

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
AA1438/14102	Motilium Oral Suspension 1mg/ml	Domperidone	55411: 946582	Spain	NM Pharma Ltd	Nil	Accepted	There are less than 3 authorised products on the market with the same active ingredient, dose and strength	N/A
AA565/84003	Betadine Ointment 100mg/g	Povidone-iodine	9454728; 9454710	Portugal	Central Procurement And Supplies Unit	Nil	Accepted	To ensure continuation of supply	N/A
AA729/06007	Flucloxacillin Oral Solution 125mg/5ml	Flucloxacillin	PA1418/016/003	Ireland	Cherubino Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/127001	MESALAZINA DOC Tablets Gastro-Resistant 400mg	Mesalazine (5-aminosalicylic acid)	035386010; 35386073	Italy	Central Procurement And Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA084/05604	Spirolon Tablet, film coated 100mg	Spirolactone	8679	Cyprus	Remedica Ltd.	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA729/42001	MORPHINE SULFATE WZF Solution for Injection 20mg/ml	Morphine hemisulfate	4050	Poland	Cherubino Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA908/33801	Candesartan Hydrochlorothiazide Krka Tablets 16mg/12.5mg	Candesartan cilexetil; Hydrochlorothiazide	PA1347/011/002	Ireland	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
AA1417/00502	BENZOAT DE BENZIL FITERMAN Cream 250mg/g	Benzyl benzoate	12415/2019/01-02-03-04	Romania	FITERMAN PHARMA S.R.L.	Nil	Accepted	To ensure continuation of supply	To undergo MRP
AA770/28501	Spirix Tablets 25mg	Spirolactone	99-0352	Latvia	JV Healthcare Limited	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA770/11902	Omeprazole Basi Tablets Gastro-Resistant 20mg	Omeprazole	5174727; 5174735; 5174743; 5174750; 5174768; 5174776; 5174800; 5174818; 5174826; 5174834; 5174842; 5174859	Portugal	JV Healthcare Limited	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A
AA565/126801	Haemate P Pdr+Solv for soln for inf/inj 500IU/1200IU	Human coagulation factor VIII (FVIII); Human von Willebrand factor (VWF)	26600080	Italy	Central Procurement And Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/126301	Molnex Solution for Injection 20mg/ml	Morphine hydrochloride trihydrate	RVG 129849	Netherlands	Central Procurement And Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A

AA908/26602	Rhodogil Tablet, film coated 750,000 IU/125mg	Spiramycin;Metronidazole	50.057: 875377	Spain	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
AA1454/00502	Flucol Capsules Hard 150mg	Fluconazole	PA0711/057/003	Ireland	Prohealth Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA908/26402	Savlon Antiseptic Cream Cetrimide Chlorhexidine Digluconate Cream 0.5% w/w0.1%w/w	Cetrimide; Chlorhexidine digluconate	PA0126/324/002	Ireland	Neofarma Pharmaceuticals Limited	Nil	Accepted	To ensure continuation of supply	N/A
AA1528/00202	Pethisom Solution for Injection 50mg/1ml	Pethidine Hydrochloride	BE489644	Belgium	Laboratories Sterop NV	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA1606/01801	Cerazette Tablet, film coated 75 mcg	Desogestrel	PA23198/016/001	Ireland	MyRX Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA770/08504	Meriofert Solution for Injection 150IU	Follicle-stimulating hormone (FSH); Luteinising hormone (LH)	043275041; 043275054; 043275066	Italy	JV Helathcare Limited	Nil	Accepted	There are no other authorised products for this active substance in the same strength or pharmaceutical form	N/A
AA770/08505	Meriofert Solution for Injection 900 IU	Follicle-stimulating hormone (FSH); Luteinising hormone (LH)	AIC 043275078	Italy	JV Helathcare Limited	Nil	Accepted	There are no other authorised products for this active substance in the same strength or pharmaceutical form	N/A
AA565/122902	Tialorid Tablets 5mg/50mg	Amiloride hydrochloride Hydrochlorothiazide	R/2060	Poland	Central Procurement And Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1123/00203	Propofol Kabi Emulsion for Inj/Inf 10mg/ml	Propofol	36849065	Italy	Fresenius Kabi Italia S.r.l.	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA288/05601	TRICOVIVAX Cutaneous Solution 50mg/ml	Minoxidil	5733472; 5733514	Portugal	V.J. Salomone Pharma Limited	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1438/14303	Levothyroxine Sodium Teva Tablet, film coated 100mcg	Levothyroxine sodium	77045: 696283, 696277, 696281	Spain	NM Pharma Ltd	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
AA770/28701	Tresyl Cream 0.643mg	Betamethasone dipro	11852/2019/01-02-03	Romania	JV Helathcare 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