

**List**  
**of the variation recommended for registration by N 6-1/19 meeting decision of**  
**the Pharmacological Council of MoH of RA dated on June 7, 2019**

President \_\_\_\_\_ E. Amroya

| 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. | Diclofenac           | diclofenac (diclofenac sodium)                                              | tablets film-coated prolonged-release     | 100mg; (20/2x10/) in blister                              | Hemofarm A.D., 26300, Vrsac, Beogradskii put bb                                                                                             | Serbia      | Hemofarm A.D., 26300, Vrsac, Beogradskii put bb                 | Serbia                 | R                   | 18311/1<br>07.06.2019 |
| 2. | Zoledro-Denk 4mg/5ml | zoledronic acid                                                             | concentrate for solution for i/v infusion | 0,8mg/ml; plastic container 5ml                           | Siegfried Hameln GmbH, Langes Feld 13, Hameln, Niedersachsen, 31789                                                                         | Germany     | Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen | Germany                | R                   | 14398/2<br>07.06.2019 |
| 3. | Rhophylac 300        | immunoglobulin anti-D (Rh) human                                            | solution for i/v and i/m injection        | 300mcg/2ml; pre-filled syringe 2ml and needle, in blister | CSL Behring AG, Wankdorfstrasse 10, CH-3000 Bern 22-batch releaser, bulk manufacturer, CSL Behring GmbH, Emil-von-Behring-Strasse 76, 35041 | Switzerland | CSL Behring AG, Wankdorfstrasse 10, CH-3000 Bern 22             | Switzerland            | R                   | 15215/1<br>07.06.2019 |

|    |          |                                           |                         |                                  |                                                                                               |         |                                                              |         |   |                       |
|----|----------|-------------------------------------------|-------------------------|----------------------------------|-----------------------------------------------------------------------------------------------|---------|--------------------------------------------------------------|---------|---|-----------------------|
|    |          |                                           |                         |                                  | Marburg,<br>Germany- primary<br>and secondary<br>packager                                     |         |                                                              |         |   |                       |
| 4. | Singlon  | montelukast<br>(montelukast<br>sodium)    | tablets<br>chewable     | 4mg;<br>(28/4x7/) in<br>blister  | Gedeon Richter<br>Polska Sp.z o.o.,<br>ul.Graniczna 35,<br>Grodzisk<br>Mazowiecki, 05-<br>825 | Poland  | Gedeon Richter<br>PLC, Gyomroi ut<br>19-21, 1103<br>Budapest | Hungary | R | 16059/1<br>07.06.2019 |
| 5. | Singlon  | montelukast<br>(montelukast<br>sodium)    | tablets<br>chewable     | 5mg;<br>(28/4x7/) in<br>blister  | Gedeon Richter<br>Polska Sp.z o.o.,<br>ul.Graniczna 35,<br>Grodzisk<br>Mazowiecki, 05-<br>825 | Poland  | Gedeon Richter<br>PLC, Gyomroi ut<br>19-21, 1103<br>Budapest | Hungary | R | 16058/1<br>07.06.2019 |
| 6. | Singlon  | montelukast<br>(montelukast<br>sodium)    | tablets film-<br>coated | 10mg;<br>(28/4x7/) in<br>blister | Gedeon Richter<br>Polska Sp.z o.o.,<br>ul.Graniczna 35,<br>Grodzisk<br>Mazowiecki, 05-<br>825 | Poland  | Gedeon Richter<br>PLC, Gyomroi ut<br>19-21, 1103<br>Budapest | Hungary | R | 16057/1<br>07.06.2019 |
| 7. | Mertenil | rosuvastatin<br>(rosuvastatin<br>calcium) | tablets film-<br>coated | 5mg;<br>(30/3x10/) in<br>blister | Gedeon Richter<br>PLC, Gyomroi ut<br>19-21, 1103<br>Budapest                                  | Hungary | Gedeon Richter<br>PLC, Gyomroi ut<br>19-21, 1103<br>Budapest | Hungary | R | 15905/1<br>07.06.2019 |
| 8. | Mertenil | rosuvastatin                              | tablets film-           | 10mg;                            | Gedeon Richter                                                                                | Hungary | Gedeon Richter                                               | Hungary | R | 15904/1               |

|     |                           |                                                                                                  |                     |                                                         |                                                          |         |                                                                  |         |   |                    |
|-----|---------------------------|--------------------------------------------------------------------------------------------------|---------------------|---------------------------------------------------------|----------------------------------------------------------|---------|------------------------------------------------------------------|---------|---|--------------------|
|     |                           | (rosuvastatin calcium)                                                                           | coated              | (30/3x10/) in blister                                   | PLC, Gyomroi ut 19-21, 1103 Budapest                     |         | PLC, Gyomroi ut 19-21, 1103 Budapest                             |         |   | 07.06.2019         |
| 9.  | Mertenil                  | rosuvastatin (rosuvastatin calcium)                                                              | tablets film-coated | 20mg; (30/3x10/) in blister                             | Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest      | Hungary | Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest              | Hungary | R | 15903/1 07.06.2019 |
| 10. | Rigevidon                 | levonorgestrel, ethinylestradiol                                                                 | tablets coated      | 0,15mg+0,03 mg; (21/1x21/) blister, (63/3x21/) blisters | Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest      | Hungary | Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest              | Hungary | R | 14454/1 07.06.2019 |
| 11. | Metformin Denk 1000       | metformin (metformin hydrochloride)                                                              | tablets film-coated | 1000mg; (30/2x15/) in blister                           | Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning | Germany | Denk Pharma GmbH & Co. KG, Prinzregentenst r. 79, 81675 Muenchen | Germany | R | 16230/1 07.06.2019 |
| 12. | Vit-B-Denk                | thiamine (thiamine hydrochloride)(vitamin B1), pyridoxine (pyridoxine hydrochloride)(vitamin B6) | tablets film-coated | 100mg+200mg ; (20/2x10/) and (100/10x10/) in blister    | Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning | Germany | Denk Pharma GmbH & Co. KG, Prinzregentenst r. 79, 81675 Muenchen | Germany | R | 16231/1 07.06.2019 |
| 13. | Captopril+HC T Denk 50/25 | captopril, hydrochlorothiazide                                                                   | tablets             | 50mg+25mg; (30/3x10/) and (100/10x10/)                  | Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529            | Germany | Denk Pharma GmbH & Co. KG, Prinzregentenst                       | Germany | R | 17814/107.06. 2019 |

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|     |                            |                                                 |                           | in blister                       | Tittmoning                                                                                 |         | r. 79, 81675<br>Muenchen,<br>Germany                                        |             |     |                       |
| 14. | Diclo-Denk<br>75 Injection | diclofenac<br>(diclofenac sodium)               | solution for<br>injection | 25mg/ml; (10)<br>ampoules 3ml    | Haupt Pharma<br>Wulfing GmbH,<br>Bethelner<br>Landstrasse 18,<br>Gronau/Leine<br>31028 for | Germany | Denk Pharma<br>GmbH & Co. KG,<br>Prinzregentenst<br>r. 79, 81675<br>Munchen | Germany     | R   | 17460/1<br>07.06.2019 |
| 15. | Betoptic S                 | betaxolol<br>(betaxolol<br>hydrochloride)       | drops eye<br>(suspension) | 2,5mg/ml; 5ml<br>vial            | S.A. Alcon-<br>Couvreur N.V.,<br>Rijksweg 14 2870<br>Puurs                                 | Belgium | Novartis<br>Pharma AG,<br>Lichtstrasse 35,<br>4056 Basel                    | Switzerland | R   | 17917/1<br>07.06.2019 |
| 16. | Hexicon                    | chlorhexidine<br>(chlorhexidine<br>bigluconate) | suppositories<br>vaginal  | 16mg;<br>(10/2x5/) in<br>blister | Nizhpharm JSC,<br>603950, Nizhny<br>Novgorod,<br>Salganskaya st., 7                        | Russia  | Nizhpharm JSC,<br>603950, Nizhny<br>Novgorod,<br>Salganskaya st.,<br>7      | Russia      | OTC | 17592/1<br>07.06.2019 |