

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
AA1411/00301	Arthrocline Tablets 200mg	Sulindac	3400931906568	France	EJ Busuttil Ltd	N/A	Accepted	There are two or less different authorised products on the market with the same active ingredient, dose and strength	N/A
AA729/27502	Palexia Tablet Prolonged Release 50mg	Tapentadol	PA2242/12/4	Ireland	Cherubino Ltd	N/A	Accepted	There are two or less different authorised products on the market with the same active ingredient, dose and strength	N/A
AA565/16505	Octreotide Teva Pdr+Solv for Susp for Inj 10mg	Octreotide	LT/1/19/4418/001	Netherlands	Central Procurement & Supplies Unit	N/A	Accepted	No authorised products are available, marketed or offered on tender	N/A

AA1228/01401	NurofenBaby 10 Supp 60mg	Ibuprofen	A.I.C. 041536020	Italy	Focused Pharma Ltd	N/A	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA770/14801	Candesartan Tablets 16mg	Candesartan cilexetil	PA2315/150/003	Ireland	JV Healthcare Limited	N/A	Accepted	There are two or less different authorised products on the market with the same active ingredient, dose and strength	N/A
AA729/27601	Varlota Tablet, film coated 100mg	Erlotinib	LT/1/16/3981/002	Lituhuania	Cherubino Ltd	N/A	Accepted	There are two or less different authorised products on the market with the same active ingredient, dose and strength	N/A

AA729/27602	Varlota Tablet, film coated 150mg	Erlotinib	LT/1/16/3981/003	Lituhuania	Cherubino Ltd	N/A	Accepted	There are two or less different authorised products on the market with the same active ingredient, dose and strength	N/A
AA565/85001	Floxapen Powder for Oral Solution 125mg/5ml	Flucloxacillin	RVG 14314	Netherlands	Central Procurement & Supplies Unit	N/A	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA729/28201	Epanutin Oral Drops Suspension 30mg/5ml	Phenytoin	42521 / 25-09-20	Greece	Cherubino Ltd	N/A	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA565/85101	Flucloxacilline Fresenius Kabi Pdr for Soln Inj/Inf 1000mg	Flucloxacillin	RVG124821	NL	Central Procurement & Supplies Unit	N/A	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA565/84301	Zyrolen Solution for Inhalation 250mcg/2mL	Ipratropium bromide	20941/13, 27447/23- 4-2008	Greece	Central Procurement & Supplies Unit	N/A	Accepted	No authorised products are available, marketed or offered on tender	N/A

AA565/64803	Posaconazole Mylan Oral Suspension 40mg/ml	Posaconazole	5769229	Portugal	Central Procurement & Supplies Unit	N/A	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA729/28501	DTPA Solution for Injection 9mg	Diethylenetriami no Pentaacetic Acid	OGYI-T-9244/01	Hungary	Cherubino Ltd	N/A	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1161/02201	Levofloxacin Arena Tablet, film coated 500mg	Levofloxacin	12188/2019/01-02	Romania	Farmarosib SRL	N/A	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1122/02901	Isotretinoin Capsules, Soft 10mg	Isotretinoin	PA0711/312/002	Ireland	Rowex Ltd	N/A	Accepted	There are two or less different authorised products on the market with the same active ingredient, dose and strength	Licence issued for 1 year to undergo an MRP

AA1122/02902	Isotretinoin Capsules, Soft 20mg	Isotretinoin	PA0711/312/003	Ireland	Rowex Ltd	N/A	Accepted	There are two or less different authorised products on the market with the same active ingredient, dose and strength	Licence issued for 1 year to undergo an MRP
--------------	--	--------------	----------------	---------	-----------	-----	----------	---	---