

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
AA1438/13201	Atarax Tablet, film coated 25mg	Hydroxyzine dihydrochloride	20030268	Bulgaria	NM Pharma Limited	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1411/12901	ALMARYTM Solution for Inj/Inf 150mg/15ml	Flecainide acetate	AIC N. 025728027	Italy	EJ Busuttil Limited	Nil	Accepted	To ensure continuation of supply to the National Health System	N/A
AA1006/00802	Nelya Tablet, film coated 0.06mg/0.015mg	Ethinylestradiol; Gestodene	17/123/10-C	Czech Republic	HEATON k.s.	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	To undergo MRP
AA729/25002	Katya Tablet, film coated 0.30mg/0.075mg	Ethinylestradiol; Gestodene	17/192/07-C	Czech Republic	Cherubino Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	To undergo MRP
AA1349/00703	Fluoxetine Normon Oral Solution, 20mg/5ml	Fluoxetine	62427	Spain	LABORATORIOS NORMON, S.A.	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	To undergo MRP
AA242/04702	Soflon 5mg tablets	Prednisone	AIC 045261017-29	Italy	Pharmabart Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	To undergo MRP
AA242/04703	Soflon 25mg tablets	Prednisone	AIC 045261056-68	Italy	Pharmabart Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	To undergo MRP
AA1606/00401	PROPRANOLOL WZF Tablets 40mg	Propranolol	R/1122	Poland	MyRX Limited	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA729/16402	Exputex Oral Solution 250mg/5ml	Carbocisteine	PA 1113/10/1	Ireland	Cherubino Limited	Nil	Accepted	To ensure continuation of supply	N/A
AA729/16102	Fusibet Cream 20mg/1mg	Fusidic acid; Betamethasone	35791 / 19-05-2009	Greece	Cherubino Limited	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A

AA1610/00101	Propylthiouracil Tablets 50mg	Propylthiouracil	PA22902/001/001	Ireland	Halewood Chemicals (Ireland) Limited	Nil	Accepted	Authorised products with the same active substance, pharmaceutical form and strength are not marketed or offered on tender	To undergo MRP
AA908/20003	Brupro Tablet, film coated 200mg	Ibuprofen	PA0074/067/001	Ireland	Neofarma Pharmaceuticals Limited	Nil	Accepted	To ensure continuation of supply	N/A
AA908/20004	Brupro Max Tablet, film coated 400mg	Ibuprofen	PA0074/067/002	Ireland	Neofarma Pharmaceuticals Limited	Nil	Accepted	To ensure continuation of supply	N/A
AA770/14104	Duloxetine Pinewood 30 mg	Duloxetine hydrochloride	PA0281/270/001	Ireland	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
AA770/14105	Duloxetine Pinewood 60 mg	Duloxetine hydrochloride	PA0281/270/002	Ireland	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
AA1006/00204	Lamya Tablet, film coated 0.075mg	Desogestrel	17/320/12-C	Czech Republic	HEATON k.s.	Nil	Accepted	To ensure continuation of supply to the National Health System	To undergo MRP
AA1006/00702	Sunya coated Tablets 0.02mg/0.075mg	Ethinylestradiol; Gestodene	17/191/07-C	Czech Republic	HEATON k.s.	Nil	Accepted	No authorised products are available marketed or offered on tender	To undergo MRP
AA1006/01002	Adele Tablets 0.15mg/0.03mg	Desogestrel; Ethinylestradiol	17/ 662/10-C	Czech Republic	HEATON k.s.	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1349/01801	Normogrip Antitussive Granules for Oral Solutions 650mg/4mg/20mg	Paracetamol; Clorphenamine maleate; Dextromethorphan hydrobromide	88698 762343	Spain	Mint Health Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	To undergo MRP
AA242/04901	Amobronic 3mg/ml syrup	Abroxol hydrochloride	AIC 025776067	Italy	Pharmabart Limited	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	To undergo MRP
AA242/05201	FUNGUS 100mg capsule hard	Fluconazole	AIC 037810013	Italy	Pharmabart Limited	Nil	Accepted	There are no other authorised products for this active substance in the same strength or pharmaceutical form	To undergo MRP

AA242/05202	FUNGUS 150mg capsule hard	Fluconazole	AIC 037810025	Italy	Pharmabart Limited	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	To undergo MRP
AA1606/00201	Famogast coated Tablets 40mg	Famotidine	R/0148	Poland	MyRX Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA729/41101	Zithroxyn Tablet, film coated 500mg	Azithromycin	71642/17/25-1-2018	Greece	Cherubino Limited	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A
AA565/124301	Nocutil Nasal Spray Solution 0.1mg/ml	Desmopressin acetate	45814.00.00	Germany	Central Procurement & Supplies Unit	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1417/00801	DIFLEX Gel 50mg/g	Diclofenac Sodium	12313/2019/01-02-03-04-05-07	Romania	Fiterman Pharma S.R.L	Nil	Accepted	No authorised products are available, marketed or offered on tender	To undergo MRP
AA565/124401	Resonium Granules for Oral Suspension 454g	Sodium polystyrene sulfonate	8250704	Portugal	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply to the National Health System	N/A