

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
AA565/00908	Flucloxacillin Oral Solution 125mg/5ml	Flucloxacillin sodium	PA1418/016/003	Ireland	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
AA565/48303	Rocaltrol Capsules, Soft 0.5mcg	Calcitriol	86/539/92-B/C	Czech Republic	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
AA565/85302	Pancuronium Inresa Solution for Injection 4mg/2ml	Pancuronium bromide	34409.00.00	Germany	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/120601	Diazepam Prodes Oral Solution 2mg/ml	Diazepam	41598	Spain	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA770/24701	Flarex Eye Drops Suspension 1mg/ml	Fluorometholone acetate	4720	Poland	JV Healthcare Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA729/20505	Valium Tablets 5mg	Diazepam	8101527	Portugal	Cherubino Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA565/61804	Tobramycin Teva Nebulise Solution 300mg/5ml	Tobramycin	5552716	Portugal	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A

AA1183/00301	Avatac Tablet, film coated 500mg	Levofloxacin	OGYI-T-22205/04-06	Hungary	MEDITOP Pharmaceutical Ltd	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	To undergo MRP
AA1348/00501	Risperidon Atid Tablet, film coated 1mg	Risperidone	60925.00.00	Germany	Dexcel Pharma GmbH	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA1438/00402	Naprosyn EC Tablets Gastro-Resistant 500mg	Naproxen	PA22657/002/002	Ireland	NM Pharma Ltd	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
AA770/05802	Flucloxacillin Fresenius Kabi Pdr for Soln Inj/Inf 1000mg	Flucloxacillin	RVG 124821	Netherlands	JV Healthcare Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA565/20303	Keflex Granules for Oral Suspension 250mg/5ml	Cefalexin monohydrate	11612/2019/01-02	Romania	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A