

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
AA1454/04001	Isotretinoin Capsules, Soft 20mg	Isotretinoin	PA0711/312/003	Ireland	Pro Health Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA1454/04002	Isotretinoin Capsules, Soft 10mg	Isotretinoin	PA0711/312/002	Ireland	Pro Health Limited	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	To undergo MRP
AA565/06412	Baclofen Sintetica Intrathecal Solution for Infusion 0.5mg/ml	Baclofen	78468.00.00	Germany	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/117401	Ursocol Capsules Hard 250mg	Ursodeoxycholic acid	33660	Finland	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/43604	Dexamethasone Tablets 2mg	Dexamethasone	PA1691/014/001	Ireland	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/118601	Spirolakton Orifarm Tablets 25mg	Spirolactone	9,578	Sweden	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/25803	Ursofalk Oral Suspension 250mg/5ml	Ursodeoxycholic acid	43/837/10-C	Czech Republic	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/105802	Idarubicin Hikma Solution for Injection 5mg/5ml	Idarubicin hydrochloride	5360839	Portugal	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/117702	Mycolat Capsules Hard 250mg	Mycophenolate mofetil	PA0711/129/001	Ireland	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1173/06303	Oestrogel Pump-Pack Gel 750mcg	Estradiol	PA1054/004/001	Ireland	Mint Health Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA908/00401	Lescol XL Tablet Prolonged Release 80mg	Fluvastatin	31/127/01-C	Czech Republic	Neofarma Pharmaceuticals Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA565/04709	Lisinopril Atb Tablets 10mg	Lisinopril dihydrate	7192/2014/01-02	Romania	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA729/24002	Techida Pdr for Soln for Injection 30mg	Diethyl-acetanilid-imino/ Diacetic Acid	OGYI-T-9210/01	Hungary	Cherubino Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA565/97603	Urbason Pdr+Solv for Soln for Inj 40mg	Methylprednisolone sodium hemisuccinate	34023	Spain	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/07806	Retrovir infusion Concentrate for Soln for Inf 10mg/ml	Zidovudine	RVG 16389	Netherlands	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/09405	Fibrovein Solution for Injection 10mg/ml	Sodium tetradecyl sulphate	34009 268 832 5 6	France	Central Procurement & Supplies Unit	Nil	Accepted	Authorised products with the same active substance, pharmaceutical form and strength not offered on tender	N/A
AA565/09404	Fibrovein Solution for Injection 3%	Sodium tetradecyl sulfate	34009 268 836 07	Ireland	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/120001	SINORA Concentrate for Soln for Inf 1mg/ml	Noradrenaline	190104	Latvia	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/24604	Propafenone ratiopharmTablet, film coated 150mg	Propafenone hydrochloride	10420.01.00	Germany	Central Procurement & Supplies Unit	Nil	Accepted	Authorised products with the same active substance, pharmaceutical form and strength not offered on tender	N/A
AA1404/00104	Taromentin Pdr for Soln for Injection 500mg+100mg	Amoxicillin/ Clavulanic acid	4400	Poland	Tarchominskie Zaklady Farmaceutyczne Polfa S.A	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP

AA565/118801	Myleran Tablet, film coated 2mg	Busulfan	6101936.00.00	Germany	Central Procurement & Supplies Unit	Nil	Accepted	Authorised products with the same active substance, pharmaceutical form and strength not offered on tender	N/A
AA565/118501	Keracutan Capsule 25mg	Acitretin	1-31433	Austria	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply to the National Health System	N/A
AA729/27504	Palexia SR Tablet Prolonged Release 50mg	Tapentadol	73243	Spain	Cherubino Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA565/04708	Lisinopril cinfa GSP Tablets 5mg	Lisinopril	64563: 607929; 820688	Spain	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply to the National Health System	N/A
AA908/31401	ENAP Tablets 5mg	Enalapril maleate	7898/2015/01-03	Romania	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
AA908/31402	ENAP Tablets 20mg	Enalapril maleate	7898/2015/01-03	Romania	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
AA1414/00202	Lidocaine Aguetant Solution for Injection 20mg/ml	Lidocaine hydrochloride	34009 339 810 9 9; 34009 362 726 0 6; 34009 339 812 1 1	France	Associated Equipment Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A