

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
AA950/00203	LACTATED RINGER'S INJECTION/VIOSER Solution for Infusion	Sodium Chloride Potassium Chloride Calcium Chloride dihydrate Sodium Lactate solution 50%	20047/17/17-12-2018	Greece	VIOSER S.A.PARENTERAL SOLUTIONS INDUSTRY	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	To undergo MRP
AA729/18703	Atropine Sulfate Solution for Injection 0.1mg/ml	Atropine sulfate monohydrate	34009 276 658 0 6	France	Cherubino Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/29303	Rythmodan Capsule 100mg	Disopyramide	BE248202	Belgium	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/75702	Lantanon Tablet, film coated 30mg	Mianserin HCl	AIC 023695036	Italy	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1404/00203	Clonazepamum TZF Tablets 0.5mg	Clonazepam	R/1356	Poland	Tarchominskie Zakłady Farmaceutyczne Polfa S.A.	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	To undergo MRP
AA1404/00204	Clonazepamum TZF Tablets 2mg	Clonazepam	R/1355	Poland	Tarchominskie Zakłady Farmaceutyczne Polfa S.A.	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	To undergo MRP
AA1411/11501	Normix Tablet, film coated 200mg	Rifaximin	25300029	Italy	EJ Busuttil Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1330/05301	Nasusaf Nasal Spray Suspension 137mcg/50mcg	Azelastine hydrochloride Fluticasone propionate	PA1986/109/001	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
AA729/23803	Topigel Gel 200mg/g	Benzocaine	5368659; 5229182; 5229281	Spain	Cherubino Ltd	Nil	Accepted	There are no other authorised products for this active substance in the same strength or pharmaceutical form	N/A

AA041/00403	Rowatinex soft Capsules Gastro-Resistant	Pinene, Camphene, Cineole, Fenchone, Borneol, Anethol	PA0074/009/001	Ireland	ROWA PHARMACEUTICAL S LTD	Nil	Accepted	No authorised products are available, marketed or offered on tender	To undergo MRP
AA729/40101	Etalpa Oral Drops Solution 2mcg/ml	Alfacalcidol	55.906: 761908	Spain	Cherubino Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1404/00402	Rifampicina TZF Capsule 300mg	Rifampicin	R/0849	Poland	Tarchominskie Zakłady Farmaceutyczne	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA1411/12201	Brinzolamide Eye Drops Suspension 10mg/ml	Brinzolamide	PA2315/149/001	Ireland	EJ Busuttil Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/121901	Dermovate Cutaneous Solution 0.5mg/g	Clobetasol propionate	8463901	Portugal	Central Procurement & Supplies Unit	Nil	Rejected	The product is already authorised in Malta	N/A
AA274/01802	Septrin Adult Oral Suspension 80mg/400mg/5ml	Trimethoprim Sulfamethoxazole	PA1691/010/004	Ireland	Alfred Gera and Sons Limited	Nil	Accepted	There are no authorised products for this active substance in the same strength or pharmaceutical form	N/A
AA565/59202	Sodium Thiosulphate 25% Solution for Infusion 100ml	Sodium thiosulphate	6073542.00.00	Germany	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1093/00108	Medica Throat Spray Menthol Oromucosal Spray 2mg/ml/0.5mg/ml	Chlorhexidine digluconate Lidocaine hydrochloride	BE167894	Belgium	Laboratoria Qualiphar N.V./S.A.	Nil	Accepted	There are no other authorised products for this active substance in the same strength or pharmaceutical form	To undergo MRP
AA1416/00301	Allefin Gel 20mg/10mg/g	Diphenhydramine hydrochloride Lidocaine hydrochloride	26329	Poland	Przedsiębiorstwo Produkcji Farmaceutycznej HASCO-LEK S.A.	Nil	Refused	Due to the unique combination which is not found elsewhere in the EEA, the MAH was asked to submit a MAA through MRP ensuring that all relevant information is made available for	N/A