

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
AA274/02301	Calpol Six Plus Fastmelts Orodispersible Tablet 250mg	Paracetamol	PA0330/017/005	Ireland	Alfred Gera & Sons Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1438/12602	Maalox Oral Suspension 40mg/35mg/ml	Magnesium hydroxide; Aluminium hydroxide	LT/1/95/1668/002	Lituhuania	NM Pharma Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1438/12601	Maalox Tablets Chewable 400mg/400mg	Magnesium hydroxide; Aluminium hydroxide	LT/1/95/1668/005	Lituhuania	NM Pharma Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA565/107501	Moviprep Powder for Oral Solution	Macrogol 3350; Sodium sulfate anhydrous; Sodium chloride; Potassium chloride; Ascorbic acid; Sodium ascorbate	BE291776	Belgium	Central Procurement& Supplies Unit	Nil	Refused	The product has a marketing authorisation	N/A
AA1488/04203UK	Flucloxacillin Oral Solution 125mg/5ml	Flucloxacillin sodium	PL 30464/0167	United Kingdom	HHP Malta (P&D Pharma) Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1045/00303	Risontel Once a week Tablet, film coated 35mg	Risedronate sodium	PA0126/197/001	Ireland	Clonmel Healthcare Ltd.	Nil	Refused	The product has a marketing authorisation	N/A
AA565/88402	Ursochol Tablets 150mg	Ursodeoxycholic acid	1527.00.00	Germany	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/106901	Bitinex Capsule 25mg	atomoxetine	14080/2021/03	Hungary	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A

AA770/10504	Nexium Tablets Gastro-Resistant 40mg	Esomeprazole	8424/2015/01	Romania	JV Healthcare Limited	Nil	Accepted	The product is to be made available at least 10% less than the price of the marketed alternative of the same brand	N/A
AA1438/12401	Crestor Tablet, film coated 5mg	Rosuvastatin	5608/2013/0123	Romania	NM Pharma Ltd	Nil	Accepted	The product is to be made available at least 10% less than the price of the marketed alternative of the same brand	N/A
AA1438/12402	Crestor Tablet, film coated 10mg	Rosuvastatin	5609/2013/0123	Romania	NM Pharma Ltd	Nil	Accepted	The product is to be made available at least 10% less than the price of the marketed alternative of the same brand	N/A
AA1438/12403	Crestor Tablet, film coated 20mg	Rosuvastatin	5609/2013/0123	Romania	NM Pharma Ltd	Nil	Accepted	The product is to be made available at least 10% less than the price of the marketed alternative of the same brand	N/A
AA565/100201UK	Human Varicella-Zoster Immunoglobulin Solution for Injection 100IU/ml	Human immunoglobulin	PL 08801/0013	United Kingdom	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1455/00201	Lidonostrum Bomba- Cutaneous Spray, Solution 10%	Lidocaine	3067899	Portugal	SIDEFARMA - Sociedade Industrial de Expans	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA1234/00102	Salment Pressurised Inhalation Suspension 25mcg/dose	Salmeterol xinafoate	21786/1502032017	Greece	S.J.A Pharm Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA1277/04402	Onkotrone Solution for Injection 2mg/ml	Mitoxantrone hydrochloride	3000713.00.00	Germany	Baxter Holding B.V	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP