.08.2013 | L04AX06  |
| POMALIDOMIDUM    | IMNOVID 4 mg      | caps.                          | 4mg        | CELGENE EUROPE B.V.        | NETHERLANDS | 850    | 05.08.2013 | L04AX06  |
| ADALIMUMABUM     | HYRIMOZ 40 mg     | sol for inj. in pre-filled pen | 40mg/0.8ml | SANDOZ GMBH                | AUSTRIA     | 1286   | 26.07.2018 | L04AB04  |
| TISAGENLECLEUCEL | KYMRIAH           | dispers. for inf.              |            | NOVARTIS EUROPHARM LIMITED | IRELAND     | 1297   | 23.08.2018 | L01      |
| TUROCTOCOG ALFA  | NOVOEIGHT 250 IU  | powd+solv. for sol. for inj.   | 250 IU     | NOVO NORDISK A/S           | DANEMARCA   | 888    | 15.11.2013 | B02BD02  |
| TUROCTOCOG ALFA  | NOVOEIGHT 500 IU  | powd+solv. for sol. for inj.   | 500 IU     | NOVO NORDISK A/S           | DANEMARCA   | 888    | 15.11.2013 | B02BD02  |
| TUROCTOCOG ALFA  | NOVOEIGHT 1000 IU | powd+solv. for sol. for inj.   | 1000 IU    | NOVO NORDISK A/S           | DANEMARCA   | 888    | 15.11.2013 | B02BD02  |
| TUROCTOCOG ALFA  | NOVOEIGHT 1500 IU | powd+solv. for sol. for inj.   | 1500 IU    | NOVO NORDISK A/S           | DANEMARCA   | 888    | 15.11.2018 | B02BD02  |
| TUROCTOCOG ALFA  | NOVOEIGHT 2000 IU | powd+solv. for sol. for inj.   | 2000 IU    | NOVO NORDISK A/S           | DANEMARCA   | 888    | 15.11.2018 | B02BD02  |

| INN                          | Trade name                  | Pharm. form                            | Strength        | MAH  | COUNTRY     | MA No. | MA date    | ATC Code |
|------------------------------|-----------------------------|--|-----------------|--|-------------|--------|------------|----------|
| TUROCTOCOG ALFA              | NOVOEIGHT<br>3000 IU        | powd+solv. for<br>sol. for inj.        | 3000 IU         | NOVO NORDISK A/S                               | DANEMARCA   | 888    | 15.11.2013 | B02BD02  |
| INSULINUM DEGLUDEC           | TRESIBA<br>100 units/ml     | sol for inj. in<br>cartridge           | 100 IU /ml      | NOVO NORDISK A/S                               | DANEMARCA   | 807    | 23.01.2013 | A10AE06  |
| ADALIMUMABUM                 | IMRALDI                     | sol for inj. in pre-<br>filled syringe | 40mg            | SAMSUNG BIOEPIS NL<br>B.V.                     | NETHERLANDS | 1216   | 29.08.2017 | L04AB04  |
| ADALIMUMABUM                 | IMRALDI                     | sol for inj. in pre-<br>filled pen     | 40mg            | SAMSUNG BIOEPIS NL<br>B.V.                     | NETHERLANDS | 1216   | 29.08.2017 | L04AB04  |
| PREGABALINUM                 | PREGABALIN<br>SANDOZ 75 mg  | caps.                                  | 75mg            | SANDOZ GMBH                                    | AUSTRIA     | 1011   | 19.06.2015 | N03AX16  |
| PREGABALINUM                 | PREGABALIN<br>SANDOZ 150 mg | caps.                                  | 150mg           | SANDOZ GMBH                                    | AUSTRIA     | 1011   | 19.06.2015 | N03AX16  |
| PEGFILGRASTIMUM              | ZIEXTENZO<br>6 mg           | sol for inj. in pre-<br>filled syringe | 6mg             | SANDOZ GMBH                                    | AUSTRIA     | 1327   | 22.11.2018 | L03AA13  |
| LUMACAFTORUM+<br>IVACAFTORUM | ORKAMBI<br>100 mg/125 mg    | film coated tabl.                      | 100mg/<br>125mg | VERTEX<br>PHARMACEUTICALS<br>(IRELAND) LIMITED | IRELAND     | 1059   | 19.11.2015 | R07AX30  |
| TRASTUZUMABUM                | OGIVRI 150 mg               | powder for conc.<br>for sol. for inf.  | 150mg           | MYLAN S.A.S.                                   | FRANCE      | 1341   | 12.12.2018 | L01XC03  |

| INN                | Trade name              | Pharm. form                        | Strength  | MAH                          | COUNTRY     | MA No. | MA date    | ATC Code |
|--------------------|-------------------------|------------------------------------|-----------|------------------------------|-------------|--------|------------|----------|
| BUROSUMABUM        | CRYSVITA<br>10 mg       | sol for inj.                       | 10mg/ml   | KYOWA KIRIN<br>HOLDINGS B.V. | NETHERLANDS | 1262   | 19.02.2018 | M05BX05  |
| BUROSUMABUM        | CRYSVITA<br>20 mg       | sol for inj.                       | 20mg/ml   | KYOWA KIRIN<br>HOLDINGS B.V. | NETHERLANDS | 1262   | 19.02.2018 | M05BX05  |
| BUROSUMABUM        | CRYSVITA<br>30 mg       | sol for inj.                       | 30mg/ml   | KYOWA KIRIN<br>HOLDINGS B.V. | NETHERLANDS | 1262   | 19.02.2018 | M05BX05  |
| INSULINUM DEGLUDEC | TRESIBA<br>100 units/ml | sol for inj. in pre-<br>filled pen | 100 IU/ml | NOVO NORDISK A/S             | DANEMARCA   | 807    | 23.01.2013 | A10AE06  |