

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
AA908/34001	Valaciclovir Bluefish Tablet, film coated 500mg	Valaciclovir hydrochloride Monohydrate	1-28549	Austria	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
AA288/05901	Decadron Tablets 0.5mg	Dexamethasone	3546686	Poland	VJ Salomone Pharma LTD.	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA135/00203	COSMEGEN Pdr for Soln for Injection 0.5mg	Dactinomycin	3400956 434299	France	RECORDATI RARE DISEASES	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA565/127701	ANSATIPINE Capsule 150mg	Rifabutin	34009 336 069 61; 34009 558 008 3 5	France	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/128301	Ciclosporina Generis Capsules, Soft 25mg	Ciclosporin	5341490; 5341599	Portugal	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/128302	Ciclosporina Generis Capsules, Soft 100mg	Ciclosporin	5341896; 5341995	Portugal	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA729/06008	Flucloxacillin Capsule 250mg	Flucloxacillin	PA1418/016/001	Ireland	Cherubino Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA729/42501	Fenofibrato Teva Capsule 200mg	Fenofibrate	72705	Spain	Cherubino Ltd.	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/07511	Sodium Bicarbonate B Braun Solution for Infusion 8.4%	Sodium bicarbonate	6723968.01.00	Germany	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA274/02801	BENYLIN Non-drowsy for Chesty Coughs Syrup 100mg/5ml/1.1mg/5ml	Guaifenesin; Levomenthol	PA23490/007/001	Ireland	Alfred Gera & Sons Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA274/02802	Benylin Children's Chesty Cough Syrup 50mg/5ml	Guaifenesin	PA23490/011/001	Ireland	Alfred Gera & Sons Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA274/02803	Benylin Children's Dry Coughs Syrup Diphenhydramine Hydrochloride 7 mg/5 ml	Diphenhydramine; Levomenthol	PA23490/008/001	Ireland	Alfred Gera & Sons Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A

AA565/16303	Mycobutin Capsules Hard 150mg	Rifabutin	30422.00.00	Germany	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1096/00312	Apotel Tablets 500mg	Paracetamol	41559/07/22-05-2008	Greece	UNI-PHARMA S.A.	Nil	Accepted	To ensure continuation of supply	To undergo MRP
AA1454/06901	Baclofen Zydus Scored Tablets 10mg	Baclofen	34009 302 847 11	France	Prohealth	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA908/34501	Spaverin Capsule 80mg	Drotaverine hydrochloride	12522/2019/01-02	Romania	Neofarma Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	To undergo MRP
AA565/118802	Myleran Tablet, film coated 2mg	Busulfan	6101936.00.00	Germany	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA084/06904	Devodil Tablets 200mg	Sulpiride	20176	Cyprus	Remedica Ltd.	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA721/01101	Adenorythm Solution for Injection 3mg/ml	Adenosine	131654/05112019	Greece	VIANEX S.A	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA565/71604	Potassium Chloride Galenica Senese Concentrate for Soln for Inf 2mEq/ml	Potassium chloride	29861059	Italy	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A

