

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
AA908/08703	Coltramyl Tablets 4mg	Thiocolchicoside	2200996	Portugal	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
AA197/00403	Audax Ear Drops Solution 20%w/v	Choline salicylate	20337	Cyprus	Mundipharma Pharmaceuticals Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	To undergo MRP
AA565/99702	Vinblastine Sulfate Teva Solution for Injection 1mg/ml	Vinblastine	71688	Germany	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1454/00102	Emazole Control Tablets Gastro-Resistant 20mg	Esomeprazole magnesium dihydrate	PA0074/100/001	Ireland	Prohealth	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
AA242/03501	Bromhexin DAK Oral Solution 0,8mg/ml	Bromhexine hydrochloride	10332	Denmark	Pharmabart Ltd.	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/24306	Metoclopramide Labesfal Solution for Injection 10mg/2ml	Metoclopramide hydrochloride monohydrate	2898492 & 5228697	Portugal	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/94601	Synacthene Solution for Injection 0.25mg/1mL	Tetracosactide	34009 318 286 93	Italy	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA084/10702	Zestaval Tablets Chewable 400mg	Albendazole	20169	Cyprus	Remedica Ltd.	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1570/00401	Uniflox Eye Drops Solution 0.3%	Ofloxacin	64/0013/02-S	Slovakia	UNIMED PHARMA, spol. s r.o.	Nil	Accepted	No authorised products are available, marketed or offered on tender	To undergo MRP

AA565/21813	Minims Phenylephrine Hydrochloride Eye Drops Solution 2.5%	Phenylephrine	PA23259/016001	Ireland	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1228/03401	PREDOX Tablet, film coated 50mg	Itopride hydrochloride	27867	Poland	Focused Pharma Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA908/22802	Triderm Cream 0.5mg/10mg/1mg	Betamethasone dipropionate; Clotrimazole; Gentamicin sulfate	7215/2014/01	Romania	NEOFARMA PHARMACEUTICALS LTD	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA908/29001	Ibalgin Duo Effect Cream 50mg/g/2mg/g	Ibuprofen; Heparinoid S	29/695/99-C	Czech Republic	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
AA1366/00102	Itraconazol Slavia Capsule 100mg	Itraconazole	12422/2019/01	Romania	S.C. Slavia Pharm SRL	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP