

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
AA729/28601UK	Metanium Nappy Rash Ointment 20%w/w	Titanium Dioxide; Titanium Peroxide; Titanium Salicylate	PL 00240/0366	United Kingdom	Cherubino Ltd	Nil	Pending	N/A	N/A
AA721/00602	Oxaviatin Concentrate for Soln for Inf 5mg/ml	Oxaliplatin	5887019/21012020	Greece	VIANEX SA	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA1414/00201	Lidocaine Aguettant Solution for Injection 20mg/ml	Lidocaine Hydrochloride	3400936272606	France	Associated Equipment Ltd	Nil	Accepted	There are fewer than three authorised products on the market with the same active ingredient, dose and strength	N/A
AA565/53905	Fluorouracil Accord Solution for Inj/Inf 50mg/mL	Fluorouracil	89351.00.00	Netherlands	Central Procurement & Supplies Unit	Nil	Rejected	The product has a marketing authorisation	N/A

AA729/27902	Daptomycin Norameda Solution for Inj/Inf 500mg	Daptomycin	34591	Finland	Cherubino Ltd	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA565/49105	Naltrexone Amomed Tablet, film coated 50mg	Naltrexone hydrochloride	11940/2019/01-04	Romania	Central Procurement & Supplies Unit	Nil	Accepted	No authorised products are available, marketed or offered on tender	N/A
AA565/53906UK	Fluorouracil AHCL Solution for Inj/Inf 50mg/ml	Fluorouracil	40593028	United Kingdom	Central Procurement & Supplies Unit	Nil	Rejected	The product has a marketing authorisation	N/A
AA908/03504	Nexium Tablets Gastro-Resistant 20mg	Esomeprazole	8423/2015/01-02	Romania	Neofarma Pharmaceuticals Limited	Nil	Accepted	The product is to be made available at least 10% cheaper given the existence of a licence in accordance with article 126(a) for the same product (but different 126(a) authorisation holder)	N/A

AA908/03505	Nexium Tablets Gastro-Resistant 40mg	Esomeprazole	8424/2015/01-02	Romania	Neofarma Pharmaceuticals Limited	Nil	Accepted	The product is to be made available at least 10% cheaper given the existence of a licence in accordance with article 126(a) for the same product (but different 126(a))	N/A
AA565/86001	Bosentan Aurobindo Tablet, film coated 125mg	Bosentan	5661947	Portugal	Central Procurement & Supplies Unit	Nil	Rejected	The product has a marketing authorisation	N/A
AA1173/07701UK	Motilium Tablet, film coated 10mg	Domperidone	PL 17780/0300	United Kingdom	Mint Health Ltd (prev Medical Logistics Ltd)	Nil	Rejected	The product has a marketing authorisation	N/A

AA1247/00201	Octenisept	Octenidine	1-20402	Austria	Premiere	Nil	Rejected	The indication mentions use in premature babies. This active ingredient is not authorised in Malta in any other product and more information on the use of this product in premature babies is required. An MRP is recommended to refer to the Assessment Report of the RMS.	N/A
	Cutaneous	dihydrochloride;							
	Solution 0.1%/2%	Phenoxyethanol			Healthcare				