

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
AA1598/00102	Bupivacaine/Adrenaline Physan Solution for Injection 5mg/ml+0.005mg/ml	Bupivacaine hydrochloride Epinephrine	45669: 615922; 607376	Spain	Laphysan S.A.U	Nil	Accepted	There are no other authorised products for this active substance in the same strength or pharmaceutical form.	To undergo MRP
AA565/109502	Cinacalcet Tillomed Tablet, film coated 30mg	Cinacalcet	046022012; 046022024; 046022036	Italy	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1116/00102	Monuril Granules for Oral Solutions 3g	Fosfomycin trometamol	PA1441/002/002	Ireland	Zambon S.p.A.	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA770/01305	Adrenaline Solution for Injection 1mg/ml	Epinephrine	38080/10	Greece	JV Healthcare Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1438/01502	Perindopril Krka Tablets 4mg	Perindopril tert-butylamine	PA1347/041/002	Ireland	NM Pharma Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1120/00102	Algotren Tablet, film coated 200mg	Ibuprofen	78321/02-07-2024	Greece	INTERMED S.A.	Nil	Accepted	To ensure continuation of supply	To undergo MRP
AA908/32401	Faverin Tablet, film coated 100mg	Fluvoxamine maleate	PA23355/024/002	Ireland	Neofarma Pharmaceuticals Ltd	Nil	Refused	The product has a marketing authorisation in Malta	N/A
AA729/40301	Dasatinib Teva film-coated Tablets 100mg	Dasatinib	84092: 725598	Spain	Cherubino Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A

AA288/05001	Efavirenz + Emtricitabina + Tenofovir Generis Tablet, film coated 600mg/200mg/245mg Generis Tablet, film coated 600mg/200mg/245mg	Efavirenz Emtricitabina Tenofovir	5794961; 5794953	Portugal	VJ Salomone Pharma LTD	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA084/05603	Spirolon Tablet, film coated 25mg	Spironolactone	7873	Cyprus	Remedica Ltd.	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA1096/00102	Hemafer Syrup 50mg/5ml	Ferric hydroxide Polymaltose Complex	41529/07/22-05-2008	Greece	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories 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
AA084/07905	Clozarem Tablets 25mg	Clozapine	20348	Cyprus	Remedica Ltd.	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA565/04220	Ondansteron Solution for Inj/Inf 2mg/ml/	Ondansetron	PA2165/013/001	Ireland	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA729/20103	Poltechnet Radionuclide Generator 8.0-175GBQ	Sodium Molybdate Sodium Pertechnetate	22500	Poland	Cherubino Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/05813	Gabapentin Aurobindo Capsule 100mg	Gabapentin	5373600	Portugal	Central Procurement & Supplies Unit	Nil	Refused	The product has a marketing authorisation in Malta	N/A
AA1411/12401	FARVICETT Cutaneous Solution 0,015%+0,15%	Chlorhexidine Gluconate Cetrimide	32644078	Italy	EJ Busuttil Ltd	Nil	Accepted	Authorised products with the same active substance, pharmaceutical form and strength are not marketed or offered on tender	N/A

AA908/32001	Bepantiseptic First Aid Cream 1.205w/w/0.255w/w/10	Phenol Clorhexidine Digluconate	PA1410/047/001	Ireland	Neofarma Pharmaceuticals Ltd	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative of the same brand	N/A
AA908/32501	Pleyris Solution for Injection 25mg	Progesterone	AIC 041348044 AIC 041348057 AIC 041348069	Italy	Neofarma Pharmaceuticals Ltd	Nil	Accepted	The product is to be made available at least 10% less than the price of the authorised alternative of the same brand	N/A
AA908/32201	Cystopurin Granules for Oral Solutions 3g	Potassium Citrate	PA1410/042/001	Ireland	Neofarma Pharmaceuticals Ltd	Nil	Accepted	The product is to be made available at least 10% less than the price of the authorised alternative of the same brand	N/A
AA565/71902	Gilurytmal Solution for Injection 50mg/10ml	Ajmaline	6118316.00.00	Germany	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA908/19105	Emazole Tablets Gastro-Resistant 20mg	Esomeprazole	PA0711/158/001	Ireland	Neofarma Pharmaceuticals Ltd	Nil	Accepted	To ensure continuation of supply	N/A
AA908/19106	Emazole Tablets Gastro-Resistant 40mg	Esomeprazole	PA0711/158/002	Ireland	Neofarma Pharmaceuticals Ltd	Nil	Accepted	To ensure continuation of supply	N/A

