

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
AA1411/09401	Testosterone EVER Pharma Solution for Injection 1000mg/4ml	Testosterone undecanoate	142130	Austria	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
AA565/116801	Mefeda Tablet Prolonged Release 36mg	Methylphenidate hydrochloride	HR-H-320399466	Croatia	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/116802	Mefeda Tablet Prolonged Release 18mg	Methylphenidate hydrochloride	392356118	Croatia	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA729/39101	Paidocort Oral Solution 3mg/ml	Prednisolone	84.003 National Code: 725289, 764703, 607513	Spain	Cherubino Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1411/09901	Cedocard I.V. Solution for Infusion 10mg/10ml	Isosorbide dinitrate	BE117135	Belgium	EJ BUSUTTIL LTD	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/104301	Microlax Rectal Solution 450mg/5ml+45mg/5ml	Sodium citrate Sodium lauryl sulfoacetate	9155333	Portugal	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/105901	Pyzypi Tablet, film coated 400mg	Pazopanib	14366/2022/01-12	Romania	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/84002	Betadine Ointment 100mg/g	Povidone iodine	9454728, 9454710	Portugal	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1316/00502	Viscolex Oral Solution 250mg/5ml	Carbocisteine	PA0281/070/001	Ireland	4 Pharma Ltd	Nil	Accepted	The product is to be made available at least 10% less than the price of the authorised alternative of	N/A
AA521/10101	Exputex Oral Solution 250mg/5ml	Carbocisteine	PA1113/010/001	Ireland	MEDICEM LIMITED	Nil	Accepted	The product is to be made available at least 10% less than the price of the authorised alternative of	N/A
AA565/55109	ADRENALINE AGUETTANT sulphite free Solution for Injection 0.1mg/ml	Adrenaline tartrate	34009 300 466 1 6 & 34009 300 549 7 0	France	Central Procurement & Supplies Unit	Nil	Accepted	Authorised products with the same active substance, pharmaceutical form and strength not offered on tender	N/A
AA1214/00203	PoltechMDP Kit for Radiopharmaceutical Preparation 5mg	Sodium pyrophosphate decahydrate	R/3441	Poland	Narodowe Centrum Badan Jadrowych	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA565/117001	Colixin 1,000,000 I.U. Powder for solution for injection or for solution for	Colistimethate sodium	5268883 ;2593986	Portugal	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA908/08803UK	Duofilm Cutaneous Solution 16.7/15%w/w	Salicylic acid Lactic acid	PL 00240/0551	United Kingdom	NEOFARMA PHARMACEUTICALS 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. Moreover, there are	N/A
AA770/23501	Trazodone EG Tablets 100mg	Trazodone hydrochloride	BE439607	Belgium	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
AA565/61803	Tobramycin Via pharma Nebulise Solution 300mg/5ml	Tobramycin	23633	Poland	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A