

DOSARE PROCEDURĂ EUROPEANĂ DISCUTATE ÎN CAPP ÎN LUNA NOIEMBRIE 2019

| Nr. Crt. | Denumire comerciala | Concentratia | Forma farmaceutica | DCI | Deținător APP | Statut A/R Baza legala- Legea 95/2006 cu modificari | Data intrării ANMDM | Tipul Procedurii | DATĂ CAPP | Observatii presedinte |
|----------|--|---|--|--|--|---|---------------------|--------------------|------------|-----------------------|
| 1 | Alprostadi Rompharm 20 micrograme | 20 micrograme | Pulbere pentru solutie perfuzabila | Alprostadi | S.C. Rompharm Company S.R.L., Romania | A - in baza art. 708 (1) | 11/1/2018 | PT/H/2177/001/DC | 11/4/2019 | |
| 2 | Candesartan cilexetil MCC 8 mg | 8 mg | Comprimate | Candesartan cilexetil | Magistra C&C SRL, Romania | R - art.738 (4) A - in baza art. 708 (1) | 2/6/2017 | PT/H/1052/002/R001 | 11/4/2019 | |
| 3 | Granored 1 mg | 1 mg | Comprimate filmate | Granisetron sub forma de clorhidrat de granisetron | Dr. Reddy s Laboratories Romania SRL | R - art.738 (4) A - in baza art. 708 (1) | 2/26/2014 | PT/H/0442/001/R001 | 11/4/2019 | |
| 4 | Benmak 2,5 mg/ml | 2,5 mg/ml | Pulbere pentru concentrat pentru solutie perfuzabila | Clorhidrat de bendamustina | Makpharm d.o.o., Croatia | R - art.738 (4) A - in baza art. 708 (1) | 8/13/2019 | DK/H/2411/001/R001 | 11/4/2019 | |
| 5 | Imatinib Terapie 100 mg | 100 mg | Comprimate filmate | Imatinib sub forma de mesilat de imatinib | Terapie S.A., Romania | R - art.738 (4) A - in baza art. 708 (1) | 5/10/2019 | FR/H/0563/001/R001 | 11/4/2019 | |
| 6 | Imatinib Terapie 400 mg | 400 mg | Comprimate filmate | Imatinib sub forma de mesilat de imatinib | Terapie S.A., Romania | R - art.738 (4) A - in baza art. 708 (1) | 5/10/2019 | FR/H/0563/002/R001 | 11/4/2019 | |
| 7 | Ciprofloxacina Aurobindo 250 mg | 250 mg | Comprimate filmate | Ciprofloxacina sub forma de clorhidrat de ciprofloxacina | Aurobindo Pharma (Malta) Limited, Malta | R - art.738 (4) A - in baza art. 708 (1) | 9/16/2019 | PT/H/1324/001/R001 | 11/11/2019 | |
| 8 | Ciprofloxacina Aurobindo 500 mg | 500 mg | Comprimate filmate | Ciprofloxacina sub forma de clorhidrat de ciprofloxacina | Aurobindo Pharma (Malta) Limited, Malta | R - art.738 (4) A - in baza art. 708 (1) | 9/16/2019 | PT/H/1324/002/R001 | 11/11/2019 | |
| 9 | Ciprofloxacina Aurobindo 750 mg | 750 mg | Comprimate filmate | Ciprofloxacina sub forma de clorhidrat de ciprofloxacina | Aurobindo Pharma (Malta) Limited, Malta | R - art.738 (4) A - in baza art. 708 (1) | 9/16/2019 | PT/H/1324/003/R001 | 11/11/2019 | |
| 10 | Vortemyl 3,5 mg | 3,5 mg | Pulbere pentru solutie injectabila | Bortezomib sub forma de bortezomib anhidru | Alvogen Ipco S.a.r.l., Luxemburg | R - art.738 (4) A - in baza art. 708 (1) | 8/26/2019 | NL/H/3175/002/R001 | 11/11/2019 | |
| 11 | Garganta 3 mg | 3 mg | Comprimate de supt | Clorhidrat de benzidamina | PharmaSwiss Ceska republica s.r.o., Republica Ceha | R - art.738 (4) A - in baza art. 708 (3) | 5/21/2019 | PL/H/0212/001/R001 | 11/11/2019 | |
| 12 | Seasonique 150 micrograme/ 30 micrograme + 10 micrograme | 150 micrograme/ 30 micrograme + 10 micrograme | Comprimate filmate | Levonorgestrel/ Etinilestradiol + Etinilestradiol | Theramex Ireland Limited, Irlanda | R - art.738 (4) A - in baza art. 710 | 4/19/2019 | FR/H/0516/001/R001 | 11/11/2019 | |

| | | | | | | | | | | |
|----|---|---|--|--|---|--|-----------|--------------------|------------|--|
| 13 | AirFlusal Forspiro 50 micrograme/ 500 micrograme/ doza | 50 micrograme/ 500 micrograme/ doza | Pulbere unidoza de inhalat | Propionat de fluticazona/Salmeterol sub forma de xinafoat de salmeterol | S.C. Sandoz S.R.L., Romania | R - art.738 (4) A - in baza art. 708 (3) | 3/6/2018 | SE/H/1323/001/R001 | 11/11/2019 | |
| 14 | AirFlusal Forspiro 50 micrograme/ 250 micrograme/ doza | 50 micrograme/ 250 micrograme/ doza | Pulbere unidoza de inhalat | Propionat de fluticazona/Salmeterol sub forma de xinafoat de salmeterol | S.C. Sandoz S.R.L., Romania | R - art.738 (4) A - in baza art. 708 (3) | 3/6/2018 | SE/H/1323/002/R001 | 11/11/2019 | |
| 15 | Ceftazidima AptaPharma 1 g | 1 g | Pulbere pentru solutie injectabila/ perfuzabila | Ceftazidima sub forma de ceftazidima pentahidrat | Apta Medica Internacional d.o.o., Slovenia | A - in baza art. 708 (1) | 6/4/2018 | HU/H/0589/001/DC | 11/18/2019 | |
| 16 | Candesartan Hidroclorotiazida Aurobindo 8 mg/12,5 mg | 8 mg/ 12,5 mg | Comprimete | Candesartan cilexeril/ Hidroclorotiazida | Aurobindo Pharma Romania S.R.L., Romania | R - art.738 (4) A - in baza art. 708 (1) | 4/22/2019 | PT/H/1135/001/R001 | 11/18/2019 | |
| 17 | Candesartan Hidroclorotiazida Aurobindo 16 mg/12,5 mg | 16 mg/ 12,5 mg | Comprimete | Candesartan cilexeril/ Hidroclorotiazida | Aurobindo Pharma Romania S.R.L., Romania | R - art.738 (4) A - in baza art. 708 (1) | 4/22/2019 | PT/H/1135/002/R001 | 11/18/2019 | |
| 18 | Candesartan Hidroclorotiazida Aurobindo 32 mg/12,5 mg | 32 mg/ 12,5 mg | Comprimete | Candesartan cilexeril/ Hidroclorotiazida | Aurobindo Pharma Romania S.R.L., Romania | R - art.738 (4) A - in baza art. 708 (1) | 4/22/2019 | PT/H/1135/003/R001 | 11/18/2019 | |
| 19 | Candesartan Hidroclorotiazida Aurobindo 32 mg/25 mg | 32 mg/25 mg | Comprimete | Candesartan cilexeril/ Hidroclorotiazida | Aurobindo Pharma Romania S.R.L., Romania | R - art.738 (4) A - in baza art. 708 (1) | 4/22/2019 | PT/H/1135/004/R001 | 11/18/2019 | |
| 20 | Linezolid Accord 2 mg/ml | 2 mg/ml | Solutie perfuzabila | Linezolid | Accord Healthcare Limited, Marea Britanie | R - art.738 (4) A - in baza art. 708 (1) | 5/29/2019 | PT/H/1195/001/R001 | 11/18/2019 | |
| 21 | Lutrate Depot 22,5 mg | 22,5 mg | Pulbere si solvent pentru suspensie injectabila cu eliberare prelungita | Acetat de leuprorelin | Angelini Pharma Osterreich GmbH, Austria | R - art.738 (4) A - in baza art. 706 | 8/5/2019 | ES/H/0141/002/R001 | 11/18/2019 | |
| 22 | Bortezomib Glenmark 3,5 mg/ml | 3,5 mg/ml | Pulbere pentru solutie injectabila | Bortezomib sub forma de bortezomib anhidru | Glenmark Pharmaceuticals s.r.o., Republica Ceha | R - art.738 (4) A - in baza art. 708 (1) | 8/27/2019 | NL/H/3178/002/R001 | 11/18/2019 | |
| 23 | Ezetimib Uriach 10 mg | 10 mg | Comprimete filmate | Ezetimib | J. Uriach y Compania S.A., Spania | R - art.738 (4) A - in baza art. 708 (1) | 7/19/2019 | NL/H/3191/001/R001 | 11/18/2019 | |
| 24 | Dotagraf 0,5 mmol/ml | 0,5 mmol/ml | Solutie injectabila in flacon unidoza | Acid gadoteric sub forma de gadoterat megluminic | Bayer AG, Germania | R - art.738 (4) A - in baza art. 708 (1) | 8/5/2019 | DE/H/3944/001/R001 | 11/18/2019 | |
| 25 | Dotagraf 0,5 mmol/ml | 0,5 mmol/ml | Solutie injectabila in flacon multidoza | Acid gadoteric sub forma de gadoterat megluminic | Bayer AG, Germania | R - art.738 (4) A - in baza art. 708 (1) | 8/5/2019 | DE/H/3944/002/R001 | 11/18/2019 | |

| | | | | | | | | | | |
|----|------------------------------------|----------------------------|---|---|---|--|-----------|--------------------|------------|--|
| 26 | Kandoset 16 mg/10 mg | 16 mg/10 mg | Comprimate | Candesartan cilexetil/Amlodipina sub forma de besilat de amlodipina | Krka,d.d., Novo mesto, Slovenia | A - in baza art. 710 | 10/5/2018 | DE/H/5108/005/DC | 11/25/2019 | |
| 27 | Dasatinib Alvogen 20 mg | 20 mg | Comprimate filmate | Dasatinib | Alvogen Pharma Trading Europe EOOD, Bulgaria | A - in baza art. 708 (1) | 6/4/2018 | DK/H/2935/001/DC | 11/25/2019 | |
| 28 | Dasatinib Alvogen 50 mg | 50 mg | Comprimate filmate | Dasatinib | Alvogen Pharma Trading Europe EOOD, Bulgaria | A - in baza art. 708 (1) | 6/4/2018 | DK/H/2935/002/DC | 11/25/2019 | |
| 29 | Dasatinib Alvogen 70 mg | 70 mg | Comprimate filmate | Dasatinib | Alvogen Pharma Trading Europe EOOD, Bulgaria | A - in baza art. 708 (1) | 6/4/2018 | DK/H/2935/003/DC | 11/25/2019 | |
| 30 | Dasatinib Alvogen 80 mg | 80 mg | Comprimate filmate | Dasatinib | Alvogen Pharma Trading Europe EOOD, Bulgaria | A - in baza art. 708 (1) | 6/4/2018 | DK/H/2935/004/DC | 11/25/2019 | |
| 31 | Dasatinib Alvogen 100 mg | 100 mg | Comprimate filmate | Dasatinib | Alvogen Pharma Trading Europe EOOD, Bulgaria | A - in baza art. 708 (1) | 6/4/2018 | DK/H/2935/005/DC | 11/25/2019 | |
| 32 | Dasatinib Alvogen 140 mg | 140 mg | Comprimate filmate | Dasatinib | Alvogen Pharma Trading Europe EOOD, Bulgaria | A - in baza art. 708 (1) | 6/4/2018 | DK/H/2935/006/DC | 11/25/2019 | |
| 33 | Soprobec 50 micrograme/doza | 50 micrograme/ doza | Solutie de inhalat presurizata | Dipropionat de beclometazona anhidra | Glenmark Pharmaceuticals s.r.o., Republica Ceha | A - in baza art. 708 (3) | 6/27/2019 | UK/H/6818/001/E001 | 11/25/2019 | |
| 34 | Soprobec 100 micrograme/doza | 100 micrograme/ doza | Solutie de inhalat presurizata | Dipropionat de beclometazona anhidra | Glenmark Pharmaceuticals s.r.o., Republica Ceha | A - in baza art. 708 (3) | 6/27/2019 | UK/H/6818/002/E001 | 11/25/2019 | |
| 35 | Soprobec 200 micrograme/doza | 200 micrograme/ doza | Solutie de inhalat presurizata | Dipropionat de beclometazona anhidra | Glenmark Pharmaceuticals s.r.o., Republica Ceha | A - in baza art. 708 (3) | 6/27/2019 | UK/H/6818/003/E001 | 11/25/2019 | |
| 36 | Soprobec 250 micrograme/doza | 250 micrograme/ doza | Solutie de inhalat presurizata | Dipropionat de beclometazona anhidra | Glenmark Pharmaceuticals s.r.o., Republica Ceha | A - in baza art. 708 (3) | 6/27/2019 | UK/H/6818/004/E001 | 11/25/2019 | |
| 37 | Adacel Polio | | Suspensie injectabila in seringa preumpluta | Vaccin diftero-pertussis acelular si poliomiolitic | Sanofi Pasteur, Franta | A - in baza art. 706 | 7/23/2019 | DE/H/0215/001/E002 | 11/25/2019 | |
| 38 | Bortezomib Sandoz 1 mg | 1 mg | Pulbere pentru solutie injectabila | Bortezomib sub forma de bortezomib anhidru | S.C. Sandoz S.R.L., Romania | R - art.738 (4) A - in baza art. 708 (1) | 8/19/2019 | DE/H/4236/001/R001 | 11/25/2019 | |
| 39 | Bortezomib Sandoz 3,5 mg | 3,5 mg | Pulbere pentru solutie injectabila | Bortezomib sub forma de bortezomib anhidru | S.C. Sandoz S.R.L., Romania | R - art.738 (4) A - in baza art. 708 (1) | 8/19/2019 | DE/H/4236/002/R001 | 11/25/2019 | |
| 40 | Pregabalina Aurobindo 75 mg | 75 mg | Capsule | Pregabalina | Aurobindo Pharma, Romania | R - art.738 (4) A - in baza art. 708 (1) | 8/22/2019 | PT/H/1322/003/R001 | 11/25/2019 | |
| 41 | Pregabalina Aurobindo 150 mg | 150 mg | Capsule | Pregabalina | Aurobindo Pharma, Romania | R - art.738 (4) A - in baza art. 708 (1) | 8/22/2019 | PT/H/1322/005/R001 | 11/25/2019 | |

| | | | | | | | | | | |
|----|------------------------------------|--------|-----------|-------------|------------------------------|--|-----------|--------------------|------------|--|
| 42 | Pregabalina Aurobindo 300 mg | 300 mg | Capsule | Pregabalina | Aurobindo Pharma, Romania | R - art.738 (4) A - in baza art. 708 (1) | 8/22/2019 | PT/H/1322/008/R001 | 11/25/2019 | |
| 43 | Aripiprazol Stada 10 mg | 10 mg | Comprimat | Aripiprazol | Stada M&D ARL, Romania | R - art.738 (4) A - in baza art. 708 (1) | 8/5/2019 | DE/H/5060/002/R001 | 11/25/2019 | |
| 44 | Aripiprazol Stada 15 mg | 15 mg | Comprimat | Aripiprazol | Stada M&D ARL, Romania | R - art.738 (4) A - in baza art. 708 (1) | 8/5/2019 | DE/H/5060/003/R001 | 11/25/2019 | |