

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
AA908/28901	Norcolut Tablets 5mg	Norethisterone	OGYI-T-3453/01	Hungary	NEOFARMA PHARMACEUTICALS LTD	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA807/01009	Cefuroxime Tablet, film coated 250mg	Cefuroxime	93460.00.00	Germany	Aurobindo Pharma (Malta) Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA1438/07005	Etalopro Tablet, film coated 5mg	Escitalopram	PA0126/212/001	Ireland	NM Pharma Ltd	Nil	Accepted	to ensure continuation of supply	N/A
AA1438/07006	Etalopro Tablet, film coated 10mg	Escitalopram	PA0126/212/002	Ireland	NM Pharma Ltd	Nil	Accepted	to ensure continuation of supply	N/A
AA1438/07007	Etalopro Tablet, film coated 15mg	Escitalopram	PA0126/212/003	Ireland	NM Pharma Ltd	Nil	Accepted	to ensure continuation of supply	N/A
AA1438/07008	Etalopro Tablet, film coated 20mg	Escitalopram	PA0126/212/004	Ireland	NM Pharma Ltd	Nil	Accepted	to ensure continuation of supply	N/A
AA1438/05503	Revaxis Suspension for Injection 0.5ml	Purified diphtheria toxoid not less than 2 IU ¹ (5 Lf) Purified tetanus toxoid not less than 20 IU ¹ (10 Lf) Inactivated poliomyelitis virus type 1 ² 29 D antigen units ³ Inactivated poliomyelitis virus type 2 ² 7 D antigen units ³ Inactivated poliomyelitis virus type 3 ² 26 D antigen units ³ aluminium hydroxide	RVG 24534	Netherlands	NM Pharma Ltd	Nil	Accepted	to ensure continuation of supply	To undergo MRP
AA1007/00202	Amoxiplus Pdr for Soln Inj/Inf 1000mg/200mg	Amoxicillin Clavulanic Acid	5521/2013/01-05	Romania	Antibiotice S.A.	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A

AA1045/01605	Sildenafil clonmel Tablet, film coated 100mg	Sildenafil Citrate	PA0126/199/003	Ireland	Clonmel Healthcare Ltd	Nil	Refused	A pending Marketing Authorisation Application was submitted for the same product in Malta	N/A
AA1379/00102	Onko BCG100 Powder and solvent for suspension for inj100mg	Live attenuated Bacillus Calmette-Guerin, Brazolian BCG Moreau substrain	4317	Poland	Synthaverse S.A.	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA565/22902	Fludrocortisone acetate Tablets 0.1mg	Fludrocortisone acetate	PA2010/064/001	Ireland	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/109201	Pamifos 3 mg/mL concentrate for solution for infusion	Pamidronate disodium	59200.00.00	Germany	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1349/00102	Amoxicillin/Clavulanic acid normon Powder for Oral Suspension 125mg/31.5mg/5ml	Amoxicillin/Clavulanic Acid	64111, 926253	Spain	Lavoratorios Norman S.A.	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA565/110601	Requip Tablet, film coated 5mg	Ropinirole	34009 388 023 7 5	France	Central Procurement & Supplies Unit	Nil	Refused	Product is already authorised in Malta	N/A
AA274/02401	Licoforte Gel 40mg/g	Hydroquinone	66899, 651542	Spain	Alfred Gera & Sons Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA565/110801	Folifer Tablet, film coated 1mg+90mg	Folic acid and iron (as ferrous sulfate)	9689513	Portugal	Central Procurement & Supplies Unit	Nil	Refused	Product is already authorised in Malta	N/A
AA1411/08501	Cefotaxime AptaPharma Pdr for Soln Inj/Inf 1g	Cefotaxime sodium	OGYT-T23687/02	Hungary	EJ BUSUTTIL LTD	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A