

AA Licence Number	Product Name	Active Ingredient/s	Source Country Authorisation Number	Source Country	Applicant	Objections Received	Status of application	Reason for decision	Conditions of Licence
AA729/28601UK	Metanium Nappy Rash Ointment 20%w/w	Titanium Dioxide; Titanium Peroxide; Titanium Salicylate	PL 00240/0366	United Kingdom	Cherubino Ltd	Nil	Accepted	To ensure continuity of supply given that no other alternatives with a Marketing Authorisation or a 126a from the EEA are marketed.	N/A
AA1369/06501UK	Warfarin Tablets 3mg	Warfarin Sodium	PL 00289/1628	United Kingdom	Health House Pharma Ltd T/As P&D Pharmaceuticals Ltd	Nil	Pending	N/A	N/A
AA1369/06502UK	Warfarin Tablets 5mg	Warfarin Sodium	PL 00289/1629	United Kingdom	Health House Pharma Ltd T/As P&D Pharmaceuticals Ltd	Nil	Pending	N/A	N/A

AA1369/07001UK	Cyproterone Acetate Tablets 50mg	Cyproterone acetate	PL 51463/0007	United Kingdom	Health House Pharma Ltd T/As P&D Pharmaceuticals Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1369/08301UK	Flutamide Tablets 250mg	Flutamide	PL 04569/0338	United Kingdom	Health House Pharma Ltd T/As P&D Pharmaceuticals Ltd	Nil	Pending	N/A	N/A
AA1369/01601	Dantrium Capsules 25mg	Dantrolene sodium	PL 20011/0032	United Kingdom	Health House Pharma Ltd T/As P&D Pharmaceuticals Ltd	Nil	Pending	N/A	N/A
AA1343/01901UK	Furosemide Tablets 40mg	Furosemide	PL 20416/0079	United Kingdom	Target Healthcare Limited	Nil	Pending	N/A	N/A
AA1122/00804	Rosuva Tablet, film coated 5mg	Rosuvastatin	PA0711/176/001	Ireland	Rowex Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1122/00805	Rosuva Tablet, film coated 10mg	Rosuvastatin	PA0711/176/002	Ireland	Rowex Ltd	Nil	Accepted	To ensure continuity of supply and difficulty identified to undergo MRP during this time	Commitment to undergo MRP

AA1122/01002	Sildenafil Tablets 100mg	Sildenafil citrate	PA0711/170/003	Ireland	Rowex Ltd	Nil	Accepted	To ensure continuity of supply and difficulty identified to undergo MRP during this time	Commitment to undergo MRP
AA084/09102	Felexin Capsules Hard 250mg	Cefalexin monohydrate	19696	Cyprus	Remedica Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	Commitment to undergo MRP
AA565/86601	Aggrastat Solution for Infusion 0.05mg/ml	Tirofiban hydrochloride monohydrate	RVG 23381	France	Central Procurement & Supplies Unit	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1122/03001	Rolyprex Tablet, film coated 5mg	Olanzapine	PA0711/124/002	Ireland	Rowex Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	Commitment to undergo MRP
AA1122/03002	Rolyprex Tablet, film coated 10mg	Olanzapine	PA0711/124/004	Ireland	Rowex Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	Commitment to undergo MRP

AA1369/08501UK	Erythromycin Tablets Gastro- Resistant 250mg	Erythromycin	PL 17907/0005	United Kingdom	Health House Pharma Ltd T/As P&D Pharmaceuticals Ltd	Nil	Pending	N/A	N/A
AA565/85202	Succinaptal  Capsule 200mg	Succimer	34009 365 710 82	France	Central Procurement & Supplies Unit	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA729/25702	Lexotan  Tablets 3mg	Bromazepam	PA2239/008/002	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
AA770/03602	Esomeprazole  Tablets Gastro- Resistant 20mg	Esomeprazole	PA 2315/127/003	Ireland	JV Healthcare  Limited	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A
AA770/03603	Esomeprazole  Tablets Gastro- Resistant 40mg	Esomeprazole	PA 2315/127/004	Ireland	JV Healthcare  Limited	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A

AA565/85002	Floxapen Pdr for Soln Inj/Inf 250mg	Flucloxacillin	PA1380/011/003	Ireland	Central Procurement & Supplies Unit	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA770/15801	Sertraline  Tablet, film  coated 50mg	Sertraline	PA2315/101/003	Ireland	JV Healthcare   Limited	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A
AA770/15802	Sertraline  Tablet, film  coated 100mg	Sertraline	PA2315/101/004	Ireland	JV Healthcare   Limited	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A
AA908/14702	Colpermin IBS Relief Capsules Gastro- Resistant 0.2ml	Peppermint oil	PA0330/034/001	Ireland	Neofarma  Pharmaceuticals  Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1218/01402	Prednisone  Biogaran  Tablets 20mg	Prednisone	34009 365 225 27	France	Biogaran	Nil	Accepted	To ensure continuity of supply given that there is a worldwide shortage for this active ingredient	N/A

AA1438/08401	Night Nurse Capsules Paracetamol Capsules Hard 500mg/10mg/ 7.5mg	Paracetamol; Promethazine Hydrochloride; Dextromethorpha n Hydrobromide	PA0678/021/001	Ireland	NM Pharma Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
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