

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
AA1488/09001UK	Haldol Decanoate Solution for Injection 100mg/ml	Haloperidol decanoate	PL 50301/0009	United Kingdom	HHP MALTA (P&D PHARMA) LIMITED	N/A	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA770/21702UK	Beechams Max Strength All in One Capsule 500/mg/100/mg/6.1	Paracetamol; Phenylephrine; Guaifenesin	PL 44673/0019	United Kingdom	JV Healthcare Limited	N/A	Refused	Directive 642/2022 amending Directive 2001/83/EC grants derogations to prevent shortages and to ensure public health protection (pre-amble 4). The application for this product does not fulfil the criteria for granting an authorisation on the basis of article 126(c) of Directive 2001/83/EC because there are several alternative products available in the EU/EEA	N/A
AA1330/04501	Lycimor Capsules Hard 300mg	Lymecycline	PA1986/118/001	Ireland	Azure Pharmaceuticals Ltd	N/A	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA770/13202	Ezetrol Tablets 10mg	Ezetimibe	PA23198/023/001	Ireland	JV Healthcare Limited	N/A	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1045/06701	Paracetamol Clonmel Tablet, film coated 500mg	Paracetamol	PA0126/361/001	Ireland	Clonmel Healthcare Ltd.	N/A	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	To undergo MRP
AA770/21001	Progynova 21 Tablet, film coated 2mg	Estradiol valerate	6930615.01.00	Germany	JV Healthcare Limited	N/A	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A

AA1541/00201	Erlotinib Stada Tablet, film coated 100mg	Erlotinib hydrochloride	99488.00.00	Germany	Stadapharm GmbH	N/A	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA565/106101	Biodacin Solution for Inj/Inf 500mg/ml	Amikacin	R/0613	Poland	Central Procurement& Supplies Unit	N/A	Accepted	To ensure continuation of supply for the National Health System	N/A
AA770/21801UK	Cystopurin sachets 3.0g	Potassium citrate	PL 00010/0322 PA1410/042/001	United Kingdom Ireland	JV Healthcare Limited	N/A	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
AA1045/00405	Easofen Tablet, film coated 200mg	Ibuprofen	PA0126/060/001	Ireland	Clonmel Healthcare Ltd.	N/A	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative.	To undergo MRP
AA1045/00406	Easofen Max Strength Tablet, film coated 400mg	Ibuprofen	PA0126/060/002	Ireland	Clonmel Healthcare Ltd.	N/A	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative.	To undergo MRP
AA729/36601	Thrombo ASS Tablet, film coated 100mg	Acetylsalicylic acid	1-19830	Austria	Cherubino Ltd	N/A	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/100902	Klean-Prep Powder for Oral Solution	Macrogol 3350; Sodium sulphate; Sodium bicarbonate; Sodium chloride; Potassium chloride	PA0294/017/001	Ireland	Central Procurement& Supplies Unit	N/A	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1411/06402UK	Baclofen Tablets BP Tablets 10mg	Baclofen	PL 13606/0066	United Kingdom	EJ Busuttil Ltd	N/A	Accepted	To ensure continuation of supply for the National Health System	N/A
AA729/27403	Orap Forte Tablets 4mg	Pimozide	BE000847	Belgium	Cherubino Ltd	N/A	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1488/09201UK	Fludrocortisone Acetate Tablets 0.1mg	Fludrocortisone acetate	PL11311/0676	United Kingdom	HHP Malta (P&D Pharma) Limited	N/A	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/103902	Flixotide suspension for inhalation in a pressured container Suspension for Infusion 50mc	Fluticasone propionate	60.477	Spain	Central Procurement& Supplies Unit	N/A	Refused	The product has a marketing authorisation in Malta	N/A
AA565/16202UK	Phenoxybenzamine Capsule 10mg	Phenoxybenzamine hydrochloride BP	PL12762/0224	United Kingdom	Central Procurement& Supplies Unit	N/A	Accepted	To ensure continuation of supply for the National Health System	N/A

AA729/08603UK	Tramadol Capsule 50mg	Tramadol hydrochloride	PL 20395/0065	United Kingdom	Cherubino Ltd	N/A	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/76502	LHRH Ferring Solution for Injection 0.1mg/1ml	Gonadorelin acetate	21964.00.00	Germany	Central Procurement & Supplies Unit	N/A	Accepted	To ensure continuation of supply for the National Health System	N/A