

# LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 8-2/20 on August 31, 2020

President \_\_\_\_\_ E. Amroyan

| N | Trade name                  | International non-proprietary (generic) names or names of active substances | dosage form           | dosage strength & output form (packaging)         | Manufacturer                                                                     | country | License holder                                                            | License holder country | Prescription status | Conclusion N & date |
|---|-----------------------------|-----------------------------------------------------------------------------|-----------------------|---------------------------------------------------|----------------------------------------------------------------------------------|---------|---------------------------------------------------------------------------|------------------------|---------------------|---------------------|
| 1 | Seretide Accuhaler / Diskus | salmeterol (salmeterol xinafoate), fluticasone (fluticasone propionate)     | powder for inhalation | 50mcg+100mcg; (1) plastic inhaler disk (60 doses) | Glaxo Wellcome Production, Zone Industrielle N 2, 23 Rue Lavoisier, 27000 Evreux | France  | Laboratoire GlaxoSmithKline, 23 rue Francois Jacob, 92500 Rueil-Malmaison | France                 | R                   | 19371<br>31.08.2020 |
| 2 | Seretide Accuhaler / Diskus | salmeterol (salmeterol xinafoate), fluticasone (fluticasone propionate)     | powder for inhalation | 50mcg+250mcg; (1) plastic inhaler disk (60 doses) | Glaxo Wellcome Production, Zone Industrielle N 2, 23 Rue Lavoisier, 27000 Evreux | France  | Laboratoire GlaxoSmithKline, 23 rue Francois Jacob, 92500 Rueil-Malmaison | France                 | R                   | 19372<br>31.08.2020 |
| 3 | Seretide Accuhaler / Diskus | salmeterol (salmeterol xinafoate), fluticasone (fluticasone propionate)     | powder for inhalation | 50mcg+500mcg; (1) plastic inhaler disk (60 doses) | Glaxo Wellcome Production, Zone Industrielle N 2, 23 Rue Lavoisier, 27000 Evreux | France  | Laboratoire GlaxoSmithKline, 23 rue Francois Jacob, 92500 Rueil-Malmaison | France                 | R                   | 19373<br>31.08.2020 |

|   |                                   |                                           |                      |                                      |                                                                                                                    |          |                                                                                                              |          |   |                     |
|---|-----------------------------------|-------------------------------------------|----------------------|--------------------------------------|--------------------------------------------------------------------------------------------------------------------|----------|--------------------------------------------------------------------------------------------------------------|----------|---|---------------------|
| 4 | Albendazole                       | albendazole                               | tablets-film coated  | 400mg; (3/3x1/) in blister           | Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64a, No4, ul. Chapaeva, Borisov, Minsk region | Belarus  | Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64, ul. Chapaeva, Borisov, Minsk region | Belarus  | R | 19374<br>31.08.2020 |
| 5 | Moxifloxan                        | moxifloxacin (moxifloxacin hydrochloride) | drops eye (solution) | 5mg/ml; (1) plastic vial-dropper 5ml | Balkanpharma-Razgrad AD, 68 Aprilsko Vastanie Blvd, 7200 Razgrad                                                   | Bulgaria | Antibiotic-Razgrad AD, 68, Aprilsko vastanie Blvd, Razgrad, 7200                                             | Bulgaria | R | 19375<br>31.08.2020 |
| 6 | Caffeine-benzoate sodium Tatpharm | caffeine (caffeine-benzoate sodium)       | tablets              | 100mg; (6) in strip                  | Tatchempharmpreparaty JSC, 420091 Republic of Tatarstan, Kazan, str. Belomorskaya 260                              | Russia   | Tatchempharmpreparaty JSC, 420091 Republic of Tatarstan, Kazan, str. Belomorskaya 260                        | Russia   | R | 19376<br>31.08.2020 |

# LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 8-2/20 on August 31, 2020

President\_\_\_\_\_E. Amroyan

| N | Trade name | International non-proprietary (generic) names or names of active substances | dosage form                  | dosage strength & output form (packaging)  | Manufacturer                                                                                                                                                                                                                                                                                                                                                                                                                  | country | License holder                                                            | License holder country | Prescription status | Conclusion N & date |
|---|------------|-----------------------------------------------------------------------------|------------------------------|--------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|---------------------------------------------------------------------------|------------------------|---------------------|---------------------|
| 1 | Nimelid    | nimesulide                                                                  | granules for oral suspension | 100mg; (10) sachets<br>2g, (30) sachets 2g | S.C. Rompharm Company S.R.L., (bld. Rompharm 4), Ilfov, 075100 Otopeni, Str. Eroilor, Nr. 1A- batch releaser, S.C. Rompharm Company S.R.L., (bld. Rompharm 2), Ilfov, 075100 Otopeni, Str. Eroilor, Nr. 1A, Romania- bulk manufacturer, packager, quality control (physicochemical), S.C. Rompharm Company S.R.L., (bld. Rompharm 1), Ilfov, 075100 Otopeni, Str. Eroilor, Nr. 1A, Romania- quality control (microbiological) | Romania | S.C. Rompharm Company S.R.L., Ilfov, 075100 Otopeni, Str. Eroilor, Nr. 1A | Romania                | R                   | 19377 31.08.2020    |

|   |            |                                                       |                                       |                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |         |                                                                                       |         |   |                  |
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| 2 | Dexarom    | dexketoprofen<br>(dexketoprofen<br>trometamol)        | solution for i/m<br>and i/v injection | 25mg/ml; (5/1x5/)<br>ampoules 2ml in<br>blister, (10/2x5/)<br>ampoules 2ml in<br>blister | S.C. Rompharm Company<br>S.R.L., (bld. Rompharm 4),<br>Ilfov, 075100 Otopeni, Str.<br>Eroilor, Nr. 1A- batch<br>releaser, S.C. Rompharm<br>Company S.R.L., (bld.<br>Rompharm 1), Ilfov,<br>075100 Otopeni, Str.<br>Eroilor, Nr. 1A, Romania-<br>bulk manufacturer,<br>primary packager, quality<br>control (microbiological),<br>S.C. Rompharm Company<br>S.R.L., (bld. Rompharm 2),<br>Ilfov, 075100 Otopeni, Str.<br>Eroilor, Nr. 1A, Romania-<br>secondary packaging,<br>quality control<br>(physicochemical) | Romania | S.C. Rompharm<br>Company S.R.L.,<br>Ilfov, 075100<br>Otopeni, Str.<br>Eroilor, Nr. 1A | Romania | R | 19378 31.08.2020 |
| 3 | Glucovance | glibenclamide, metformin<br>(metformin hydrochloride) | tablets film-<br>coated               | 2,5mg+500mg;<br>(30/2x15/) in blister                                                    | Merck Sante s.a.s., 2 rue<br>du Pressoir Vert, 45400<br>Semoy                                                                                                                                                                                                                                                                                                                                                                                                                                                    | France  | Merck Sante<br>s.a.s., 37 rue<br>Saint Romain-<br>69379 Lyon                          | France  | R | 19379 31.08.2020 |
| 4 | Glucovance | glibenclamide, metformin<br>(metformin hydrochloride) | tablets film-<br>coated               | 5mg+500mg;<br>(30/2x15/) in blister                                                      | Merck Sante s.a.s., 2 rue<br>du Pressoir Vert, 45400<br>Semoy                                                                                                                                                                                                                                                                                                                                                                                                                                                    | France  | Merck Sante<br>s.a.s., 37 rue<br>Saint Romain-<br>69379 Lyon                          | France  | R | 19380 31.08.2020 |

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| 5 | Diltiazem<br>Lannacher 90mg  | diltiazem (diltiazem<br>hydrochloride) | tablets film-<br>coated<br>prolonged-<br>release | 90mg; (20/2x10/)<br>blisters    | G.L. Pharma GmbH,<br>Schlossplatz 1, 8502<br>Lannach- batch releaser,<br>G.L. Pharma GmbH,<br>Industriestrasse 1, 8502<br>Lannach, Austria- bulk<br>manufacturer, packager,<br>quality control<br>(physicochemical), G.L.<br>Pharma GmbH,<br>Arnethgasse 3, 1160<br>Vienna, Austria- quality<br>control (microbiological) | Austria | Bausch Health<br>LLC.,<br>Shabolovka st.<br>31, building 5,<br>115162,<br>Moscow | Russia | R | 19381 31.08.2020 |
| 6 | Diltiazem<br>Lannacher 180mg | diltiazem (diltiazem<br>hydrochloride) | tablets film-<br>coated<br>prolonged-<br>release | 180mg; (30/3x10/) in<br>blister | G.L. Pharma GmbH,<br>Schlossplatz 1, 8502<br>Lannach- batch releaser,<br>G.L. Pharma GmbH,<br>Industriestrasse 1, 8502<br>Lannach, Austria- bulk<br>manufacturer, packager,<br>quality control<br>(physicochemical), G.L.<br>Pharma GmbH,<br>Arnethgasse 3, 1160<br>Vienna, Austria- quality<br>control (microbiological) | Austria | Bausch Health<br>LLC.,<br>Shabolovka st.<br>31, building 5,<br>115162,<br>Moscow | Russia | R | 19382 31.08.2020 |

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|----|---------|---------------------------------------|----------------------------|---------------------------------------------|------------------------------------------------------------------|-------------|-------------------------------------------------------------|---------|---|------------------|
| 7  | Elidel  | pimecrolimus                          | cream for external use     | 10mg/g; aluminium tube 15g                  | MEDA Manufacturing, Avenue JF Kennedy, 33700 Merignac            | France      | MEDA Pharma GmbH & Co. KG, Benzstrasse 1, 61352 Bad Homburg | Germany | R | 19383 31.08.2020 |
| 8  | Monural | fosfomycin (fosfomycin trometamol)    | granules for oral solution | 3g; (1) sachet 8g, (2) sachets 8g           | Zambon Switzerland Ltd., Via Industria 13, CH-6814, Cadempino    | Switzerland | Zambon S.P.A., Via Lillo Del Duca, 10, Bresso, 20091        | Italy   | R | 19384 31.08.2020 |
| 9  | Lomexin | fenticonazole (fenticonazole nitrate) | capsules vaginal           | 200mg; (6/1x6/) in blister                  | Catalent Italy S.p.A., Via Nettunense km. 20,100, Aprilia, 04011 | Italy       | Recordati Ireland Ltd., Raheens East, Ringaskiddy, Co Cork  | Ireland | R | 19385 31.08.2020 |
| 10 | Lomexin | fenticonazole (fenticonazole nitrate) | capsules vaginal           | 600mg; (1) in blister, (2/1x2/) in blister  | Catalent Italy S.p.A., Via Nettunense km. 20,100, Aprilia, 04011 | Italy       | Recordati Ireland Ltd., Raheens East, Ringaskiddy, Co Cork  | Ireland | R | 19386 31.08.2020 |
| 11 | Lomexin | fenticonazole (fenticonazole nitrate) | capsules vaginal           | 1000mg; (1) in blister, (2/1x2/) in blister | Catalent Italy S.p.A., Via Nettunense km. 20,100, Aprilia, 04011 | Italy       | Recordati Ireland Ltd., Raheens East, Ringaskiddy, Co Cork  | Ireland | R | 19387 31.08.2020 |



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| 12 | Fastum gel | ketoprofen | gel | 25mg/g; aluminum<br>tube 30g, aluminum<br>tube 50g, aluminum<br>tube 100g | A. Menarini<br>Manufacturing Logistics<br>and Services S.r.l., Via<br>Sette Santi, 3 50131<br>Firenze | Italy | A. Menarini<br>Industrie<br>Farmaceutiche<br>Riunite S.r.l.,<br>Via Sette Santi,<br>3 50131 Firenze | Italy | R | 19388 31.08.2020 |
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# LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decisionN 8-2/20 on August 31, 2020

President\_\_\_\_\_E. Amroyan

| N | Trade name         | International non-proprietary (generic) names or names of active substances | dosage form                           | dosage strength & output form (packaging)      | Manufacturer                                                                                    | country     | License holder                                               | License holder country | Prescription status | Conclusion N & date     |
|---|--------------------|-----------------------------------------------------------------------------|---------------------------------------|------------------------------------------------|-------------------------------------------------------------------------------------------------|-------------|--------------------------------------------------------------|------------------------|---------------------|-------------------------|
| 1 | Dexmedetomidine    | dexmedetomidine (dexmedetomidine hydrochloride)                             | concentrate for solution for infusion | 100mcg/ml; (5) ampoules 2ml                    | EVER Pharma Jena GmbH, Otto-Schott-Strasse 15, 07745 Jena                                       | Germany     | EVER Valinject GmbH, Oberburgau 3, 4866 Unterach am Attersee | Austria                | R                   | 18769/1/1<br>31.08.2020 |
| 2 | Diclofenac-Asteria | diclofenac (diclofenac sodium)                                              | solution for injection                | 75mg/3ml; (5) ampoules 3ml                     | Hankook Korus Pharm Co., Ltd, 78 Daepungsandan-ro, Daeso-myeon, Eumseong-gun, Chungcheongbuk-do | Korea South | Asteria LLC, 28 Tigran Mets str., office 24, 0018 Yerevan    | Republic of Armenia    | R                   | 16477/1/1<br>31.08.2020 |
| 3 | Diclofenac-Asteria | diclofenac (diclofenac sodium)                                              | tablets                               | 100mg; (20/2x10/) and (100/10x10/), in blister | Hankook Korus Pharm Co., Ltd, 30, Gangjeon-ro, Jecheon-si, Chungcheongbuk-do                    | Korea South | Asteria LLC, 28 Tigran Mets str., office 24, 0018 Yerevan    | Republic of Armenia    | R                   | 15171/1/1<br>31.08.2020 |



|   |        |             |                     |                           |                                                                                                                                                                                       |        |                                                                           |        |   |                         |
|---|--------|-------------|---------------------|---------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|---------------------------------------------------------------------------|--------|---|-------------------------|
| 4 | Cordix | clopidogrel | tablets film-coated | 75mg; 28(2x14) in blister | Adamed Pharma S.A., 5, Marszalka Jozefa Pilsudskiego St., 95-200 Pabianice- batch releaser, Adamed Pharma S.A., 33, Szkolna St., 95-054 Ksawerow, Poland- bulk manufacturer, packager | Poland | Adamed Pharma S.A., 6A, Pienkow, Mariana Adamkiewicza St., 05-152 Czosnow | Poland | R | 17058/1/2<br>31.08.2020 |
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# LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision 8-2/20 on August 31, 2020

President\_\_\_\_\_E. Amroyan

| N | Trade name | International non-proprietary (generic) names or names of active substances | dosage form | dosage strength & output form (packaging)  | Manufacturer                                                                                     | country | License holder                                                            | License holder country | Prescription status | Conclusion N & date |
|---|------------|-----------------------------------------------------------------------------|-------------|--------------------------------------------|--------------------------------------------------------------------------------------------------|---------|---------------------------------------------------------------------------|------------------------|---------------------|---------------------|
| 1 | Betaserc   | betahistine (betahistine dihydrochloride)                                   | tablets     | 8mg; (30/1x30/) in blister                 | Mylan Laboratories SAS, Route de Belleville, Lieu-dit Maillard, 01400 Chatillon sur Chalaronne   | France  | Abbott Healthcare Products B.V., C.J. van Houtenlaan 36, NL-1381 CP Weesp | the Netherlands        | R                   | 17656/2 31.08.2020  |
| 2 | Betaserc   | betahistine (betahistine dihydrochloride)                                   | tablets     | 16mg; (30/2x15/) in blister                | Mylan Laboratories SAS, Route de Belleville, Lieu-dit Maillard, 01400 Chatillon sur Chalaronne   | France  | Abbott Healthcare Products B.V., C.J. van Houtenlaan 36, NL-1381 CP Weesp | the Netherlands        | R                   | 17657/2 31.08.2020  |
| 3 | Betaserc   | betahistine (betahistine dihydrochloride)                                   | tablets     | 24mg; (20/1x20/) and (60/3x20/) in blister | Mylan Laboratories SAS, Route de Belleville, Lieu-dit Maillard, 01400 Chatillon sur Chalaronne f | France  | Abbott Healthcare Products B.V., C.J. van Houtenlaan 36, NL-1381 CP Weesp | the Netherlands        | Г                   | 17655/2 31.08.2020  |

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|---|------------------|-----------------------------------------|------------------------------------|-------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|------------------------------------------------------------------|---------|---|--------------------|
| 4 | Dalacin          | clindamycin (clindamycin hydrochloride) | capsules                           | 150mg; (16/2x8/) in blister               | Fareva Amboise, Zone Industrielle, 29 route des Industries, 37530 Poce-sur-Cisse f                                                                                                                                              | France  | Pfizer H.C.P. Corporation, 235, East 42nd Street, New York 10017 | USA     | R | 18181/1 31.08.2020 |
| 5 | Dalacin          | clindamycin (clindamycin hydrochloride) | capsules                           | 300mg; (16/2x8/) in blister               | Fareva Amboise, Zone Industrielle, 29 route des Industries, 37530 Poce-sur-Cisse                                                                                                                                                | France  | Pfizer H.C.P. Corporation, 235, East 42nd Street, New York 10017 | USA     | R | 18182/1 31.08.2020 |
| 6 | Sorbifer Durules | ferrous sulphate, ascorbic acid         | tablets film-coated                | 320mg+60mg; (30) and (50) in glass bottle | Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65                                                                                                                                                                    | Hungary | Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38     | Hungary | R | 16398/1 31.08.2020 |
| 7 | Diklofen         | diclofenac (diclofenac sodium)          | solution for i/v and i/m injection | 25mg/ml; (5) ampoules 3ml                 | Galenika a.d. Batajnicky drum bb, 11080 Belgrade-batch releaser, secondary packager, Mefar Ilac Sanayii A.S., Ramazanoglu Mah. Ensar Cad. No. 20, Kurtkoy-Pendik, TR-34906 Istanbul, Turkey-bulk manufacturer, primary packager | Serbia  | Galenika a.d. Batajnicky drum bb,Belgrade                        | Serbia  | R | 14188/1 31.08.2020 |

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|----|-----------|------------------------------------------------------|---------------------|---------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|-------------------------------------------------------|-------------|---|--------------------|
| 8  | GalvusMet | vildagliptin, metformin<br>(metformin hydrochloride) | tablets film-coated | 50mg+850mg;<br>(30/3x10/) and<br>(60/6x10/) in blister  | Novartis Pharma<br>Produktions GmbH,<br>Oeflinger Strasse 44, 79664<br>Wehr (Baden<br>Wuerttemberg) -batch<br>releaser, packager, Novartis<br>Singapore Pharmaceutical<br>Manufacturing Pte. Ltd.,<br>10 Tuas Bay Lane, 637461<br>Singapore-bulk<br>manufacturer | Germany | Novartis Pharma<br>AG, Lichtstrasse<br>35, 4056 Basel | Switzerland | R | 16336/2 31.08.2020 |
| 9  | GalvusMet | vildagliptin, metformin<br>(metformin hydrochloride) | tablets film-coated | 50mg+1000mg;<br>(60/6x10/) in blister                   | Novartis Pharma<br>Produktions GmbH,<br>Oeflinger Strasse 44, 79664<br>Wehr (Baden<br>Wuerttemberg) -batch<br>releaser, packager, Novartis<br>Singapore Pharmaceutical<br>Manufacturing Pte. Ltd.,<br>10 Tuas Bay Lane, 637461<br>Singapore-bulk<br>manufacturer | Germany | Novartis Pharma<br>AG, Lichtstrasse<br>35, 4056 Basel | Switzerland | R | 16337/3 31.08.2020 |
| 10 | GalvusMET | vildagliptin, metformin<br>(metformin hydrochloride) | tablets film-coated | 50mg+850mg;<br>(30/3x10/) and<br>(60/6x10/) in blister  | Novartis Pharma<br>Produktions GmbH,<br>Oeflinger Strasse 44, 79664<br>Wehr                                                                                                                                                                                      | Germany | Novartis Pharma<br>AG, Lichtstrasse<br>35, 4056 Basel | Switzerland | R | 18039/3 31.08.2020 |
| 11 | GalvusMET | vildagliptin, metformin<br>(metformin hydrochloride) | tablets film-coated | 50mg+1000mg;<br>(30/3x10/) and<br>(60/6x10/) in blister | Novartis Pharma<br>Produktions GmbH,<br>Oeflinger Strasse 44, 79664<br>Wehr                                                                                                                                                                                      | Germany | Novartis Pharma<br>AG, Lichtstrasse<br>35, 4056 Basel | Switzerland | R | 18038/4 31.08.2020 |

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| 12 | Zanotazon             | colecalfiferol                                                                                                                     | capsules soft       | 50000IU; (20/1x20/) in blister                                                           | Zahravi Pharmaceutical Co., Across Agriculture Institute, 19km to Tabriz Road, Bostan Abad, Bostan Abad Shahr, Zip Code: 515755367 | Iran                   | Giga Farm LLC, Gogunc str.3/5, Gyumri                                           | Republic of Armenia    | R | 17538/3 31.08.2020 |
| 13 | Avamigran             | propyphenazone, caffeine, camylofin (camylofin hydrochloride), mecloxadine (mecloxadine citrate), ergotadine (ergotadine tartrate) | tablets film-coated | 200mg+80mg+25mg+20mg+0,75mg; (10) in plastic container                                   | Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo                                                                                       | Bosnia And Herzegovina | Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo                                    | Bosnia And Herzegovina | R | 17201/1 31.08.2020 |
| 14 | Enterofuryl           | nifuroxazide                                                                                                                       | suspension oral     | 200mg/5ml; 90ml suspension in 125ml glass bottle and plastic measuring spoon (2.5ml/5ml) | Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo                                                                                       | Bosnia And Herzegovina | Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo                                    | Bosnia And Herzegovina | R | 16380/1 31.08.2020 |
| 15 | Enterofuryl           | nifuroxazide                                                                                                                       | capsules            | 100mg; (30/3x10/) in blister                                                             | Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo                                                                                       | Bosnia And Herzegovina | Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo                                    | Bosnia And Herzegovina | R | 16943/1 31.08.2020 |
| 16 | Enterofuryl           | nifuroxazide                                                                                                                       | capsules            | 200mg; (16/2x8/) in blister                                                              | Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo                                                                                       | Bosnia And Herzegovina | Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo                                    | Bosnia And Herzegovina | R | 16944/1 31.08.2020 |
| 17 | Metronidazole-Asteria | metronidazole                                                                                                                      | tablets             | 500mg; (30/3x10/) and (100/10x10/), in blister                                           | Hankook Korus Pharm Co., Ltd, 30, Gangjeo-ro, Jecheon-si, Chungcheongbuk-do                                                        | Korea South            | GL Corporation, Woori Venture Tower #201, 70, Seonyu-ro, Yeongdeungpo-ku, Seoul | South Korea            | R | 14424/4 31.08.2020 |

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| 18 | Apo-Pantoprazole  | pantoprazole (pantoprazole sodium sesquihydrate) | tablets enteric-coated     | 20mg; (100) plastic container | Apotex Inc., 150 Signet Drive, Toronto, Ontario, M9L 1T9-batch releaser, bulk manufacturer, Apotex Inc., 4100 Weston Road, Toronto, Ontario, M9L 2Y6, Canada -packager | Canada      | Apotex Inc., 150 Signet Drive, Toronto, Ontario, M9L 1T9             | Canada      | R   | 14355/1 31.08.2020 |
| 19 | Apo-Pantoprazole  | pantoprazole (pantoprazole sodium sesquihydrate) | tablets enteric-coated     | 40mg; (100) plastic container | Apotex Inc., 150 Signet Drive, Toronto, Ontario, M9L 1T9-batch releaser, bulk manufacturer, Apotex Inc., 4100 Weston Road, Toronto, Ontario, M9L 2Y6, Canada -packager | Canada      | Apotex Inc., 150 Signet Drive, Toronto, Ontario, M9L 1T9             | Canada      | R   | 14354/1 31.08.2020 |
| 20 | Diazolin-Darnitsa | mebhydrolin                                      | tablets                    | 100mg; (10/1x10/) in blister  | Darnitsa Pharmaceutical Firm PrJSC, 02093, Kyiv, Boryspilska Str.,13                                                                                                   | Ukraine     | Darnitsa Pharmaceutical Firm PrJSC, 02093, Kyiv, Boryspilska Str.,13 | Ukraine     | OTC | 17386/1 31.08.2020 |
| 21 | Afinitor          | everolimus                                       | tablets                    | 5mg; (30/3x10/) in blister    | Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein                                                                                                              | Switzerland | Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel                     | Switzerland | R   | 15497/2 31.08.2020 |
| 22 | Monural           | fosfomycin (fosfomycin trometamol)               | granules for oral solution | 3g; (1), (2) sachets 8g       | Zambon Switzerland Ltd., Via Industria 13, CH-6814, Cadempino                                                                                                          | Switzerland | Zambon S.P.A., Via Lillo Del Duca, 10, Bresso, 20091                 | Italy       | R   | 14688/3 31.08.2020 |



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| 23 | Solcoseryl      | hemodialysate from calves blood protein-free                                                             | solution for i/m and i/v injection | 42,5mg/ml; (25/5x5/) ampoules 2ml, blisters                                                | Legacy Pharmaceuticals Switzerland GmbH, Ruhrbergstrasse 21, 4127 Birsfelden                                                                                                                                                                 | Switzerland     | MEDA Pharmaceuticals Switzerland GmbH, Hegnaustrasse 60, 8602 Wangen-Bruttisellen | Switzerland | R   | 14375/1 31.08.2020 |
| 24 | Solcoseryl      | hemodialysate from calves blood protein-free                                                             | solution for i/m and i/v injection | 42,5mg/ml; (5) ampoules 5ml                                                                | Legacy Pharmaceuticals Switzerland GmbH, Ruhrbergstrasse 21, 4127 Birsfelden                                                                                                                                                                 | Switzerland     | MEDA Pharmaceuticals Switzerland GmbH, Hegnaustrasse 60, 8602 Wangen-Bruttisellen | Switzerland | R   | 14374/1 31.08.2020 |
| 25 | Pinosol         | oleum pini silvestris, oleum eucalypti, thymol, tocopherol acetate, oleum menthae piperitae, guaiazulene | drops nasal                        | (0.3752g/10g+0.05g/10g+0.0032g/10g+0.17g/10g+0.1g/10g+0.002g/10g); 10ml glass vial-dropper | Saneca Pharmaceuticals. a.s., Nitrianska 100, 920 27 Hlohovec                                                                                                                                                                                | Slovak Republic | Sanofi Russia JSC, 125009, Tverskaya street 22, Moscow                            | Russia      | OTC | 17300/2 31.08.2020 |
| 26 | Engerix B Adult | hepatitis B surface antigene (recombinant DNA)                                                           | suspension for injection           | 20mcg/ml; pre-filled syringe/(1 dose) and needle                                           | GlaxoSmithKline Biologicals s.a., Rue de l' Institut, 89 B-1330 Rixensart-batch releaser, bulk manufacturer, Glaxo SmithKline Biologicals NL der SmithKline Beecham Pharma GmbH & Co. K.G., Zirkusstrasse 40, 01069 Dresden Germany-packager | Belgium         | GlaxoSmithKline Biologicals s.a., Rue de l' Institut, 89 B-1330 Rixensart         | Belgium     | R   | 16312/1 31.08.2020 |

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| 27 | Engerix B Junior | hepatitis B surface antigene<br>(recombinant DNA) | suspension for<br>injection | 10mcg/0,5ml; pre-<br>filled syringe/(1 dose)<br>and needle | GlaxoSmithKline<br>Biologicals s.a., Rue de l'<br>Institut, 89 B-1330<br>Rixensart-batch releaser,<br>bulk manufacturer, Glaxo<br>SmithKline Biologicals NL<br>der SmithKline Beecham<br>Pharma GmbH & Co. K.G.,<br>Zirkusstrasse 40, 01069<br>Dresden Germany-<br>packager | Belgium | GlaxoSmithKline<br>Biologicals s.a.,<br>Rue de l' Institut,<br>89 B-1330<br>Rixensart | Belgium  | R   | 16313/1 31.08.2020 |
| 28 | Fentavera        | fentanyl                                          | patch<br>transdermal        | 50mcg/h; (5) patches                                       | Acino AG, Am Windfeld<br>35, 83714 Miesbach - batch<br>releaser, Luye Pharma AG,<br>Am Windfeld 27 and 35,<br>83714 Miesbach, Germany -<br>bulk manufacturer,<br>packager, quality control                                                                                  | Germany | Acino AG, Am<br>Windfeld 35,<br>83714 Miesbach                                        | Germany  | R   | 18857/2 31.08.2020 |
| 29 | ACC 100          | acetylcysteine                                    | tablets<br>effervescent     | 100mg; (20) in plastic<br>container                        | Salutas Pharma GmbH,<br>Otto-von-Guericke-Alle-1,<br>39179 Barleben-batch<br>releaser, Hermes Pharma<br>Ges.m.b.H, Allgau 36, 9400<br>Wolfsberg, Austria-bulk<br>manufacturer, packager,<br>quality control                                                                 | Germany | Sandoz<br>Pharmaceuticals<br>d.d., Verovskova<br>Str. 57, 1526<br>Ljubljana           | Slovenia | OTC | 18715/2 31.08.2020 |



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| 30 | ACC 200                     | acetylcysteine                      | tablets effervescent            | 200mg; (20) in plastic container                        | Salutas Pharma GmbH,<br>Otto-von-Guericke-Alle-1,<br>39179 Barleben-batch<br>releaser, Hermes Pharma<br>Ges.m.b.H, Allgau 36, 9400<br>Wolfsberg, Austria-bulk<br>manufacturer, packager,<br>quality control | Germany | Sandoz<br>Pharmaceuticals<br>d.d., Verovskova<br>Str. 57, 1526<br>Ljubljana   | Slovenia   | OTC | 18716/2 31.08.2020 |
| 31 | Pedeks                      | permethrin                          | solution for external use       | 5mg/g; 60ml glass bottle                                | LMP Ltd., 1, Vietalvas street, Riga, LV-1009                                                                                                                                                                | Latvia  | LMP Ltd., 1, Vietalvas street, Riga, LV-1009                                  | Latvia     | OTC | 15169/2 31.08.2020 |
| 32 | Dicloton 75mg/3ml           | diclofenac (diclofenac sodium)      | solution for injection/infusion | 25mg/ml; (5) ampoules 3ml                               | Medochemie Ltd., 48 Iapetou street, Agios Athanassios Industrial Area, 4101 Agios Athanassios, Limassol                                                                                                     | Cyprus  | Medochemie Ltd., 1-10 Constantinoupolos street, 3011 Limassol                 | Cyprus     | R   | 14621/2 31.08.2020 |
| 33 | Upsarin Ursa with vitamin C | acetylsalicylic acid, ascorbic acid | tablets effervescent            | 330mg+200mg; (10) in plastic container                  | UPSA SAS, 979, Avenue des Pyrenees, 47520 Le Passage, France                                                                                                                                                | France  | UPSA SAS, 3, rue Joseph Monier-92500 Rueil-Malmaison                          | France     | R   | 14912/3 31.08.2020 |
| 34 | Arlevert                    | cinnarizine, dimenhydrinate         | tablets                         | 20mg+40mg; (20/1x20/) in blister, (50/2x25/) in blister | Hennig Arzneimittel GmbH & Co. KG, Liebigstrasse 1 - 2, 65439 Floersheim-am-Main                                                                                                                            | Germany | Menarini International Operations Luxembourg S.A., 1, avenue de la Gare, 1611 | Luxembourg | R   | 15763/1 31.08.2020 |

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| 35 | Elidel       | pimecrolimus                  | cream                   | 10mg/g; 15g aluminium tube                             | MEDA Manufacturing,<br>Avenue JF Kennedy, 33700<br>Merignac            | France      | MEDA Pharma<br>GmbH & Co. KG,<br>Benzstrasse 1,<br>61352 Bad<br>Homburg       | Germany | R   | 14745/2 31.08.2020 |
| 36 | Fluimucil    | acetylcysteine                | tablets<br>effervescent | 600mg; (10/5x2/)<br>blisters                           | Zambon Switzerland Ltd.,<br>Via Industria 13, CH-6814,<br>Cadempino    | Switzerland | Zambon S.P.A.,<br>Via Lillo Del<br>Duca, 10, Bresso,<br>20091                 | Italy   | OTC | 14599/2 31.08.2020 |
| 37 | Clostilbegyt | clomifene (clomifene citrate) | tablets                 | 50mg; (10) in glass vial                               | Egis Pharmaceuticals PLC,<br>9900, Kormend, Matyas<br>Kiraly u. 65     | Hungary     | Egis<br>Pharmaceuticals<br>PLC, 1106<br>Budapest,<br>Kereszturi ut 30-<br>38  | Hungary | R   | 16103/1 31.08.2020 |
| 38 | Hartil       | ramipril                      | tablets                 | 5mg; (14/2x7/) in<br>blister, (28/4x7/) in<br>blister  | Egis Pharmaceuticals PLC,<br>1165 Budapest,<br>Bokenyfoldi st. 118-120 | Hungary     | Egis<br>Pharmaceuticals<br>PLC, 1106<br>Budapest,<br>Kereszturi st. 30-<br>38 | Hungary | R   | 18395/1 31.08.2020 |
| 39 | Hartil       | ramipril                      | tablets                 | 10mg; (14/2x7/) in<br>blister, (28/4x7/) in<br>blister | Egis Pharmaceuticals PLC,<br>1165 Budapest,<br>Bokenyfoldi st. 118-120 | Hungary     | Egis<br>Pharmaceuticals<br>PLC, 1106<br>Budapest,<br>Kereszturi st. 30-<br>38 | Hungary | R   | 18396/1 31.08.2020 |

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| 40 | Lomexin                 | fenticonazole (fenticonazole nitrate) | capsules vaginal          | 200mg; (6) blister                        | Catalent Italy S.p.A., Via Nettunense km. 20,100, Aprilia, 04011                      | Italy   | Recordati Ireland Ltd., Raheens East, Ringaskiddy, Co Cork                            | Ireland | R | 14690/3 31.08.2020 |
| 41 | Lomexin                 | fenticonazole (fenticonazole nitrate) | capsules vaginal          | 600mg; (1) blister, (2) blister           | Catalent Italy S.p.A., Via Nettunense km. 20,100, Aprilia, 04011                      | Italy   | Recordati Ireland Ltd., Raheens East, Ringaskiddy, Co Cork                            | Ireland | R | 14691/3 31.08.2020 |
| 42 | Lomexin                 | fenticonazole (fenticonazole nitrate) | capsules vaginal          | 1000mg; (1) blister, (2) blister          | Catalent Italy S.p.A., Via Nettunense km. 20,100, Aprilia, 04011                      | Italy   | Recordati Ireland Ltd., Raheens East, Ringaskiddy, Co Cork                            | Ireland | R | 14692/3 31.08.2020 |
| 43 | Albunorm Octapharma 5%  | albumin human                         | solution for i/v infusion | 50mg/ml; 100ml, 250ml, 500ml glass bottle | Octapharma Pharmazeutika Produktionsges. m.b.H., Oberlaaer Strasse 235, A-1100 Vienna | Austria | Octapharma Pharmazeutika Produktionsges. m.b.H., Oberlaaer Strasse 235, A-1100 Vienna | Austria | R | 14930/3 31.08.2020 |
| 44 | Albunorm Octapharma 20% | albumin human                         | solution for i/v infusion | 200mg/ml; 50ml and 100ml glass bottle     | Octapharma Pharmazeutika Produktionsges. m.b.H., Oberlaaer Strasse 235, A-1100 Vienna | Austria | Octapharma Pharmazeutika Produktionsges. m.b.H., Oberlaaer Strasse 235, A-1100 Vienna | Austria | R | 14931/3 31.08.2020 |

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| 45 | Fentavera   | fentanyl                                                                                         | patch<br>transdermal    | 75mcg/h; (5) patches                                                                                       | Acino AG, Am Windfeld<br>35, 83714 Miesbach - batch<br>releaser, Luye Pharma AG,<br>Am Windfeld 27 and 35,<br>83714 Miesbach, Germany -<br>bulk manufacturer,<br>packager, quality control | Germany                | Acino AG, Am<br>Windfeld 35,<br>83714 Miesbach                              | Germany                | R | 18858/2 31.08.2020 |
| 46 | Armenicum   | iodine, potassium iodide,<br>lithium chloride, polyvinyl<br>alcohol, dextrin, sodium<br>chloride | capsules                | 28,76mg+43,14mg+0,7<br>2mg+10,79mg+359,53<br>mg+32,36mg;<br>(40/4x10/) blisters,<br>(40) plastic container | Arpimed LLC, Kotayk<br>Marz, Abovyan, 2nd Micro-<br>District, 19 Building                                                                                                                  | Republic of<br>Armenia | 'Armenicum+'<br>CJSC, 37<br>Nalbandayan,<br>Yerevan 0001                    | Republic of<br>Armenia | R | 13877/1 31.08.2020 |
| 47 | Clavoton 1g | amoxicillin (amoxicillin<br>trihydrate), clavulanic acid<br>(potassium clavulanate)              | tablets film-<br>coated | 875mg+125mg;<br>(14/2x7/), in blister                                                                      | Medochemie Ltd- Factory<br>B, 48 Iapetou street, Agios<br>Athanassios Industrial<br>Area, 4101 Agios<br>Athanassios, Limassol                                                              | Cyprus                 | Medochemie Ltd.,<br>1-10<br>Constantinoupole<br>os street, 3011<br>Limassol | Cyprus                 | R | 14987/1 31.08.2020 |
| 48 | Diflucan    | fluconazole                                                                                      | capsules                | 50mg; (7/1x7/) in<br>blister                                                                               | Fareva Amboise, Zone<br>Industrielle, 29 route des<br>Industries, 37530 Poce-sur-<br>Cisse                                                                                                 | France                 | Pfizer H.C.P.<br>Corporation, 235,<br>East 42nd street<br>New York 10017    | USA                    | R | 18201/2 31.08.2020 |
| 49 | Diflucan    | fluconazole                                                                                      | capsules                | 150mg; (1) blister                                                                                         | Fareva Amboise, Zone<br>Industrielle, 29 route des<br>Industries, 37530 Poce-sur-<br>Cisse                                                                                                 | France                 | Pfizer H.C.P.<br>Corporation, 235,<br>East 42nd street<br>New York 10017    | USA                    | R | 18202/2 31.08.2020 |

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| 50 | Hemomycin | azithromycin (azithromycin dihydrate) | tablets film-coated       | 500mg; (3), in blister                                                                                                                                          | Hemofarm A.D., 26300, Vrsac, Beogradskii put bb                                                                                                                                                | Serbia   | Hemofarm A.D., 26300, Vrsac, Beogradskii put bb           | Serbia      | R | 15125/1 31.08.2020 |
| 51 | Emanera   | esomeprazole (esomeprazole magnesium) | capsules gastro-resistant | 20mg; (7/1x7/) in blister, (14/2x7/) in blister, (15/3x5/) in blister, (28/4x7/) in blister, (30/3x10/) in blister, (56/8x7/) in blister, (60/6x10/) in blister | KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto                                                                                                                                      | Slovenia | KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto | Slovenia    | R | 19133/1 31.08.2020 |
| 52 | Emanera   | esomeprazole (esomeprazole magnesium) | capsules gastro-resistant | 40mg; (7/1x7/) in blister, (14/2x7/) in blister, (15/3x5/) in blister, (28/4x7/) in blister, (30/3x10/) in blister, (56/8x7/) in blister, (60/6x10/) in blister | KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto                                                                                                                                      | Slovenia | KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto | Slovenia    | R | 19134/1 31.08.2020 |
| 53 | Votrient  | pazopanib                             | tablets film-coated       | 400mg; (30) in plastic container                                                                                                                                | Glaxo Wellcome S.A., Avda Extremadura, 3, 09400 Aranda de Duero, Burgos-batch releaser, packager, Glaxo Operations UK Ltd, Priory Street, Ware, Hertfordshire, SG12 0DJ, UK- bulk manufacturer | Spain    | Novartis Pharma AG, Lichtstrasse 35, 4056 Basel           | Switzerland | R | 16566/2 31.08.2020 |

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| 54 | ACC 100               | acetylcysteine                             | powder for oral solution | 100mg; (20) sachets 3g        | Salutas Pharma GmbH,<br>Otto-von-Guericke-Alle-1,<br>39179 Barleben-batch<br>releaser, Lindopharm<br>GmbH, Neustrasse 82, D-<br>40721 Hilden, Germany-<br>bulk manufacturer,<br>packager | Germany | Sandoz<br>Pharmaceuticals<br>d.d., Verovskova<br>Str. 57, 1000<br>Ljubljana | Slovenia | OTC | 14430/1 31.08.2020 |
| 55 | ACC 200               | acetylcysteine                             | powder for oral solution | 200mg; (20) sachets 3g        | Salutas Pharma GmbH,<br>Otto-von-Guericke-Alle-1,<br>39179 Barleben-batch<br>releaser, Lindopharm<br>GmbH, Neustrasse 82, D-<br>40721 Hilden, Germany-<br>bulk manufacturer,<br>packager | Germany | Sandoz<br>Pharmaceuticals<br>d.d., Verovskova<br>Str. 57, 1000<br>Ljubljana | Slovenia | OTC | 14431/1 31.08.2020 |
| 56 | Azithro-Denk<br>500mg | azithromycin (azithromycin<br>monohydrate) | tablets film-<br>coated  | 500mg; (3/1x3/) in<br>blister | Artesan Pharma GmbH &<br>Co. KG, Wendlandstrasse<br>1, 29439 Luechow                                                                                                                     | Germany | Denk Pharma<br>GmbH & Co. KG,<br>Prinzregentenstr.<br>79, 81675<br>Muenchen | Germany  | R   | 18882/1 31.08.2020 |