

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
AA729/01502	Artinibsa Solution for Injection 40mg/ml/10mcg/ml	Articaine Hydrochloride; Adrenaline	61.479	Spain	Cherubino Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	Nil
AA1001/00503	Lithimole Eye Drops Solution 0.50%	Timolol maleate	43848/04-05-2023	Greece	COOPER Pharmaceuticals S.A.	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA729/37001UK	Phenobarbital Sodium Solution for Injection 60mg/ml	Phenobarbital Sodium	PL 01883/6189R	United Kingdom	Cherubino Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	Nil
AA1330/01403	Zolmitriptan Sandoz Smelttablet Orodispersible Tablet 2.5mg	Zolmitriptan	RVG 106554	Netherlands	Azure Pharmaceuticals 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	Nil
AA1513/03401	Metvixia Cream 168mg/g	Methyl aminolevulinate	34009 377 198 58	France	Pharma Regulatory Services 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	Nil
AA1228/03201	Rifacol Coated Tablets 200mg	Rifaximin	5604/07-09-2018	Greece	Focused Pharma Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength.	Nil
AA1411/07601	Ritalmex Capsule 200mg	Mexiletine hydrochloride	OGYI-3696/01	Hungary	EJ Busuttil Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA908/28301	Nelya Tablet, film coated 0.06mg/0.015mg	Gestodene; Ethinyl estradiol	17/123/10-C	Czech Republic	Neofarma Pharmaceuticals 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.	Nil

AA565/35504	Cotrim-ratiopharm@Ampoules SF Concentrate for Soln for Inf 480mg/5ml	Co-trimoxazole	6688456.00.00	Germany	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	Nil
<del>AA1173/08801UK</del>	<del>Resuvastatin Tablet, film coated 20mg</del>	<del>Resuvastatin</del>	<del>PL 49565/0085</del>	<del>United Kingdom</del>	<del>Mint Health Ltd</del>	<del>Nil</del>	<del>Accepted</del>	<del>To ensure continuation of supply for the National Health System</del>	<del>Nil</del>
AA1290/00102	Fosfoseptic Granules for Oral Solutions 3g	Fosfomycin trometamol	BG/MA/MP-61858/8	Bulgaria	Adipharm EAD	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	To undergo MRP

Updated 13/09/2024 -  
Erroneously included in  
the list