

| 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 |
|-------------------|---|-----------------------------------|-------------------------------------|----------------|------------------------------------|---------------------|-----------------------|---|------------------------------------|
| AA1228/02303 | Valaciclovir 1A Pharma. Tablet, film coated 500mg | Valacyclovir | 70516.00.00 | Germany | Focused Pharma Ltd | Nil | Accepted | There are fewer than three authorised products on the market | N/A |
| AA1228/02304 | Valaciclovir 1A Pharma Coated Tablets 1000mg | Valacyclovir | 70517.00.00 | Germany | Focused Pharma Ltd | Nil | Accepted | To ensure continuation of supply for the National Health System | N/A |
| AA1161/00602 | Haloperidol Laropharm Tablets 0.5mg | Haloperidol | 14273/2022/01 | Romania | Farmarosib SRL | Nil | Accepted | To ensure continuation of supply for the National Health System | To undergo MRP |
| AA565/91003 | Everlimus Zentiva Tablets 10mg | Everolimus | 99495.00.00 | Germany | Central Procurement& Supplies Unit | Nil | Accepted | To ensure continuation of supply for the National Health System | N/A |
| AA565/66609 | Atomoxetine HCl Aurobindo Capsules Hard 40mg | Atomoxetine hydrochloride | RVG 121293 | Netherlands | Central Procurement& Supplies Unit | Nil | Accepted | To ensure continuation of supply for the National Health System | N/A |
| AA565/12406 | Largactil Tablet, film coated 25mg | Chlorpromazine | 23665 | Spain | Central Procurement& Supplies Unit | Nil | Accepted | To ensure continuation of supply for the National Health System | N/A |
| AA729/04306 | Paracetamol Suppositories 80mg | Paracetamol | PA1113/4/3 | Ireland | Cherubino Ltd | Nil | Accepted | There are fewer than three authorised products on the market | N/A |
| AA1438/12201UK | Benzydamine Hydrochloride Oromucosal Spray 0.15%w/v | Benzydamine hydrochloride | PL 39360/0012 | United Kingdom | NM Pharma Ltd | Nil | Refused | There are alternative products available in the European Union including Malta. The requirements of Directive 642/2002 (to allow in the case of shortages/severe problems with availability) are not satisfied. | N/A |
| AA908/07105 | Omeprazole Pinewood Capsules Gastro-Resistant 20 mg | Omeprazole | PA0281/152/001 | Ireland | Neofarma Pharmaceuticals Limited | Nil | Accepted | The product does not have a Marketing Authorisation in Malta | N/A |
| AA908/07301 | Norgesic Tablets 35mg/450mg | Orphenadrine citrate/ Paracetamol | 53907/15-12-2008 | Greece | Neofarma Pharmaceuticals Limited | 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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| AA1545/00501UK | Amikacin Solution for Inj/Inf 250mg/ml | Amikacin | PL 11311/0604 | United Kingdom | Tillomed Malta Ltd | Nil | Accepted | To ensure continuation of supply for the National Health System | N/A |
| AA908/28401 | Calpol Six Plus Fastmelts Orodispersible Tablet 250mg | Paracetamol | PA0330/017/005 | 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 |
| AA770/02103UK | Furosemide BP Solution for Injection 10mg/ml | Furosemide | PL 01502/0032 | United Kingdom | JV Healthcare Limited | Nil | Accepted | To ensure continuation of supply for the National Health System | N/A |