

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
AA565/122501	Norit Carbomix Granules for Oral Suspension 50g	Activated carbon	BE084874	Belgium	Central Procurement& Supplies Unit	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA729/39801	Disipal Tablet, film coated 50mg	Orphenadrine hydrochloride	13013040	Italy	Cherubino Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1554/00501	Panadol Actifast Lemon Tablets 500mg	Paracetamol	PA 678/39/17	Ireland	Consolidated Packaging Ltd	Nil	Refused	A product with the same active ingredient, strength and pharmaceutical form and having a Marketing Authorisation in Malta is available	N/A
AA565/123601	BetaGalen Cream 0.1%	Betamethasone valerate	16945.00.01	Germany	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1183/00401	Spaverin Tablets 80mg	Drotaverine Hydrochloride	OGYI-T-22489/02-03	Hungary	MEDITOP 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
AA908/19001	Nolvadex D Tablet, film coated 20mg	Tamoxifen	37383/07/04-04-2008	Greece	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
AA1568/00202	Attoxem Capsules Hard 40mg	Atomoxetine	HR-H-203615656	Croatia	Ideal Trade Links, UAB	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA992/00501	Baladex Syrup 50mg/30mg	Theophylline/ Guaifenesin	4243	Poland	Aflofarm Farmacja Polska Sp. z o.o.	Nil	Refused	Due to the unique combination which is not found elsewhere in the EEA, the MAH was asked to submit a MAA through MRP ensuring that all relevant information is made available for regulatory review and decision-making	N/A
AA565/47702	Isozid Tablets 100mg	Isoniazid	6192548.01.00	Germany	Central Procurement& Supplies Unit	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA865/01301	Nalbix Vaginal Tablets 100mg	Clotrimazole	9437509	Portugal	Laboratorios Azevedos Indústria Farmacêutica S.A	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA1330/03505	Levothyroxine Sodium Teva Tablets 75mcg	Levothyroxine Sodium	RVG 108555	Netherlands	Azure Pharmaceuticals Ltd	Nil	Accepted	To ensure continuation of supply	N/A
AA288/04801	Colircusi Antiedema Eye Drops Solution 50mg/ml	Sodium chloride	58.38	Spain	V.J. Salomone Pharma Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A

AA1416/00403	Ibum Supermax Capsules, Soft 600mg	Ibuprofen	24920	Poland	Przedsiębiorstwo Produkcji Farmaceutycznej HASCO-LEK S.A.	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	To undergo MRP
AA908/04806	Motilium Fastmelts Orodispersible Tablet 10mg	Domperidone	PA23490/022/001	Ireland	Neofarma Pharmaceuticals Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1123/04701	Paclitaxel Kabi Concentrate for Soln for Inf 6mg/ml	Paclitaxel	39405030	Italy	Fresenius Kabi Italia S.R.L.	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA1096/00202	Articlox Solution for Injection 1mg/2ml	Hydroxocobalamin acetate	45550/09-09-2009	Greece	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Nil	Accepted	No authorised products are available, marketed or offered on tender	To undergo MRP
AA770/11003	Dalacin C Vaginal Cream 2% w/w	Clindamycin	21162/2-5-2003	Greece	JV HEALTHCARE LTD	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA729/40201	Glycerol Trinitrate Carinopharm Concentrate for Soln for Inf 1mg/ml	Glyceryl trinitrate	4985.00.00	Germany	Cherubino Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1411/11603	Vesanoid Capsules, Soft 10mg	Tretinoin	29838024	Italy	EJ BUSUTTIL LTD	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA288/04901	Alopurinol Generis Tablets 300mg	Allopurinol	5762547	Portugal	VJ Salomone Pharma LTD	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A