

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
AA565/87901	Gabbroral Tablets 250mg	Paromomycin	BE018724	Italy	Central Procurement& Supplies Unit	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1488/03201UK	Calcichew Tablets Chewable 500mg	Calcium carbonate	PL 16189/0023	United Kingdom	HHP Malta (P&D Pharma) Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	Commitment to identify alternatives sources from the EEA and issued for specific tender only
AA770/06803UK	Irinotecan Hydrochloride Concentrate for Soln for Inf 20mg/ml	Irinotecan hydrochloride trihydrate	PL 41013/0001	United Kingdom	JV Healthcare Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	Commitment to identify alternatives sources from the EEA and issued for specific tender only
AA565/02904	Lanoxin Solution for Injection 0.500mg/2mL	Digoxin	BE058213	France	Central Procurement& Supplies Unit	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1106/00403	Contracne Capsules, Soft 10mg	Isotretinoin	34009 358 120 49	France	Laboratoires Bailleul S.A.	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1106/00404	Contracne Capsules, Soft 20mg	Isotretinoin	34009 358 116 77	France	Laboratoires Bailleul S.A.	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1093/00205	Toularynx Bromhexine Syrup 5mg/5ml	Bromhexine Hydrochloride	BE155364	Belgium	Laboratoria Qualiphar N.V./S.A	Nil	Accepted	No authorised products are available, marketed or offered on tender	Commitment to undergo MRP
AA729/29301	Fluodesossigiucosio (18F) Solution for Injection 250MBq	Fludeoxyglucose	44466011	Italy	Cherubino Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A

AA1488/01701UK	Quinine Sulfate Coated Tablets 200mg	Quinine sulfate	PL 00289/5242R	United Kingdom	HHP Malta (P&D Pharma) Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	Commitment to identify alternatives sources from the EEA and issued for specific tender only
AA041/00402	Rowatinex Gastro-resistant Capsules, Soft	Alpha-pinene; Beta-pinene; Camphene; Borneol; Anethol; Fenchone; Cineol	PA0074/009/001	Ireland	ROWA PHARMACEUTICALS LTD	Nil	Accepted	To ensure continuity of supply and difficulty identified to undergo MRP during this time	Commitment to undergo MRP
AA565/60705	Atosiban SUN Solution for Injection 6.75 mg/0.9 ml	Atosiban	EU/1/13/852/001	Netherlands	Central Procurement & Supplies Unit	Nil	Refused	The product has a marketing authorisation	N/A
AA1122/03101	Calcipotriol/Betamethasone Rowex Ointment 50mcg/g + 0.5mg/g	Calcipotriol monohydrate; Betamethasone Dipropionate	PA0711/254/001	Ireland	Rowex Ltd	Nil	Refused	The product has a marketing authorisation	N/A
AA565/88201	Calciferol BBP Solution for Injection 7.5mg/ml	Ergocalciferol	86/672/69-S/C	Slovakia	Central Procurement & Supplies Unit	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1343/02101UK	Fludrocortisone acetate Tablets 0.1mg	Fludrocortisone acetate	PL 39699/0071	United Kingdom	Target Healthcare Limited	Nil	Accepted	No authorised products are available, marketed or offered on tender	Commitment to identify alternatives sources from the EEA and issued for specific tender only