

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
AA084/04604	Perofen Coated Tablets 400mg	Ibuprofen	8595	Cyprus	Remedica 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
AA1343/02501UK	Ethosuximide neuraxpharm Capsules, Soft 250mg	Ethosuximide	PL 49718/0070	United Kingdom	Target Healthcare Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1501/00801UK	Nimotop Solution for Infusion 0.02%	Nimodipine	PL 00010/0138	United Kingdom	Smartway Pharmaceuticals Limited	Nil	Refused	The product has a marketing authorisation	N/A
AA565/91501	Prednesol Tablets 5mg	Prednisolone sodium phosphate	PA1113/001/001	Ireland	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuity of supply given that there is a worldwide shortage for this active ingredient	N/A
AA565/45802	Kemadrin Tablets 5mg	Procyclidine hydrochloride BP	PL 39699/0046	Germany	Central Procurement& Supplies Unit	Nil	Refused	The product has a marketing authorisation	N/A
AA1488/04401UK	Baclofen Tablets 10mg	Baclofen	PL 00289/0243	United Kingdom	HHP Malta (P&D Pharma) Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1488/04301UK	Haloperidol Tablets 1.5mg	Haloperidol	PL 0289/0305	United Kingdom	HHP Malta (P&D Pharma) Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1343/02601UK	Valganciclovir Tablet, film coated 450mg	Valganciclovir	PL 04569/1443	United Kingdom	Target Healthcare 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	No authorised products are available, marketed or offered on tender	N/A
AA1501/00701UK	Quinine Sulfate Tablets 200mg	Quinine Sulfate	PL 0142/5073 R	United Kingdom	Smartway Pharmaceuticals Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A

AA1488/04501UK	Thiotepa Riemser Pdr/Conc/Soln for Infus 15mg	Thiotepa	PLGB 42336/0008	United Kingdom	HHP Malta (P&D Pharma) Limited	Nil	Refused	The product has a marketing authorisation	N/A
AA1454/01201	Intestal Tablets 262.5mg	Bismuth subsalicylate	OGYI-T-23191/01	Hungary	Prohealth	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1454/01501	Ceftriaxone Hikma Pdr for Soln for Infusion 2g	Ceftriaxone sodium	57192.00.01	Germany	Prohealth	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1343/02701UK	Morphine Oral Solution 10mg/5ml	Morphine sulfate	PL 00156/0036	United Kingdom	Target Healthcare Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA908/04804	Motilium Fastmelts Orodispersible Tablet 10mg	Domperidone	PA330/040/001	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
AA1488/04601UK	Ditropan Tablets 5mg	Oxybutynin hydrochloride	PL 45043/0036	United Kingdom	HHP Malta (P&D Pharma) Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1161/01202	Propranolol Arena Tablets 10mg	Propranolol hydrochloride	12927/2020/01	Romania	Farmarosib SRL	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1411/01401	Dobutamine hameln Concentrate for Soln for Inf 12.5mg/ml	Dobutamine	RVG 32409	Netherlands	EJ Busuttil Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1173/08101UK	Co-codamol Tablets 30mg/500mg	Codeine phosphate; Paracetamol	PL 17907/0235	United Kingdom	Mint Health Ltd	Nil	Refused	The rational provided by the applicant is not justifiable to procure a product from a third country	N/A
AA1411/01501	Phenylephrine Hydrochloride Altan Solution for Infusion 10mg/ml	Phenylephrine	70 638	Spain	EJ Busuttil Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1438/01302	Venlafaxine Retard Mylan Tablet Prolonged Release 75mg	Venlafaxine hydrochloride	RVG 100007	Netherlands	NM Pharma Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA770/14503	Erlotinib AmaroX Tablet, film coated 150mg	Erlotinib	RVG 119579	Netherlands	JV Healthcare Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A

AA1006/00203	Lamya Tablet, film coated 0.075mg	Desogestrel	17/320/12-C	Czech Republic	Heaton k.s.	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA565/91801	Cordarone Solution for Injection 150mg/3ml	Amiodarone hydrochloride	13/134/82-C	Czech Republic	Central Procurement& Supplies Unit	Nil	Refused	The product has a marketing authorisation	N/A
AA565/14706	Pneumovax 23 Solution for Injection	Pneumococcal polysaccharide	PEI.H.01834.01.3	Germany	Central Procurement& Supplies Unit	Nil	Refused	The product has a marketing authorisation	N/A
AA1106/00702	Tolexine Microgranules Tablets 100mg	Doxycycline monohydrate	34009 339 655 32	France	Laboratoires Bailleul S.A.	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1501/00301UK	Doxazosin Tablets 2mg	Doxazosin	PL 16363/0289	United Kingdom	Smartway Pharmaceuticals Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1454/01001	Spaverin Tablets 80mg	Drotaverine hydrochloride	OGYI-T-22489/02	Hungary	Prohealth	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA979/00301	Isitri Solution for Injection 10mg/10ml	Isosorbide Dinitrate	5740246	Portugal	Laboratorios Basi -Industria Farmaceutica, SA	Nil	Accepted	No authorised products are available, marketed or offered on tender	To undergo an MRP
AA521/09101	Rosuva Tablet, film coated 5mg	Rosuvastatin	PA0711/176/001	Ireland	Medicem Ltd	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A
AA521/09102	Rosuva Tablet, film coated 10mg	Rosuvastatin	PA0711/176/002	Ireland	Medicem Ltd	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A

AA1454/01601	Acyclovir Hikma Pdr for Soln for Infusion 250mg	Aciclovir	91119.00.00	Germany	Prohealth	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative. No authorised products are available, marketed or offered on tender	N/A
AA1173/08201	Taromentin Tablet, film coated 875mg+125mg	Amoxicillin	10877	Poland	Mint Health Ltd	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A
AA729/04702	Diazepam Faes Rectal Solution 10mg	Diazepam	58000	Spain	Cherubino Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1488/04701UK	Melphalan Tablets 2mg	Melphalan	PL 39699/0043	United Kingdom	HHP Malta (P&D Pharma) Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA729/29501	DMSA Pdr for Soln for Injection 1.5mg	Dimercaptosuccinic acid (DMSA)	OGYI-T-9245/01	Hungary	Cherubino Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1045/04701	Cinacalcet Clonmel Tablet, film coated 30mg	Cinacalcet hydrochloride	PA0126/306/001	Ireland	Clonmel Healthcare Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1033/01203	Capecitabine Pharmacare Tablet, film coated 150mg	Capecitabine	5.66761E+13	Portugal	Pharmacare Premium Limited	Nil	Accepted	To ensure continuity of supply until the process prior to the start of the MRP are completed	To undergo an MRP
AA1033/01204	Capecitabine Pharmacare Tablet, film coated 500mg	Capecitabine	5667670	Portugal	Pharmacare Premium Limited	Nil	Accepted	To ensure continuity of supply until the process prior to the start of the MRP are completed	To undergo an MRP