

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
AA565/120701	Etalpa Oral Drops Solution 2 mcg/ml	ALFACALCIDOL	55906; 761908	Spain	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
AA565/04710	Lisinopril Teva Tablets 10mg	Lisinopril dihydrate	RVG 26332	Netherlands	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/25804	Ursofalk Oral Suspension 250mg/5ml	Ursodeoxycholic acid	39200.00.01	Germany	Central Procurement & Supplies Unit	Nil	Accepted	There are no other authorized products for this active substance in the same strength or pharmaceutical form	N/A
AA770/25301	Refen Solution for Injection 75mg	Diclofenac sodium	1958/2009/01	Romania	JV Healthcare	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1161/01102	Lipivim Capsule 200mg	Micronized fenofibrate	9079/2016/01	Romania	Farmarosib SRL	Nil	Accepted	To ensure continuation of supply for the National Health System	To underog MRP
AA565/66611	Atomoxetine AmaroX Capsules Hard 40mg	Atomoxetine hydrochloride	RVG 130362	Netherlands	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1411/11101	Bromo-Biliron Pdr for Soln for Injection 5.0mg	Mebrofenin	OGYI-T-9941/01	Hungary	EJ BUSUTTIL LTD	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/122101	Medikinet Tablets 10mg	Methylphenidate hydrochloride	BE 381543	Belgium	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/46403	Captopril Mylan Generics Tablets 25mg	Captopril	35317559	Italy	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1454/04501	Levetiracetam Aurovitas Oral Solution 100mg/ml	Levetiracetam	5713771	Portugal	Prohealth Limited	Nil	Refused	The product has a Marketing Authorisation in Malta	N/A
AA565/120901	Miconazole nitrate/hydrocortisone Teva hydrophilic Cream 20/10mg/g	Miconazole nitrate / Hydrocortisone Teva	RVG 15469	Netherlands	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A

AA770/19004	Canesten Cutaneous Suspension 1%	Clotrimazole	28106/24-8-1999	Greece	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
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