

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
AA908/26003	Actifed Tablets 60mg/2.5mg	Pseudoephedrine hydrochloride; Triprolidine hydrochloride	PA23490/029/002	Ireland	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	N/A
AA908/11404	Azithromycin Sandoz Tablet, film coated 500mg	Azithromycin dihydrate	10655/2018/01-02-03	Romania	Neofarma Pharmaceuticals Limited	Nil	Accepted	To ensure the continuation of supply to the private market	N/A
AA1096/00602	UNIPLEX Cream 5% w/w	Aciclovir	8570/06.02.2007	Greece	Uni-Pharma S.A	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	To undergo MRP
AA1411/16001	EYETOBRIN Eye Drops Solution 0.3% w/v	Tobramycin	107677/12-10-2022	Greece	EJ Busuttil Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA274/02901	Imodium Instants Orodispersible Tablet 2mg	Loperamide hydrochloride	PA23490/025/001	Ireland	Alfred Gera & Sons Limited	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA115/02605	Tripan Tablet, film coated 20mg	Tadalafil	22616	Cyprus	Delorbis Pharmaceuticals 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

AA729/00104	Xilonibsa Solution for Injection 20mg/mL+0.0125mg/ml	Lidocaine Hydrochloride; Epinephrine	40858: 606710, 615955	Spain	Cherubino Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA242/06201	Temozolomide Novumgen Capsule 20mg	Temozolomide	5837646	Portugal	Pharmabart Limited	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A
AA1525/00301	Atorvastatin Vivanta Tablet, film coated 10mg	Atorvastatin Calcium Trihydrate	2202656.00.00	Germany	Vivanta Generics s.r.o	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA1525/00302	Atorvastatin Vivanta Tablet, film coated 20mg	Atorvastatin Calcium Trihydrate	2202657.00.00	Germany	Vivanta Generics s.r.o	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA1525/00303	Atorvastatin Vivanta Tablet, film coated 40mg	Atorvastatin Calcium Trihydrate	2202658.00.00	Germany	Vivanta Generics s.r.o	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA565/130101	Ciprofloxacin Basi Solution for Infusion 2mg/ml	Ciprofloxacin	5893847	Portugal	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1001/00802	Nafloxin Solution for Infusion 200mg/100ml	Ciprofloxacin Lactate	156885/24/1-8- 2025	Greece	COOPER Pharmaceuticals S.A.	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP

AA1411/15701	MILRINON Carinopharm Solution for Inj/Inf 1mg/ml	Milrinone	85951.00.00	Germany	EJ Busuttil Limited	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A
AA1045/00803	Tamnic Hard Capsules Modified Release 400mcg	Tamsulosin hydrochloride	PA0126/395/001	Ireland	Clonmel Healthcare Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA908/30103	AirFluSal Forspiro Inhalation Powder 50mcg/500mcg	Salmeterol xinafoate; Fluticasone propionate	12945/2020/01-07	Romania	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
AA770/30001	Flagyl Tablets 400mg	Metronidazole	PA0814/003/002	Ireland	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