

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
AA1488/04801UK	Tensipine MR Tablet Prolonged Release 10mg	Nifedipine	PL 06831/0048	United Kingdom	HHP Malta (P&D Pharma) Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA729/29701	Brainal Tablet, film coated 30mg	Nimodipine	58780	Spain	Cherubino Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA729/29601	Metaiodobenzylguanidine -131I Solution for Injection 10MBq/37ml	Iobenguane	19000	Poland	Cherubino Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1277/04601UK	Desflurane Inhalation Vapour Liquid 100%v/v	Desflurane	PL00116/0327	United Kingdom	Baxter Holding B.V	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1488/04901UK	Clopixol-Acuphase Solution for Injection 50mg/ml	Zuclopenthixol acetate	PL 00458/0063	United Kingdom	HHP Malta (P&D Pharma) Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1488/04902UK	Clopixol Tablet, film coated 10mg	Zuclopenthixol	PL 00458/0028	United Kingdom	HHP Malta (P&D Pharma) Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1488/04903UK	Clopixol Tablet, film coated 2mg	Zuclopenthixol	PL 00458/0027	United Kingdom	HHP Malta (P&D Pharma) Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA041/00601	XTEX Oral Solution 250mg	Carbocisteine	PA0074/071/001	Ireland	Rowa Pharmaceuticals Limited	Nil	Accepted	To ensure continuity of supply until the process prior to the start of the MRP are completed	To undergo an MRP
AA004/00403	Tricef Tablet, film coated 400mg	Cefixime	4549796; 4549895; 9725119; 4549994	Portugal	Bial-Portela & CA, S.A.,	Nil	Accepted	To ensure continuity of supply until the process prior to the start of the MRP are completed	To undergo an MRP

AA004/00404	Tricef Powder for Oral Suspension 20mg/ml	Cefixime	9725200	Portugal	Bial-Portela & CA, S.A.,	Nil	Accepted	To ensure continuity of supply until the process prior to the start of the MRP are completed	To undergo an MRP
AA1488/05101UK	Zonegran Capsules Hard 50mg	Zonisamide	PLGB 12762/0669	United Kingdom	HHP Malta (P&D Pharma) Limited	Nil	Refused	The product has a marketing authorisation	N/A
AA1045/01904	Olanzapine Tablet, film coated 2.5mg	Olanzapine	PA0126/210/001	Ireland	Clonmel Healthcare Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	To undergo an MRP
AA729/29901	Ciprolen Tablet, film coated 250mg	Ciprofloxacin	11860/2019/01	Romania	Cherubino Ltd	Nil	Accepted	To ensure continuity of supply until the process prior to the start of the MRP are completed	To undergo an MRP
AA274/01801	Seprin Adult Oral Suspension 80mg/400mg per 5ml	Trimethoprim; Sulfamethoxazole	PA1691/010/004	Ireland	Alfred Gera & Sons Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1411/00802	Levetiracetam Farnoz Oral Solution 100mg/ml	Levetiracetam	5383658	Portugal	EJ BUSUTTIL LTD	Nil	Accepted	No authorised products are available, marketed or offered on tender	To undergo an MRP
AA1501/00901UK	Dapsone Tablets 100mg	Dapsone	PL 33155/0084	United Kingdom	Smartway Pharmaceuticals Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1488/05001UK	Aprotinin Solution for Injection 10,000 KIU/ml	Aprotinin	PL 40621/0020	United Kingdom	HHP Malta (P&D Pharma) Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1488/05401UK	Clomipramine Capsules Hard 10mg	Clomipramine hydrochloride	PL 04569/0229	United Kingdom	HHP Malta (P&D Pharma) Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1501/00201UK	Sulfadiazine Tablets 500mg	Sulfadiazine	PL 29831/0191	United Kingdom	Smartway Pharmaceuticals Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1233/00102	Colircusi Antiedema Eye Drops Solution 50mg/ml	Sodium chloride	58380; 990051	Spain	Novartis Farmaceutica S.A	Nil	Accepted	No authorised products are available, marketed or offered on tender	To undergo an MRP
AA1488/05201UK	Ventolin TM Solution for Infusion 5mg/5ml	Salbutamol sulfate	PL 10949/0087	United Kingdom	HHP Malta (P&D Pharma) Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A

AA1173/08301UK	Golden Eye Eye Drops Solution 0.1%w/v	Propamidine isethionate	PL 16794/0010	United Kingdom	Mint Health Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA729/30101	Eskazole Tablets 400mg	Albendazole	60407	Spain	Cherubino Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1349/00501	Montelukast NORMON Granules 4mg	Montelukast sodium	74176; 680984	Spain	Laboratorios Normon S.A	Nil	Accepted	No authorised products are available, marketed or offered on tender	To undergo an MRP
AA908/25001	Coldrex MaxGrip Menthol & Berries Oral Solution 1000mg/10mg/70mg	Paracetamol; Phenylephrine hydrochloride; Ascorbic acid	13-0130	Latvia	Neofarma Pharmaceuticals Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA223/00303	Gelofusine Ecobag, Solution for Infusion 40g/l	Succinylated gelatin; Sodium chloride; Sodium hydroxide	PA0736/011/001	Ireland	B. Braun Melsungen AG	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	To undergo an MRP
AA729/10903	Amoxicillin Ardine Powder for Oral Suspension 125mg/5ml	Amoxicillin trihydrate	52.373	Spain	Cherubino Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	To undergo an MRP
AA1173/08401UK	Disulfiram Tablets 200mg	Disulfiram	PL 25298/0151	United Kingdom	Mint Health Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1488/05601UK	Sulfadiazine Tablets 500mg	Sulfadiazine	PL 29831/0191	United Kingdom	HHP Malta (P&D Pharma) Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1488/05301UK	Retrovir Oral Solution 100mg/10ml	Zidovudine	PL 35728/0004	United Kingdom	HHP Malta (P&D Pharma) Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA721/00901	Clidacin BA Free Solution for Inj/Inf 300mg/2ml	Clindamycin phosphate	2158/02-02-2022	Greece	VIANEX SA	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1228/01801	Eletrip Hormosan Tablet, film coated 40mg	Eletriptan	7000562.00.00	Germany	Focused Pharma Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A

AA115/01902	Montol Tablets Chewable 5mg	Montelukast sodium	21119	Cyprus	Delorbis Pharmaceuticals Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	To undergo an MRP
AA1438/00803	Ciprofloxacin Mylan Tablet, film coated 250mg	Ciprofloxacin	RVG 26276	Netherlands	NM Pharma Ltd	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A
AA1438/00804	Ciprofloxacin Mylan Tablet, film coated 500mg	Ciprofloxacin	RVG 26277	Netherlands	NM Pharma Ltd	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A
AA729/30001	Orosoothe Oromucosal Spray 0.15%w/v	Benzydamine hydrochloride	PA1113/016/001	Ireland	Cherubino Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA004/00302	Diacol Syrup 1.8 mg/ml	Dextromethorphan hydrobromide	2008290	Portugal	Bial-Portela & CA, S.A.	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	To undergo an MRP
AA032/02704	Dexamed Tablets 0.5mg	Dexamethasone	19974	Cyprus	Medochemie Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	To undergo an MRP
AA729/10102	Cefuroxime Generis Tablet, film coated 250mg	Cefuroxime axetil	5722145	Portugal	Cherubino Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1369/04102UK	Aciclovir Tablets 800mg	Aciclovir	PL 0142/0403	United Kingdom	Health House Pharma Ltd T/As P&D Pharmaceuticals Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A