

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
AA908/15002	Non-Drowsy Sudaplus Tablets 500mg/30mg	Paracetamol; Pseudoephedrine hydrochloride	PA23490/021/001	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
AA565/130001	Custodiol Cardioplegic/Organ Preservation Solution 1000ml	Sodium chloride; Potassium chloride; Magnesium chloride hexahydrate; Calcium chloride dihydrate; Histidine; Histidine hydrochloride monohydrate; Tryptophan; Mannitol; Potassium hydrogen 2-oxopentanedioat	43815.00.00	Germany	Central Procurement & Supplies Unit	Nil	Refused	The product is not in line with the details of Marketing Authorisation of the source country	N/A
AA908/08103	Optrex Clear Eyes Eye Drops Solution 12.5% v/v/0.0.01%w/v	Hamamelis Water; Naphazoline Hydrochloride	PA0979/079/001	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
AA908/35701	Milk of Magnesia Oral Suspension 415mg/5ml	Magnesium hydroxide	PA1186/010/001	Ireland	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
AA084/10502	Alutril Forte Tablets Chewable 500mg/250mg	Magnesium trisilicate; Hydrated Aluminium oxide	19914	Cyprus	Remedica Ltd.	Nil	Accepted	No authorised products are available, marketed, or offered on tender	To undergo MRP
AA1096/00313	Apotel Extra Tablets 500/65mg	Paracetamol; Caffeine	44050/2992008	Greece	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories 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