

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
AA1411/08203	Dotarem Solution for Injection 279.3mg/ml	Gadoteric acid	12086/38455	Finland	EJ Busuttil Ltd	Nil	Accepted	The product is to be made available at least 10% less than the price of the cheapest authorised alternative	N/A
AA1544/00201	Pamintu Solution for Injection 10mg/ml	Protamine Sulfate	20200217	Bulgaria	Onko Pharmaceuticals Bulgaria EOOD	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA1500/00601	Trióxido De Arsénio Generis Concentrate for Soln for Inf 1mg/ml	Arsenic trioxide	5786215	Portugal	Eugia Pharma (Malta) Limited.	Nil	Accepted	To ensure continuation of supply for the National Health System	To undergo MRP
AA565/04219	Ondansetron Aurovitas Solution for Inj/Inf 4 mg/2 ml	Ondansetron	5703814	Portugal	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA1343/05601	Furantoin Oral Suspension 10mg/ml	Nitrofurantoin	34.388	Spain	Target Healthcare Limited	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A
AA565/53912	5-Fluorouracil Ebewe Concentrate for Susp for Inf 50mg/ml	Fluorouracil	20000369	Bulgaria	Central Procurement& Supplies Unit	Nil	Accepted	To ensure continuation of supply for the National Health System	N/A