

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
AA1454/05001	Benzetacil Pdr+Solv for Soln for Inj 1200000IU	Benzathine Benzylpenicillin	55835	Spain	Prohealth Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA908/31701	Gabantin Capsules Hard 300mg	Gabapentin	39482/17/19-12-2019	Greece	Neofarma Pharmaceuticals Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA242/04501	Peptonorm Oral Suspension 5ml/1000mg	Sucralfate	14100/05-02-2014	Greece	PHARMABART LTD	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1495/00102	Antrolin Rectal Cream 0.3+1.5%	Nifedipine Lidocaine hydrochloride	35396011	Italy	Neopharmed Gentili S.p.A.	Nil	Accepted	No authorised products are available, marketed or offered on tender	To undergo MRP
AA1173/09001	Chloramphenicol VUAB Pdr for Soln for Injection 1g	Chloramphenicol sodium succinate	15/125/10-C	Czech Republic	VUAB Pharma a.s.	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA1411/11201	Ceftriaxone AptaPharma 1 g powder for solution for injection/infusion	Ceftriaxone sodium	OGYI-T-23794/01	Hungary	EJ Busuttil Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1228/04001	Alocare Cutaneous Spray, Solution 2.275mg/ml	Finasteride	734303	Spain	Focused Pharma Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1106/00703	Tolexine microgranules Tablets 100mg	Doxycycline monohydrate	34009 347 482 7 1	France	LABORATOIRES BAILLEUL S.A.	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient,	To undergo MRP
AA908/24202	Famotidine Alkaloid Tablet, film coated 20mg	Famotidine	20030378	Bulgaria	Neofarma Pharmaceuticals Limited	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient,	N/A
AA639/01106	Rennie Medicated Chewing Gum 750mg	Calcium carbonate	PA1410/089/001	Ireland	Bayer Limited	Nil	Accepted	No authorised products are available, marketed or offered on	To undergo MRP
AA1045/00103	Azithromycin Clonmel Tablet, film coated 250mg	Azithromycin dihydrate	PA0126/150/001	Ireland	Clonmel Healthcare Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient,	N/A
AA1106/00102	Ketrel Cream 0,05%	Tretinoin	34009 340 883 6 0	France	LABORATOIRES BAILLEUL S.A.	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient,	To undergo MRP
AA288/04501	Tenofovir Aurovitas Tablet, film coated 245mg	Tenofovir disoproxil fumarate	5723333	Portugal	VJ Salomone Pharma LTD.	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1513/04001	Dibenzylan 10 Capsules Hard 10mg	Phenoxybenzamine hydrochloride	6337975.00.00	Germany	Pharma Regulatory Services Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/122401	Hydrocortone Tablets 10mg	Hydrocortisone	PA1986/054/001	Ireland	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A