

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
AA770/10303	GLUCOPHAGE Tablet, film coated 500mg	Metformin hydrochloride	PA 2286/005/001	Ireland	JV Healthcare 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
AA770/26801	COXIDEM Pdr for Soln for Injection 40mg	Parecoxib	93580/12102021	Greece	DEMO S.A. PHARMACEUTICAL INDUSTRY	Nil	Refused	There is a marketing authorisation in Malta	N/A
AA1454/14101	Esmolol Hikma Solution for Injection 10mg/ml	Esmolol hydrochloride	94286.00.00	Germany	Prohealth Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA1606/01301	Lametta Tablet, film coated 2.5mg	Letrozole	10611	Poland	MyRX Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1411/02002	Micropaque Rectal Suspension 100g/100ml	Barium sulfate	34009 550 021 0 9	France	EJ BUSUTTIL LTD	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1411/13701	Dantrium Capsule 25mg	Dantrolene sodium	RVG 06978	Netherlands	EJ BUSUTTIL LTD	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1416/00401	IBUM dla dzieci, Suppositories 125mg	Ibuprofen	20571	Poland	Przedsiębiorstwo Produkcji Farmaceutycznej Hasc-LEK	Nil	Accepted	No authorised products are available, marketed or offered on tender	To undergo MRP
AA1416/00402	IBUM dla dzieci Suppositories 60mg	Ibuprofen	20570	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
AA908/20102	Phenergan 25 mg film-coated tablets	Promethazine hydrochloride	PA23180/011/002	Ireland	Neofarma Pharmaceuticals Limited	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA908/32601	Arilin Rapid Vaginal Suppositories	Metronidazole	2722.00.01	Germany	Neofarma Pharmaceuticals Limited	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
AA242/05001	BATTIZER 750 mg film-coated tablets	Ciprofloxacin	AIC 038108039	Italy	Pharmabart Ltd.	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A

AA1173/06304	Oestrogel transdermal Gel 0.75mg/dose	Estradiol	BE154831	Belgium	MINT HEALTH LTD	Nil	Accepted	To ensure continuation of supply	N/A
AA1438/01103	Candesartan Krka Tablets 8mg	Candesartan cilexetil	PA1347/026/002	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
AA1438/01104	Candesartan Krka Tablets 16mg	Candesartan cilexetil	PA1347/026/003	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
AA1411/13601	Kemadrin Tablets 5mg	Procyclidine hydrochloride	PA 1691/5/0	Ireland	EJ BUSUTTIL LTD	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A