

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
AA1411/13101	Bupivacaine Fisiopharma Solution for Injection 2.5mg/ml	Bupivacaine hydrochloride	35246026	Italy	EJ BUSUTTIL LTD	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1411/13501	Tuberculin PPD Evans Solution for Injection 2 units/0.1ml	Tuberculin units	58.281: 685461, 724783	Spain	EJ BUSUTTIL LTD	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/53506	Mitomycin medac Pdr+Solv for Soln for Inj 40mg	Mitomycin	5675947	Portugal	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/125001	Naltex Tablet, film coated 50mg	Naltrexone hydrochloride	17612	Poland	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1349/00902	Normotus antitussive Oral Solution 2mg/ml	Dextromethorphan hydrobromide	MA: 67155, NC: 652460	Spain	LABORATORIOS NORMON, 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
AA1525/00201	Pirfenidone Vivanta Tablet, film coated 267mg	Pirfenidone	RVG 128461	Netherlands	Vivanta Generics s.r.o.	Nil	Refused	There is a Marketing Authorisation for this product	N/A