

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
AA1411/06401	Baclofen Sintetica Intrathecal Solution for Injection 2mg/ml	Baclofen	78469.00.00	Germany	EJ Busuttil Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/10003UK	Gaviscon Infant Powder for Oral Solution	Sodium alginate; Magnesium alginate	PL 00063/0099	United Kingdom	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/102803	Unilux Solution for Injection 370mg	Iopamidol	1-30683	Austria	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA274/02102UK	Co-trimoxazole Oral Suspension 40mg/200mg	Sulfamethoxazole; Trimethoprim	PL 39699/0037	United Kingdom	Alfred Gera & Sons Ltd	Nil	Refused	The product has a marketing authorisation	N/A
AA084/07904	Clozarem Tablets 100mg	Clozapine	19378	Cyprus	Remedica Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA565/108101	Mezym 25000 Tablets Gastro-Resistant 356.1mg	Lipase 25000	6106/2014/010	Romania	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1438/12501	Haloperidol-Grindeks Solution for Injection 5mg/ml	Haloperidol	00-1198	Latvia	NM Pharma Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/26007	Adenorythm 3mg/mL Solution for infusion	Adenosine	131653/05-11-2019	Greece	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA770/08402	Pleyris Solution for Injection 25mg	Progesterone	AIC 041348057	Italy	JV Healthcare Limited	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA984/00603	Salazidin Tablets Gastro-Resistant 500mg	Sulfasalazine	11887/2019/01-02	Romania	AC HELCOR Pharma S.R.L.	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP

AA565/107901	Isoprotrace kit for radiopharmaceutical preparation Ear/Eye Drops, solution 10 micrograms	Gozetotide trifluoroacetate	RVG 130527	Netherlands	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
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