

| 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 |
|-------------------|-----------------------------------------------------------------------------|----------------------------------------|----------------------------------------------|----------------|------------------------------------|---------------------|-----------------------|-----------------------------------------------------------------------------------------------------------------|------------------------------------|
| AA908/08006       | NUROFEN FORTE EXPRESS Coated Tablets 400mg                                  | Ibuprofen sodium dihydrate             | LT/1/97/0271/023                             | Lituhuania     | Neofarma Pharmaceuticals Limited   | Nil                 | Accepted              | The product is to be made available at least 10% less than the price of the cheapest authorised alternative     | N/A                                |
| AA1173/05403      | Gabapentin Aurovitas Capsules Hard 100mg                                    | Gabapentin                             | 24513                                        | Poland         | Mint Health Limited                | Nil                 | Accepted              | No authorised products are available, marketed or offered on tender                                             | N/A                                |
| AA1173/05404      | Gabapentin Aurovitas Capsules Hard 300mg                                    | Gabapentin                             | 24514                                        | Poland         | Mint Health Limited                | Nil                 | Accepted              | The product is to be made available at least 10% less than the price of the cheapest authorised alternative     | N/A                                |
| AA565/49204       | Cabergoline ratiopharm Tablets 0.5mg                                        | Cabergoline                            | 37576028                                     | Italy          | Central Procurement& Supplies Unit | Nil                 | Accepted              | To ensure continuation of supply for the National Health System                                                 | N/A                                |
| AA908/26702       | Gliclazide Retard Mylan Controlled releas Tablets 80mg                      | Gliclazide                             | RVG 26307                                    | Netherlands    | Neofarma Pharmaceuticals Limited   | Nil                 | Accepted              | There are fewer than three authorised products on the market with the same active ingredient, dose and strength | N/A                                |
| AA1343/06101      | Carnicor Oral Solution 300mg/ml                                             | L-carnitine                            | 55501.N.C.962373, 627489                     | Spain          | Target Healthcare Limited          | Nil                 | Accepted              | No authorised products are available, marketed or offered on tender                                             | N/A                                |
| AA565/00409       | Levodopa+carbidopa+entacapo ne Generis Tablet, film coated 100mg/25mg/200mg | Levodopa,carbidopa,en tacapone.        | 5625371; 5625305                             | Portugal       | Central Procurement& Supplies Unit | Nil                 | Accepted              | To ensure continuation of supply for the National Health System                                                 | N/A                                |
| AA565/129801      | PPD Tuberculin Mammalian Solution for Injection 5TU/0.1ml                   | Tuberculin purified protein derivative | 11-11522/<br>13.12.2010<br>Reg. No. 20000719 | Bulgaria       | Central Procurement& Supplies Unit | Nil                 | Accepted              | To ensure continuation of supply for the National Health System                                                 | N/A                                |
| AA1438/15701      | Xylo-Nasal Nasal Drops Soln 1mg/ml                                          | Xylometazoline hydrochloride           | 13735/2021/01                                | Romania        | NM Pharma Ltd                      | Nil                 | Accepted              | There are fewer than three authorised products on the market with the same active ingredient, dose and strength | N/A                                |
| AA565/129501      | Inepitant Capsules Hard 125mg/80mg                                          | Aprepitant                             | 75582/25062024                               | Greece         | Central Procurement& Supplies Unit | Nil                 | Accepted              | To ensure continuation of supply for the National Health System                                                 | N/A                                |
| AA1454/07001      | Flucloxacillin Pdr for Soln Inj/Inf 1000mg                                  | Flucloxacillin                         | PA1862/003/003                               | Ireland        | Prohealth                          | Nil                 | Accepted              | To ensure continuation of supply for the National Health System                                                 | N/A                                |
| AA565/110501      | Holoxan Pdr for Soln for Infusion 2g                                        | ifosfamide                             | 9700326                                      | Bulgaria       | Central Procurement& Supplies Unit | Nil                 | Accepted              | To ensure continuation of supply for the National Health System                                                 | N/A                                |
| AA908/06505       | Imodium Plus Tablets 2mg/125mg                                              | Loperamide hydrochloride Simeticone    | PA23490/030/001                              | Ireland        | Neofarma Pharmaceuticals Limited   | Nil                 | Accepted              | There are fewer than three authorised products on the market with the same active ingredient, dose and strength | N/A                                |
| AA770/18303       | Xylocaine 2% - Adrenaline Solution for Injection 20mg/ml 5mcg/ml            | Lidocaine; Adrenaline                  | RVG 30238                                    | Netherlands    | 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                                |
| AA565/50106       | Hydrocortisone Tablets 5mg                                                  | Hydrocortisone                         | PA22865/003/003                              | Ireland        | Central Procurement& Supplies Unit | Nil                 | Accepted              | There are no other authorised products for this active substance in the same strength or pharmaceutical form    | N/A                                |

|              |                                                   |                  |                         |                   |                                       |     |          |                                                                                                                       |                   |
|--------------|---------------------------------------------------|------------------|-------------------------|-------------------|---------------------------------------|-----|----------|-----------------------------------------------------------------------------------------------------------------------|-------------------|
| AA565/48304  | ROCALtrol Capsules, Soft<br>0.50mcg               | Calcitriol       | 86/539/92-B/C           | Czech<br>Republic | Central Procurement&<br>Supplies Unit | Nil | Accepted | There are no other authorised products<br>for this active substance in the same<br>strength or pharmaceutical form    | N/A               |
| AA565/129101 | UNITIMOLOL Eye Drops<br>Solution 0,5%             | timolol maleate  | 50578                   | Latvia            | Central Procurement&<br>Supplies Unit | Nil | Accepted | To ensure continuation of supply for the<br>National Health System                                                    | N/A               |
| AA240/01503  | Maxilin Pdr/Conc/Soln for Infus<br>500mg          | Clarithromycin   | 46783/21-09-2009        | Greece            | Anfarm Hellas SA                      | Nil | Accepted | To ensure continuation of supply for the<br>National Health System                                                    | To undergo<br>MRP |
| AA1045/05803 | Galfer Oral Suspension<br>140mg/5ml               | Ferrous Fumarate | PA0126/314/002          | Ireland           | Clonmel Healthcare Ltd                | Nil | Accepted | To ensure continuation of supply for the<br>National Health System                                                    | To undergo<br>MRP |
| AA1411/16201 | Nexium Granules for Oral<br>Suspension 10mg       | Esomeprazole     | 034972556;<br>034972568 | Italy             | EJ Busuttil Ltd                       | Nil | Accepted | To ensure continuation of supply for the<br>National Health System                                                    | N/A               |
| AA729/42701  | Nimodipine Stadaforma Tablet,<br>film coated 30mg | Nimodipine       | 84780                   | Spain             | Cherubino Ltd                         | Nil | Accepted | There are fewer than three authorised<br>products on the market with the same<br>active ingredient, dose and strength | N/A               |