

| 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 |
|-------------------|---|---|-------------------------------------|----------------|------------------------------------|---------------------|-----------------------|---|------------------------------------|
| AA770/21501UK     | Lemsip Max Cold & Flu Lemon Oral Powder 1000mg/12.2mg | Paracetamol<br>Phenylephrine  | PL00063/0069                        | United Kingdom | JV Healthcare Limited              | Nil                 | Refused               | There are several alternative products available in the European Union including Malta. The requirements of Directive 642/2002 (to allow in the case of shortages/severe problems with availability) are not satisfied. | N/A                                |
| AA770/21701UK     | Beechams Cold & Flu Sachets 600mg/10mg                | Paracetamol<br>Phenylephrine<br>Hydrochloride                                   | PL 44673/0016                       | United Kingdom | JV Healthcare Limited              | Nil                 | Refused               | There are several alternative products available in the European Union including Malta. The requirements of Directive 642/2002 (to allow in the case of shortages/severe problems with availability) are not satisfied. | N/A                                |
| AA1073/00202      | Septofort Lozenges 2mg                                | Chlorhexidine digluconate   | 69/836/95-C                         | Czech Republic | Walmart a.s.                       | Nil                 | Issued                | No authorised products are available, marketed or offered on tender with the required specifications  | To undergo MRP                     |
| AA1411/06501      | Cefuroxime AptaPharma Pdr for Soln Inj/Inf 750mg      | Cefuroxime  | OGYI-T 23480/03                     | Hungary        | EJ Busuttil Ltd                    | Nil                 | Issued                | To ensure continuation of supply for the National Health System.  | N/A                                |
| AA1513/03301      | Sudocrem Anticeptic Healing Cream                     | Zinc oxide<br>Benzyl alcohol<br>Benzyl benzoate<br>Benzyl cinnamate<br>Wool fat | PA0436/054/001                      | Ireland        | Pharma Regulatory Services Limited | Nil                 | Issued                | No authorised products are available, marketed or offered on tender.  | N/A                                |

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|---------------|---|--|-----------------|----------------|-------------------------------------|-----|---------|---|----------------|
| AA197/00303   | Mucobroxol Syrup 15mg/5ml   | Ambroxol Hydrochloride   | 19999           | Cyprus         | Mundipharma Pharmaceuticals Limited | Nil | Issued  | There are fewer than three authorised products on the market with the same active ingredient, dose and strength   | To undergo MRP |
| AA1241/00301  | Renoscint MAG3 Kit for Radiopharmaceutical Preparation 1mg        | Betiatide  | OGYI-T-23275/02 | Hungary        | Medi-Radiopharma Ltd.               | Nil | Issued  | To ensure continuation of supply for the National Health System   | To undergo MRP |
| AA770/21502UK | Lemsip Max Day & Night Cold & Flu Relief Capsule 500mg/25mg/6.1mg | Paracetamol<br>Caffeine<br>Phenylephrine hydrochloride<br>Paracetamol<br>Phenylephrine hydrochloride | PL00063/0143    | United Kingdom | JV Healthcare Limited               | Nil | Refused | There are several alternative products available in the European Union including Malta. The requirements of Directive 642/2002 (to allow in the case of shortages/severe problems with availability) are not satisfied. | N/A            |
| AA1045/07301  | Abiraterone Clonmel Tablet, film coated 500mg                     | Abiraterone acetate  | PA0126/336/001  | Ireland        | Clonmel Healthcare Ltd.             | Nil | Issued  | Authorised products with the same active substance, pharmaceutical form and strength are not marketed   | N/A            |
| AA565/11906   | Flutamide AL Tablets 250mg  | Flutamide  | 42660.00.00     | Germany        | Central Procurement & Supplies Unit | Nil | Issued  | To ensure continuation of supply for the National Health System   | N/A            |
| AA264/00301UK | Human Rabies Immunoglobulin Solution for Injection 150IU/ml       | Human Immunoglobulin G   | PL08801/0014    | United Kingdom | Bio Products Laboratory Limited     | Nil | Issued  | To ensure continuation of supply for the National Health System   | To undergo MRP |
| AA729/36501UK | Acitretin Capsule 10mg  | Acitretin  | PL 06831/0251   | United Kingdom | Cherubino Ltd                       | Nil | Issued  | To ensure continuation of supply for the National Health System   | N/A            |
| AA1411/06701  | Abiraterone Dr. Reddys Tablet, film coated 500mg                  | Abiraterone acetate  | 85945/730902.4  | Spain          | EJ Busuttil Ltd                     | Nil | Issued  | To ensure continuation of supply for the National Health System   | N/A            |
| AA565/60706   | Atosiban Altan Concentrate for Soln for Inf 37.5mg/5ml            | Atosiban   | 5715115         | Portugal       | Central Procurement & Supplies Unit | Nil | Issued  | To ensure continuation of supply for the National Health System   | N/A            |

|             |  |  |                 |        |                                     |     |         |   |     |
|-------------|--|--|-----------------|--------|-------------------------------------|-----|---------|---|-----|
| AA908/26802 | Movicol Unflavoured Powder for Oral Solution   | Macrogol 3350<br>Sodium bicarbonate<br>Potassium chloride<br>Sodium chloride | 34009 494 76534 | France | Neofarma Pharmaceuticals Limited    | Nil | Refused | The product has a marketing authorisation in Malta              | N/A |
| AA565/15204 | Haldol Decanoas Solution for Injection 50mg/ml | Haloperidol  | AIC 25333016    | Italy  | Central Procurement & Supplies Unit | Nil | Issued  | To ensure continuation of supply for the National Health System | N/A |