

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
AA154/05604UK	Flucloxacillin Solution for Inj/Inf 250mg	Flucloxacillin sodium	PL 29831/0091	United Kingdom	Wockhardt UK Ltd	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA729/06006UK	Flucloxacillin Oral Solution 125mg/5mL	Flucloxacillin	PL 30464/0167	United Kingdom	Cherubino Ltd	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1420/00301	Valganciclovir Aurovitas Tablet, film coated 450mg	Valganciclovir hydrochloride	5668918	Portugal	Generis Phar, Unipessoal, Lda	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA565/17403UK	Lioresal Intrathecal Solution for Inj/Inf 50micrograms/1ml	B-(Aminomethyl)-p-chlorohydrocinnamic acid	PL 00101/0500	United Kingdom	Central Procurement& Supplies Unit	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1349/00601	Entecavir Normon Tablet, film coated 0.5mg	Entecavir	82134	Spain	Laboratorios Normon S.A	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA729/30501	Glucolon Tablets 5mg	Glibenclamide	50337	Spain	Cherubino Ltd	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1488/05701UK	Amitriptyline Tablet, film coated 10mg	Amitriptyline hydrochloride	PL 00289/0178	United Kingdom	HHP Malta (P&D Pharma) Limited	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1343/03201UK	Clobazam Accord Tablets 10mg	Clobazam	PL 20075/0671	United Kingdom	Target Healthcare Limited	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1454/01801	Destoxican Tablets 50mg	Naltrexone hydrochloride	3875390; 5795299; 3887593; 5795398	Portugal	Prohealth	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1207/00801UK	Magnesium Sulfate Solution for Inj/Inf 50%w/v	Magnesium sulfate heptahydrate	PL 47015/0010	United Kingdom	AS KALCEKS	No	Accepted	No authorised products are available, marketed or offered on tender	N/A

AA1454/01901	Letrozole Farmoz Tablets 2.5mg	Letrozole	5093356; 5093364; 5093372.	Portugal	Prohealth	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1330/00202	Donepezil Tablet, film coated 5mg	Donepezil hydrochloride	PA2315/033/001	Ireland	Accord Healthcare Ireland Limited	No	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A
AA1330/00203	Donepezil Tablet, film coated 10mg	Donepezil hydrochloride	PA2315/033/002	Ireland	Accord Healthcare Ireland Limited	No	Accepted		N/A
AA1343/03301UK	Rasagiline Brown & Burk Tablets 1mg	Rasagiline	PL 25298/0097	United Kingdom	Brown & Burk UK Limited	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA565/94101	Tobrex Eye Drops Solution 3mg/ml	Tobramycin	8740902	Portugal	Novartis Farma - Produtos Farmacéuticos,	No	Refused	The product has a marketing authorisation	N/A
AA1343/03101UK	Gabapentin Brown & Burk Capsules Hard 100mg	Gabapentin	PL 25298/0076	United Kingdom	Brown & Burk UK Ltd	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA979/00102	Supofen Suppositories 250mg	Paracetamol	5591136	Portugal	Laboratórios Basi - Indústria Farmacêutica, S.A.	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA908/25002	Coldrex Maxgrip Lemon Powder for Oral Solution 1000/10/40 mg	Paracetamol; Phenylephrine hydrochloride; Ascorbic acid	03-0233	Latvia	Neofarma Pharmaceuticals Limited	No	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA729/30401	Norfloxacin Helcor Tablet, film coated 400mg	Norfloxacin	9028/2016/01	Romania	AC Helcor Pharma S.R.L	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA115/03101	Dareq Tablet, film coated 5mg	Desloratadine	21529	Cyprus	Delorbis Pharmaceuticals Ltd	No	Accepted	No authorised products are available, marketed or offered on tender	N/A

AA1349/00701	Fluoxetine Normon Oral Solution 20mg/5ml	Fluoxetine	62427, 742486	Spain	LABORATORIOS NORMON, S.A.	No	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1411/02001	Micropaque Oral Suspension 100ml/100g	Barium sulfate	34009 306 749 9 4; 34009 306 750 7 6; 34009 550 021 0 9	France	GUERBET	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA729/06006UK	Flucloxacillin Oral Solution 125mg/5mL	Flucloxacillin	PL 30464/0167	United Kingdom	Athlone Pharmaceuticals Limited	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1228/00202	Pleyris Solution for Inj/Inf 25mg	Progesterone	41348057	Italy	IBSA FARMACEUTICI ITALIA	No	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA130/00303	Nucleo C.M.P Forte Capsule 5mg/3mg	Cytidine-5'-disodium monophosphate; Uridine-5'-trisodium triphosphate; Uridine-5'-disodium diphosphate; Uridine-5'-disodium monophosphate	51533	Spain	Ferrer Internacional, S.A	No	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA729/12805	Trandate Solution for Injection 5mg/ml	Labetalol hydrochloride	55318	Spain	Cherubino Ltd	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA729/30601	Calcitonin Almirall Solution for Injection 100IU	Salmon calcitonin (synthetic)	56996	Spain	Cherubino Ltd	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA115/03201	Clomentin Tablet, film coated 20mg	Escitalopram Oxalate	21243	Cyprus	Delorbis Pharmaceuticals Ltd	No	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A

AA115/03202	Clomentin Tablet, film coated 10mg	Escitalopram Oxalate	21241	Cyprus	Delorbis Pharmaceuticals Ltd	No	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A
AA1488/05801UK	Danaparoid Sodium Solution for Injection 750units/0.6ml	Danaparoid Sodium	PL 46302/0228	United Kingdom	HHP Malta (P&D Pharma) Limited	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1330/03801	Valsartan Tablet, film coated 80mg	Valsartan	PA2315/188/002	Ireland	Azure Pharmaceuticals Ltd	No	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A
AA1330/03802	Valsartan Tablet, film coated 160mg	Valsartan	PA2315/188/003	Ireland	Azure Pharmaceuticals Ltd	No	Accepted		N/A
AA1093/00105	Medica Throat Tablets Strawberry Lozenges 5mg/1mg	Chlorhexidine hydrochloride; Lidocaine hydrochloride	BE464782	Belgium	Laboratoria Qualiphar N.V./S.A	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1093/00106	Medica Throat Spray Lemon Oromucosal Spray 2/0.5mg/ml	Chlorhexidine hydrochloride; Lidocaine hydrochloride	BE179575	Belgium	Laboratoria Qualiphar N.V./S.A	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA908/25101	Tetralysal Capsule 300mg	Lymecycline	3400936759800	France	Neofarma Pharmaceuticals Limited	No	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA729/28602UK	Metanium Nappy Rash Ointment 20%w/w	Titanium dioxide; Titanium peroxide; Titanium salicylate	PL 00240/0366	United Kingdom	Cherubino Ltd	No	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA565/08702UK	Sando-K Tablets Effervescent 521.5mg	Potassium chloride; Potassium bicarbonate	PL 44490/0003	United Kingdom	Central Procurement& Supplies Unit	No	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A

AA565/86101	Atecor Tablets 25mg	Atenolol	PA0711/003/001	Ireland	Central Procurement& Supplies Unit	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1511/00401	Carboplatin Kelix bio Concentrate for Soln for Inj 10mg/ml	Carboplatin	2202027.00.00	Germany	Kelix bio (Malta) Limited	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1343/01302UK	Madopar Tablets Dispersible 100mg/25mg	Levodopa; Benserazide	PL 00031/0221	United Kingdom	Target Healthcare Limited	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1513/00101	Xylocaine/Adrenaline Solution for Injection 20/0.005 mg/ml	Lidocaine; Adrenaline	34009 311 524 1	France	Pharma Regulatory ServicesLimited	No	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1438/09401	Prednisolon Mylan Tablets 20mg	Prednisolone	RVG 105828	Netherlands	NM Pharma Ltd	No	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA242/01501	Glycerin / Zarbis Suppositories 2.4g	Glycerol	135284/20/140121	Greece	Pharmabart Ltd	No	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1511/00501	Methotrexate Kelix bio Concentrate for Soln for Inf 25mg/ml	Metothrexate	2205789.00.00	Germany	Kelix bio (Malta) Limited	No	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1511/00502	Methotrexate Kelix bio Solution for Inj/Inf 2.5mg/ml	Metothrexate	2205788.00.00	Germany	Kelix bio (Malta) Limited	No	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA729/30701UK	Audavate RD Ointment 0.025%	Betamethasone valerate	PL 0142/1199	United Kingdom	Cherubino Ltd	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1501/01001UK	Vinorelbine Solution 10mg/ml	Vinorelbine	PL 0142/1231	United Kingdom	Smartway Pharmaceuticals Limited	No	Accepted	No authorised products are available, marketed or offered on tender	N/A

AA1488/06501UK	Verapamil Tablets 40mg	Verapamil hydrochloride	PL 0289/0271	United Kingdom	Health House Pharma Ltd T/As P&D Pharmaceuticals Ltd	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1349/00801	Carvedilol Norman Tablets 6.25mg	Carvedilol	68876-659187	Spain	Laboratorios Normon S.A	No	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1330/03701	Spironolactone Tablet, film coated 100mg	Spironolactone	PA2315/119/003	Ireland	Azure Pharmaceuticals Ltd	No	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1454/02101	Hedelix Cough Syrup 0.8g/100ml	Ivy leaves	6428904.00.00	Germany	Prohealth	No	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1488/06201UK	Catapres Tablets 100mcg	Clonidine hydrochloride	PL 22824/0010	United Kingdom	HHP Malta (P&D Pharma) Limited	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1411/02401UK	Gentamicin Eye Drops Solution 0.3%w/v	Gentamicin	PL 15872/004	United Kingdom	EJ Busuttil Ltd	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1227/00102	Flihaler Pressurised Inhalation Suspension 250mcg/dose	Fluticasone Propionate	6985/17/07112018	Greece	D.A.S.T Biotech Pharm Ltd	No	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA565/94501	Ringer lactate Solution for Infusion 1000ml	Sodium chloride; Sodium lactate solution; Potassium chloride; Calcium chloride dihydrate	6724011.00.00	Germany	Central Procurement& Supplies Unit	No	Refused	The product has a marketing authorisation	N/A
AA1454/02201	Paclitaxel Ribosepharm Concentrate for Soln for Inf 6mg/ml	Paclitaxel	59091.00.00	Germany	Prohealth	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1161/02401	Amiodarona Arena Tablets 200mg	Amiodarone hydrochloride	9977/2017/01-02	Romania	Farmarosib SRL	No	Accepted	No authorised products are available, marketed or offered on tender	N/A

AA1488/06601UK	Care Senna Tablets 7.5mg	Hydroxyanthracene glycosides	PL 44893/0031	United Kingdom	HHP Malta (P&D Pharma) Limited	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1488/01002UK	Nitrofurantoin Tablets 50mg	Nitrofurantoin	PL 08553/0087	United Kingdom	HHP Malta (P&D Pharma) Limited	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1343/02903UK	Xaggitin XL Tablet Prolonged Release 27mg	Methylphenidate Hydrochloride	PL 01883/0360	United Kingdom	Target Healthcare Limited	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1343/01901UK	Furosemide Tablets 40mg	Furosemide	PL 20416/0079	United Kingdom	Target Healthcare Limited	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1343/02401UK	Doxazosin Tablets 2mg	Doxazosin mesilate	PL 17907/0256	United Kingdom	Target Healthcare Limited	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1207/00601UK	Furosemide Solution for Inj/Inf 10mg/ml	Furosemide	PL 47015/0017	United Kingdom	AS KALCEKS	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA908/25401	Sindolor Gel 5mg/5mg/20mg/g	Piroxicam; Cyclobenzaprine hydrochloride; Lidocaine	14027/2021/01-05	Romania	Neofarma Pharmaceuticals Limited	No	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA729/04603UK	Aciclovir Oral Suspension 200mg/5ml	Aciclovir	PL 00427/0119	United Kingdom	Cherubino Ltd	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1404/00103	Taromentin Oral Suspension 400mg	Amoxicillin; Clavulanic acid	17027	Poland	Tarchomińskie Zakłady Farmaceutyczne "Polfa" Spółka Akcyjna	No	Accepted	To ensure continuity of supply given that there is a worldwide shortage for this active ingredient	N/A
AA1454/02301	Ambroxol Tussilene Syrup 6mg/ml	Ambroxol hydrochloride.	5394507	Portugal	Prohealth	No	Accepted	To ensure continuity of supply given that there is a shortage for this active ingredient	N/A
AA1343/02801UK	Linezolid Tablet, film coated 600mg	Linezolid	PL 06831/0313	United Kingdom	Target Healthcare Limited	No	Accepted	No authorised products are available, marketed or offered on tender	N/A

AA1411/01801	Zoledronic Acid Altan Solution for Infusion 5mg/100ml	Zoledronic acid	78125	Spain	EJ Busuttil Ltd	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1511/00901	Gemcitabine Kelix bio Pdr for Soln for Infusion 38mg/ml	Gemcitabine	2203820.00.00	Germany	Kelix bio (Malta) Limited	No	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA770/16601	Arvekap Pdr+Solv for Soln for Inj 0.1mg	Arvekap	38904/4-9-2008	Greece	JV Healthcare Limited	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1343/03401UK	Diamorphine Hydrochloride Pdr for Soln for Injection 5mg	Diamorphine hydrochloride	PL 29831/0062	United Kingdom	Target Healthcare Limited	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1411/02201	Gilurytmal Solution for Infusion 50mg/10ml	Ajmaline	6118316.00.00	Germany	EJ Busuttil Ltd	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA908/25601	Diacol Syrup 27mg/15ml	Dextromethorphan hydrobromide	2008290	Portugal	Neofarma Pharmaceuticals Limited	No	Accepted	To ensure continuity of supply given that there is a shortage for this active ingredient	N/A
AA1488/06301UK	Busulfan Tablet, film coated 2mg	Busulfan	PL 39699/0042	United Kingdom	HHP Malta (P&D Pharma) Limited	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1501/00101UK	Moxifloxacin Tablets 400mg	Moxifloxacin	PL 33155/0011	United Kingdom	Smartway Pharmaceuticals Limited	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1511/00701	Irinotecan Kelix bio Concentrate for Soln for Inj 20mg/ml	Irinotecan	7002823.00.00	Germany	Kelix bio (Malta) Limited	No	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA770/16701	Cefotaxime Pdr for Soln Inj/Inf 1g	Cefotaxime sodium	PA1122/019/002	Ireland	JV Healthcare Limited	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA084/05503	Remedium Tablets 5mg	Diazepam	7750	Cyprus	Remedica Ltd	No	Accepted	No authorised products are available, marketed or offered on tender	N/A

AA1043/00102UK	Primidone SERB Tablets 250mg	Primidone	PL 26080/0003	United Kingdom	Serb	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1353/00401	Potassium Chloride Monico Concentrate for Soln for Inf 2mEq/mL	Potassium chloride	30815017	Italy	Monico ApA	No	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA154/09202UK	Amoxicillin Sodium Solution for Injection 500mg	Amoxicillin Sodium	PL 29831/0012	United Kingdom	Wockhardt UK Ltd	No	Accepted	<p>To ensure continuity of supply given that there is a worldwide shortage for this active ingredient</p> <p>There are fewer than three authorised products on the market with the same active ingredient, dose and strength</p> <p>To ensure continuity of supply given that there is a worldwide shortage for this active ingredient</p> <p>There are fewer than three authorised products on the market with the same active ingredient, dose and strength</p>	N/A
AA1096/01101	Spasmo-Apotel Solution for Injection 600+20mg/4ml	Paracetamol; Hyoscine butylbromide	8570/07	Greece	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A	No	Accepted		N/A
AA1513/00301	Amoksiklav Powder for Oral Solution 600mg/42.9mg/5ml	Amoxicillin; Clavulanic acid	13749/2021/01-02	Romania	Pharma Regulatory Services Limited	No	Accepted		N/A
AA1438/00602	Vaqta Adult Suspension for Injection 50U/mL	Hepatitis A virus	RVG 20798	Netherlands	NM Pharma Ltd	No	Accepted		N/A
AA1513/00401UK	Minims Dexamethasone sodium phosphate Eye Drops Solution 0.1%w/v	Dexamethasone sodium phosphate	PL 03468/0072	United Kingdom	Pharma Regulatory Services Limited	No	Accepted	No authorised products are available, marketed or offered on tender	N/A