

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
AA288/02702	Ritalin Tablets 10mg	Methylphenidate hydrochloride	6094573.00.00	Germany	V.J.Salomone Pharma Limited	Nil	Accepted	To ensure continuation of supply	N/A
AA288/05401	Rubifen 10mg tablets	Methylphenidate hydrochloride	55.369	Spain	V.J.Salomone Pharma Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1196/00501	Clorocil Eye Ointment 10mg/g	Chloramphenicol	9948406	Portugal	Laboratório Edol - Produtos Farmacêuticos, S.A.	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA729/04604	Aciclovir Oral Suspension 200mg/5ml	Aciclovir	PA22697/001/001	Ireland	Cherubino Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1621/00101	Cialis for Men Tablet, film coated 10mg	Tadalafil	PA25208/001/001	Ireland	A. Nattermann & Cie. GmbH	Nil	Refused	The Marketing Authorisation Holder is to undergo MRP ensuring the submission of a dossier in line with Directive 2001/83/EC, thereby ensuring that all relevant information is made available for regulatory review and decision-making	N/A
AA1343/06001	Diazeoan Prodes Oral Solution 2mg/ml	Diazepam	762434: 41598	Spain	Target Healthcare Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA770/15405	PREDNISOLONE ZENTIVA LAB Orodispersible Tablet 20mg	Prednisolone	34009 391 065 9 5	France	JV Healthcare 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
AA565/110902	ANAFRANIL Tablet, film coated 25mg	Clomipramine hydrochloride	21643010	Italy	Central Procurement & Supplies Unit	Nil	Refused	Product is already authorised in Malta - MA1423/00102	N/A
AA1134/00101	Nocutil Nasal Spray Solution 0.1mg/ml	Desmopressin acetate	OGYI-T-6796/02	Hungary	Gebro Pharma GmbH	Nil	Refused	Product is already authorised in Malta - MA1134/00201	N/A
AA770/12002	Dilaclan Capsule 500mg	Amoxicillin trihydrate	5714555	Portugal	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

AA908/06504	Imodium instant Orodispersible Tablet 2mg	Loperamide hydrochloride	9091	Poland	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
AA565/88002	Aprepitant Viatrix, Capsules Hard 125mg/80mg	Aprepitant	24420	Poland	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA770/01105	Ondansetron Bluefish Orodispersible Tablet 4mg	Ondansetron	72468	Spain	JV Healthcare 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
AA1045/00410	Easofen for children strawberry Oral Suspension 100mg/5ml	Ibuprofen	PA0126/060/003	Ireland	Clonmel Healthcare Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	To undergo MRP
AA1045/00409	Easofen for Children Six Plus Strawberry Oral Suspension 200mg	Ibuprofen	PA0126/060/004	Ireland	Clonmel Healthcare Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	To undergo MRP
AA565/60707	Atosiban EVER Pharma Solution for Injection 6.75mg/0.9ml	Atosiban	95870.00.00	Germany	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1425/00801	Amlodipine Tablets 5mg	Amlodipine besilate	5877162	Portugal	Ipca Produtos Farmacêuticos Unipessoal Lda	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA770/13005	Atorvastatin Teva Tablet, film coated 40mg	Atorvastatin	PA0749/110/003	Ireland	JV Healthcare Limited	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A
AA770/13006	Atorvastatin Teva Tablet, film coated 20mg	Atorvastatin	PA0749/110/002	Ireland	JV Healthcare Limited	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A
AA1454/05801	Vitamin B1 Hevert Solution for Injection 200mg	Thiamine chloride hydrochloride	6290736.00.00	Germany	Prohealth Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1454/05701	Kalufar Tablet, film coated 50mg	Bicalutamide	HR-H-425313835	Croatia	Prohealth Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1330/03803	Valsartan Teva Tablet, film coated 80mg	Valsartan	PA0749/084/002	Ireland	Azure Pharmaceuticals Ltd	Nil	Accepted	To ensure continuation of supply	N/A
AA1330/03804	Valsartan Teva Tablet, film coated 160mg	Valsartan	PA0749/084/003	Ireland	Azure Pharmaceuticals Ltd	Nil	Accepted	To ensure continuation of supply	N/A

AA1454/02102	Hedelix Cough Syrup Syrup 0.8g/100ml	Extract from ivy leaves	6428904.00.00	Germany	Prohealth Limited	Nil	Accepted
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There are no authorised products are
available, marketed or offered on
tender

N/A