

<b>AA Licence Number</b>	<b>Product Name</b>	<b>Active Ingredient/s</b>	<b>Source Country Authorisation Number</b>	<b>Source Country</b>	<b>Applicant</b>	<b>Objections Received</b>	<b>Status of application</b>
AA1454/06201	Cetrine Allergy Tablet, film coated 10mg	Cetirizine dihydrochloride	PA0711/075/002	Ireland	Prohealth Ltd	Nil	Accepted
AA908/33501	Viscolex Syrup Oral Solution 250mg/5ml	Carbocisteine	PA0281/070/001	Ireland	Neofarma Pharmaceuticals LTD	Nil	Accepted
AA770/29101	Orgaran Solution for Injection 750 ax units	Danaparoid sodium	43761.00.00	Germany	JV Healthcare Limited	Nil	Accepted
AA565/23903	Danazol Polfarmex Tablets 200mg	Danazolium	9253	Poland	Central Procurement & Supplies Unit	Nil	Accepted
AA565/118502	Keracutan Capsule 25mg	Acitretin	1-31433	Austria	Central Procurement & Supplies Unit	Nil	Accepted
AA1411/12801	SALAZOPYRIN Suppositories 500mg	Sulfasalazine	RVG 00633	Netherlands	EJ BUSUTTIL LTD	Nil	Accepted
AA908/33201	Lamya Tablet, film coated 0,075mg	Desogestrel	17/320/12-C	Czech Republic	NEOFARMA PHARMACEUTICALS LTD	Nil	Accepted
AA565/123602	BetaGalen® Cutaneous Solution 0.1%	Betamethasone	16945.00.03	Germany	Central Procurement & Supplies Unit	Nil	Accepted
AA565/126401	FULCIN Tablets 125mg	Grisoefulvin	16762015	Italy	Central Procurement & Supplies Unit	Nil	Accepted

AA565/124502	Fucithalmic® Eye Drops Solution 10mg/g	anhydrous fusidic acid	15657.00.00	Ireland	Central Procurement & Supplies Unit	Nil	Refused
AA1349/01002	Mucibron Forte Oromucosal Spray 6mg/ml	Ambroxol hydrochloride	83276: 722321	Spain	LABORATORIOS NORMON, S.A.	Nil	Accepted
AA1513/04701	Sandimmun Concentrate for Soln for Inj 50mg/ml	ciclosporin	PA0896/027/002	Ireland	Pharma Regulatory Services Limited	Nil	Accepted
AA1411/14901	AMICASIL vial Solution for Injection 500mg/2ml	Amikacin	53420/9102024	Greece	EJ BUSUTTIL LTD	Nil	Accepted
AA729/41901	Stemetil Tablets 5mg	Prochlorperazine maleate	PA22657/005/002	Ireland	Cherubino Ltd	Nil	Accepted
AA1454/14201	Rosuva Tablet, film coated 5mg	Rosuvastatin	PA0711/176/001	Ireland	Prohealth Ltd	Nil	Accepted
AA1454/14202	Rosuva Tablet, film coated 10mg	Rosuvastatin	PA0711/176/002	Ireland	Prohealth Ltd	Nil	Accepted
AA1454/14203	Rosuva Tablet, film coated 20mg	Rosuvastatin	PA0711/176/003	Ireland	Prohealth Ltd	Nil	Accepted
AA1454/03803	Quetex Tablet, film coated 25mg	Quetiapine hemifumarate	PA0711/156/001	Ireland	ProHealth Limited	Nil	Accepted

Reason for decision	Conditions included in the Licence
To ensure continuation of supply	To undergo MRP
The product is to be made available at least 10% less than the price of the authorised alternative of the same brand	N/A
To ensure continuation of supply for the National Health System	N/A
There are no other authorised products for this active substance in the same strength or pharmaceutical form	N/A
To ensure continuation of supply for the National Health System	N/A
To ensure continuation of supply for the National Health System	N/A
There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
To ensure continuation of supply for the National Health System	N/A
To ensure continuation of supply for the National Health System	N/A

Marketing Authorisation approved for the same product in Malta - MA625/00201	N/A
The product is to be made available at least 10% less than the price of the cheapest authorised alternative	To undergo MRP
To ensure continuation of supply for the National Health System	N/A
To ensure continuation of supply for the National Health System	N/A
There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
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