

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
AA072/00902	Parotycin EA. SOL. Ear Drops Solution 1+1.3+50mg/ml	Fludrocortisone acetate; Polymyxin B sulfate equivalent to Polymyxin B; Lidocaine hydrochloride	660781412052015	Greece	ADELCO-CHROMATOURGIA ATHINONE. COLOCOTRONIS BROS S.A.	Nil	Accepted	No authorised products are available, marketed or offered on tender	To undergo an MRP
AA1343/03001UK	Venlasov XL Capsules Hard 75mg	Venlafaxine hydrochloride	PL 06464/2656	United Kingdom	Target Healthcare Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1501/00501UK	Benzylpenicillin benzathine Pdr+Solv for Susp for Inj 1.2 Million I.U	Benzylpenicillin benzathine	PL 41542/0006	United Kingdom	Smartway Pharmaceuticals Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1349/00502	Montelukast Normon Tablet, film coated 10mg	Sodium montelukast	75844	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	N/A
AA115/03002	Statezol Tablet, film coated 10mg/10mg	Rosuvastatin calcium; Ezetimibe	23578	Cyprus	Delorbis Pharmaceuticals Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	To undergo an MRP
AA115/03001	Statezol Tablet, film coated 5mg/10mg	Rosuvastatin calcium; Ezetimibe	23577	Cyprus	Delorbis Pharmaceuticals Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	To undergo an MRP
AA1228/02001	Normix Tablets 200mg	Rifaximin	12333/2019/01-04	Romania	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
AA565/92501	Streptomycin Sulphate Reig Jofré Solution for Injection 1gram	Streptomycin	16129: 604660; 700711	Spain	Central Procurement& Supplies Unit	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA188/02601	Lemoxol Pdr for Soln Inj/Inf 1g	Ceftazidime	40884/09/10	Greece	Demo SA Pharmaceutical Industry	Nil	Accepted	No authorised products are available, marketed or offered on tender	To undergo an MRP

AA1096/00304	Apotel Suppositories 125mg	Paracetamol	77792/04-11-2009	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	To undergo an MRP
AA154/02802UK	Sulfadiazine Tablets 500mg	Sulfadiazine	PL 29831/0191	United Kingdom	Wockhardt UK Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA084/05702	Methotrexate Tablet, film coated 2.5mg	Methotrexate	9132	Cyprus	Remedica Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	To undergo an MRP
AA565/93501	Vitalipid Adult Emulsion for Infusion	Ergocalciferol; Phytomenadione; Vitamin A; Alpha-tocopherol	OGYI-T-4309/01	Sweden	Central Procurement& Supplies Unit	Nil	Refused	The product has a marketing authorisation	N/A
AA1411/01601	Deferasirox beta Tablet, film coated 180mg	Deferasirox	2203830.00.00	Germany	EJ Busuttil Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA729/30301	Chloramphenicol VUAB Pdr for Soln for Injection 1g	Chloramphenicol	15/125/10-C	Czech Republic	Cherubino Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1454/02001	Carboplatin Hikma Solution for Infusion 10mg/ml	Carboplatin	3002152.00.00	Germany	Prohealth	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA729/30201	Fucidine Tablet, film coated 250mg	Sodium fusidate	39143	Spain	Cherubino Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA908/11402	Azithromycin Aurobindo Tablet, film coated 500mg	Azithromycin	RVG 117670	Netherlands	Neofarma Pharmaceuticals Limited	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A
AA908/19703	Duloxetine Capsules Hard 30mg	Duloxetine	PA1347/051/002	Ireland	Neofarma Pharmaceuticals Limited	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A

AA908/19704	Duloxetine Capsules Hard 60mg	Duloxetine	PA1347/051/004	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
AA565/93701UK	Physeptone/Methadone Hydrochloride Tablets 5mg	Methadone Hydrochloride	PL 01883/0062	United Kingdom	Central Procurement& Supplies Unit	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1488/03801UK	Nozinan Solution for Inj/Inf 25mg/ml	Levomepromazine hydrochloride	PL 04425/0659	United Kingdom	HHP Malta (P&D Pharma) Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA565/93102	Medaxone Pdr for Soln Inj/Inf 1g	Ceftriaxone sodium	5761168	Cyprus	Central Procurement& Supplies Unit	Nil	Refused	The product has a marketing authorisation	N/A
AA1488/06101UK	Aciclovir Oral Suspension 200mg/5ml	Aciclovir	PL 39307/0034	United Kingdom	HHP Malta (P&D Pharma) Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA908/06503	Imodium Instant Tablets 2mg	Loperamide hydrochloride	9091	Poland	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
AA1411/02101UK	Labetalol Tablet, film coated 100mg	Labetalol	PL 11311/0375	United Kingdom	EJ Busuttil Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1411/02102UK	Labetalol Tablet, film coated 200mg	Labetalol	PL 11311/03760002	United Kingdom	EJ Busuttil Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A