

| 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 |
|-------------------|-------------------------------------------------|-----------------------------------------------------------------|-------------------------------------|----------------|---------------------------------------|---------------------|-----------------------|----------------------------------------------------------------------------------------------------------------------|------------------------------------|
| AA1411/10102      | Sorbisterit, powder for Oral Suspension 90% w/m | Calcium Polystyrene Sulfonate                                   | RVG 10261                           | Netherlands    | EJ Busuttil Ltd                       | Nil                 | Accepted              | To ensure continuation of supply for the National Health System                                                      | N/A                                |
| AA565/128901      | Rive Eye Drops Solution 1mg/ml                  | Diclofenac Sodium                                               | 5903539                             | Portugal       | Central Procurement and Supplies Unit | Nil                 | Accepted              | To ensure continuation of supply                                                                                     | N/A                                |
| AA565/72002       | Nefrocarnit® Solution for Injection 1g/5ml      | Levocarnitine                                                   | 2143.00.00                          | Germany        | Central Procurement and Supplies Unit | Nil                 | Accepted              | To ensure continuation of supply for the National Health System                                                      | N/A                                |
| AA1316/00802      | Lanzol Hard Capsules Gastro-Resistant 30mg      | Lansoprazole                                                    | PA0711/067/002                      | Ireland        | 4 Pharma Ltd                          | Nil                 | Accepted              | The product is to be made available at least 10% less than the price of the authorised alternative of the same brand | N/A                                |
| AA565/128601      | TRIACORT Suspension for Injection 40mg/1ml      | Triamcinolone acetonide                                         | 33919010                            | Italy          | Central Procurement and Supplies Unit | Nil                 | Accepted              | To ensure continuation of supply for the National Health System                                                      | N/A                                |
| AA565/127401      | Rivaroxaban Abdi Tablet, film coated 20mg       | Rivaroxaban                                                     | 2203550.00.00                       | Germany        | Central Procurement and Supplies Unit | Nil                 | Accepted              | To ensure continuation of supply for the National Health System                                                      | N/A                                |
| AA565/127402      | Rivaroxaban Abdi Tablet, film coated 10mg       | Rivaroxaban                                                     | 2203548.00.00                       | Germany        | Central Procurement and Supplies Unit | Nil                 | Accepted              | To ensure continuation of supply for the National Health System                                                      | N/A                                |
| AA1123/02402      | Soluvit Pdr for Soln for Infusion               | Thiamine mononitrate; Nicotinamide; Sodium Pantothenate; Biotin | 27984018                            | Italy          | Fresenius Kabi Italia S.r.l.          | Nil                 | Accepted              | To ensure continuation of supply for the National Health System                                                      | To undergo MRP                     |
| AA1513/04801      | Pentacarinat Pdr for Soln for Injection 300mg   | Pentamidine                                                     | AIC 027625019                       | Italy          | Pharma Regulatory Services Limited    | Nil                 | Accepted              | There are fewer than three authorised products on the market with the same active ingredient, dose and strength      | N/A                                |
| AA565/82702       | Yomesan Tablets Chewable 500mg                  | Niclosamide                                                     | 6245026.00.00                       | Germany        | Central Procurement and Supplies Unit | Nil                 | Accepted              | To ensure continuation of supply for the National Health System                                                      | N/A                                |