

| AA Licence Number | Product Name  | Active Ingredient/s                        | Source Country Authorisation Number | Source Country | Applicant                           | Objections Received | Status of application | Reason for decision   | Conditions included in the Licence |
|-------------------|---|--|-------------------------------------|----------------|-------------------------------------|---------------------|-----------------------|---|------------------------------------|
| AA1545/00701      | Milrinone Tillomed Solution for Inj/Inf 1mg/ml        | Milrinone                                  | 34009 550 803 74                    | France         | Tillomed Malta Limited              | Nil                 | Accepted              | To ensure continuation of supply for the National Health System   | To undergo MRP                     |
| AA565/107401      | Neo Cytamen Solution for Injection 1000mcg/2.5ml      | Hydroxocobalamin                           | A.I.C.019969029                     | Italy          | Central Procurement& Supplies Unit  | Nil                 | Accepted              | To ensure continuation of supply for the National Health System   | N/A                                |
| AA565/47503       | Humatin Capsules Hard 250mg                           | Paromomycin                                | AIC 016531016                       | Italy          | Central Procurement & Supplies Unit | Nil                 | Accepted              | To ensure continuation of supply for the National Health System   | N/A                                |
| AA729/36701       | Solpadol Caplets Tablets 500mg/30mg                   | Paracetamol; Codeine phosphate hemihydrate | PA1113/027/001                      | Ireland        | Cherubino Ltd                       | Nil                 | Accepted              | There are fewer than three authorised products on the market with the same active ingredient, dose and strength | N/A                                |
| AA565/109001      | Roxazin Tablet, film coated 20mg                      | Rosuvastatin                               | 5840103                             | Portugal       | Central Procurement& Supplies Unit  | Nil                 | Accepted              | To ensure continuation of supply for the National Health System   | N/A                                |
| AA565/38106       | Furosemide Sandoz Intravenous Inf Solution 250mg/25ml | Furosemide                                 | RVG25841                            | Netherlands    | Central Procurement& Supplies Unit  | Nil                 | Accepted              | To ensure continuation of supply for the National Health System   | N/A                                |
| AA908/09605       | Atacand Tablets 8mg                                   | Candesartan cilexetil                      | 6232/2014/01-08                     | Romania        | NEOFARMA PHARMACEUTICALS LTD        | Nil                 | Accepted              | There are fewer than three authorised products on the market with the same active ingredient, dose and strength | N/A                                |
| AA908/09606       | Atacand Tablets 16mg                                  | Candesartan cilexetil                      | 6232/2014/01-08                     | Romania        | NEOFARMA PHARMACEUTICALS LTD        | Nil                 | Accepted              | There are fewer than three authorised products on the market with the same active ingredient, dose and strength | N/A                                |

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| AA908/09607    | Atacand Plus Tablets 16mg/12.5mg                       | Candesartan cilexetil;<br>Hydrochlorothiazide | 63.209         | Spain          | NEOFARMA<br>PHARMACEUTICALS LTD        | Nil | Accepted | There are fewer than<br>three authorised products<br>on the market with the<br>same active ingredient,<br>dose and strength | N/A               |
| AA1488/09301UK | Pethidine Solution for Injection<br>50mg/ml            | Pethidine hydrochloride                       | PL 01883/6150R | United Kingdom | HHP MALTA (P&D PHARMA)<br>LIMITED      | Nil | Accepted | To ensure continuation of<br>supply for the National<br>Health System   | N/A               |
| AA242/02102UK  | Montelukast Tablet, film coated<br>10mg                | Montelukast                                   | PL 16363/0255  | United Kingdom | Pharmabart Ltd.                        | Nil | Refused  | This product has a<br>Marketing Authorisation<br>in Malta   | N/A               |
| AA1570/00301   | Olopatadine Unimed Pharma Eye<br>Drops Solution 1mg/ml | Olopatadine<br>hydrochloride                  | 64/0045/20-S   | Slovakia       | UNIMED PHARMA, spol. s<br>r.o.         | Nil | Accepted | There are fewer than<br>three authorised products<br>on the market with the<br>same active ingredient,<br>dose and strength | To undergo<br>MRP |
| AA1411/07901   | Hypnomidate Solution for Injection<br>2mg/ml           | Etomidate                                     | 319.00.00      | Germany        | EJ BUSUTTIL LTD                        | Nil | Accepted | To ensure continuation of<br>supply for the National<br>Health System   | N/A               |
| AA565/108901UK | Sodium Glycerophosphate Solution<br>for Infusion 21.6% | Sodium<br>glycerophosphate<br>pentahydrate    | PL 08828/0147  | United Kingdom | Central Procurement &<br>Supplies Unit | Nil | Accepted | To ensure continuation of<br>supply for the National<br>Health System   | N/A               |
| AA565/42703    | Sulfasalazine EN Tablets Gastro-<br>Resistant 500mg    | Sulfasalazine                                 | 13702/2021/01  | Slovenia       | Central Procurement &<br>Supplies Unit | Nil | Accepted | To ensure continuation of<br>supply for the National<br>Health System   | N/A               |
| AA565/53505    | Mitomycin medac Solution for Inj/Inf<br>1mg/ml         | Mitomycin                                     | 91370.00.00    | Germany        | Central Procurement &<br>Supplies Unit | Nil | Accepted | To ensure continuation of<br>supply for the National<br>Health System   | N/A               |
| AA565/24104    | Levofloxacin Aurobindo Tablet, film<br>coated 500mg    | Levofloxacin                                  | RVG107790      | Netherlands    | Central Procurement &<br>Supplies Unit | Nil | Accepted | To ensure continuation of<br>supply for the National<br>Health System   | N/A               |