

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
AA460/00802	Flixonase Allergy Relief Nasal Spray Suspension 50micrograms	Fluticasone propionate	PA0678/095/001	Ireland	Haleon Ireland Limited	Nil	Accepted	To ensure continuation of supply	To undergo MRP
AA565/126001	Laevolac 666.7 mg/mL syrup	Liquid Lactulose	5553961	Portugal	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/126201	Pirfenidone Generis Tablets 267mg	Pirfenidone	5862362	Portugal	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA770/28201	Loniten Tablets 5mg	Minoxidil	24756025	Italy	JV Healthcare 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
AA770/28401	TIOTEPA SEACROSS Pdr/Conc/Soln for Infus 15mg	Thiotepa	51337018	Italy	JV Healthcare Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA770/28302	Xatral SR Tablet Prolonged Release 10mg	Alfuzosin hydrochloride	11628/2019/01-02	Romania	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
AA1438/00604	VAQTA Adult Suspension for Injection 50IU/ML	Hepatitis A virus Amorphous Aluminium hydroxyphosphate sulphate	RVG 20798	Netherlands	NM Pharma Limited	Nil	Accepted	To ensure continuation of supply	N/A
AA565/80004	GONASI HP Pdr+Solv for Soln for Inj 1,000 IU	Chorionic Gonadotrophin	3763253	Italy	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA908/33001	Broncoliber extended release Capsule 120mg	Ambroxol hydrochloride	9745828	Portugal	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
AA807/12401	Irinotecan Aurovitas Concentrate for Soln for Inf 20mg/ml	Irinotecan hydrochloride trihydrate	5065438	Portugal	Aurobindo Pharma (Malta) Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA1227/00103	Flihaler Inhalation Gas 250mcg	Fluticasone propionate	6985/17/07-11-2018	Greece	D.A.S.T. BIOTECH PHARM LTD	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	To undergo MRP
AA1414/00102	Adrenaline (Epinephrine) Solution for Injection 1mg/10ml	Adrenaline	PA1968/002/001	Ireland	Associated Equipment Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP