

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
AA565/96701	Apocard Solution for Injection 10mg/ml	Flecainide acetate	57.514	Spain	Central Procurement and Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/24704UK	Riluzole SUN 50 mg film-coated tablets.	Riluzole	PL 31750/0010	The Netherlands	Central Procurement and Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/42306	Vinorelbine 10 mg/mL, concentrate for solution	Vinorelbine	5108311; 5108337	Portugal	Central Procurement and Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/08303	Atropine Sulphate Aguettant 0.1 mg/mL solution for injection in pre-filled syringe	Atropine sulphate monohydrate	34009 276 65806	France	Central Procurement and Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1488/08001UK	Modafinil Tablets 200mg	Modafinil	PL 16363/0302	United Kingdom	HHP MALTA (P&D PHARMA) LIMITED	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/02602UK	Digoxin 0.05mg/ml oral solution	Digoxin	PL 39699/0007	United Kingdom	Central Procurement and Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/98301	Arsenic Trioxide Generis 1 mg/mL concentrate for solution for infusion	Arsenic trioxide	5786215	Portugal	Central Procurement and Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1411/03502UK	Dasatinib Zentiva 20mg film-coated tablets	Dasitinib	PL 17780/0842	United Kingdom	EJ BUSUTTIL LTD	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/89401	Dalacin C 150 mg hard capsules	Clindamycin hydrochloride	22633059	Italy	Central Procurement and Supplies Unit	Nil	Refused	The product has a marketing authorisation	N/A
AA729/33101UK	GalliAD Radionuclide Generator 0.74 -1.85 GBq	Germanium	PL43883/0001	United Kingdom	Cherubino Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA770/18501UK	Ixiaro suspension for injection 0.5ml	Japanese encephalitis virus strain	PL 43185/0001	United Kingdom	JV Healthcare Limited	Nil	Refused	The product has a marketing authorisation	N/A

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AA729/32801	Gabapentine 50 mg/ml Focus, Oral solution	Gabapentin	RVG 125650	The Netherlands	Cherubino Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1438/10701	Dimestil Gel 1 mg/g	Dimetindene maleate	22-0064	Latvia	NM Pharma Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA565/89301	Decadron tablets 0.5 mg	Dexamethasone	3546686; 3546587	Portugal	Central Procurement and Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/95103	Voriconazole Vocate Pdr for Soln for Infusion 200mg	Voriconazole	73946/11-07-2022	Greece	Central Procurement and Supplies Unit	Nil	Refused	The product has a marketing authorisation	N/A
AA521/09401	Rosuvastatin Rowa Tablet, film coated 5mg	Rosuvastatin	PA0074/093/001	Ireland	Rowa Pharmaceuticals Limited	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA565/99101	Luan 2.5% Gel 2.5g/100g	Lidocaine hydrochloride	5638010	Italy	Central Procurement and Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/24305	Metoclopramide Labesfal solution for injection 10 mg/2 mL	Metoclopramide, hydrochloride monohydrate	5228697	Portugal	Central Procurement and Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1411/03501UK	Dasatinib Zentiva 100mg film-coated tablets	Dasitinib	PL 17780/0876	United Kingdom	EJ BUSUTTIL LTD	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1438/11001	Ursogrix 250 mg hard capsules	Ursodeoxycholic acid	PA22992/002/001	Ireland	NM Pharma Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/98601	Bromhexine Generis 0.8 mg/mL, syrup	Bromhexine	5465810	Portugal	Central Procurement and Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1124/00103	Ciprofloxacin Solution for Infusion 2mg/ml	Ciprofloxacin	PA1122/005/001	Ireland	Noridem Enterprises Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	Commitment to undergo MRP

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AA1488/07901UK	Demeclocycline Hydrochloride Hard capsule 150mg	Demeclocycline hydrochloride	PL 12762/0154	United Kingdom	HHP Malta (P&D Pharma) Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA288/03001	Zolmitriptano Generis Phar 2.5 mg orodispersible tablets	Zolmitriptan	5399159, 5399167, 5399175	Portugal	V.J.Salomone Pharma Limited	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1234/00201	Habitek Tablet,film-coated 10mg	Cetirizine hydrochloride	107533/11-11-2020	Greece	S.J.A. PHARM LTD	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	Commitment to undergo MRP
AA188/02801	Butolir Nebuliser Solution 0.5mg/2ml	Budesonide	23051	Cyprus	Demo Pharmaceutical Industry S.A.	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	Commitment to undergo MRP
AA188/02802	Butolir Nebuliser Solution 1mg/2ml	Budesonide	23052	Cyprus	Demo Pharmaceutical Industry S.A.	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	Commitment to undergo MRP
AA565/89201	Accupaque solution for injection 300mg	Iohexol	3004002.00.00	Germany	Central Procurement and Supplies Unit	Nil	Refused	The product has a marketing authorisation	N/A
AA565/34804	Tramadol-ratiopharm 100 mg/2 mL solution for injection	Tramadol hydrochloride	6025891.00.00	Germany	Central Procurement and Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1488/07802UK	Phenergan Solution for Injection 25mg/ml	Promethazine hydrochloride	PL 53886/0056	United Kingdom	HHP Malta (P&D Pharma) Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/53908	Fluorouracil Teva Solution for Infusion 50mg/ml	Fluorouracil	26542050	Italy	Central Procurement and Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A

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AA565/30202	Cynomel 0.025mg tablet	Liothyronine sodium	34009 302 775 5 3	France	Central Procurement and Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA729/33201	MST Continus Tablets 30mg	Morphine sulphate	57897	Spain	Cherubino Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1488/08101UK	Clopidogrel film-coated tablet 75mg	Clopidogrel	PL 21880/0249	United Kingdom	HHP MALTA (P&D PHARMA) LIMITED	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/55512	Cytarabine hikma solution for injection 100 mg/5 ml	Cytarabine	034164 083; 034164 071	Portugal	Central Procurement and Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA729/10904	Amoxicillin CF 500 mg powder for solution for injection or infusion	Sodium amoxicillin	RVG 57326	The Netherlands	Cherubino Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA521/09301	Modafinil bluefish tablet 100mg	Modafinil	PA1436/031/001	Ireland	Medicem Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA565/14807	Adisocol Tablets 150mg	Ursodeoxycholic Acid	83490: 723751	Spain	Central Procurement and Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/26602	Ceftazidime Qilu 1 g powder for solution for injection/infusion	Ceftazidime	45576042	Spain	Central Procurement and Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA984/00801	Carvedilol helcor tablet 25mg	Carvedilol	12049/2019/01-02	Romania	AC HELCOR PHARMA SRL	Nil	Accepted	To ensure continuation of supply for the National Health System	Commitment to undergo MRP
AA1349/00702	Fluoxetine Normon Capsules Hard 20mg	Fluoxetine hydrochloride	62426	Spain	LABORATORIOS NORMON, S.A.	Nil	Accepted	To ensure continuation of supply for the National Health System	Commitment to undergo MRP
AA565/99201UK	Hyoscine Solution for Injection 400mcg/ml	Hyoscine hydrobromide	PL 01883/6135R	United Kingdom	Central Procurement and Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A

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AA565/49508	Budesonida Aldo-Union Nebulise Solution 0.25mg/ml	Budesonide	66.943: 651628-9	Spain	Central Procurement and Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA770/18601	Sertraline Tablet, film coated 50mg	Sertraline	PA2315/177/001	Ireland	JV Healthcare Limited	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A
AA770/18602	Sertraline Tablet, film coated 100mg	Sertraline	PA2315/177/002	Ireland	JV Healthcare Limited	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A
AA565/62207	Azactam 1000 mg powder for solution for injection	Aztreonam	5752902 & 5752878	Portugal	Central Procurement and Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA770/18201	Amlodipine Tablets 10mg	Amlodipine	PA749/67/2	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
AA770/18202	Amlodipine Tablets 5mg	Amlodipine	PA749/67/1	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
AA1291/00301	Fentadur transdermal patch 50mcg/h	Fentanyl	44179/12	Greece	LAVIPHARM S.A.	Nil	Accepted	To ensure continuation of supply for the National Health System	Commitment to undergo MRP
AA908/25802	Perindopril glenmark tablets 4mg	Perindopril tertbutylamine	RVG 33699	The Netherlands	NEOFARMA PHARMACEUTICALS LTD	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A

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AA565/49507	Budesonide Aldo-Union Pressurised Inhalation Suspension 200mcg	Budesonide	61664	Spain	Central Procurement and Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1001/00402	Xalaprost Eye Drops Solution 0.005%w/v	Latanoprost	30816/06-04-2022	Greece	COOPER S.A. Pharmaceuticals	Nil	Accepted	To ensure continuation of supply for the National Health System	Commitment to undergo MRP
AA565/12102UK	Cobalin-H Hydroxocobalamin Solution for Injection 1000 microgram/ml	Anhydrous hydroxocobalamin	PL 20072/0217	United Kingdom	Central Procurement and Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/06410	Baclofen Neuraxpharm Intrathecal Solution for Infusion 0.5mg/ml	Baclofen	7001761.00.00	Germany	Central Procurement and Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/99501	Sandostatin LAR Pdr for Soln for Injection 20mg	Octreotide	RVG 18236	The Netherlands	Central Procurement and Supplies Unit	Nil	Refused	The product has a marketing authorisation	N/A
AA565/25403UK	Sulpiride 200mg/5ml Oral Solution	Sulpiride	PL 41871/0020	United Kingdom	Central Procurement and Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA729/27702	Dantrium Capsule 25mg	Dantrolene sodium	PA 1336/004/001	Ireland	Cherubino Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/99601	Carnicor Oral Solution 300mg/ml	Carnitine	55.501: 962373; 627489	Spain	Central Procurement and Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/41904	Ancotil tablet 500mg	Flucytosine	34009 317 964 3 5	France	Central Procurement and Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/98701	InfectoScab 5% cream	Permethrin	51164.00.00	Germany	Central Procurement and Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/06409	Baclofen Aguettant Intrathecal Solution for Injection 0.05 mg/1 mL	Baclofen	BE384483	Belgium	Central Procurement and Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A

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AA135/00202	Cosmegen Lyovac Pdr for Soln for Injection 500mcg	Dactinomycin	3400956434299	France	Recordati Rare Disease	Nil	Accepted	To ensure continuation of supply for the National Health System	Commitment to undergo MRP
AA240/00104	Aristin-C Solution for Infusion 200 mg/100 ml	Ciprofloxacin lactate	43167/10/29-06-2	Greece	Anfarm Hellas SA	Nil	Accepted	To ensure continuation of supply for the National Health System	Commitment to undergo MRP
AA1438/11101	Roswera 5 mg film-coated tablets	Rosuvastatin	9170/2016/05	Romania	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
AA1438/11102	Roswera 10 mg film-coated tablets	Rosuvastatin	9171/2016/05	Romania	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
AA1438/11103	Roswera 20 mg film-coated tablets	Rosuvastatin	9173/2016/05	Romania	NM Pharma Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1438/11104	Roswera 40 mg film-coated tablets	Rosuvastatin	9175/2016/05	Romania	NM Pharma Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA729/33501UK	Warfarin Sodium Oral Suspension 1mg/1ml	Warfarin sodium	PL 00427/0156	United Kingdom	Cherubino Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA729/33701UK	Calamine Lotion BP Cream 15/5%(w/v)	Calamine; Zinc oxide	PL 12965/0003	United Kingdom	Cherubino Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A

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AA1349/01301	Sertraline Normon Tablet, film coated 50mg	Sertraline	65923, 819854	Spain	Laboratorios NORMON, S.A.	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	Commitment to undergo MRP
AA1349/01302	Sertraline Normon Tablet, film coated 100mg	Sertraline	65922; 819847	Spain	Laboratorios NORMON, S.A.	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	Commitment to undergo MRP
AA1228/02201	Linoladiol N 100 micrograms/g vaginal cream	Estradiol hemihydrate	54/679/96-C	Czech Republic	Focused pharma	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1513/01901	Tazopenil 4 g/0.5 g powder for solution for infusion	Piperacillin; Tazobactam	38181020	Italy	Pharma Regulatory Services Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/98901UK	Cidofovir Tillomed 75 mg/ml Concentrate for Solution for Infusion	Cidofovir anhydrous	PL 11311/0587	United Kingdom	Central Procurement and Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA115/03401	Cleron Tablet, film coated 500mg	Clarithromycin	18053	Cyprus	Delorbis Pharmaceuticals Ltd	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	Commitment to undergo MRP
AA729/27402	Orap Forte Tablets 4mg	Pimozide	49504	Spain	Cherubino Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/100001	Sugammadex Rompharm Solution for Injection 100mg/ml	Sugammadex sodium	13906/2021/01	Romania	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/02603UK	Digoxin Solution for Inj/Inf 250microgram/ml	Digoxin	PL 39633/0006	United Kingdom	Central Procurement and Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A

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AA565/27903UK	Oily phenol solution for infusion/injection 5%w/v	Phenol BP	PL 35104/0012	United Kingdom	Central Procurement and Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/99301	Mesalazine Mylan Generics Tablets Gastro-Resistant 400mg	Mesalazine	33529052	Italy	Central Procurement and Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1528/00101	Natriclo concentrate for solution for infusion 3g/10ml	Sodium chloride	BE251307	Belgium	LABORATOIRES STEROP NV	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1411/03601	Dacarbazine Lipomed Pdr for Soln Inj/Inf 200mg	Dacarbazine	PA1760/001/001	Ireland	EJ Busuttil Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1438/10501	Paxetin 20 mg film-coated tablets	Paroxetine	12940/2020/02	Romania	NM Pharma Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA565/21314	Linezolid Kabi Solution for Infusion 2mg/mL	Linezolid	5657838	Portugal	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/16802UK	Liothyronine Sodium Solution for Injection 20 micrograms	Liothyronine sodium	PL 12762/0176	United Kingdom	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA770/18301	Xylocaine + adrenaline solution for injection 20 mg/ml + 5 microgram/ml	Lidocaine; Adrenaline	RVG 30238	The Netherlands	JV Healthcare Limited	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA729/12905	Octreotide Bendalis Solution for injection/infusion 0.2mg/mL	Octreotide	2200138.00.00	Germany	Cherubino Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA770/18701UK	Pabrinex Solution for Infusion 5ml	Thiamine hydrochloride; Riboflavin; Pyridoxine; Ascorbic acid;	PL 16508/0049	United Kingdom	JV Healthcare Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A

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AA565/59006	Fentanyl Aurovitas Transdermal Patch 50mcg/h	Fentanyl	5119235	Portugal	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1366/00201	Miconazol Slavia Cream 20mg/g	Miconazole Nitrate	8029/2015/01	Romania	S.C. Slavia Pharm SRL	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	Commitment to undergo MRP
AA188/01403	Veracol Pdr for Soln for Infusion 1g	Ceftriaxone	41843/07/17-4-2008	Greece	Demo SA Pharmaceutical Industry	Nil	Accepted	No authorised products are available, marketed or offered on tender	Commitment to undergo MRP
AA1411/03301UK	Amfexa 5 mg Tablets	Dexamfetamine sulfate	PL 11243/0021	United Kingdom	EJ BUSUTTIL LTD	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/20103	Fludarabine Teva Solution for Inj/Inf 25mg/ml	Fludarabine phosphate	BE303721	Belgium	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/10708	Gentamicin sulphate EIPICO Eye Drops Solution 3mg/ml	Gentamicin	11077/2018/01	Romania	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/78405	Methotrexate-GRY solution for injection 5mg/2ml	Methotrexate disodium	2385.00.03	Germany	Central Procurement and Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA188/03101	Ondansetron Solution for Injection 2mg/ml	Ondansetron	PA1122/004/001	Ireland	Demo SA Pharmaceutical Industry	Nil	Accepted	To ensure continuation of supply for the National Health System	Commitment to undergo MRP
AA1330/00405	Duloxetine Accord Capsules Gastro-Resistant 30mg	Duloxetine	PA2315/268/001	Ireland	Azure Pharmaceuticals Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A

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AA1330/00406	Duloxetine Accord Capsules Gastro-Resistant 60mg	Duloxetine	PA2315/268/002	Ireland	Azure Pharmaceuticals Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA188/03001	Gentamicin Solution for Inj/Inf 40mg/ml	Gentamicin	PA1122/023/002	Ireland	Demo SA Pharmaceutical Industry	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	Commitment to undergo MRP
AA1228/02301	Valaciclovir Hexal Tablet, film coated 500mg	Valaciclovir hydrochloride	70544.00.00	Germany	Focused Pharma Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1228/02302	Valaciclovir Hexal Tablet, film coated 1000mg	Valaciclovir hydrochloride	76454.00.00	Germany	Focused Pharma Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1488/08201UK	Tetrabenazine Tablets 25mg	Tetrabenazine	PL 40546/0050	United Kingdom	Central Procurement and Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/31605UK	Quinine Sulphate BP Tablets 300mg	Quinine sulphate BP	PL 40147/0071	United Kingdom	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/100501	Primacine Granules for Oral Suspension 250mg/5ml	Erythromycin ethyl succinate	PA0281/026/008	Ireland	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1161/00302	Doxazosin Arena Tablets 1mg	Doxazosin mesilate	4644/2004/01	Romania	Farmarosib SRL	Nil	Accepted	To ensure continuation of supply for the National Health System	Commitment to undergo MRP

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AA288/03101UK	Warfarin Sodium Oral Suspension 1mg/1ml	Warfarin sodium	PL 00427/0156	United Kingdom	VJ Salomone Pharma LTD	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA770/18801	Flutamid AL Tablets 250mg	Flutamide	42660.00.00	Germany	JV Healthcare Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/100601	Aerodur Turbohaler Powder for Inhalation 0.5mg	Terbutaline sulphate	13662.00.00	Germany	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/56902	Aurorix Tablet, film coated 150mg	Moclobemide	8757435	Portugal	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/12608	Magnesium Sulphate Kalceks Solution for Inj/Inf 200mg/ml	Magnesium sulphate heptahydrate	39/300/18-C	Czech Republic	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/09904	Ciproxine Granules for Oral Suspension 50mg/ml	Ciprofloxacin	BE213507	Belgium	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1123/03901	Sodium chloride Fresenius Kabi Italia Solution For Infusion 0.9%	Sodium chloride	031938590; 031938424	Italy	Fresenius Kabi Italia S.r.l.	Nil	Accepted	To ensure continuation of supply for the National Health System	Commitment to undergo MRP
AA565/88303	Topotecanum Accord Concentrate for Soln for Inf 1mg/mL	Topotecan	20222	Poland	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA729/27002	Deprexolet Tablet, film coated 10mg	Mianserin hydrochloride	11209	Poland	Cherubino Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/100801	Calco Solution for Injection 100IU/mL	Synthetic salmon calcitonin	27488028	Italy	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A

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
AA1411/03801	Pulmozyme Nebulise Solution 2500U/2.5ml	Dornase alfa	6524/2014/01	Romania	EJ Busuttil Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1330/04201	Lansoprazole Capsules Gastro-Resistant 30mg	Lansoprazole	PA2315/128/002	Ireland	Azure Pharmaceuticals Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1488/06802UK	Ethambutol Tablet, film coated 400mg	Ethambutol hydrochloride	PL 17509/0082	United Kingdom	HHP Malta (P&D Pharma) Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1411/03901UK	Mivacurium Solution for Injection 2mg/ml	Mivacurium	PL 39699/0094	United Kingdom	EJ Busuttil Ltd	Nil	Refused	The product has a marketing authorisation	N/A
AA565/100101	Farvicett Cutaneous Solution 0.015% + 0.15%	Chlorhexedine gluconate; Cetrimide	032644054, 032644066	Italy	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/01003	Curosurf Endotrachpulm Inst, Susp 120mg/1.5ml	Phospholipid fraction from porcine lung	2139889	Portugal	Central Procurement& Supplies Unit	Nil	Refused	The product has a marketing authorisation	N/A
AA565/100401	Lenalidomide Grindeks Capsules Hard 10mg	Lenalidomide	25799	Spain	Central Procurement& Supplies Unit	Nil	Refused	The product has a marketing authorisation	N/A
AA565/80802	Alexan Solution for Injection 20mg/ml	Cytarabine	R/6640	Poland	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA729/34201UK	Panadol Extra Soluble Tablets 500/65mg	Paracetamol; Caffeine	PL44673/0077	United Kingdom	Cherubino Ltd	Nil	Refused	There are several alternative products available in the European Union. The requirements of Directive 642/2002 (to allow in the case of shortages/severe problems with availability) are not satisfied.	N/A

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
AA729/13003UK	Procyclidine Tablets 5mg	Procyclidine hydrochloride	PL 13606/0154	United Kingdom	Cherubino Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1488/06102UK	Aciclovir Tablets 200mg	Aciclovir	PL 16363/0556	United Kingdom	HHP Malta (P&D Pharma) Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA242/01701UK	Codeine Phosphate Tablets 30mg	Codeine phosphate	PL 17907/0169	United Kingdom	Pharmabart Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1096/00405	T4 Tablets 25mcg	Levothyroxine sodium anhydrous	18689/16-03-2007	Greece	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	Commitment to undergo MRP
AA1096/00406	T4 Tablets 50mcg	Levothyroxine sodium anhydrous	8570/06-02-2007	Greece	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	Commitment to undergo MRP
AA1096/00407	T4 Tablets 100mcg	Levothyroxine sodium anhydrous	8570/06-02-2007	Greece	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	Commitment to undergo MRP
AA565/101201	Kreon 25,000 Capsules Hard	Porcine pancreatic powder	22525.00.00	Germany	Central Procurement& Supplies Unit	Nil	Refused	The product has a marketing authorisation	N/A
AA1438/10601	Aleve Feminax for Menstrual Pain Tablets,film coated 275mg	Naproxen sodium	RVG 09006	The Netherlands	NM Pharma 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
AA565/101001	Clovate Cream 0.5mg/g	Clobetasol propionate	55 746; 952036	Spain	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A

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
AA565/100301	Mydrum Eye Drops Solution 5mg/ml	Tropicamide	2203848.00.00	Germany	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1411/03701UK	Vancomycin Capsules Hard 125mg	Vancomycin	PL 13606/0196	United Kingdom	EJ Busuttil Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/101101	Claversal Rectal Foam 1g	Mesalazine	61335: 675520	Spain	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1404/00701	Rifamazid Capsules Hard 150mg+100mg	Rifampicin; Isoniazid	R/0861	Poland	Tarchominskie Zaklady Farmaceutyczne Polfa S.A.	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA729/33801UK	Radian B Muscle Rub Cream	Menthol; Camphor; Methyl Salicylate; Camphor Oil, White; Oleoresin capsicum 500,000 water soluble; Camphor and camphor oil, white	PL 00240/0360	United Kingdom	Cherubino Ltd	Nil	Accepted	To ensure continuation of supply	N/A
AA521/09402	Rosuvastatin Rowa Tablet, film coated 10mg	Rosuvastatin	PA0074/093/002	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
AA729/19402UK	Magnesium Sulphate Paste BP Cream 78.8/85.8%	Dried magnesium sulphate; Phenol	PL 03436/0002	United Kingdom	Cherubino Ltd	Nil	Accepted	To ensure continuation of supply	N/A
AA729/33301UK	Oilatum Shower Gel 70% w/w	Light liquid paraffin	PL 00240/0465	United Kingdom	Cherubino Ltd	Nil	Refused	There are alternative products available in the European Union. The requirements of Directive 642/2002 (to allow in the case of shortages/severe problems with availability) are not satisfied.	N/A

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
AA729/33302UK	Oilatum plus bath additive 63.4% w/w	Light liquid paraffin; Benzalkonium chloride; Triclosan	PL 00240/0462	United Kingdom	Cherubino Ltd	Nil	Refused	There are alternative products available in the European Union. The requirements of Directive 642/2002 (to allow in the case of shortages/severe problems with availability) are not satisfied.	N/A
AA729/33304UK	Oilatum (Adult & Junior) Cream 6 and 15 %w/w	Light liquid paraffin; White soft paraffin	PL 00240/0466	United Kingdom	Cherubino Ltd	Nil	Refused	There are alternative products available in the European Union. The requirements of Directive 642/2002 (to allow in the case of shortages/severe problems with availability) are not satisfied.	N/A
AA729/33901UK	Polytar Scalp Shampoo 4%w/w	Coal tar solution	PL 00240/0470	United Kingdom	Cherubino Ltd	Nil	Refused	There are alternative products available in the European Union. The requirements of Directive 642/2002 (to allow in the case of shortages/severe problems with availability) are not satisfied.	N/A
AA565/27706	Morphine HCl Sterop Solution for Inj 10mg/ml	Morphine hydrochloride	BE414346	Belgium	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1438/10801	Imodium Instant Melt Orodispersible Tablets 2mg	Loperamide hydrochloride	RVG 33724	The Netherlands	NM Pharma Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA565/50103UK	Hydrocortisone Tablets 10mg	Hydrocortisone	PL 28444/0155	United Kingdom	Central Procurement and Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A

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
AA729/33401UK	Dentinox Teething Gel 0.33/0.10 % w/w	Lidocaine hydrochloride BP; Cetylpyridinium chloride BP	PL 52731/0006	United Kingdom	Cherubino Ltd	Nil	Refused	There are alternative products available in the European Union. The requirements of Directive 642/2002 (to allow in the case of shortages/severe problems with availability) are not satisfied.	N/A
AA1353/00501	Morfina Cloridrato Monico Solution for Injection 10mg/1ml	Morphine hydrochloride trihydrate	030798 033	Italy	Monico spa	Nil	Accepted	To ensure continuation of supply for the National Health System	Commitment to undergo MRP
AA1454/02801	Levil Tablet, film coated 1000mg	Levetiracetam	OGYI-T-21821/04	Hungary	Prohealth	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1454/02802	Levil Tablet, film coated 500mg	Levetiracetam	OGYI-T-21821/02	Hungary	Prohealth	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1438/11301	Microlax Sorbitol Citrate And Sodium Laurylsulfoacetate Rectal Solution 4.4650g	70% Crystallisable sorbitol; Sodium citrate; Sodium laurylsulfoacetate	34009 349 687 5 4; 34009 306 747 6 5; 34009 349 688 1 5; 34009 562 072 4 4; 34009 551 871 8 9; 34009 365 710 82	France	NM Pharma Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1343/03901	Succicaptal Capsule 200mg	Succimer	34009 365 710 8 2	France	Target Healthcare Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA729/34501UK	Duofilm Solution for Injection 16.7 and 15 % w/w	Salicylic acid; Lactic acid	PL00240/0551	United Kingdom	Cherubino Ltd	Nil	Refused	There are alternative products available in the European Union. The requirements of Directive 642/2002 (to allow in the case of shortages/severe problems with availability) are not satisfied.	N/A

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
AA729/12904	Octreo-ratiopharm Powder And Solvent For Prolonged-Release 20 mg	Octreotide acetate	139155	Austria	Cherubino Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1330/04101	Tramadol hydrochloride Capsules Hard 50mg	Tramadol hydrochloride	PA2315/214/001	Ireland	Azure Pharmaceuticals Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA841/01501UK	Metronidazole Tablets 200mg	Metronidazole	PL 20416/0105	United Kingdom	Crescent Pharma Ltd.	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA950/00601	Sodium Chloride + Dextrose Solution for Infusion 0.9%+5%(w/v)	Sodium chloride; Dextrose (glucose) monohydrate	127597/14122018	Greece	VIOSER S.A.PARENTERAL SOLUTIONS INDUSTRY	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA242/01801UK	Baclofen Oral Solution 5mg/5ml	Baclofen	PL 20416/0193	United Kingdom	Pharmabart Ltd.	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/100701	Glucosteril Solution for Infusion 5%	Glucose monohydrate	6072666.00.00	Germany	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1438/11401	Dafalgan Codeine Tablets Effervescent 500mg/30mg	Paracetamol; Codeine phosphate hemihydrate	34009 333 167 78	France	NM Pharma Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1228/02501	Fosfomycin Vigapharma Sachet 3g	Fosfomycin	20-0104	Latvia	Focused Pharma Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1330/04001	Protizole Tablets Gastro-Resistant 20mg	Pantoprazole	PA2315/260/001	Ireland	Azure Pharmaceuticals Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A

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
AA1330/04002	Protizole Tablets Gastro-Resistant 40mg	Pantoprazole	PA2315/260/002	Ireland	Azure Pharmaceuticals Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1411/04001UK	Fluoxetine Oral Solution 20mg/5ml	Fluoxetine	PL 04917/0038	United Kingdom	EJ Busuttil Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1488/08301UK	Chloral Hydrate Oral Solution	Chloral hydrate	PL 23138/0021	United Kingdom	HHP Malta (P&D Pharma) Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/64103	Calcium folinate Normon Solution for Injection 50mg	Calcium folinate	70341, 662054	Spain	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/95104	Voriconazole Normon Pdr for Soln for Infusion 200mg	Voriconazole	80941 711115	Spain	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA521/09501	Risponse Tablet, film coated 0.5mg	Risperidone	PA0711/106/002	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
AA565/47902	Bleomycin Mylan Pdr+Solv for Soln for Inj 15,0000IU	Bleomycin	49313	Spain	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/35005UK	Phenobarbital Sodium Solution for Injection 30mg/ml	Phenobarbital sodium	PL 01883/6188R	United Kingdom	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1096/00408	T4 Tablets 75mcg	Levothyroxine sodium hydrate	8570/06-02-2007	Greece	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A

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
AA1411/04101	Benda-5 FU Solution for Injection 50mg/ml	Fluorouracil	55983.00.00	Germany	EJ Busuttil Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/24203UK	Lariam/Mefloquine Tablets 250mg	Mefloquine	PL 45043/0042	United Kingdom	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA729/05404UK	Dapsone Tablets 50mg	Dapsone	PL 11311/0575	United Kingdom	Cherubino Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA521/09601	Serlan Tablet, film coated 100mg	Sertraline	PA0711/065/002	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
AA521/09602	Serlan Tablet, film coated 50mg	Sertraline	PA0711/065/001	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
AA242/01901UK	Anastrozole Tablet, film coated 1mg	Anastrozole	PL 20416/0413	United Kingdom	Pharmabart Ltd.	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1330/03002	Clopidogrel Tablet, film coated 75mg	Clopidogrel	PA2315/198/001	Ireland	Azure Pharmaceuticals Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA727/00206	Utrogestan soft capsule 100 mg	Progesterone	361 986-9 or 34009 361 986 9 2; 323 275-1 or 34009 323 275 1 5; 323 276-8 or 34009 323 276 8 3; 358 767-8 or 34009	France	Besins Healthcare SA	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A

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
AA1173/08501	Tetracyclinum TZF Tablet, film coated 250mg	Tetracycline hydrochloride	R/3488	Poland	Mint Health Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA729/34101UK	Germolene Antiseptic Cream	Phenol; Chlorhexidine digluconate solution	PL00010/0263	United Kingdom	Cherubino Ltd	Nil	Refused	There are several alternative products available in Malta and the European Union. The requirements of Directive 642/2002 (to allow in the case of shortages/severe problems with availability) are not satisfied.	N/A
AA565/102401UK	CellCept Concentrate for Soln for Inf 500mg	Mycophenolate mofetil	PLGB 00031/0848	United Kingdom	Central Procurement& Supplies Unit	Nil	Refused	The product has a marketing authorisation	N/A
AA1411/04201UK	Ganciclovir Pdr/Conc/Soln for Infus 500mg	Ganciclovir	PL 44853/0001	United Kingdom	EJ Busuttil Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/37702	Carbomix Granules for Oral Suspension 50g	Charcoal	PA1418/007/001	Ireland	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/06505UK	Cyclizine Lactate Solution for Injection 50mg/ml	Cyclizine lactate	PL 20072/0010	United Kingdom	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/99401	Gemcit solution for infusion 38 mg/ml	Gemcitabine hydrochloride	5182803	Portugal	Central Procurement and Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1454/02901	Zoledronic Acid Hikma Concentrate for Soln for Inf 4mg/5ml	Zoledronic acid monohydrate	85419.00.00	Germany	Prohealth	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/102501	Keppra Tablet, film coated 250mg	Levetiracetam	EU/1/00/146/027	Netherlands	Central Procurement& Supplies Unit	Nil	Refused	The product has a marketing authorisation	N/A

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
AA1488/04202UK	Flucloxacillin Pdr for Soln for Infusion 2	Flucloxacillin	PL 29831/0091	United Kingdom	HHP Malta (P&D Pharma) Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA729/34401UK	Haldol Oral Solution 2mg/ml	Haloperidol	PL 00242/0035R	United Kingdom	Cherubino Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1438/11402	Dafalgan Codeine Tablet, film coated 500mg/30mg	Paracetamol/Codeine phosphate hemihydrate	34009 332 758 15	France	NM Pharma Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA242/02001UK	Ethambutol Tablets 400mg	Ethambutol Hydrochloride	PL 17509/0082	United Kingdom	Pharmabart Ltd.	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/78102	Uro-Tainer Chlorhexidine Solution for Bladder Irrigation 1000mL	Chlorhexidine diacetate	6727.00.00	Germany	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/27904UK	Phenol Solution for Injection 5%	Phenol	PL 01883/6153R	United Kingdom	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/41702UK	Atenolol Solution for Infusion 0.5mg	Atenolol	PL 43252/0041	United Kingdom	Central Procurement& Supplies Unit	Nil	Refused	The applicant already holds a licence for the same product	N/A
AA565/33505	Hypnomidate Solution for Injection 2mg/ml	Etomidate	319.00.00	Germany	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1411/04301UK	Menopur Pdr+Solv for Soln for Inj 150IU	Menotrophin	PL03194/0109	United Kingdom	EJ Busuttil Ltd	Nil	Accepted	To ensure continuity of supply given that there is a worldwide shortage for this active ingredient	N/A
AA908/27001	Rosuvastatin Rowa Tablet, film coated 5mg	Rosuvastatin	PA0074/093/001	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

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
AA908/27002	Rosuvastatin Rowa Tablet, film coated 10mg	Rosuvastatin	PA0074/093/002	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
AA1438/04202	Gaviscon Oral Suspension 500mg/267mg	Sodium alginate Sodium bicarbonate	3400936916258; 3400933095253; 3400936916319	France	NM Pharma Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1404/00702	Rifamazid Capsules Hard 300mg + 150mg	Rifampicin Isoniazid	R/0862	Poland	Tarchominskie Zaklady Farmaceutyczne Polfa S.A.	Nil	Accepted	To ensure continuation of supply for the National Health System	Commitment to undergo MRP
AA565/102701	Flucillin Capsule 250mg	Flucloxacillin sodium	PA0281/031/004	Ireland	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1161/02601	Aciclovir Arena Capsule 200mg	Micronized aciclovir	10147/2017/01-02	Romania	Farmarosib SRL	Nil	Accepted	To ensure continuation of supply for the National Health System	Commitment to undergo MRP
AA1161/02602	Aciclovir Arena Capsule 400mg	Micronized aciclovir	10148/2017/01	Romania	Farmarosib SRL	Nil	Accepted	To ensure continuation of supply for the National Health System	Commitment to undergo MRP
AA1330/04301	Nitrofurantoin Capsules Hard 50mg	Nitrofurantoin	PA22871/024/001	Ireland	Azure Pharmaceuticals Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	Commitment to undergo MRP
AA1330/04302	Nitrofurantoin Capsules Hard 100mg	Nitrofurantoin	PA22871/024/002	Ireland	Azure Pharmaceuticals Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	Commitment to undergo MRP
AA729/08005UK	Ondansetron Tablets 8mg	Ondansetron	PL 45841/0017	United Kingdom	Cherubino Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A

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
AA115/02503	Epibal Capsules Hard 75mg	Pregabalin	22807	Cyprus	Delorbis Pharmaceuticals Ltd.	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A
AA115/02504	Epibal Capsules Hard 150mg	Pregabalin	22808	Cyprus	Delorbis Pharmaceuticals Ltd.	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A
AA1513/02202	Minims Tropicamide Eye Drops Solution 0.5%	Tropicamide	PA23259/023/001	Ireland	Pharma Regulatory Services Limited	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1438/11701	Nexium Tablets Gastro-Resistant 20mg	Esomeprazole magnesium trihydrate	8423/2015/01	Romania	NM Pharma 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
AA1438/11702	Nexium Tablets Gastro-Resistant 40mg	Esomeprazole magnesium trihydrate	8424/2015/01	Romania	NM Pharma 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
AA1343/04001	Venlafaxine Bluefish Capsules Hard 75mg	Venlafaxine hydrochloride	26793	Sweden	Target Healthcare Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA770/13502UK	Finasteride Tablet, film coated 1mg	Finasteride	PL20075/0085	United Kingdom	JV Healthcare Limited	Nil	Refused	There are several alternative products available in Malta and the European Union. The requirements of Directive 642/2002 (to allow in the case of shortages are not satisfied.	N/A

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
AA1045/01107	Simtan Tablets 10mg	Simvastatin	PA0126/125/002	Ireland	Clonmel Healthcare Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1045/01108	Simtan Tablets 20mg	Simvastatin	PA0126/125/003	Ireland	Clonmel Healthcare Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1045/01109	Simtan Tablets 40mg	Simvastatin	PA0126/125/004	Ireland	Clonmel Healthcare Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA158/00503	Beclo-Asma Pressurised Inhalation Soln 50 micrograms	Beclomethasone dipropionate	81.667 : 714441	Spain	Laboratorio ALDO-UNION, S.L.	Nil	Accepted	To ensure continuation of supply for the National Health System	Commitment to undergo MRP
AA1330/01802	Omeprazole Teva Capsules Gastro-Resistant 20mg	Omeprazole	PA0749/160/002	Ireland	Azure Pharmaceuticals Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1174/00601	Aripiprazol Generis Oral Solution 1mg/mL	Aripiprazole	5775671	Portugal	Generis Farmaceutica S.A.	Nil	Accepted	To ensure continuation of supply for the National Health System	Commitment to undergo MRP
AA1454/03001	Milrinone Hikma Solution for Injection 1mg/ml	Milrinone Lactate	79469.00.00	Germany	Prohealth	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A

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
AA729/34301UK	Savlon Antiseptic Cream 0.5% & 0.1% w/w	Cetrimide; Chlorhexidine digluconate	PL00240/0469	United Kingdom	Cherubino Ltd	Nil	Refused	The product has a Marketing Authorisation in Malta and an authorisation in accordance with article 126a is not possible in line with the requirements of article 126a (1) of Directive 2001/83/EC.	N/A
AA288/03301	Cinet Oral Suspension 1mg/ml	Domperidone	9621706 & 9621714	Portugal	VJ Salomone Pharma LTD.	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/103201	Truxima Concentrate for Soln for Inf 100mg	Rituximab	45266020	Italy	Central Procurement& Supplies Unit	Yes	Refused	The product has a marketing authorisation	N/A
AA565/35305	Sufentanil Altan Solution for Injection 5micrograms/mL	Sufentanil	70.299,698251	Spain	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1411/04501	EMB-Fatol Tablet, film coated 400mg	Ethambutol Hydrochloride	6193016.01.00	Germany	EJ Busuttil Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA729/34601UK	Alfacalcidol Capsules, Soft 0.25mcg	Alfacalcidol	PL 13606/0217	United Kingdom	Cherubino Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA729/34701	Cinacalcet Generis Tablet, film coated 30mg	Cinacalcet	5773627	Portugal	Cherubino Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1411/04401	Tardocillin 1200 Suspension for Injection 4ml	Benzathine benzylpenicillin	6070615.00.00	Germany	EJ Busuttil Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA908/05903	Sopulmin Paediatric Suppositories 100mg	Sobrerol	25533187	Italy	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

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
AA908/05904	Sopulmin Syrup 40mg/5ml	Sobrerol	25533151	Italy	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
AA770/08705	Jext Solution for Injection 300mcg	Adrenaline	RVG 106309	Netherlands	JV Healthcare Limited	Nil	Accepted	To ensure continuity of supply given that there is a worldwide shortage for this active ingredient	N/A
AA841/01601UK	Amlodipine Tablets 5mg	Amlodipine besilate	PL20416/0586	United Kingdom	Crescent Pharma Ltd.	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA729/19602UK	Quinine Sulfate Tablets 300mg	Quinine sulfate	PL13606/0059	United Kingdom	Cherubino Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1348/00401	Amlodipin (besilat) Dexcel Tablets 10mg	Amlodipine Besilate	69715.00.00	Germany	Dexcel Pharma GmbH	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/12609	Magnesium Sulfate Cutaneous Paste 38.5%w/w	Magnesium sulfate	PA0484/021/001	Ireland	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA158/00402	Atroaldo Pressurised Inhalation Soln 20 microgram	Ipratropium bromide monohydrate	72581, 672312, 605412	Spain	Laboratorio Aldo-Union S.L.	Nil	Accepted	To ensure continuation of supply for the National Health System	Commitment to undergo MRP
AA1488/08401UK	Mycophenolate Mofetil Tillomed Capsule 250mg	Mycophenolate mofetil	PL 11311/0591	United Kingdom	HHP Malta (P&D Pharma) Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1488/08402UK	Mycophenolate Mofetil Tillomed Tablet, film coated 500mg	Mycophenolate mofetil	PL 11311/0551	United Kingdom	HHP Malta (P&D Pharma) Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1228/02601	Condyllox Solution 5mg/1ml	Podophyllotoxin	9692.00.00	Germany	Focused Pharma Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A

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
AA521/09701	Emazole Tablets Gastro-Resistant 20mg	Esomeprazole	PA0711/158/001	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
AA521/09702	Emazole Tablets Gastro-Resistant 40mg	Esomeprazole	PA0711/158/002	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
AA908/26203	Septolete omni Oromucosal Spray, Soln 1.5mg/ml+5.0mg/ml	Benzydamine hydrochloride; Cetylpyridinium chloride	13684/2021/01	Romania	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
AA1541/00101	BLEO-cell Pdr for Soln for Injection 7.5-10 mg	Bleomycin sulphate	46095.00.00	Germany	Stadapharm GmbH	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1021/00601	Gemcitabine Pdr for Soln for Infusion 1000mg	Gemcitabine hydrochloride	5347968	Portugal	Venus Pharma GmbH	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA908/26701	Gliclazide Retard Mylan Tablet Prolonged Release 80mg	Gliclazide	RVG 26307	Netherlands	Neofarma Pharmaceuticals Limited	Nil	Accepted	To market an alternative product which is authorised in the EEA and to replace a product which was previously sourced from the UK	N/A
AA565/35602UK	Betaloc Solution for Injection 1mg/ml	Metoprolol tartrate	PL 30883/0007	United Kingdom	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/36602UK	Dispersible Aspirin Tablets 300mg	Aspirin	PL 08977/0003	United Kingdom	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A

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
AA1289/00102	Sarcop Cream 50mg/g	Permethrin	62971	Portugal	UNIPHARMA, S.A.	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA770/14102	Duloxetine Accord Capsules Gastro-Resistant 60mg	Duloxetine	PA2315/268/002	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
AA729/07802UK	Sotalol Hydrochloride Tablets 80mg	Sotalol hydrochloride	PL11311/0071	United Kingdom	Cherubino Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1488/08501UK	Diamox Pdr for Soln for Injection 500mg	Acetazolamide	PL 12762/0146	United Kingdom	HHP Malta (P&D Pharma) Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA770/18901	Cerubidine Pdr+Solv for Soln for Inj 20mg	Daunorubicin	RVG 05633	Netherlands	JV Healthcare Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA729/34801	Aldobronquial Syrup 2mg/5ml	Salbutamol	54578		Cherubino Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA565/36909	Sodium Chloride Solution for Infusion 0.9%	Sodium Chloride	33671/18-05-2007	Greece	Central Procurement& Supplies Unit	Yes	Refused	The product has a marketing authorisation	N/A
AA729/34901	Thiola Tablet, film coated 250mg	Tiopronin	2206044.00.00	Germany	Cherubino Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/50104UK	Hydrocortisone Tablets 10mg	Hydrocortisone	PL 52104/0020	United Kingdom	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA115/02603	Tripan Tablet, film coated 20mg	Tadalafil	22616	Cyprus	Delorbis Pharmaceuticals Ltd	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	Commitment to undergo MRP

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
AA565/103701UK	Micalax Micro Enema 0.90/9.0% w/v	Sodium alkylsulphoacetate; Sodium citrate	PL 36301/0019	United Kingdom	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1207/01001	Rocuronium bromide Solution for Inj/Inf 10mg/ml	Rocuronium bromide	PA2165/004/001	Ireland	AS Kalceks	Nil	Accepted	To ensure continuation of supply for the National Health System	Commitment to undergo MRP
AA729/04703	Stesolid Rectal Solution 5mg/2.5ml	Diazepam	8643544	Portugal	Cherubino Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA979/00701	Carplexil Cream 10mg/g	Hydrocortisone	5182910	Portugal	Laboratorios Basi -Industria Farmaceutica, SA	Nil	Accepted	To ensure continuation of supply for the National Health System	Commitment to undergo MRP
AA154/05605UK	Flucloxacillin Pdr for Soln Inj/Inf 1g	Sodium flucloxacillin monohydrate	PL 29831/0093	United Kingdom	Wockhardt UK Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA908/27101	Hirudoid Gel 300mg/100g	Mucopolysaccharide polysulfate	14.83	Austria	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
AA1330/01002	Ciprofloxacin Teva Tablet, film coated 500mg	Ciprofloxacin	PA0749/031/003	Ireland	Azure 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
AA729/20203UK	Erythromycin BP Tablets 250mg	Erythromycin	PL 13606/0016	United Kingdom	Cherubino Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1411/04601	Lipiodol Ultra Fluide Solution for Injection 480mg/ml	Iodine content	34009 306 216 08	France	Central Procurement& Supplies Unit	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A

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
AA1228/02701	Gyno-Daktarin Vaginal Cream 20mg/g	Miconazole nitrate	BE 000987	Belgium	Focused Pharma Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA979/00801	Broncosil Syrup 3mg/ml	Ambroxol hydrochloride	5752035, 5751870, 5752019, 5751854,5752027,5751862	Portugal	Laboratorios Basi -Industria Farmaceutica, SA	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	Commitment to undergo MRP
AA1207/01101	Molnex Solution for Injection 20mg/ml	Morphine hydrochloride	RVG 129849	Netherlands	AS KALCEKS	Nil	Accepted	To ensure continuation of supply for the National Health System	Commitment to undergo MRP
AA1096/00310	APOTEL espresso aroma Granules 1000mg	Paracetamol	57970/28-06-2021	Greece	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A	Nil	Accepted	No authorised products are available, marketed or offered on tender	Commitment to undergo MRP
AA1544/00101	Kopaq Solution for Injection 350mg/ml	Iohexol	20190137	Bulgaria	Onko PharmaceuticalsBulgaria LTD	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	Commitment to undergo MRP
AA770/03403UK	Fentanyl Solution for Injection 50mcg/ml	Fentanyl	PL01502/0062	United Kingdom	JV Healthcare Limited	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1360/00301	Magnesium sulphate Concentrate for Soln for Inf 2g/10ml	Magnesium sulphate heptahydrate	030797 029	Italy	PAC3 Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/31607UK	Quinine Sulfate Tablets 300mg	Quinine sulfate	PL13606/0059	United Kingdom	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA729/35101	Dysurgal Tablets 0.5mg	Atropine sulphate	5899.99.99	Germany	Cherubino Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A

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
AA117/00704	Tetralysal Capsule 300mg	Lymecycline	PA22743/016/001	Ireland	Galderma International	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA729/35201	Claversal Rectal Foam 1g	Mesalazine	61.335	Spain	Cherubino Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA979/00901	Saline Solution Basi Solution for Infusion 9mg/ml	Sodium chloride	5775101	Portugal	Laboratorios Basi -Industria Farmaceutica, SA	Nil	Accepted	To ensure continuation of supply for the National Health System	Commitment to undergo MRP
AA1343/00502UK	Bendroflumethiazide Tablets 2.5mg	Bendroflumethiazide	PL 00142/0380	United Kingdom	Target Healthcare Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA729/35001	Water for Injection DeltaMedica Solvent for Parenteral Use	Water for injections	2559.99.99	Germany	Cherubino Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1161/00402	Amitriptilina Arena Tablet, film coated 25mg	Amitriptyline hydrochloride	13252/2020/01	Romania	Farmarosib SRL	Nil	Accepted	To ensure continuation of supply for the National Health System	Commitment to undergo MRP
AA841/00103UK	Fennings Paracetamol Oral Suspension 120mg/5ml	Paracetamol	PL 20416/0523	United Kingdom	Crescent Pharma Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA774/00202	Tosidrin Oral Drops Solution 10mg/ml	Dihydrocodeine bitartrate	30982	Spain	Laboratorio de Aplicaciones Farmacodinamicas S.A	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	Commitment to undergo MRP
AA1488/08601UK	Valoid / Cyclizine Lactate Solution for Injection 50mg	Cyclizine lactate	PL 20072/0010	United Kingdom	HHP Malta (P&D Pharma) Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A

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
AA1330/01302	Citalopram Teva Tablet, film coated 20mg	Citalopram	PA0749/019/002	Ireland	Azure Pharmaceuticals Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1343/04201	Clotrimazolum Hasco Cream 10mg/g	Clotrimazole	10823	Poland	Target Healthcare Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/103801	Maracex Solution for Inj/Inf 20mg/ml	Morphine hydrochloride	24750	Latvia	Central Procurement& Supplies Unit	Nil	Refused	The product has a marketing authorisation	N/A
AA770/02302UK	Flumazenil Solution for Inj/Inf 500mcg	Flumazenil	PL 01502/0128	United Kingdom	JV Healthcare Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA729/35301UK	Tensipine Tablet, film coated 10mg	Nifedipine	PL06831/0048	United Kingdom	Cherubino Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/65502UK	Uniphyllin Continus Tablet Prolonged Release 200mg	Theophylline	PL 40739/0328	United Kingdom	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA242/02101UK	Montelukast Tablet, film coated 10mg	Montelukast	PL 17907/0474	United Kingdom	Pharmabart Ltd.	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA908/11403	Azithromycin Sandoz Tablet, film coated 500mg	Azithromycin	10655/2018/01	Romania	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
AA1349/01401	Deratin Complex Honey and Lemon Lozenges 5mg/4mg/3mg	Chlorhexidine dihydrochloride; Benzocaine; Enoxolone	79996 706956	Spain	Laboratorios Normon S.A	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	Commitment to undergo MRP

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
AA1349/01402	Deratin Complex Mint Flavour Lozenges 5mg/4mg/3mg	Chlorhexidine dihydrochloride; Benzocaine; Enoxolone	79995 706957	Spain	Laboratorios Normon S.A	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	Commitment to undergo MRP
AA1454/03301	Teicoplanin Sala Pdr for Soln Inj/Inf 200mg	Teicoplanin	78750: 607118	Spain	Prohealth	Yes	Accepted	To ensure continuation of supply for the National Health System	N/A
AA770/19201UK	Liothyronine Sodium Pdr for Soln for Injection 20mcg	Liothyronine sodium	PL 12762/0176	United Kingdom	JV Healthcare Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/26310	Ventolin Solution 5mg/ml	Salbutamol sulfate	14/219/72-C	Czech Republic	Central Procurement& Supplies Unit	Nil	Refused	The product has a marketing authorisation	N/A
AA1161/00502	Omeprazol Arena Capsules Gastro-Resistant 20mg	Omeprazole	591/2008/01-06	Romania	Farmarosib SRL	Nil	Accepted	To ensure continuation of supply for the National Health System	Commitment to undergo MRP
AA1454/03101	Ribodoxo Solution for Injection 2mg/ml	Doxorubicin hydrochloride	24959.00.00	Germany	Prohealth	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA774/00303	Algidrin Powder for Oral Suspension 600mg	Ibuprofen lysine	63196	Spain	Laboratorio de AplicacionesFarmacodinamicas S.A	Nil	Accepted	To ensure continuation of supply for the National Health System	Commitment to undergo MRP
AA1454/03201	Tadalafil Farnoz Tablet, film coated 5mg	Tadalafil	5739651	Portugal	Prohealth	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1528/00201	Pethisom Solution for Injection 100mg/2ml	Pethidine hydrochloride	BE489653	Belgium	Laboratoires Sterop NV	Nil	Accepted	To ensure continuation of supply for the National Health System	Commitment to undergo MRP
AA565/21602UK	Slow Sodium Tablet, film coated 600mg	Sodium chloride	PL44490/0004	United Kingdom	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/46402UK	Captopril Tablets 25mg	Captopril	PL 20075/0309	United Kingdom	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A

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
AA770/03304UK	Morphine Sulfate Solution for Injection 10mg/ml	Morphine sulfate	PL01502/0063	United Kingdom	JV Healthcare Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1504/00901	Arpoya Tablets 5mg	Aripiprazole	92906.00.00	Germany	Torrent Pharma (Malta) Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	Commitment to undergo MRP
AA1343/04301	Haloperidol-Richter Tablets 1.5mg	Haloperidol	LT/1/94/0737/001	Lituhuania	Target Healthcare Limited	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA770/08706	Jext Solution for Injection 150mcg	Adrenaline	RVG 106307	Netherlands	JV Healthcare Limited	Nil	Accepted	To ensure continuity of supply given that there is a worldwide shortage for this active ingredient	N/A
AA639/00802	Cystopurin Granules for Oral Solutions 3g	Potassium citrate	PA 1410/42/1	Ireland	Bayer Limited	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	Commitment to undergo MRP
AA908/27201	Panadol Cold & Flu & Cough Capsules Hard 500mg/6.1mg/100mg	Paracetamol; Phenylephrine hydrochloride; Guaifenesin	73752/14/3-10-2016	Greece	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
AA565/10203UK	Aspirin Tablets Dispersible 300mg	Aspirin		United Kingdom	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1411/04701UK	Isoniazid Solution for Injection 50mg/2ml	Isoniazid	PL 16853/0109	United Kingdom	EJ Busuttil Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA908/08102	Optrex Clear Eyes Eye Drops Solution 12.5%v/v + 0.01%w/v	Hamamelis water (distilled witch hazel); Naphazoline hydrochloride	PA 979/79/1	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

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
AA242/02201	Enema Flex Phosphates Rectal Solution (16+6)g/100ml	Sodium dihydrogen phosphate dihydrate; Disodium hydrogen phosphate dodecahydrate	107284/12-11-21	Greece	Pharmabart Ltd.	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA242/02301UK	Doxazosin Tablets 4mg	Doxazosin mesylate	PL 17907/0257	United Kingdom	Pharmabart Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA521/03604	Allopurinol Teva Tablets 300mg	Allopurinol	PA0749/099/003	Ireland	Medicem Limited	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A
AA1343/04401	Mastical Tablets Chewable 500mg	Calcium carbonate	58.828	Spain	Target Healthcare Limited	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1122/01102	Diclac Suppositories 100mg	Diclofenac Sodium	PA0711/009/009	Ireland	Rowex Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	Commitment to undergo MRP
AA1528/00301	Magnesium Sulfate Sterop Concentrate for Soln for Inf 2g/10ml	Magnesium sulfate heptahydrate	BE259287	Belgium	Laboratoires Sterop NV	Nil	Accepted	No authorised products are available, marketed or offered on tender	Commitment to undergo MRP
AA1343/04601	Ivercare EFG Tablets 3mg	Ivermectin	86297	Spain	Target Healthcare Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA770/19701UK	Metronidazole Solution for Infusion 500mg/100ml	Metronidazole	PL 24598/0052	United Kingdom	JV Healthcare Limited	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A

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
AA1411/04801	Salbutamol Renaudin Solution for Injection 5mg/5ml	Salbutamol	34009 570 262 33	France	EJ Busuttil Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1513/02701	Paclitaxel Concentrate for Soln for Inf 6mg/ml	Paclitaxel	LT/1/10/2115/002	Lituhuania	Pharma Regulatory Services Limited	Nil	Accepted	To ensure continuation of supply	N/A
AA1343/04501UK	Lacosamide Glenmark Tablet, film coated 100mg	Lacosamide	PL 25258/0326	United Kingdom	Target Healthcare Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/00207UK	Warfarin Tablets 3mg	Warfarin sodium	PL00289/1628	United Kingdom	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1513/02301	Adcortyl Intra-articular/Intradermal Injection Suspension for Injection 10mg/ml	Triamcinolone acetonide	PA0002/018/003	Ireland	Pharma Regulatory Services Limited	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA770/19801	Corgard Tablets 80mg	Nadolol	34009 347 832 89	France	JV Healthcare Limited	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1513/02501	Kenalog (Triamcinolone acetonide) Suspension for Injection 40mg/ml	Triamcinolone acetonide	OGYI-T-01198/01	Hungary	Pharma Regulatory Services Limited	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1349/01601	Mirtazapine Flas Normogen Orodispersible Tablet 15mg	Mirtazapine	84115	Spain	Laboratorios Normon S.A	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	Commitment to undergo MRP
AA1349/01602	Mirtazapine Flas Normogen Orodispersible Tablet 30mg	Mirtazapine	84116	Spain	Laboratorios Normon S.A	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	Commitment to undergo MRP

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AA729/33601UK	Care Codeine Oral Solution 15mg/5ml	Codeine phosphate	PL 00240/0099	United Kingdom	Cherubino Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1411/04901	Aprepitant Mylan Capsules Hard 125mg/80mg	Aprepitant	24420	Poland	EJ Busuttil Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/91103	Omnipaque Solution for Injection 300mg/ml	Iohexol	50543/09/8-2-10	Greece	Central Procurement& Supplies Unit	Nil	Refused	The product has a marketing authorisation	N/A
AA242/02401UK	Carvedilol Tablets 6.25mg	Carvedilol	PL 17907/0098	United Kingdom	Pharmabart Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/105401UK	Ilube Eye Drops Solution 5%w/v	Acetylcysteine	PL47069/0002	United Kingdom	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1511/01001	Oxaliplatin Kelix bio Concentrate for Soln for Inf 5mg/ml	Oxaliplatin	90004.00.00	Germany	Kelix bio (Malta) Limited	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	Commitment to undergo MRP
AA565/06304UK	Itraconazole Oral Solution 10mg	Itraconazole	PL39307/0069	United Kingdom	Central Procurement& Supplies Unit	Nil	Refused	The product has a marketing authorisation	N/A
AA565/66607	Atomoxetine Accord Capsules Hard 25mg	Atomoxetine hydrochloride	RVG 121659	Netherlands	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1438/11801	Prosinus Tablet, film coated 500mg/30mg	Paracetamol; Pseudoephedrine hydrochloride	11792/2019/01-02	Romania	NM Pharma Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1501/01101UK	Prednisolone Tablets Gastro-Resistant 5mg	Prednisolone	PL 20416/0412	United Kingdom	Smartway Pharmaceuticals Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA729/35401UK	Fluconazole Capsule 150mg	Fluconazole	PL 00289/0485	United Kingdom	Cherubino Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A

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AA1438/11501	Lemsip Powder for Oral Solution 500mg	Paracetamol	BE352502	Belgium	NM Pharma Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1234/00301	Prelocoril Tablets for Oral Solution 20mg	Prednisolone sodium phosphate	65901/16-6-2022	Greece	S.J.A Pharm Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	Commitment to undergo MRP
AA1234/00302	Prelocortil Tablets for Oral Solution 5mg	Prednisolone sodium phosphate	65900/16-6-2022	Greece	S.J.A Pharm Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	Commitment to undergo MRP
AA1177/00505	Panadol Advance Tablet, film coated 500mg	Paracetamol	21168	Cyprus	Haleon Hellas	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	Commitment to undergo MRP
AA978/00401	Dexaris Nasal Spray Suspension (0.2028+0.5)mg/ml	Dexamethasone isonicotinate; Oxymetazoline hydrochloride	79944/20/08-02-2	Greece	Galenica SA	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	Commitment to undergo MRP
AA1177/00506	Panadol Extra Advance Tablet, film coated 500mg/65mg	Paracetamol; Caffeine	22031	Greece	Haleon Hellas	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	Commitment to undergo MRP
AA908/27301	Pantoprazole Teva Tablet, film coated 20mg	Pantoprazole	RVG 104919	Netherlands	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

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AA084/10003	Clonotril Tablets 0.5mg	Clonazepam	9144	Cyprus	Remedica Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	Commitment to undergo MRP
AA770/19901UK	Dukoral suspension and effervescent Powder for Oral Solution 3ml	Recombinant cholera toxin B subunit; Vibrio cholerae 01	PL 46066/0001	United Kingdom	JV Healthcare Limited	Nil	Refused	The product has a marketing authorisation	N/A
AA1438/11901	Acyclovir Fiterman Cream 50mg/g	Aciclovir	11898/2019/01-02	Romania	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
AA1500/00501	Lenalidomida Generis Capsules Hard 15mg	Lenalidomide	5824479	Portugal	Eugia Pharma (Malta) Limited	Nil	Accpted	To ensure continuation of supply for the National Health System	N/A
AA979/00501	Toceliv Syrup 2mg/ml	Dextromethorphan hydrobromide	5704234	Portugal	Laboratorios Basi -Industria Farmaceutica, SA	Nil	Accpted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	Commitment to undergo MRP
AA770/19301	Zolmitriptan Sandoz Orodispersible Tablet 2.5mg	Zolmitriptan	RVG 106554	Netherlands	JV Healthcare Limited	Nil	Accpted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A
AA565/34303	Cytotec Tablets 200micrograms	Misoprostol	40410/07/1952008	Ireland	Central Procurement& Supplies Unit	Nil	Accpted	To ensure continuation of supply for the National Health System	N/A
AA288/03601UK	Norethisterone Tablets 5mg	Norethisterone	PL29831/0152	United Kingdom	VJ Salomone Pharma LTD.	Nil	Accpted	To ensure continuation of supply for the National Health System	N/A
AA729/20802	Adenosine Altamedics Solution for Infusion 30mg/10ml	Adenosine	82188.00.00	Germany	Cherubino Ltd	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A
AA283/00501	Estreva Gel 0.1%	Estradiol hemihydrate	NL20619	France	VIVIAN CORPORATION LTD.	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	Commitment to undergo MRP

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
AA032/07203	Vacontil Capsules Hard 2mg	Loperamide	8524	Cyprus	Medochemie Ltd.	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1291/00205	Nitrong Transdermal Patch 5mg/24hrs	Nitroglycerin	40044/10	Greece	LAVIPHARM HELLAS S.A.	Nil	Accepted	To ensure continuation of supply for the National Health System	Commitment to undergo MRP
AA1291/00206	Nitrong Transdermal Patch 10mg/24hrs	Nitroglycerin	40047/10	Greece	LAVIPHARM HELLAS S.A.	Nil	Accepted	To ensure continuation of supply for the National Health System	Commitment to undergo MRP