

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
AA1438/07802	Omeprazole Teva-ratio EFG Hard Tablet Prolonged Release 20mg	Omeprazole	69124: 659589; 696842; 659590; 696843; 602626; 659591; 696844	Spain	NM Pharma Limited	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A
AA729/25102	Sunya Tablet, film coated 0.020mg/0.075mg	Ethinylestradiol gestodene	17/191/07-C	Czech Republic	Cherubino Ltd	Nil	Accepted	there are fewer than three authorised products on the market with the same active ingredient, dose and strength	To undergo MRP
AA1454/01302	Calcium Chloride Galenica Senese Concentrate for Soln for Inf 1g/10ml	Calcium chloride dihydrate	AIC 029830027, AIC 029830041, AIC 029830078	Italy	Prohealth Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA908/25402	Sindolor Gel 5mg/5mg/20mg/g	Piroxicam; Cyclobenzaprine hydrochloride; Lidocaine	14027/2021/01-02-03-04-05	Romania	Neofarma Pharmaceuticals Limited	Nil	Accepted	To ensure continuation of supply	N/A
AA908/07106	Omeprazole Teva hard Capsules Gastro-Resistant 20mg	Omeprazole	PA0749/160/002	Ireland	NEOFARMA PHARMACEUTICALS LTD	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
AA1411/00702	Hydrocortison DMB Tablets 20mg	Hydrocortisone	RVG 50730	Netherlands	EJ BUSUTTIL LTD	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1454/05401	Remifentanil Sala Pdr/Conc/Soln for Inj or Infus 1mg	Remifentanil	73183: 677269	Spain	Prohealth Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA1454/05301	Rocuronium Bromide Hikma Hypodermic Solution / Solution for Infusion 10mg/ml	Rocuronium bromide	89258.00.00	Germany	Prohealth Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1353/00202	Sodium Bicarbonate Monico Solution for Infusion 8.4%/100ml	sodiumm hydrogen carbonate	030819 155	Italy	Monico spa	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1411/13301	Haldol Decanoas Solution for Injection 50mg/ml	Haloperidol decanoate	MA 025333016	Italy	EJ BUSUTTIL LTD	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1253/00105	Tafixyl Tablet, film coated 500mg	Tranexamic acid	5695358; 5695366; 5695374; 5695408; 5695416; 5695424; 5695432; 5695440	Portugal	Pharma Bavaria Internacional (PBI) Portugal, Unipessoal Lda.	Nil	Accepted	To ensure continuation of supply	To undergo MRP

AA565/54402	Mysoline Tablets 250mg	Primidone	PA1777/001/001	Ireland	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1277/02303	Numeta G16%E Emulsion for infusion		PA2299/030/001	Ireland	Baxter Holding B.V	Nil	Accepted	To ensure continuation of supply for the National Health System	Yes
AA908/02702	Glucophage XR Tablet Prolonged Release 500mg	Metformin hydrochloride	18/166/04-C	Czech Republic	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
AA908/02703	Glucophage XR Tablet Prolonged Release 1000mg	Metformin hydrochloride	18/222/11-C	Czech Republic	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
AA565/20104	Fludarabine Teva Concentrate for Soln for Inj 25mg/ml	Fludarabine phosphate	BE303721	Belgium	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A

