

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
AA770/13903	Pantoprazole Teva Pharma Tablets Gastro-Resistant 20mg	Pantoprazole	PA0749/144/001	Ireland	JV Healthcare Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA770/13904	Pantoprazole Teva Pharma Tablets Gastro-Resistant 40mg	Pantoprazole	PA0749/144/002	Ireland	JV Healthcare Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1411/05701	Impavido Capsule 50mg	Miltefosine	56589.01.00	Germany	EJ BUSUTTIL LTD	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1504/00902UK	Arpoya Tablets 5mg	Aripiprazole	PL 36687/0171	United Kingdom	Torrent Pharma (Malta) Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1438/12301	TETATOX suspension for injection	Purified tetanus toxoid	20010491	Bulgaria	NM Pharma Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA770/20601	Fluzac Capsule 20mg	Fluoxetine	PA711/110/1	Ireland	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
AA770/20701	Teicoplanin Pdr+Solv for soln for inf/inj 200mg	Teicoplanin	PA1122/009/001	Ireland	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
AA565/106302	Pyrafat Tablets 500mg	Pyrazinamide	17448	Austria	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1513/03001	Xylanaest Solution for Injection 2%	Lidocaine hydrochloride; Adrenaline	17.975	Austria	Pharma Regulatory Services Limited	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A

AA1187/02003	Fematab 1mg film-coated tablet	Estradiol hemihydrate	PA 2010/11/1	Ireland	Mylan IRE Healthcare Limited	Nil	Refused	The product has a marketing authorisation	N/A
AA1228/02901	Salbutamol Hasco 2mg/5ml Syrup	Salbutamol	R/3175	Poland	Focused Pharma Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1228/03001	Loniten Tablets 5mg	Minoxidil	AIC 024756025	Italy	Focused Pharma Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1414/00401	Sodium Valproate Aguetant Solution for Injection 400mg/4ml	Sodium valproate	34009 378 575 74	France	LABORATOIRE AGUETTANT	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/105101	Soderm Cream 1.22mg/g	Betamethasone valerate	36974.00.00	Germany	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1330/04401	Tevanate Once Weekly Tablets 70mg	Alendronic acid	PA0749/016/001	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