

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
AA565/22508	Pilocarpine-Isopto Eye Drops Solution 4%	Pilocarpine hydrochloride	BE038735	Belgium	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1411/11301	Ciproxin 250 mg/5 mL granules and solvent for oral suspension	Ciprofloxacin	AIC 026664084	Italy	EJ BUSUTTIL LTD	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/72402	Betoptic Eye Drops Solution 0.5%w/v	Betaxolol hydrochloride	87333/01-11-2022	Greece	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA770/14902	Naprosyn EC Tablets Gastro-Resistant 500mg	Naproxen	PA22657/002/002	Ireland	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
AA770/26001	Travogen Cream 1%	Isoconazole	32260/5-9-1995	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
AA729/17504	Relief Capsules Hard 4mg	Thiocolchicoside	94738/06082024	Greece	Cherubino Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA729/17505	Relief Gel 2.5mg/g	Thiocolchicoside	35813/14042022	Greece	Cherubino Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA729/17506	Relief Solution for Injection 4mg/2ml	Thiocolchicoside	94737/06082024	Greece	Cherubino Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1454/04301	Fluorouracil PhaRes Solution for Injection 50mg/ml	Fluorouracil	89558.00.00	Germany	Prohealth Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1414/00203	Lidocaine, Adrenaline Solution for Injection 20mg/ml/0.005mg/ml	Lidocaine Adrenaline	34009 302 764 8 8	France	Associated Equipment Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1444/00801	Novapio Tablets 15mg	Pioglitazone	18/134/17-C	Czech Republic	Novatin Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender.	MRP process initiated
AA1444/00802	Novapio Tablets 30mg	Pioglitazone	18/135/17-C	Czech Republic	Novatin Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender.	MRP process initiated
AA1444/00803	Novapio Tablets 45mg	Pioglitazone	18/136/17-C	Czech Republic	Novatin Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender.	MRP process initiated
AA1444/00701	Gapulsid Tablets 1mg	Cinitapride Hydrogen Tartrate	49/138/22-C	Czech Republic	Novatin Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender.	MRP process initiated

AA084/08503	Credanil 100 mg/10 mg tablets	Carbidopa monohydrate Levodopa	14411	Cyprus	Remedica Ltd.	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA565/57602	Cytomel Tablets 25mcg	Liothyronine sodium	RVG 108769	Netherlands	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/62106	Piperacillin/Tazobactam Kabi Pdr for Soln for Infusion 2 g/0.25 g	Piperacillin Tazobactam	5143516	Portugal	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA770/25601	Suprefact Solution for Injection 1mg/ml	Buserelin	57011: 969626	Spain	JV Healthcare Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA846/00105	Gaviscon Advance Chewable Tablets Sodium alginate 500 mg, Potassium hydrogen carbonate 100 mg	Sodium Alginate Potassium Bicarbonate	PA0979/011/008	Ireland	Charles de Giorgio Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA770/21002	Progynova Tablets 1mg	Estradiol valerate	BE223255	Belgium	JV Healthcare Limited	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA565/20707	Bicalutamide 50 PCH Tablet, film coated 50mg	Bicalutamide	RVG 34467	Netherlands	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/122301	Depakine Chronosphere 100 Granules Prolonged Release 66.66mg+29.03mg	Sodium valproate Valproic acid	11950	Poland	Central Procurement & Supplies Unit	Nil	Accepted	There are no other authorised products for this active substance in the same strength or pharmaceutical form	N/A
AA565/10709	Gentamicin DS Solution for Injection 40mg/ml	Gentamicin sulphate	9800176	Bulgaria	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1098/00102	Ursobil Capsules Hard 250mg	Ursodeoxicholic acid	24444059	Italy	ABC FARMACEUTICI S.p.A.	Nil	Accepted	No authorised products are available, marketed or offered on tender	Commitment provided by the MAH to undergo MRP
AA565/15208	Haldol Solution for Injection 5mg/ml	Haloperidol	25373059	Italy	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/29504	Brevibloc Solution for Infusion 10mg/ml	Esmolol hydrochloride	72.608	Spain	Central Procurement & Supplies Unit	Nil	Refused	Product has a Marketing Authorisation in Malta	N/A