

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
AA1122/01302	Domerid Tablets 10mg	Domperidone maleate	PA0711/046/001	Ireland	Rowex Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA521/09801	Lanzol Capsules Gastro-Resistant 30mg	Lansoprazole	PA0711/067/002	Ireland	Medicem Limited	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
AA912/00801	Cefuroxime Stada Tablets 500mg	Cefuroxime axetil	49168.02.00	Germany	PharmaMT	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	To undergo MRP
AA1213/01002	Calpol Six Plus Oral Suspension 250mg/5ml	Paracetamol	PA0330/017/003	Ireland	Labomed Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA729/23302UK	Prednisolone Tablets 1mg	Prednisolone	PL 29831/0177	United Kingdom	Cherubino Ltd	Nil	Refused	The Product is already authorised in Malta	N/A
AA770/21201UK	Paracetamol Solution for Infusion 10mg/ml	Paracetamol	PL 43252/0041	United Kingdom	JV Healthcare Limited	Nil	Accepted	there are fewer than three authorised products on the market with the same active ingredient, dose and strength	To undergo MRP
AA1411/06301	Pyrafat Tablet, film coated 500mg	Pyrazinamide	7079.00.00	Germany	EJ Busuttil Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/78702	Isoptin Solution for Injection 5mg/2ml	Verapamil hydrochloride	5758487	Portugal	Central Procurement & Supplies Unit	Nil	Refused	The Product is already authorised in Malta	N/A
AA565/70102	Artane Tablets 2mg	Trihexyphenidyl hydrochloride	2204857.00.00	Italy	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A

AA1173/07302	Camcolit Tablets 400mg	Lithium carbonate	RVG 09013	Netherlands	Mint Health Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA521/00107	Ferrograd Tablet Prolonged Release 325mg	Dried ferrous sulphate	PA1235/1/1	Ireland	Medicem Limited	Nil	Accepted	there are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA565/108001	Ameride Tablets 5mg/50mg	Amiloride hydrochloride; Hydrochlorothiazide	53.265	Spain	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/84902	Clobetasol Acis Crinale Cutaneous Solution 0.5mg/g	Clobetasol propionate	49883.00.02	Germany	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/29502	Brevibloc Solution for Infusion 10mg/ml	Esmolol hydrochloride	5303045	Portugal	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/107301	Alspiron Tablet, film coated 25mg	Spirolactone	12201/2019/01-02	Romania	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A