

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
AA565/11403	Acetylcysteine "Macure" Concentrate for Soln for Inf 1ml/200mg	Acetylcysteine	69657	Denmark	Central Procurement And Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA908/26302	EMETIRAL 5 mg film-coated tablets	prochlorperazine maleate	2067/2009/01	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
AA770/10505	Nexium 20 mg Gastro-resistant Tablets	esomeprazole	8423/2015/01-2	Romania	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
AA770/16403	FIBROVEIN 1% Solution for Injection	sodium tetradecyl sulfate	3.40093E+12	France	JV Healthcare Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1454/06301	Lorat 10mg Tablets	loratadine	PA0711/088/001	Ireland	Prohealth Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	To undergo MRP
AA565/54103	TETANUS GAMMA Solution for Injection 250 IU/1ml	tetanus immunoglobulin	22488062	Italy	Central Procurement And Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1606/01501	PLEYRIS 25 mg solution for injection	progesterone	41348071	Italy	MyRx 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
AA565/82102	Spersacarpine 2% (20 mg/mL) eye drops, solution	pilocarpine hydrochloride	6309068.00.00	Germany	Central Procurement And Supplies Unit	Nil	Accepted	To ensure continuation of supply to the National Health system	N/A
AA565/79604	Ketamin Inreasa 50 mg/ml (2ml) solution for injection	ketamine	26671.00.00	Germany	Central Procurement And Supplies Unit	Nil	Accepted	Authorised products with the same active substance, pharmaceutical form and strength not offered on tender	N/A
AA565/13004	Entocort rectal 2.3 mg, tablets and liquid for the preparation of a rectal suspension	budesonide	28247.00.00	Germany	Central Procurement And Supplies Unit	Nil	Accepted	There are no authorised products for this active substance in the same strength or pharmaceutical form	N/A
AA1411/01102	Chlorphenamine 10 mg/ml Solution for Injection	chlorphenamine	PA2262/003/001	Ireland	EJ Busuttill Limited	Nil	Accepted	To ensure continuation of supply to the National Health system	N/A
AA565/64304	Vesanoid 10 mg soft capsule	tretinoin	65.396,700700	Germany	Central Procurement And Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A

AA908/18102	Ditropan 5mg Tablets	oxybutynin hydrochloride	57185 971812	Spain	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
AA1606/01701	Rizatriptan AL 10 mg orodispersible tablets	rizatriptan	82107.00.00	Germany	MyRx Limited	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA565/126102	Jext 150 micrograms Solution for injection in a pre-filled pen	epinephrine	80540.00.00	Germany	Central Procurement And Supplies Unit	Nil	Accepted	To ensure continuation of supply to the National Health system	N/A
AA1404/00502	Amotaks 500mg/5ml (amoxicillin) granules for oral suspension	amoxicillin	17011	Poland	Tarchomińskie Zakłady Farmaceutyczne Polfa S.A.	Nil	Accepted	There are no other authorised products for this active substance in the same strength or pharmaceutical form	To undergo MRP
AA1513/04601	EpiPen 150 micrograms solution for injection in pre-filled pen	epinephrine	PA23355/011/001	Ireland	Pharma Regulatory Services Limited	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1513/04602	EpiPen 300 micrograms solution for injection in pre-filled pen	epinephrine	PA23355/011/002	Iceland	Pharma Regulatory Services Limited	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1454/06601	Topotecan Hikma 4 mg powder for concentrate for solution for infusion	topotecan hydrochloride	82813.00.00	Germany	Prohealth Limited	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	To undergo MRP
AA242/05901	Zurim 300 mg tablets	allopurinol	9193748/9193755	Portugal	Pharmabart Ltd.	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A