

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
AA1411/12701	Argatra® Multidose Concentrate for Soln for Inf 100mg/ml	Argatroban monohydrate	81323.00.00	Germany	EJ Busuttil Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	To undergo MRP
AA242/05701	Hydroxyzine Orifarm Tablet, film coated 25mg	Hydroxyzine hydrochloride	51784	Sweden	Pharmabart Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA018/02605	Concerta XL Tablet Prolonged Release 27mg	Methylphenidate HCl	PA22612/002/004	Ireland	Janssen-Cilag International NV	Nil	Accepted	No authorised products are available, marketed or offered on tender	To undergo MRP
AA729/30402	NORFLOXACIN HELCOR Tablet, film coated 400mg	Norfloxacin	9028/2016/01-02	Romania	Cherubino Ltd	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA908/25102	Tetralysal Capsule 300mg	Lymecycline	367 597-4: 16	France	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
AA908/24303	Esomeprazole Aristo Capsules Hard 20mg	Esomeprazole	PA1983/001/001	Ireland	Neofarma Pharmaceuticals Limited	Nil	Accepted	To ensure continuation of supply	N/A
AA908/24304	Esomeprazole Aristo Capsules Hard 40mg	Esomeprazole	PA1983/001/002	Ireland	Neofarma Pharmaceuticals Limited	Nil	Accepted	To ensure continuation of supply	N/A