

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
AA1606/00801	IBUFEN Baby Suppositories 60mg	Ibuprofen	18856	Poland	MyRX Limited	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1454/01502	Ceftriaxone Hikma Pdr for Soln for Infusion 2g	Ceftriaxome	57192.00.01	Germany	Prohealth	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA807/12101	Atomoxetine PUREN Capsules Hard 18mg	Atomoxetine	2200379.00.00	Germany	Aurobina Pharma (Malta) Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA274/02701	XYLOCAINE/ADRENALINE Solution for Injection 10mg/ml,0.0005mg/ml	Lidocaine hydrochloride Adrenaline tartrate	3400931152125	France	Alfred Gera & Sons Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA729/41201	Sorafenib Teva Tablet, film coated 200mg	Sorafenib	84240	Spain	Cherubino Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1346/00301	Dexamethasone ABR Tablets 2mg	Dexamethasone	20190081	Bulgaria	Antibiotic-Razgrad AD	Nil	Accepted	To ensure continuation of supply	To undergo MRP
AA565/43502	ATOVAQUONE BIOGARAN Oral Suspension 750mg/5ml	Atovaquone	3400930189948	France	Central Procurement & Supplies Unit	Nil	Accepted	There are no other authorised products for this active substance in the same strength and pharmaceutical form	N/A
AA1349/00503	Montelukast Normon GSP Tablet, film coated 10mg	Montelukast	75844: 689528	Spain	Laboratorios Normon S.A.	Nil	Accepted	To ensure continuation of supply	To undergo MRP
AA1349/00504	Montelukast NORMON GSP Granules 4mg	Montelukast	74176: 680984	Spain	Laboratorios Normon S.A.	Nil	Accepted	To ensure continuation of supply	To undergo MRP
AA1349/00402	Trazodone Normon Tablets 100mg	Trazodone	78585: 701861;; 701860; 606413; 606412; 701865; 701864	Spain	Laboratorios Normon S.A.	Nil	Accepted	To ensure continuation of supply	To undergo MRP
AA1045/04702	Cinacalcet Clonmel Tablet, film coated 30mg	Cinacalcet	PA 0126/306/001	Ireland	Clonmel Healthcare Ltd	Nil	Accepted	To ensure continuation of supply	To undergo MRP