

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
AA565/49510	Budena Nebulise Solution 0.5mg/ml	Budesonide	85220 7288640	Spain	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1512/00201	Succinaptal Capsule 200mg	Succimer	3400936571082	France	SERB SAS	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA565/94902UK	Granocyte Pdr+Solv for soln for inf/inj 13.4 million/IU.	Lenograstim	PL 12185/0002	United Kingdom	Central Procurement& Supplies Unit	Nil	Accepted	There are no other authorised products for this active substance in the same strength or pharmaceutical form	N/A
AA1227/00301	RINOSOL Pressurised Inhalation Soln 250mcg	Beclomethasone dipropionate	35471/15/2752016	Greece	D.A.S.T Biotech Pharm Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA565/108701	Vitamin D3 Kern Pharma Oral Solution 2,000 IU/ml	Cholecalciferol (Vitamin D3)	22903	Spain	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/108301	Diulo Tablets 5mg	Metolazone	8578773	Portugal	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA242/03001	Pilexam Solution for Injection 100mg	Tranexamic acid	51944	Denmark	Pharmabart Ltd.	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/46502	Sandimmun Solution for Infusion 50mg/ml	Ciclosporin	11096	Denmark	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA912/01302	Erlotinib Stada Tablet, film coated 100mg	Erlotinib hydrochloride	99488.00.00	Germany	Stadapharm GmbH	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA1568/00101	Diltiazem Arena Tablets 60mg	Diltiazem Hydrochloride	9501/2016/02	Romania	Ideal Trade Links, UAB	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A

AA908/17103	Itraconazole Slavia Capsules Hard 100mg	Itraconazole	12422/2019/01	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
AA1228/03101	Propranolol accord Tablets 40mg	Propranolol hydrochloride	20799=20800	Poland	Focused Pharma Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1411/07401UK	Dilute Adrenaline (Epinephrine) Solution for Injection 100 mcg	Adrenaline acid tartrate	PL 01883/0065	United Kingdom	EJ Busuttil Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA084/09404	Risperidone Remedica Tablet, film coated 2mg	Risperidone	20639	Cyprus	Remedica Ltd.	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP