

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
AA908/19106	Emazole Tablets Gastro-Resistant 40mg	Esomeprazole	PA0711/158/002	Ireland	Neopharma Pharamceuticals Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1411/08402	Dexamethasone Kalceks Solution for Inj/Inf 4mg/ml	Dexamethasone Sodium phosphate	26779	Poland	EJ Busuttil Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1411/10301	NITROFURANTOIN "Agepha" Tablets 50.0mg	Nitrofurantoin in Macrocrystalline form	1-15045	Austria	EJ Busuttil Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/48102	Zinacef Solution for Injection 250mg	Cefuroxime sodium	PA23311/002/001	Ireland	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/115003	Temelor Solution for Injection 4mg/ml	Lorazepam	5814447	Portugal	Central Procurement & Supplies Unit	Nil	Refused	Product already has a Marketing Authorisation in Malta	N/A
AA908/31501	Tamis PRAS Tablet Prolonged Release 0.4mg	Tamsulosin hydrochloride	20192	Poland	Neopharma Pharamceuticals 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
AA908/24402	Levonorgestrel Rowex Tablets 1.5mg	Levonorgestrel	PA0711/267/001	Ireland	Neopharma Pharamceuticals Ltd	Nil	Accepted	To ensure continuation of supply	N/A
AA1438/08001	Acidex Oral Suspension 10ml	Sodium alginate Sodium bicarbonate Calcium carbonate	PA0281/075/001	Ireland	NM Pharma Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA565/75409	Methylphenidate HCl CF Tablet Prolonged Release 27mg	Methylphenidate hydrochloride	RVG 124094	Netherlands	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1045/01803	Montelair Tablets Chewable 5mg	Montelukast	PA0126/215/002	Ireland	Clonmel Healthcare Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA1045/01804	Montelair Tablets Chewable 4mg	Montelukast	PA0126/215/001	Ireland	Clonmel Healthcare Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA1411/00402	Trasylol® Solution for Infusion 10,000 KIE/ml	Concentrated Aprotinin Solution	34579.00.00	Germany	EJ Busuttil Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/117002	Colixin Pdr for Soln for Injection 1,000,000IU	Colistimethate sodium	74156	Spain	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/114702	Ludiomil Tablet, film coated 25mg	Maprotiline hydrochloride	9416065	Portugal	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A

