

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
AA1411/12101	Pentoxifylline Ratiopharm Extended release Tablets 400mg	Pentoxifylline	6652.00.00	Germany	EJ BUSUTTIL LTD	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1228/04201	Debretin forte 200mg	Trimebutine maleate	27969	Poland	Focused Pharma Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA240/02104	Talgan Nebuliser Solution 1mg/2ml	Budesonide	20939/15/02-03-2017	Greece	Anfarm Hellas S.A.	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA908/16904	Tadalafil CF Tablet, film coated 5mg	Tadalafil	RVG 124325	Netherlands	NEOFARMA PHARMACEUTICALS LTD	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A
AA565/35903	Candesartan Heumann Tablets 8mg	Candesartan cilexetil.	82319.00.00	Germany	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/35904	Candesartan Heumann Tablets 16mg	Candesartan cilexetil.	82320.00.00	Germany	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1006/00602	Vreya Tablet, film coated 0.035mg/2mg	Ethinylestradiol Cyproterone acetate	17/088/06-C	Czech Republic	HEATON k.s.	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	Commitment provided by the MAH to undergo MRP
AA565/123201	Diproderm Cream 0.5mg/g	Betamethasone	53.193	Spain	Central Procurement & Supplies Unit	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA115/02102	Floxaval Tablet, film coated 500mg	Levofloxacin	21387	Cyprus	Delorbis Pharmaceuticals Ltd.	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	To undergo MRP
AA288/04701	Nitrazepam Auro Tablets 5mg	Nitrazepam	RVG 50283	Netherlands	V.J. Salomone Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A