

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
AA908/21902	Ezetrol Tablets 10mg	Ezetimibe	PA23198/023/001	Ireland	NEOFARMA PHARMACEUTICALS LTD	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
AA908/29402	Codipront Syrup 2.22+0.733mg/ml	Codeine Phenyltoloxamine	9275701	Portugal	NEOFARMA PHARMACEUTICALS LTD	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA908/29401	Codipront Capsule 30/10mg	Codeine Phenyltoloxamine	9275602	Portugal	NEOFARMA PHARMACEUTICALS LTD	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA729/19003	Tetrabenazine Tablets 25mg	Tetrabenazine	PA934/4/1	Ireland	Cherubino Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA521/05003	Glucophage Tablet, film coated 500mg	Metformin hydrochloride	PA 2286/005/001	Ireland	Medicem 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
AA288/04001	RENOCIS Kit for Radiopharmaceutical Preparation 1mg	Dimercaptosuccinic acid	PA677/5/1	Ireland	VJ Salomone Pharma LTD.	Nil	Accepted	to ensure continuation of supply to the NHS	N/A
AA1576/00101UK	Levetiracetam Concentrate for Soln for Inf 100mg/ml	Levetiracetam (Form-I)	PL 49445/0069	United Kingdom	Amarox Pharma B.V.	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/110701	Propycil Tablets 50mg	Propylthiouracil	20020923	Bulgaria	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1343/05301UK	Entocort Enema Enema 0.02mg/100ml	Budesonide	PL 36633/0007	United Kingdom	Target Healthcare Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A

AA1411/08201	Dotarem Solution for Injection 0.5mmol/ml(20ml)	Gadoteric acid	34009 301 991 7 6	France	EJ BUSUTTIL LTD	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength and to ensure continuation of supply	N/A
AA1411/08202	Dotarem Solution for Injection 0.5mmo/ml(15ml)	Gadoteric acid	34009 301 991 5 2	France	EJ BUSUTTIL LTD	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength and to ensure continuation of supply	N/A
AA770/02104UK	Furosemide Oral Solution 40mg/5ml	Furosemide	PL 04917/0073	United Kingdom	JV Healthcare Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1343/05201	Disulfiram Tablets 200mg	Disulfiram	PL 00289/2558	United Kingdom	Target Healthcare Ltd.	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA288/03801UK	Sulfasalazine Oral Suspension 250mg/5ml	Sulfasalazine	PL 00427/0196	United Kingdom	V.J.Salomone Pharma Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA242/03301UK	Amlodipine Tablets 5mg	Amlodipine	PL20416/0586	United Kingdom	Pharmabart Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA242/03302UK	Amlodipine Tablets 10mg	Amlodipine	PL 20416/0589	United Kingdom	Pharmabart Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA770/22701UK	Cytarabine Solution for Inj/Inf 20mg/ml	Cytarabine	PL 20075/0538	United Kingdom	JV Healthcare Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA077/02701UK	Suxamethonium Chloride Solution for Injection 50mg/ml	Suxamethonium chloride	PL 12762/0604	United Kingdom	Mercury Pharmaceuticals Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1513/02402UK	Fluorouracil Accord Solution for Inj/Inf 50mg/5ml	Flourouracil	PL20075/0078	United Kingdom	Pharma Regulatory Services Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1411/00603UK	Calcichew-D3 Tablets Chewable 1000mg/800IU	Calcium carbonate Cholecalciferol concentrate	PL 45043/0075	United Kingdom	EJ Busuttill Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A

AA1411/07701UK	Bendroflumethiazide Tablets 5mg	Bendroflumethiazide	PL17907/0083	United Kingdom	EJ Busuttil Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1513/03701	Ritmodan Capsules Hard 100mg	Disopyramide	21894035	Italy	Pharma Regulatory Services Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/110901	Anafranil Tablet, film coated 25mg	Clomipramine hydrochloride	44656	Spain	Central Procurement & Supplies Unit	Nil	Refused	Product is already authorised in Malta	N/A
AA565/80902	Hydrapres Tablets 25mg	Hydralazine hydrochloride	55961	Spain	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA288/03901UK	Codeine Phosphate Tablets 30mg	Codeine phosphate	PL 29831/0049	United Kingdom	V.J. Salomone Pharma Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA908/17503	Ciprofloxacin Teva Tablet, film coated 250mg	Ciprofloxacin	PA0749/031/002	Ireland	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
AA908/17504	Ciprofloxacin Teva Tablet, film coated 500mg	Ciprofloxacin	PA0749/031/003	Ireland	Neofarma Pharmaceuticals Limited	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A
AA770/22801	Calpol Six Plus Fastmelts Tablet Prolonged Release 250mg	Paracetamol	PA0330/017/005	Ireland	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