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
AA1411/04502	EMB-Fatol® Tablet, film coated 400mg	Ethambutol dihydrochloride	6193016.01.00	Germany	EJ Busuttil Limited	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1411/03602	Dacarbazine Lipomed Pdr for Soln Inj/Inf	Dacarbazine citrate	PA1760/001/001	Ireland	EJ Busuttil Limited	Nil	Accepted	To ensure the continuation of supply to the National Health System	N/A
AA565/130401	GADRAL Oral Suspension 800mg/10ml	Anhydrous magaldrate	33232036	Italy	Central Procurement & Supplies Unit	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA565/59203	Sodium Thiosulphate Solution for Infusion 25%	SODIUM THIOSULFATE	6073542.00.00	Germany	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA729/35102	Dysurgal 0.5mg	Atropine Sulphate	5899.99.99	Denmark	Cherubino Ltd.	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA908/20505	Glucophage Unidie Tablet Prolonged Release 500mg	Metformin hydrochloride	40628012040628	Italy	Neofarma Pharmaceuticals Limited	Nil	Accepted	To ensure continuity of supply	N/A
AA770/18204	Amlodipine Teva Tablets 10mg	Amlodipine	PA0749/067/002	Ireland	JV Healthcare 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
AA770/18203	Amlodipine Teva Tablets 5mg	Amlodipine	PA0749/067/001	Ireland	JV Healthcare 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
AA565/01313	Ropinirol AL Tablet, film coated 0.25mg	Ropinirole hydrochloride	68832.00.00	Germany	Central Procurement & Supplies Unit	Nil	Accepted	To ensure the continuation of supply to the National Health System	N/A
AA565/79101	Eritrocel Pdr+Solv for Soln for Inj 1000mg	erythromycin lactobionate	5165253	Ireland	Central Procurement & Supplies Unit	Nil	Accepted	To ensure the continuation of supply to the National Health System	N/A
AA521/09403	ROSUVA Tablet, film coated 5mg	Rosuvastatin calcium	PA0711/176/001	Ireland	Medichem Limited	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A

AA521/09404	ROSUVA Tablet, film coated 10mg	Rosuvastatin calcium	PA0711/176/002	Ireland	Medichem Limited	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A