

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
AA729/40401	Bisacodyl AIWA 5 mg Enteric-coated tablets	Bisacodyl	2499.99.99.00.00	Germany	Cherubino Ltd	N/A	Accepted	To ensure continuation of supply for the National Health System	N/A
AA521/10301	Loniten 5 mg tablets   AA521	Minoxidil	PA0822/130/001	Ireland	Medicem Ltd	N/A	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA565/124501	Fucithalmic Eye Drops Solution	Fuscidic Acid anhydrous	15657.00.00	Germany	Central Procurement & Supplies Unit	N/A	Refused	The product has a Marketing Authorisation in Malta ie. MA625/00201	N/A
AA770/27101	DORMIDEN 1 mg Powder for Concentrate for Solution for Injection or Infusion	remifetanil hydrochloride	24294/17/06-12-2018	Greece	JV Healthcare Limited	N/A	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1411/11602	Vesanoid Capsules, Soft 10mg	Tertinoin	PA1868/001/001	Ireland	EJ Busuttil Ltd	N/A	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	Yes
AA908/32701	COLCHICINE SEID Tablets 0.5mg	colchicine	78947; 703194	Spain	NEOFARMA PHARMACEUTICALS LTD	N/A	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
A729/41001	Bactrimel concentrate for solution for infusion 96 mg/ml	timethoprim; sulfamethoxazole	RVG 07231	Netherlands	Cherubino Ltd	N/A	Accepted	No authorised products are available, marketed or offered on tender	To undergo MRP
AA242/05301	MONDEX 875 mg/125 mg Film-coated tablets	amoxicillin; clavulanic acid	36847010	Italy	Pharmabart Ltd.	N/A	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	To undergo MRP
AA242/048011	ZIMACROL 500 mg film-coated tablets	azithromycin dihydrate	39039019	Italy	Pharmabart Ltd.	N/A	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	To undergo MRP
AA908/32801	Progynova 2 mg coated tablets	estradiol valerate	RVG 05311	Netherlands	NEOFARMA PHARMACEUTICALS LTD	N/A	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA242/05101	CLARITROL 500 mg film-coated tablets	clarithromycin	AIC 038887028	Italy	Pharmabart Ltd.	N/A	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	To undergo MRP