

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
AA908/04114	Canesten Cutaneous Solution 1%	Clotrimazole	28106/24-8-1999	Greece	Neofarma Pharmaceuticals LTD	Nil	Accepted	To ensure continuation of supply	N/A
AA908/34301	Rivaroxaban Teva Tablet, film coated 10mg	Rivaroxaban	PA22579/002/001	Ireland	Neofarma Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA908/34302	Rivaroxaban Teva Tablet, film coated 15mg	Rivaroxaban	PA22579/002/002	Ireland	Neofarma Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA908/34303	Rivaroxaban Teva Tablet, film coated 20mg	Rivaroxaban	PA22579/002/003	Ireland	Neofarma Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA770/29701	BETOPTIC S Eye Drops Suspension 2.5mg/ml	Betaxolol	RVG 15337	Netherlands	JV Healthcare Limited	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA565/85006	Floxapen Powder for Oral Suspension 250mg/5ml	Magnesium flucloxacillin	8378919	Portugal	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA770/10304	GLUCOPHAGE UNIDIE Tablet Prolonged Release 500mg	Metformin	AIC 040628024	Italy	JV Healthcare Ltd	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A
AA908/34401	Kwells Tablets 300mcg	Hyoscine Hydrobromide	PA2261/006/001	Ireland	Neofarma Ltd	Nil	Accepted	There are fewer than 3 authorised products on the market with the same active ingredient, dose and strength	N/A
AA908/02403	LAMISIL 1% Cream	Terbinafine	88114/25-11-2016	Greece	Neofarma Pharmaceuticals Limited	Nil	Accepted	To ensure continuation of supply	N/A
AA908/33802	Candesartan Krka Tablets 8mg	Candesartan cilexetil	PA1347/026/002	Ireland	Neofarma Pharmaceuticals Limited	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A

AA908/33803	Candesartan Krka Tablets 16mg	Candesartan cilexetil	PA1347/026/003	Ireland	Neofarma Pharmaceuticals 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
AA1045/02505	Etalopro Tablet, film coated 5mg	Escitalopram oxalate	PA0126/212/001	Ireland	Clonmel Healthcare Ltd	Nil	Accepted	To ensure continuation of supply to the National Health System	To undergo MRP
AA1045/02506	Etalopro Tablet, film coated 10mg	Escitalopram oxalate	PA0126/212/002	Ireland	Clonmel Healthcare Ltd	Nil	Accepted	To ensure continuation of supply to the National Health System	To undergo MRP
AA1045/02507	Etalopro Tablet, film coated 15mg	Escitalopram oxalate	PA0126/212/003	Ireland	Clonmel Healthcare 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	To undergo MRP
AA1045/02508	Etalopro Tablet, film coated 20mg	Escitalopram oxalate	PA0126/212/004	Ireland	Clonmel Healthcare Ltd	Nil	Accepted	To ensure continuation of supply to the National Health System	To undergo MRP
AA1411/15201	Vitaros Cream 3mg/g	Alprostadil	5660311	Portugal	EJ Busuttil Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1454/06801	Doxazosin AAA-Pharma Tablets 4mg	Doxazosin mesylate	43163.02.00	Germany	Prohealth	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA565/127601	Temozolomide Novumgen Capsule 20mg	Temozolomide	5837646	Portugal	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1454/00103	Emazole Tablets Gastro-Resistant 20mg	Esomeprazole	PA0711/158/001	Ireland	Prohealth Ltd	Nil	Accepted	To ensure continuation of supply	To undergo MRP
AA1454/00104	Emazole Tablets Gastro-Resistant 40mg	Esomeprazole	PA0711/158/002	Ireland	Prohealth Ltd	Nil	Accepted	To ensure continuation of supply	To undergo MRP