

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
AA1411/15001	Glyceryl trinitrate-carinopharm Concentrate for Soln for Inf 1mg/ml	Glyceryl trinitrate	4985.00.00	Germany	EJ Busuttil Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1454/06001	Brupro for Children Oral Suspension 100mg/5ml	Ibuprofen	PA0074/067/004	Ireland	Prohealth Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA1454/06002	Brupro for Children Six Plus Oral Suspension 200mg/5ml	Ibuprofen	PA0074/067/005	Ireland	Prohealth Limited	Nil	Accepted	To ensure continuation of supply	To undergo MRP
AA1454/06003	Brupro Max Tablet, film coated 400mg	Ibuprofen	PA0074/067/002	Ireland	Prohealth 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	To undergo MRP
AA770/29301	Opralix Cream 2.5% + 2.5% w/w	Lidocaine Prilocaine	6666/16/11012017	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
AA1096/01103	SPASMO-APOTEL coated Tablets 500+10 mg	Paracetamol; Hyoscine butylbromide.	1.9416E+12	Greece	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A	Nil	Accepted	There are no other authorised products for this active substance in the same strength or pharmaceutical form	To undergo MRP
AA115/03303	Statol Tablet, film coated 5mg	Rosuvastatin calcium	22934	Cyprus	Delorbis Pharmaceuticals Ltd.	Nil	Accepted	To ensure continuation of supply	To undergo MRP
AA115/03304	Statol Tablet, film coated 10mg	Rosuvastatin calcium	22935	Cyprus	Delorbis Pharmaceuticals Ltd.	Nil	Accepted	To ensure continuation of supply	To undergo MRP