

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
AA565/14607	Labetalol S.A.L.F. Solution for Inj/Inf 5mg/ml	Labetalol hydrochloride	5709217	Portugal	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1438/13801	Ibuprofen Teva Tablet, film coated 400mg	Ibuprofen	67,900	Spain	NM Pharma Limited	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A
AA770/27401	Perphyl Syrup 667mg/ml	Lactulose	5632278	Portugal	JV Healthcare Limited	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA565/104403	Remodulin Solvent for Parenteral Use 5mg	Treprostinil sodium	5683289	Portugal	Central Procurement & Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1411/14001	Colistimethate Sodium Altan Pharma Solution for Inj/Inf 1 million IU	Colistimethate sodium	66292: 838185	Spain	EJ BUSUTTIL LTD	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1349/00305	Aripiprazole Normon Oral Solution 1mg/ml	Aripiprazole	709218: 80482	Spain	LABORATORIOS NORMON, S.A.	Nil	Accepted	To ensure continuation of supply	To undergo MRP
AA214/01303	Ferrovin Concentrate for Soln for Inf 20mg/ml	Iron (III) hydroxide sucrose complex	91886/19/11-02-2020	Greece	Rafarm S.A.	Nil	Accepted	There are no other authorised products for this active substance in the same strength and pharmaceutical form	To undergo MRP
AA770/12303	Valsartan Teva Tablet, film coated 80mg	Valsartan	PA0749/084/002	Ireland	JV Healthcare Limited	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA770/12304	Valsartan Teva Tablet, film coated 160mg	Valsartan	PA0749/084/003	Ireland	JV Healthcare Limited	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA1454/02002	Carboplatin Hikma Solution for Infusion 10mg/ml	Carboplatin	3002152.00.00	Germany	Prohealth Limited	Nil	Accepted	To ensure continuation of supply	To undergo MRP