

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
AA565/42902	Lutrate Depot Monthly Pdr+Solv for Susp for Inj 3.75mg	leuprorelin acetate	83377	Spain	Central Procurement & Supplies Unit	N/A	Accepted	To ensure continuation of supply for the National Health System	Nil
AA565/81202	Orgaran Solution for Injection 750 AF XA units	Danaparoid sodium	BE165846	Belgium	Central Procurement & Supplies Unit	N/A	Accepted	To ensure continuation of supply for the National Health System	Nil
AA565/49513	Budesonida Aldo-Union Inhalation Powder 0.5mg/ml	budesonide	66942: 651626	Spain	Central Procurement & Supplies Unit	N/A	Accepted	To ensure continuation of supply for the National Health System	Nil
AA1438/09002	Fluoxetine Teva-Rimafar EFG Capsules Hard 20mg	Fluoxetine	64592: 999744, 999745, 999746	Spain	NM Pharma Limited	N/A	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	Nil
AA1196/00401	Bertocil Eye Drops Solution 5mg/ml	Betaxolol Hydrochloride	9742809	Portugal	Laboratório Edol - Produtos Farmacêuticos, S.A.	N/A	Accepted	Authorised products with the same active substance, pharmaceutical form and strength are not marketed or offered on tender	To undergo MRP
AA729/30002	Orosoothe Oromucosal Spray 0.15% w/v	benzydamine hydrochloride	PA1113/016/001	Ireland	Cherubino Ltd	N/A	Accepted	To ensure continuation of supply	Nil
AA1438/13701	Dexketoprofen Teva Tablet, film coated 25mg	Dexketoprofen trometamol	77871 699154	Spain	NM Pharma Limited	N/A	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	Nil
AA770/10303	GLUCOPHAGE Tablet, film coated 500mg	Metformin hydrochloride	PA 2286/5/1	Ireland	JV Healthcare limited	N/A	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	Nil
AA1438/14201	Tamnic Hard Capsules Modified Release 400 mcg	Tamsulosin hydrochloride	PA0126/151/001	Ireland	NM Pharma Limited	N/A	Accepted	The product is to be made available at least 10% less than the price of the authorised alternative of the same brand	Nil
AA565/31006	Pentacarinat Pdr for Soln Inj/Inf 300mg	Pentamidine isethionate	BE149791	Belgium	Central Procurement & Supplies Unit	N/A	Accepted	To ensure continuation of supply for the National Health System	Nil