

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
AA1173/09101	Everolimus Biocon 5 mg Tablets	Everolimus	2205454.00.00	Germany	Mint Health Ltd	N/A	Accepted	To ensure continuation of supply to the National Health System	N/A
AA1173/09102	Everolimus Biocon Tablets 10mg	Everolimus	2205455.00.00	Germany	Mint Health Ltd	N/A	Accepted	To ensure continuation of supply to the National Health System	N/A
AA908/19705	Duloxetine Krka Capsules Gastro-Resistant 30mg	Duloxetine hydrochloride	PA1347/051/002	Ireland	NEOFARMA PHARMACEUTICALS LTD	N/A	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA908/19706	Duloxetine Krka Capsules Gastro-Resistant 60mg	Duloxetine hydrochloride	PA1347/051/004	Ireland	NEOFARMA PHARMACEUTICALS LTD	N/A	Accepted	To ensure continuation of supply to the National Health System	N/A
AA1513/04401	Minurin Nasal Spray Solution 0.1mg/ml	Desmopressin acetate	58566; 673119	Spain	Pharma Regulatory Services Limited	N/A	Accepted	To ensure continuation of supply	N/A
AA1438/00505	Amaryl Tablets 1mg	Glimepiride	2415/2010/01-12	Romania	NM Pharma Ltd	N/A	Accepted	To ensure continuation of supply	N/A
AA1438/00506	Amaryl Tablets 2mg	Glimepiride	2416/2010/01-11	Romania	NM Pharma Ltd	N/A	Accepted	To ensure continuation of supply	N/A
AA908/25003	Coldrex MaxGrip Menthol & Berries Powder for Oral Solution 1000mg/10mg/70mg	Paracetamol; Phenylephrine hydrochloride; Ascorbic acid	13-0130	Latvia	NEOFARMA PHARMACEUTICALS LTD	N/A	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA908/25004	Coldrex MaxGrip Lemon Powder for Oral Solution 1000mg/10mg/40mg	Paracetamol; Phenylephrine hydrochloride; Ascorbic acid	03-0233	Latvia	NEOFARMA PHARMACEUTICALS LTD	N/A	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA288/04402	Trandate Solution for Injection 5mg/ml	Labetalol hydrochloride	55.318	Spain	VJ Salomone Pharma LTD.	N/A	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA1513/04301	Atropine sulphate S.A.L.F. Solution for Injection 0.5mg/ml	Atropine sulphate monohydrate	A.I.C. 030653012	Italy	Pharma Regulatory Services Limited	N/A	Accepted	To ensure continuation of supply for the National Health System	N/A

AA1438/08402	Night Nurse Paracetamol Promethazine Hydrochloride Dextromethorphan Hydrobromide Capsules Hard 500/10/7.5mg	Paracetamol; Promethazine hydrochloride; Dextromethorphan hydrobromide	PA0678/021/001	Ireland	NM Pharma Ltd	N/A	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA565/70103	Artane Tablets 2mg	Trihexyphenidyl Hydrochloride	AIC 003488057	Italy	Central Procurement & Supplies Unit	N/A	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/78412	Methotrexat-GRY® Solution for Injection 5mg/2ml	Methotrexate disodium	2385.00.03	Germany	Central Procurement & Supplies Unit	N/A	Accepted	To ensure continuation of supply for the National Health System	N/A
AA729/23002	Pharmecort Cream 0.1%	Mometasone furoate	44975/10/24-06- 2011	Greece	Cherubino Ltd	N/A	Accepted	To ensure continuation of supply for the National Health System	N/A
AA729/29202	Oestraclin Gel 0.6mg/g	Oestradiol	59577	Spain	Cherubino Ltd	N/A	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA565/93005	Meladinine Tablets 10mg	Methoxsalen	34009 306 566 1 7	France	Central Procurement & Supplies Unit	N/A	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1389/00302	Pirver Oral Solution 10mg/ml	Prednisolone; Sodium phosphate	76192/10-07-2024	Greece	MEDICAIR BIOSCIENCE LABORATORIES CY LTD	N/A	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP