

| 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 |
|-------------------|--|-----------------------------|-------------------------------------|----------------|---|---------------------|-----------------------|---|------------------------------------|
| AA1608/00101 | PoltechMIBI Radio-Pharm Precursor 1mg | Copper(I) tetrafluoroborate | R/3269 | Poland | National Centre for Nuclear Research | Nil | Accepted | To ensure continuation of supply for the National Health System | To undergo MRP |
| AA1349/00703 | Fluoxetine Normon Oral solution 20mg/5ml | Fluoxetine | 62427 | Spain | LABORATORIOS NORMON, S.A. | Nil | Accepted | There are fewer than three authorised products on the market with the same active ingredient, dose and strength | To undergo MRP |
| AA729/27003 | Deprexolet Tablet, film coated 30mg | Mianserin hydrochloride | 11210 | Poland | Cherubino Ltd | Nil | Accepted | To ensure continuation of supply for the National Health System | N/A |
| AA1416/00601 | Hydrokortyzon Allefin Max Cream 10mg/g | Hydrocortisone acetate | 27594 | Poland | Przedsiębiorstwo Produkcji Farmaceutycznej HASCO-LEK S.A. | Nil | Accepted | The product is to be made available at least 10% less than the price of the cheapest authorised alternative | To undergo MRP |
| AA1343/05901 | Trandate Tablet, film coated 200mg | Labetalol hydrochloride | 700707: 54528 | Spain | Target Healthcare Limited | Nil | Accepted | To ensure continuation of supply for the National Health System | N/A |
| AA084/08803 | Promethazine Tablet, film coated 25mg | Promethazine hydrochloride | 8518 | Cyprus | Remedica Ltd. | Nil | Accepted | To ensure continuation of supply for the National Health System | To undergo MRP |
| AA1349/00306 | Aripiprazole Normon EFG Tablets 5mg | Aripiprazole | 79809: 706372 | Spain | LABORATORIOS NORMON, S.A. | Nil | Accepted | There are no other authorised products for this active substance in the same strength and pharmaceutical form | To undergo MRP |
| AA1349/00307 | Aripiprazole Normon EFG Tablets 10mg | Aripiprazole | 79810: 706373 | Spain | LABORATORIOS NORMON, S.A. | Nil | Accepted | There are no other authorised products for this active substance in the same strength and pharmaceutical form | To undergo MRP |
| AA1349/00308 | Aripiprazole Normon EFG Tablets 15mg | Aripiprazole | 79811: 706375 | Spain | LABORATORIOS NORMON, S.A. | Nil | Accepted | There are no other authorised products for this active substance in the same strength and pharmaceutical form | To undergo MRP |
| AA565/85203 | SUCCICAPTAL Capsule 200mg | Succimer | 34009 365 710 8 2 | France | Central Procurement & Supplies Unit | Nil | Accepted | No authorised products are available, marketed or offered on tender | N/A |

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|--------------|---|---------------------------|----------------------|----------|------------------------------------|-----|----------|--|-------------------|
| AA084/04607 | Perofen Tablet, film coated 400mg | Ibuprofen | 8597 | Cyprus | Remedica Ltd. | Nil | Accepted | To ensure continuation of supply | To undergo MRP |
| AA1161/01203 | Propranolol Arena Tablets 10mg | Propranolol hydrochloride | 12927/2020/01 | Romania | Farmarosib SRL | Nil | Accepted | To ensure continuation of supply for the National Health System | To undergo MRP |
| AA908/28202 | VOLTADOL 24-HOURS Medicated Plaster 140mg | Diclofenac sodium | 131054-55/06-11-2024 | Greece | NEOFARMA PHARMACEUTICALS LTD | Nil | Refused | The product has a marketing authorisation in Malta - MA460/01201 | N/A |
| AA1454/05601 | Gentamicin DS Solution for Injection 40mg/ml | Gentamicin sulphate | 9800176 | Bulgaria | Prohealth Limited | Nil | Accepted | To ensure continuation of supply for the National Health System | To undergo MRP |