

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
AA908/20702	Monuril 3000 Granules for Oral Solutions 3g	Phosphomycin	RVG 13066	Netherlands	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
AA729/01403	Scandinibsa Solution for Injection 30mg/ml	Mepivacaine hydrochloride	39732	Estonia	Cherubino Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA565/61503	Isoprenaline (Isoproterenol) Solution for Injection 200micrograms/ml	Isoprenaline	30794010	Italy	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1213/01001	Calpol Six Plus Fastmelts Orodispersible Tablet 250mg	Paracetamol	PA0330/017/005	Ireland	Labomed Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1513/02901	Lidocain-adrenalin Solution for Injection 20mg/0.01mg/ml	Lidocaine hydrochloride; Adrenaline	OGYI-T-3050/03	Hungary	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
AA1045/06801	Pirfenidone Clonmel Tablet, film coated 267mg	Pirfenidone	PA0126/350/001	Ireland	Clonmel Healthcare Ltd.	Nil	Accepted	No authorised products are available, marketed or offered on tender	To undergo MRP
AA1045/06802	Pirfenidone Clonmel Tablet, film coated 801mg	Pirfenidone	PA0126/350/001	Ireland	Clonmel Healthcare Ltd.	Nil	Accepted	No authorised products are available, marketed or offered on tender	To undergo MRP
AA1436/00102	Medical Nitrous Oxide Inhalation Gas 98%	Nitrous Oxide	PA 0208/001/001	Ireland	BOC Gases Ireland Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	To undergo MRP

AA1122/02403	AirFluSal Forspiro Inhalation Powder 50mcg/250mcg	Salmeterol; Fluticasone Propionate	PA0711/237/001	Ireland	Rowex Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	To undergo MRP
AA1122/02404	AirFluSal Forspiro Inhalation Powder 50mcg/500mcg	Salmeterol; Fluticasone Propionate	PA0711/237/002	Ireland	Rowex Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	To undergo MRP
AA565/69103	Betamethasone Ointment 0.1%	Betamethasone	5940192	Portugal	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA770/03502	Aminophylline Injection Solution for Injection 250mg/10ml	Aminophylline	408690903032010	Greece	JV Healthcare Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA729/36301	Bendaepi Solution for Injection 2mg/ml	Epirubicin	68254.00.00	Germany	Cherubino Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1161/01503	Simvastatina Arena Tablet, film coated 20mg	Simvastatin	11972/2019/01-02-03-04-05	Romania	Farmarosib SRL	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA1513/03002	Xylanaest 1% with epinephrine Solution for Injection 1:200,000 - Vials: 1	Lidocaine hydrochloride; Adrenaline	17.908	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