

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
AA1161/02104	Atorvastatina Arena 10mg	Atorvastatin	112235/2018/0108	Romania	Farmarosib SRL	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA1161/02105	Atorvastatina Arena Tablet, film coated 20mg	Atorvastatin	11236/2018/01-08	Romania	Farmarosib SRL	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA1161/02106	Atorvastatina Arena Tablet, film coated 40mg	Atorvastatin	11237/2018/01-08	Romania	Farmarosib SRL	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA565/06110	Haloperidol Richter Solution for Injection 5mg/ml	Haloperidol	1269/2008/01	Romania	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA908/08005	Nurofen Strawberry Oral Suspension 20mg/ml	Ibuprofen	5645724	Portugal	NEOFARMA PHARMACEUTICALS LTD	Nil	Refused	The product has a marketing authorisation in Malta	N/A
AA1314/00306	Pentasa Suppositories 1g	Mesalazine	PA1009/006/002	Ireland	EJ Busuttil Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A

AA1173/08601UK	Doxazosin Tablets 2mg	Doxazosin mesilate	PL 49565/0005	United Kingdom	Mint Health Ltd	Nil	Refused	Directive 642/2022 amending Directive 2001/83/EC grants derogations to prevent shortages and to ensure public health protection (pre-amble 4). The application for this product does not fulfil the criteria for granting an authorisation on the basis of article 126(c) of Directive 2001/83/EC because there are several alternative products available in the EU/EEA	N/A
AA242/01502	Glycerin Microenema For Babies Enema 1.8g/2.5ml	Glycerin (glycerol)	43572/10	Greece	PHARMABART 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
AA565/108401	Altroaldo Pressurised Inhalation Soln 20mcg	Ipratropium bromide	72581	Spain	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1411/07301UK	Tomudex Pdr for Soln for Infusion 2mg	Raltitrexed	PL04515/0225	United Kingdom	EJ Busuttil Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1416/00201	Clotrimazolum Hasco Cream 10mg/g	Clotrimazole	10823	Poland	PRZEDSIĘBIORSTWO PRODUKCJI FARMACEUTYCZNEJ HASCO-LEK S.A.	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/108501	Areloger Tablets 7.5mg	Meloxicam	PA0577/057/001	Ireland	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA242/03101UK	Donepezil Hydrochloride Tablet, film coated 5mg	Donepezil hydrochloride	PL 16363/0376	United Kingdom	Pharmabart Ltd.	Nil	Refused	The products have a marketing authorisation in Malta	N/A
AA242/03102UK	Donepezil Hydrochloride Tablet, film coated 10mg	Donepezil hydrochloride	PL 16363/0377	United Kingdom	Pharmabart Ltd.	Nil	Refused	The products have a marketing authorisation in Malta	N/A
AA1411/05102UK	Posaconazole Oral Suspension 40mg/ml	Posaconazole	PL 45043/0009	United Kingdom	EJ Busuttil Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A