

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
AA1228/03301	Tussidex Capsules, Soft 30mg	DEXTROMETHORPHAN HYDROBROMIDE	9551	Poland	Focused Pharma Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1513/03501	Fulcin Tablets 125mg	Griseofulvin	AIC 016762015	Italy	Pharma Regulatory Services Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/77703	Ganciclovir Rompharm Concentrate for Soln for Inf 500mg	Ganciclovir	14152/2021/01, 14152/2021/02	Romania	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA908/09813	Amaryl Tablets 1mg	Glimepiride	2415/2010/01-12	Romania	NEOFARMA PHARMACEUTICALS LTD	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA908/09814	Amaryl Tablets 2mg	Glimepiride	2416/2010/01-11	Romania	NEOFARMA PHARMACEUTICALS LTD	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA908/09815	Amaryl Tablets 4mg	Glimepiride	2418/2010/01-11	Romania	NEOFARMA PHARMACEUTICALS LTD	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA242/03501	Bromhexin DAK Oral Solution 0,8mg/ml	Bromhexine hydrochloride	10332	Denmark	Pharmabart Ltd.	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA729/28002	Viamal Trauma Gel 100mg/03.68mg/2mg	Diethylamine salicylate,Heparin sodium,Menthol	25208024	Italy	Cherubino Ltd	Nil	Accepted	there are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA908/14905	Flucloxacilline Mylan Capsule 500mg	Flucloxacillin sodium	RVG 10928	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

AA565/72702	Durogesic Transdermal Patch 25 mcg	Fentanyl	83556/17/08.04.2019	Greece	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/109801	Solidon Tablet, film coated 100mg	Chlorpromazine	7513/18/3012019	Greece	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA908/10905	Enalapril Maleate Teva Tablets 5mg	Enalapril maleate	RVG 25289	Netherlands	NEOFARMA PHARMACEUTICALS LTD	Nil	Accepted	there are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA908/10906	Enalapril Maleate Teva Tablets 20mg	Enalapril maleate	RVG 25291	Netherlands	NEOFARMA PHARMACEUTICALS LTD	Nil	Accepted	there are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA565/99602	Carnicor Solution for Injection 200mg/ml	L-carnitine	55334	Spain	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/83201	Argatra Multidose Concentrate for Soln for Inf 100mg/ml	Argatroban	81323.00.00	Ireland	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/49512	Budesonida Aldo-Union Nebulise Solution 0.25mg/ml	Budesonide	66.943 / 651628.7	Spain	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1570/00101	Antalerg Eye Drops Solution 0.05%	azelastine hydrochloride	64/0133/01-S	Slovakia	UNIMED PHARMA, spol. s r.o.	Nil	Accepted	there are fewer than three authorised products on the market with the same active ingredient, dose and strength	To undergo MRP
AA565/109701	Norepine Concentrate for Soln for Inf 1mg/ml	Noradrenaline	BE357244	Belgium	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA521/07503	Solpadol Caplets Tablets 500mg/30mg	Paracetamol, Codeine phosphate hemihydrate	PA1113/027/001	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