

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
AA565/19704	Mometasone Atb Ointment 1mg/g	Mometasone furoate	11889/2019/01	Romania	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/55302	Suxamethonium-Labesfal Solution for Injection 100mg/2ml	Suxamethonium chloride	5582002; 2687390	Portugal	Central Procurement& Supplies Unit	Nil	Accepted	There are no other authorised products for this active substance in the same strength or pharmaceutical	N/A
AA565/06305	Itraconazole Focus care Oral Solution 10mg/ml	Itraconazole	RVG 128247	Netherlands	Central Procurement& Supplies Unit	Nil	Refused	The product has a Marketing Authorisation in Malta	N/A
AA565/78411	Methotrexate-GRY Solution for Injection 50mg/2ml	Methotrexate disodium	3190.01.00	Germany	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/81703	Rifamazid Capsules Hard 150mg/100mg	Rifampicin/Isoniazid	R/0861	Poland	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/26105	Fungizone Pdr for Soln for Infusion 50mg	Amphotericin B	22189	Poland	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/07510	Sodium bicarbonate NOVA ARGENTIA Tablets 500mg	Sodium bicarbonate	AIC30580017	Italy	Central Procurement& Supplies Unit	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1438/01402	Itraconazole Generis Capsule 100mg	Itraconazole	4892188	Portugal	NM Pharma Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient,	N/A
AA565/51105	Water for Injections Labesfal Solvent for Parenteral Use 100%	Water for injections	5208343	Portugal	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/46602	Provigil Tablets 200mg	Modafinil	PA0749/198/002	Ireland	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1330/02105	Fluoxetine CF 20 Tablets Effervescent 20mg	Fluoxetine	RVG 24609	Netherlands	Azure Pharmaceuticals Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient,	N/A
AA565/32203	Biltricide Tablet, film coated 600mg	Praziquantel	964.00.00	Germany	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/98903	CIDOFOVIR TILLOMED Concentrate for Soln for Inf 75mg/ml	Cidofovir	49238013	Italy	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1093/00109	Medica Throat Tablets Menthol Oromucosal Solution 5mg/1ml	Chlorhexidine/ Dihydrochloride/ Lidocaine Hydrochloride	BE172435	Belgium	Laboratoria Qualiphar N.V./S.A.	Nil	Accepted	There are no other authorised products for this active substance in the same strength or	To undergo MRP
AA1093/00206	Toularynx Codeine Syrup 11,49mg/15ml	Codeine phosphate hemihydrate	BE190906	Belgium	Laboratoria Qualiphar N.V./S.A.	Nil	Accepted	There are no other authorised products for this active substance in the same strength or	To undergo MRP
AA1228/04301	Famogast 40mg	Famotidine	R/0148	Poland	Focused Pharma Ltd	Nil	Accepted	No authorised products are available, marketed or offered on	N/A
AA084/10103	Monorem R Tablet Prolonged Release 60mg	Isosorbide mononitrate	21764	Cyprus	Remedica Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP

AA565/10805	Modafinil Aristo Tablets 200mg	Modafinil	2201827.00.00	Germany	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1454/04801	Esciprex Tablet, film coated 5mg	Escitalopram	PA0711/194/001	Ireland	ProHealth Limited	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A
AA1454/04802	Esciprex Tablet, film coated 10mg	Escitalopram	PA0711/194/002	Ireland	ProHealth Limited	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A
AA1454/04803	Esciprex Tablet, film coated 20mg	Escitalopram	PA0711/194/003	Ireland	ProHealth Limited	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A
AA1045/01805	Montelair Tablet, film coated 10mg	Montelukast	PA0126/215/003	Ireland	Clonmel Healthcare Ltd	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A
AA729/39501	Rinoduo Nasal Spray Solution 137mcg/50mcg	Azelastine hydrochloride/ Fluticasone Propionate	86723	Spain	Cherubino Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active	N/A
AA565/34305	Cytotec Tablets 200mcg	Misoprostol	40410/07/19-5-20	Greece	Central Procurement& Supplies Unit	Nil	Accepted	There are no other authorised products from this active substance in the same strength and	N/A