LEGAL NOTICE No. 283

## REPUBLIC OF TRINIDAD AND TOBAGO

THE FOOD AND DRUGS ACT, CHAP. 30:01

## **NOTIFICATION**

## APPROVAL IN RESPECT OF NEW DRUGS

ISSUED by the Minister on the recommendation of the Drug Advisory Committee in accordance with paragraph 7, Division 3 of the Second Schedule of the Food and Drugs Regulations.

The Minister signifies his approval in respect of the following new drugs:

| Trade Name and Form  | Manufacturer   | Country of Origin | Condition of Sale |
|--|--|-------------------|-------------------|
| Mabthera Solution for<br>Subcutaneous Injection<br>1400mg/11.7ml<br>(Change of Marketing<br>Authorisation Holder<br>and Change of Label) | F. Hoffmann-La Roche Ltd., Kaiseraugst, Switzerland For: F. Hoffmann-La Roche Ltd., Basel, Switzerland | Switzerland       | Third Schedule    |
| Kadcyla Powder for<br>Concentrate for Solution<br>for Infusion 100mg<br>(Additional<br>Manufacturing Site and<br>Change of Label)        | do.  | do.               | do.               |
| Kadeyla Powder for<br>Concentrate for Solution<br>for Infusion 160mg<br>(Change of<br>Manufacturing Site and<br>Change of Label)         | do.  | do.               | do.               |

| Trade Name and Form   | Manufacturer   | Country of Origin | Condition of Sale |
|---|--|-------------------|-------------------|
| Herceptin Solution for<br>Injection 600mg/5ml<br>(Change of Marketing<br>Authorisation Holder<br>and Change of Label) | F. Hoffmann-La Roche Ltd., Kaiseraugst, Switzerland For: F. Hoffmann-La Roche Ltd., Basel, Switzerland                   | Switzerland       | Third Schedule    |
| Perjeta Concentrate for<br>Solution for Infusion<br>420mg/14ml<br>(Additional Indication)                             | Roche Diagnostics GmbH, Mannheim, Germany For: F. Hoffmann-La Roche Ltd., Basel, Switzerland                             | Germany           | do.               |
| Zelboraf Film-Coated Tablets 240mg (Change of Name and Address of Manufacturer and Change of Label)                   | Delpharm Milano<br>S.r.l.,<br>Segrate, Milan,<br>Italy<br>For:<br>F. Hoffmann-La<br>Roche Ltd.,<br>Basel,<br>Switzerland | Italy             | do.               |
| Adalat Oros Tablets 30mg (Change of Marketing Authorisation Holder and Change of Name of Manufacturer)                | Primary Packager: Bayer AG, Germany Secondary Packager: Bayer S.A., Guatemala  | Guatemala         | do.               |

| Trade Name and Form   | Manufacturer   | Country of Origin | Condition of Sale |
|---|--|-------------------|-------------------|
| Avelox Film-Coated Tablets 400mg (Change of Marketing Authorisation Holder and Change of Name of Manufacturer)  | Primary Packager: Bayer AG, Germany Secondary Packager: Bayer S.A., Guatemala For: Bayer AG, Germany | Guatemala         | Third Schedule    |
| Ciproxina Solution for Infusion 0.2g (Change of Name of Marketing Authorisation Holder, Change of Name of Manufacturing and Packaging Site and Change of Label) | Bayer AG,<br>Germany   | Germany           | do.               |
| Ciproxina Solution for Infusion 0.4g (Change of Name of Marketing Authorisation Holder, Change of Name of Manufacturing and Packaging Site and Change of Label) | do.  | do.               | do.               |
| Levitra Film Coated Tablets 5mg (Change of Name of Marketing Authorisation Holder, Change of Name of Manufacturing and Packaging Site and Change of Label)      | do.  | do.               | do.               |

| Trade Name and Form   | Manufacturer         | Country of Origin | Condition of Sale |
|---|----------------------|-------------------|-------------------|
| Levitra Film Coated Tablets 10mg (Change of Name of Marketing Authorisation Holder, Change of Name of Manufacturing and Packaging Site and Change of Label)                                 | Bayer AG,<br>Germany | Germany           | Third Schedule    |
| Levitra Film Coated Tablets 20mg (Change of Name of Marketing Authorisation Holder and Change of Name of Manufacturing and Packaging Site)  | do.                  | Germany           | do.               |
| Nebido Solution for<br>Injection 1000mg/4ml<br>(Change of Name of<br>Marketing<br>Authorisation Holder,<br>Change of Name of<br>Manufacturing and<br>Packaging Site and<br>Change of Label) | do.                  | do.               | do.               |
| Primoteston Depot Injectable Solution 250mg (Change of Name of Marketing Authorisation Holder, Change of Name of Manufacturing and Packaging Site and Change of Label)                      | do.                  | do.               | do.               |

| Trade Name and Form   | Manufacturer   | Country of Origin | Condition of Sale |
|---|--|-------------------|-------------------|
| Proviron Tablets 25mg<br>(Change of Name of<br>Marketing<br>Authorisation Holder<br>and Change of Label)  | Schering do Brasil, Quimica e Farmaceutica Ltda. Brazil For: Bayer AG, Germany | Brazil            | Third Schedule    |
| Jaydess® Intrauterine Delivery System (Change of Name of Marketing Authorisation Holder and Change of Label)  | Bayer Oy, Turku,<br>Finland<br>For:<br>Bayer AG,<br>Germany                    | Finland           | do.               |
| Natele Easy Gel Soft Capsules (Change of Name of Marketing Authorisation Holder)  | Berlimed, S.A.,<br>Spain<br>For:<br>Bayer AG,<br>Germany                       | Spain             | Freely            |
| Gadovist Solution for Injection 1.0mmol/ml (Change of Name of Marketing Authorisation Holder, Manufacturer and Packager, Additional Indication and Change of Label) | Bayer AG,<br>Germany   | Germany           | Third Schedule    |
| Stivarga Film-Coated<br>Tablets 40mg<br>(New Indication)  | do.  | do.               | do.               |

| Trade Name and Form  | Manufacturor  | Country of Onicia | Condition of Calo |
|--|---|-------------------|-------------------|
|  | Manufacturer  | Country of Origin | Condition of Sale |
| Clarityne Tablets 10mg<br>(Change of Name of<br>Product and Change of<br>Label)  | Schering-Plough Lab N.V., Belgium For: Bayer S.A., Guatemala  | Belgium           | Freely            |
| Tarceva Film-Coated Tablets 100mg (Additional Indication, Change of Name and Address of Manufacturer, Additional Primary and Secondary Packager and Change of Label) | Delpharm Milano S.r.l., Italy Packed by: F. Hoffmann-La Roche Ltd., Kaiseraugst, Switzerland For: F. Hoffmann-La Roche Ltd. Basel, Switzerland      | Italy             | Third Schedule    |
| Tarceva Film-Coated Tablets 150mg (Additional Indication, Change of Name and Address of Manufacturer, Additional Primary and Secondary Packager and Change of Label) | do.   | do.               | do.               |
| Cellcept® Capsules 250mg (Change of Name and Address of Manufacturer, Additional Secondary Packaging Site and Change of Label)                                       | Delpharm Milano S.r.l., Milan, Italy Packed by: F. Hoffmann-La Roche Ltd, Kaiseraugst, Switzerland For: F. Hoffmann-La Roche Ltd Basel, Switzerland | do.               | do.               |

| Trade Name and Form   | Manufacturer  | Country of Origin | Condition of Sale |
|---|---|-------------------|-------------------|
| Cellcept® Film-Coated Tablets 500mg (Additional Manufacturing Site and Change of Label)   | F. Hoffmann-La Roche Ltd., Basel, Switzerland By: Recipharm Leganes, Spain Packed by: F. Hoffmann-La Roche Ltd., Kaiseraugst, Switzerland                                   | Switzerland       | Third Schedule    |
| Cellcept® Film-Coated Tablets 500mg (Change of Name and Address of Manufacturing Site, Additional Secondary Packaging Site and Change of Label) | Delpharm Milano S.r.l., Italy Packed by: F. Hoffmann-La Roche Ltd., Basel, Switzerland For: F. Hoffmann-La Roche Ltd., Basel, Switzerland                                   | Italy             | do.               |
| Xeloda Film-Coated Tablets 500mg (Additional Manufacturing Site and Packager and Change of Label)   | Shanghai Roche Pharmaceuticals Ltd., Shanghai, China Packed by: F. Hoffmann-La Roche Ltd., Kaiseraugst, Switzerland Made for: F. Hoffmann-La Roche Ltd., Basel, Switzerland | Switzerland       | do.               |

| Trade Name and Form   | Manufacturer  | Country of Origin | Condition of Sale |
|---|---|-------------------|-------------------|
| Xeloda Film-Coated Tablets 500mg (Additional Manufacturing Site and Packager and Change of Label)                                       | Excella GmbH & Co. KG, Feucht, Germany Packed by: F. Hoffmann La Roche Ltd., Kaiseraugst, Switzerland Made for: F. Hoffmann-La Roche Ltd., Basel, Switzerland | Switzerland       | Third Schedule    |
| Xenical Capsules 120mg (Change of Marketing Authorisation Holder, Change of Name and Address of Manufacturing Site and Change of Label) | CHEPLAPHARM Arzneimittel GmbH, Germany By: Delpharm Milano S.r.l., Segrate, Italy   | Italy             | do.               |
| Coreg Tablets 6.25mg<br>(Change of Marketing<br>Authorisation Holder,<br>Change of<br>Manufacturing Site and<br>Change of Label)        | do.   | do.               | do.               |
| Coreg Tablets 12.5mg<br>(Change of Marketing<br>Authorisation Holder,<br>Change of<br>Manufacturing Site and<br>Change of Label)        | do.   | do.               | do.               |

| Trade Name and Form  | Manufacturer  | Country of Origin | Condition of Sale |
|--|---|-------------------|-------------------|
| Coreg Tablets 25mg<br>(Change of Marketing<br>Authorisation Holder,<br>Change of<br>Manufacturing Site,<br>Change of Packaging<br>and Change of Label) | CHEPLAPHARM Arzneimittel GmbH, Germany By: Delpharm Milano S.r.l., Segrate, Italy                           | Italy             | Third Schedule    |
| Dermovate Cream 0.05% w/w (Change of Name of Manufacturer and Change of Label)   | GlaxoSmithKline<br>Brasil LTDA,<br>Rio de Janeiro,<br>Brazil  | Brazil            | do.               |
| Dermovate Ointment 0.05% w/w (Change of Name of Manufacturer and Change of Label)  | do.   | do.               | do.               |
| Trizivir Film-Coated Tablets 300mg/150mg/300mg (Additional Manufacturing Site and Change of Label)   | GlaxoSmithKline<br>Pharmaceuticals<br>S.A.,<br>Poznan, Poland   | Poland            | do.               |
| Kivexa Film-Coated<br>Tablets 600mg/300mg<br>(Additional<br>Manufacturing Site and<br>Change of Label)   | GlaxoSmithKline Pharmaceuticals S.A., Poznan, Poland Packed by: Glaxo Wellcome S.A., Aranda de Duero, Spain | Spain             | do.               |
| 3TC Film Coated Tablets 150mg (Additional Manufacturing Site and Change of Label)  | GlaxoSmithKline<br>Pharmaceuticals<br>S.A.,<br>Poznan, Poland   | Poland            | do.               |

| Trade Name and Form  | Manufacturer   | Country of Origin | Condition of Sale |
|--|--|-------------------|-------------------|
| Retrovir Oral Syrup 50mg/5ml (Change of Manufacturing Site and Change of Label)  | GlaxoSmithKline<br>Inc.,<br>Mississauga  | Canada            | Third Schedule    |
| Duratocin Solution for<br>Injection 100mcg/ml<br>(Addition of Secondary<br>Packager and Change of<br>Label)  | Ferring GmbH, Germany Secondary Packager: Ferring- Léčiva a.s., Czech Republic | Czech Republic    | do.               |
| Tractocile Solution for<br>Injection 7.5mg/ml<br>(6.75mg/0.9ml)<br>(Addition of Secondary<br>Packaging Site, Change<br>of Artwork and Change<br>of Label)              | do.  | do.               | do.               |
| Tractocile Concentrate<br>for Solution for Infusion<br>7.5mg/ml (37.5mg/5ml)<br>(Addition of Secondary<br>Packaging Site, Change<br>of Artwork and Change<br>of Label) | do.  | do.               | do.               |
| Firmagon Powder and<br>Solvent for Solution for<br>Injection 120mg<br>(Additional<br>Manufacturing and<br>Packaging Site, Change<br>of Artwork and Change<br>of Label) | do.  | do.               | do.               |

| Trade Name and Form  | Manufacturer   | Country of Origin | Condition of Sale |
|--|--|-------------------|-------------------|
| Firmagon Powder and<br>Solvent for Solution for<br>Injection 80mg<br>(Addition of<br>Manufacturing and<br>Packaging Site, Change<br>of Artwork and Change<br>of Label) | Ferring GmbH, Germany Secondary Packager: Ferring- Léčiva a.s., Czech Republic     | Czech Republic    | Third Schedule    |
| Pentasa Slow Release Tablets 500mg (Change of Packaging, Change of Artwork and Change of Label)  | Ferring<br>International<br>Center S.A.,<br>Switzerland                            | Switzerland       | do.               |
| Pentasa Prolonged Release Granules Sachets 2g (Change of Packaging Change of Artwork and Change of Label)  | Ferring International Center S.A., Switzerland For Holder: Ferring AG, Switzerland | do.               | do.               |
| Picoprep Powder for<br>Oral Solution/Sachet<br>10mg, 3.5g, 12g<br>(Change of Packaging<br>and Change of Artwork)   | Ferring Pharmaceuticals (China) Co. Ltd., China For Holder: Ferring GmbH, Germany  | China             | do.               |
| Glypressin Powder and<br>Solvent for Solution for<br>Injection 1mg/5ml<br>(Addition of Secondary<br>Packaging Site and<br>Change of Label)                             | Ferring GmbH, Germany Secondary Packager: Ferring-Léčiva a.s., Czech Republic      | Czech Republic    | do.               |

| Trade Name and Form   | Manufacturer  | Country of Origin | Condition of Sale |
|---|---|-------------------|-------------------|
| Menopur Powder and<br>Solvent for Solution for<br>Injection 75 IU<br>(Addition of Secondary<br>Packaging Site and<br>Change of Label)                   | Ferring GmbH, Germany Secondary Packager: Ferring-Léčiva a.s., Czech Republic                       | Czech Republic    | Third Schedule    |
| Gonapeptyl Depot Powder and Solvent for Suspension for Injection Pre-Filled Syringe 3.75mg/ml (Additional Secondary Packaging Site and Change of Label) | do.   | do.               | do.               |
| Differin Gel 0.1% (Change of Condition of Sale, Change of Name of Manufacturer, Change of Name of Packaging and Change of Label)                        | G.Production Inc. Distributed by: Galderma Laboratories L.P., U.S.A.                                | Canada            | Freely            |
| Azopt 1% (Brinzolamide Ophthalmic Suspension) 5ml, 10ml (Change of Marketing Authorization Holder and Change of Label)                                  | Alcon Laboratories Inc. For: Novartis Pharma AG, Basel Switzerland                                  | USA               | Third Schedule    |
| Azarga Eye Drops Suspension (Change of Marketing Authorization Holder and Change of Label)  | S.A. Alcon-<br>Couvreur N.V.,<br>Belgium<br>For:<br>Novartis Pharma<br>AG,<br>Basel,<br>Switzerland | Belgium           | do.               |

| Trade Name and Form   | Manufacturer  | Country of Origin | Condition of Sale |
|---|---|-------------------|-------------------|
| Betoptic S Ophthalmic<br>Suspension 0.25%<br>(Change of Marketing<br>Authorization Holder<br>and Change of Label)                               | Alcon Laboratories Inc. For: Novartis Pharma AG, Basel, Switzerland                                 | USA               | Third Schedule    |
| DuoTrav Sterile Ophthalmic Solution 40mcg/ml + 5mg/ml (Change of Name of Product, Change of Marketing Authorization Holder and Change of Label) | S.A. Alcon-<br>Couvreur N.V.,<br>Belgium<br>For:<br>Novartis Pharma<br>AG,<br>Basel,<br>Switzerland | Belgium           | do.               |
| Nevanac Ophthalmic<br>Suspension, 0.1%<br>(Change of Marketing<br>Authorization Holder<br>and Change of Label)                                  | Alcon Laboratories Inc. For: Novartis Pharma AG, Basel, Switzerland                                 | USA               | do.               |
| Patanol Ophthalmic<br>Solution, 0.1%<br>(Change of Marketing<br>Authorization Holder<br>and Change of Label)                                    | Alcon Laboratories Inc. For: Novartis Pharma AG, Basel, Switzerland                                 | do. °             | do.               |
| Pataday Ophthalmic<br>Solution 0.2%<br>(Change of Marketing<br>Authorization Holder,<br>Change of Packaging<br>and Change of Label)             | do.   | do.               | do.               |

| Trade Name and Form   | Manufacturer  | Country of Origin | Condition of Sale |
|---|---|-------------------|-------------------|
| Vigadexa Sterile Ophthalmic Solution 0.5%/ 0.1% 2.5ml, 5ml (Change of Packaging and Change of Label)                                  | Novartis<br>Biociencias S.A.<br>Sao Paolo – SP                          | Brazil            | Third Schedule    |
| Vigamox Ophthalmic<br>Solution 0.5%<br>(Change of Marketing<br>Authorization Holder<br>and Change of Label)                           | Alcon Laboratories Inc. For: Novartis Pharma AG, Basel, Switzerland     | USA               | do.               |
| Systane Icaps Tablets -<br>(Change of Name of<br>Product and Change of<br>Shelf Life  | Alcon<br>Laboratories Inc.  | do.               | Freely            |
| Buscopan Solution for<br>Injection 20mg/ml<br>(Change of Marketing<br>Authorization Holder<br>and Distributor and<br>Change of Label) | Boehringer<br>Ingelhiem Espana<br>For<br>Sanofi-Aventis de<br>Panama    | Spain             | Third Schedule    |
| Dulcolax Tablets 5mg – (Carton) (Change of Marketing Authorization Holder and Distributor, Change of Packaging and Change of Label)   | Boehringer Ingelheim Promeco S.A. de C.V. For: Sanofi-Aventis de Panama | Mexico            | Freely            |
| Dulcolax Tablets 5mg – (Bottle) (Change of Marketing Authorization Holder and Distributor and Change of Label)                        | do.   | do.               | do.               |

| Trade Name and Form  | Manufacturer             | Country of Origin      | Condition of Sale |
|--|--------------------------|------------------------|-------------------|
| Pharmaton Kiddi Syrup - Orange Flavour 100ml, 200ml (Change of Marketing Authorization Holder and Distributor and Change of Label) | Ginsana SA               | Switzerland            | Freely            |
| Painol Allergy Syrup<br>(Additional Name of<br>Product and Change of<br>Artwork)   | Bpi Genethics<br>Limited | Trinidad and<br>Tobago | do.               |
| Painol Jr Pain and Fever Raspberry Flavoured Syrup (Change of Artwork and Additional Name of Product)                              | do.                      | do.                    | do.               |
| Painol Jr Nausea Relief Syrup (Change in Dosage, Additional Name of Product and Change of Artwork)                                 | do.                      | do.                    | do.               |
| Painol Cough Expectorant Syrup (Additional Name of Product and Change of Artwork)  | do. °                    | do.                    | do.               |
| Genethics Paracetamol Syrup B.P. (Change in Name of Product, Change in Name and Address of Manufacturer)                           | do.                      | do.                    | do.               |

| Trade Name and Form   | Manufacturer                                     | Country of Origin      | Condition of Sale |
|---|--|------------------------|-------------------|
| Genethics Diphenhydramine Elixir (Change in Name and Address of Manufacturer)   | Bpi Genethics<br>Limited                         | Trinidad and<br>Tobago | Freely            |
| Genethics Sports Balm<br>Ultra with Capsicum-<br>Stick Applicator<br>(Change of Artwork)  | do.  | do.                    | do.               |
| Clavix-75 Film Coated Tablets (Additional Manufacturing Site, Change of Name, Change of Packaging and Change of Label)  | Intas<br>Pharmaceuticals<br>Ltd.                 | India                  | Third Schedule    |
| Zarzio Solution for<br>Injection or Infusion in<br>Pre-filled Syringe<br>30MU/0.5ml<br>(Change of Name and<br>Address of<br>Manufacturer and<br>Change of Country of<br>Origin) | Sandoz GmbH                                      | Austria                | do.               |
| Bromocriptine Tablets 2.5mg (Change of Distributor and Change of Label)   | Apotex Inc.<br>Distributed by:<br>AA Pharma Inc. | Canada                 | do.               |
| Imipramine Tablets 10mg (Change of Distributor and Change of Label)   | do.  | do.                    | do.               |
| Imipramine Tablets 25mg (Change of Distributor and Change of Label)   | do.  | do.                    | do.               |

| Trade Name and Form   | Manufacturer                               | Country of Origin | Condition of Sale |
|---|--|-------------------|-------------------|
| Sulfatrim Tablets 800-<br>160mg<br>(Change of Distributor<br>and Change of Label) | Apotex Inc. Distributed by: AA Pharma Inc. | Canada            | Third Schedule    |
| Sulfatrim Tablets 400-<br>80mg<br>(Change of Distributor<br>and Change of Label)  | do.  | do.               | do.               |
| Mefloquine Tablets 250mg (Change of Distributor and Change of Label)              | do.  | do.               | do.               |
| ISDN Tablets 30mg<br>(Change of Distributor<br>and Change of Label)               | do.  | do.               | do.               |
| Norflox Tablets 400mg<br>(Change of Distributor<br>and Change of Label)           | do.  | do.               | do.               |
| Folic Acid Tablets 5mg<br>(Change of Distributor<br>and Change of Label)          | do.  | do.               | Freely            |
| Flurbiprofen Tablets<br>100mg<br>(Change of Distributor<br>and Change of Label)   | do.  | do.               | Third Schedule    |
| Flurbiprofen Tablets 50mg (Change of Distributor and Change of Label)             | do.  | do.               | do.               |
| Nitrofurantoin Tablets<br>100mg<br>(Change of Distributor<br>and Change of Label) | do.  | do.               | do.               |

| Trade Name and Form   | Manufacturer  | Country of Origin | Condition of Sale |
|---|---|-------------------|-------------------|
| Metronidazole Tablets 250mg (Change of Distributor and Change of Label)   | Apotex Inc. Distributed by: AA Pharma Inc.  | Canada            | Third Schedule    |
| Methyldopa Tablets 250mg (Change of Distributor and Change of Label)  | do.   | do.               | do.               |
| VFEND Powder for Solution for Infusion 200mg (Change of Product License Holder, Change of Name of Manufacturer and Primary Packager, Change of Artwork and Change of Label) | Pharmacia & Upjohn Company LLC, USA Secondary Packager: Fareva Amboise, France License Holder: Pfizer Europe MA EEIG, Belgium | France            | do.               |
| Ecalta Powder for<br>Solution for Injection<br>100mg/vial<br>(Change of<br>Manufacturer and<br>Change of Label)   | Manufacturer and Packager: Pharmacia & Upjohn Company LLC, USA License Holder: Vicuron Holdings LLC                           | USA               | do.               |
| Xalkori ® Capsules 200mg (Change of Product License Holder, Change of Artwork, New Indication and Change of Label)  | Manufacturer and Packager: Pfizer Manufacturing Deutschland GmbH, Germany License Holder: Pfizer Europe MA EEIG, Belgium      | Germany           | do.               |

| Trade Name and Form  | Manufacturer   | Country of Origin | Condition of Sale |
|--|--|-------------------|-------------------|
| Xalkori ® Capsules 250mg (Change of Product License Holder, Change of Artwork, New Indication and Change of Label)                 | Manufacturer and Packager: Pfizer Manufacturing Deutschland GmbH, Germany License Holder: Pfizer Europe MA EEIG, Belgium | Germany           | Third Schedule    |
| Inlyta Film-Coated Tablets 1mg (Change of Product License Holder, Change of Artwork and Change of Label)                           | do.  | do.               | do.               |
| Inlyta Film-Coated Tablets 5mg (Change of Product License Holder, Change of Artwork and Change of Label)                           | do.  | do.               | do.               |
| Lyrica Capsules 25mg<br>(Change of Product<br>License Holder, Change<br>of Artwork, Change of<br>Packaging and Change<br>of Label) | do.  | do.               | do.               |
| Lyrica Capsules 75mg<br>(Change of Product<br>License Holder, Change<br>of Artwork and Change<br>of Label)                         | do.  | do.               | do.               |
| Lyrica Capsules 150mg<br>(Change of Product<br>License Holder, Change<br>of Artwork and Change<br>of Label)                        | do.  | do.               | do.               |

| Trade Name and Form   | Manufacturer   | Country of Origin | Condition of Sale |
|---|--|-------------------|-------------------|
| Lyrica Capsules 300mg<br>(Change of License<br>Holder, Change of<br>Artwork and Change of<br>Label)               | Manufacturer and Packager: Pfizer Manufacturing Deutschland GmbH, Germany License Holder: Pfizer Europe MA EEIG, Belgium | Germany           | Third Schedule    |
| Sutent Hard Gelatin Capsules 12.5mg (Change of Product License Holder, Change of Artwork and Change of Label)     | Pfizer Italia Srl., Ascoli Piceno, Italy License Holder: Pfizer Europe MA EEIG, Belgium                                  | Italy             | do.               |
| Sutent Hard Gelatin Capsules 25mg (Change of Product License Holder, Change of Artwork and Change of Label)       | do.  | do.               | do.               |
| Sutent Hard Gelatin Capsules 50mg (Change of Product License Holder, Change of Artwork and Change of Label)       | do.  | do.               | do.               |
| Viagra ODT® Orodispersible Tablets 50mg (Change of Product License Holder, Change of Artwork and Change of Label) | Fareva Amboise<br>License Holder:<br>Pfizer Europe MA<br>EEIG,<br>Belgium  | France            | do.               |

| Trade Name and Form   | Manufacturer   | Country of Origin | Condition of Sale |
|---|--|-------------------|-------------------|
| Prevenar 13® Pneumococcal 13- Valent Conjugate Vaccine (Diphtheria CRM197 Protein) (Change of Secondary Packager, Change of Product License Holder and Change of Label) | Manufacturer and Primary Packager: Pfizer Ireland Pharmaceuticals, Ireland Secondary Packager: Pfizer Manufacturing Belgium NV, Belgium License Holder: Pfizer Europe MA EEIG, Belgium | Belgium           | Third Schedule    |
| Celebrex Capsules 200mg (Change of Product Name of License Holder, Change of Packaging and Change of Label)   | Pfizer Pharmaceuticals LLC, Puerto Rico Packager: R-Pharm Germany GmbH, Germany License Holder: Pfizer Pharma PFE GmbH, Germany  | Germany           | do.               |
| Sayana Suspension for<br>Injection 104mg/0.65ml<br>(Change of Packaging,<br>Change of Artwork and<br>Change of Label)   | Manufacturer & Packager: Pfizer Manufacturing Belgium NV, Belgium Product License Holder: Pfizer S.A. Belgium  | Belgium           | do.               |

| Trade Name and Form  | Manufacturer   | Country of Origin | Condition of Sale |
|--|--|-------------------|-------------------|
| Depo-Provera Sterile Aqueous Suspension for Intramuscular Use 150mg (Change of Name of Manufacturer, Change of Artwork, Change of Packaging and Change of Label) | Manufacturer & Packager: Pfizer Manufacturing Belgium NV, Belgium Product License Holder: Pfizer S.A. Belgium  | Belgium           | Third Schedule    |
| Xeljanz Film-Coated Tablets 5mg (Change of Product License Holder, Change of Artwork, New Indication, Change of Packaging and Change of Label)                   | Manufacturer and Primary Packager: Pfizer Manufacturing Deutschland GmbH Germany Secondary Packager: Pfizer Pharmaceuticals LLC, Puerto Rico Licence Holder: PF PRISM C.V. Netherlands | USA               | do.               |
| Ferrol Children's Elixir - Strawberry Flavoured Liquid, Alcohol Free 120ml (Change of Packaging and Label)   | New GPC Inc.<br>Distributed by:<br>A1 Farm, E.B.D.<br>Guyana   | Guyana            | Freely            |
| Ferrol Expectorant - Cherry Flavoured Flavoured Liquid 120ml (Change of Packaging and Label)   | do.  | do.               | do.               |

| Trade Name and Form  | Manufacturer  | Country of Origin | Condition of Sale |
|--|---|-------------------|-------------------|
| Ferrol DM - Orange Flavoured Liquid – Alcohol Free - Sugar Free 120ml (Change of Packaging and Label)        | New GPC Inc.<br>Distributed by:<br>A1 Farm, E.B.D.<br>Guyana  | Guyana            | Freely            |
| Elocom® Cream 0.1% (Change in Product Name, Change in Formulation, Change of Artwork and Change of Importer) | Manufactured & Packaged by: Schering-Plough Labo N.V.   | Belgium           | Third Schedule    |
| Lasix Injectable Solution 20mg/2ml (Additional Manufacturing Site)   | Sanofi-Aventis<br>Farmaceutic Ltd.,<br>Suzano   | Brazil            | do.               |
| Epilim Chrono 500<br>Controlled Release<br>Tablets<br>(Additional<br>Manufacturing Site)                     | Sanofi-Aventis S.A., Spain Marketing Authorisation Holder: Sanofi UK                                | Spain             | do.               |
| Forxiga Film Coated Tablets 5mg (Change of Name of Manufacturer and Change of Packaging Site)                | Manufactured & Packaged by: AstraZeneca Pharmaceuticals LP, USA For: AstraZeneca CAMCAR S.A. Panama | USA               | do.               |
| Forxiga Film Coated Tablets 10mg (Change of Name of Manufacturer and Change of Packaging Site)               | do.   | do.               | do.               |

| Trade Name and Form  | Manufacturer  | Country of Origin | Condition of Sale |
|--|---|-------------------|-------------------|
| Seroquel Film-Coated Tablets 100mg (Change of Manufacturer and Change of Packaging Site)               | AstraZeneca Pharmaceuticals LP, USA Packaged by: AstraZeneca S.A. de C,V., Mexico For: AstraZeneca UK Limited, UK             | Mexico            | Third Schedule    |
| Seroquel XR Extended -<br>Release Tablets 50mg<br>(New Manufacturing<br>Site)                          | AstraZeneca Pharmaceuticals LP, Newark, USA Packaged by: AstraZeneca UK Limited, Macclesfield For: AstraZeneca UK Limited, UK | UK                | do.               |
| Seroquel XR Extended-<br>Release Tablets 200mg<br>(New Manufacturing<br>Site)                          | do.   | do.               | do.               |
| Seroquel XR Extended-<br>Release Tablets 300mg<br>(New Manufacturing<br>Site)                          | · do.   | do.               | do.               |
| Pulmicort Nebulising<br>Suspension 0.5mg/ml<br>Sterile Single-Dose<br>Units<br>(Additional Indication) | AstraZeneca AB,<br>Södertälje   | Sweden            | do.               |
| Tagrisso Film Coated<br>Tablets 40mg<br>(Additional Indication)  | AstraZeneca AB  | do.               | do.               |

| Trade Name and Form  | Manufacturer  | Country of Origin | Condition of Sale |
|--|---|-------------------|-------------------|
| Tagrisso Film Coated<br>Tablets 80mg<br>(Additional Indication)  | AstraZeneca AB  | Sweden            | Third Schedule    |
| Galvus Met Film-<br>Coated Tablets<br>50mg/500mg<br>(Change of<br>Manufacturing and<br>Packaging Source) | Novartis Pharma Produktions GmbH, Germany For: Novartis Pharma AG, Basel, Switzerland | Germany           | do.               |
| Gilenya Hard Capsules<br>0.5mg<br>(Additional Indication)  | Novartis Pharma Stein AG, Switzerland For: Novartis Pharma AG, Basel, Switzerland     | Switzerland       | do.               |
| Xolair Powder and<br>Solvent for Solution for<br>Injection 150mg<br>(New Indication)                     | Novartis Pharma Stein AG, Switzerland For: Novartis Pharma AG, Basel, Switzerland     | do.               | do.               |
| Aclasta Solution For<br>Infusion 5mg<br>(Additional<br>Manufacturer and<br>Source)                       | Fresenius Kabi Austria GmbH, Graz For: Novartis Pharma AG, Basel, Switzerland         | Austria           | do.               |

| Trade Name and Form  | Manufacturer   | Country of Origin | Condition of Sale |
|--|--|-------------------|-------------------|
| Myfortic Gastro-<br>Resistant Tablets 180mg<br>(Change of<br>Manufacturing and<br>Packaging Source and<br>Change of Importer)  | Novartis Pharma Produktions GmbH, Wehr, Germany For: Norvartis Pharma AG, Basel, Switzerland       | Ģermany           | Third Schedule    |
| Myfortic Gastro-<br>Resistant Tablets 360mg<br>(Change of<br>Manufacturing and<br>Packaging Site and<br>Change of Importer)  | Novartis Pharma Produktions GmbH, Wehr, Germany For: Norvartis Pharma AG, Basel, Switzerland       | do.               | do.               |
| Zometa Concentrate for<br>Solution for Infusion<br>4mg/5ml<br>(Additional Source,<br>Additional Presentation<br>and Change of<br>Importer)                                   | Fresenius Kabi<br>Austria GmbH,<br>Austria<br>For:<br>Novartis Pharma<br>AG, Basel,<br>Switzerland | Austria           | do.               |
| Elidel Cream 1% (Change of Marketing Authorisation Holder, Change of Manufacturer, Additional Manufacturing Site, Change of Artwork, Change of Label and Change of Importer) | MEDA Manufacturing, France For: MEDA Pharma GmbH & Co. KG Germany                                  | France            | do.               |

| Trade Name and Form   | Manufacturer                     | Country of Origin      | Condition of Sale |
|---|----------------------------------|------------------------|-------------------|
| No More Congestion<br>Syrup<br>(Additional Name of<br>Product and Change of<br>Artwork)                 | Bpi Genethics<br>Limited         | Trinidad and<br>Tobago | Freely            |
| No More Allergies Syrup (Additional Name of Product and Change of Artwork)                              | do.                              | do.                    | do.               |
| No More Nausea Syrup<br>(Additional Name of<br>Product, Change of<br>Artwork and Change in<br>Dosage)   | do.                              | do.                    | do.               |
| No More Pain & Fever<br>Syrup<br>(Additional Name of<br>Product and Change of<br>Artwork)               | do.                              | do.                    | do.               |
| Revolade Film-Coated Tablets 25mg (Change of Marketing Authorisation Holder and Additional Indications) | Glaxo Operations<br>UK Limited   | United Kingdom         | Third Schedule    |
| Revolade Film-Coated Tablets 50mg (Change of Marketing Authorization Holder and Additional Indications) | do.                              | do.                    | do.               |
| Gemibine 200 Lyophilized Powder for Injection (Change in Formulation)                                   | Intas<br>Pharmaceuticals<br>Ltd. | India                  | do.               |

| Trade Name and Form   | Manufacturer                     | Country of Origin | Condition of Sale |
|---|----------------------------------|-------------------|-------------------|
| Gemibine 1000 Lyophilized Powder for Injection (Change in Formulation)          | Intas<br>Pharmaceuticals<br>Ltd. | India             | Third Schedule    |
| ARASID-100 Cytarabine Injection BP 100mg/ml, 1ml vial (Change in Formulation)   | do.                              | do.               | do.               |
| ARASID-500 Cytarabine Injection BP 100mg/ml, 5ml vial (Change in Formulation)   | do.                              | do.               | do.               |
| ARASID-1000 Cytarabine Injection BP 100mg/ml, 10ml vial (Change in Formulation) | do.                              | do.               | do.               |

| Trade Name and Form  | Manufacturer  | Country of Origin | Condition of Sale |
|--|---|-------------------|-------------------|
| BeneFIX Powder and Solvent for Solution for Injection 250IU (Change in Licence Holder, Change in Diluent Manufacturing Site and Change in Shelf-Life for Active Substance) | Powder Manufacturer: Wyeth Farma, S.A., Madrid, Spain Solvent Manufacturer: Vetter Pharma- Fertigung GmbH & Co. KG, Langenargen, Gemany Secondary Packager: Wyeth Farma, S.A., Madrid, Spain License Holder: Pfizer Europe MA EEIG, Belgium | Spain             | Third Schedule    |
| BeneFIX Powder and Solvent for Solution for Injection 500IU (Change in Licence Holder, Change in Diluent Manufacturing Site and Change in Shelf-Life for Active Substance) | do. ⁵   | do.               | do.               |

| Trade Name and Form  | Manufacturer   | Country of Origin | Condition of Sale |
|--|--|-------------------|-------------------|
| Eliquis Film-Coated<br>Tablets 2.5mg<br>(New Indication)                             | Bristol-Myers Squibb Manufacturing Company, Puerto Rico EEUU Packager: Bristol-Myers Squibb S.r.L., Italy License Holder: Bristol-Myers Squibb/Pfizer EEIG, UK   | Italy             | Third Schedule    |
| Eliquis Film-Coated<br>Tablets 5mg<br>(New Indication)                               | do.  | do.               | do.               |
| Xyntha Powder and<br>Solvent for Solution for<br>Injection 250IU<br>(New Indication) | Powder Manufactured by: Wyeth Pharma S.A., Madrid, Spain Secondary Packager: Wyeth Farma, S.A., Madrid, Spain Solvent Manufacturer: Vetter Pharma- Fertigung GmbH & Co. KG, Germany Licence Holder: Wyeth Pharmaceuticals Inc. Philadelphia, USA | Spain             | do.               |

| Trade Name and Form   | Manufacturer   | Country of Origin | Condition of Sale |
|---|--|-------------------|-------------------|
| Xyntha Powder and<br>Solvent for Solution for<br>Injection 500IU<br>(New Indication)  | Powder Manufactured by: Wyeth Pharma S.A., Madrid, Spain Secondary Packager: Wyeth Farma, S.A., Madrid, Spain Solvent Manufacturer: Vetter Pharma- Fertigung GmbH & Co. KG, Germany Licence Holder: Wyeth Pharmaceuticals Inc. Philadelphia, USA | Spain             | Third Schedule    |
| Enbrel Solution for Injection in Pre-Filled Pen 50mg (Additional Indication, Change in Manufacturer, Primary Packager and Pen Assembly, Change in Product License Holder, Change in Name of Product, Change of Artwork and Change of Label) | Pfizer Manufacturing Belgium NV, Belgium Primary Packager: Pfizer Manufacturing Belgium NV, Belgium Secondary Packager: Wyeth Pharmaceuticals, UK License Holder: Pfizer Europe MA EEIG, Belgium   | UK                | do.               |

| Trade Name and Form  | Manufacturer   | Country of Origin | Condition of Sale |
|--|--|-------------------|-------------------|
| Enbrel Solution for Injection in Pre-Filled Syringe 50mg (Change in Manufacturer and Primary Packager, Change of Product License Holder, Change in Name of Product, Change of Artwork and Change of Label) | Pfizer Manufacturing Belgium NV, Belgium Primary Packager: Pfizer Manufacturing Belgium NV, Belgium Secondary Packager: Wyeth Pharmaceuticals, UK License Holder: Pfizer Europe MA EEIG, Belgium | UK                | Third Schedule    |
| Actemra Solution for<br>Subcutaneous Injection<br>Pre-Filled Syringe<br>162mg<br>(Additional Indications)  | Vetter Pharma-<br>Fertigung<br>GmbH & Co. KG<br>For:<br>F. Hoffmann-La<br>Roche Ltd.,<br>Basel,<br>Switzerland   | Germany           | do.               |

| Trade Name and Form  | Manufacturer   | Country of Origin | Condition of Sale |
|--|--|-------------------|-------------------|
| Mircera Solution for<br>Injection Pre-Filled<br>Syringes 50mcg/0.3ml -<br>(Additional Packager,<br>Change of Artwork and<br>Change of Importer)                    | F. Hoffmann-La Roche Ltd Basel, Switzerland Manufacturer: F. Hoffmann-La Roche Ltd Kaiseraugst, Switzerland Primary Packager: F. Hoffmann-La Roche Ltd Switzerland Secondary Packager: Roche Diagnostics GmbH, Germany | Germany           | Third Schedule    |
| Mircera Solution for<br>Injection Pre-Filled<br>Syringes 75mcg/0.3ml<br>(Additional Packager,<br>Change of Artwork,<br>Change of Importer and<br>Change of Label)  | do.  | do.               | do.               |
| Mircera Solution for<br>Injection Pre-Filled<br>Syringes 100mcg/0.3ml<br>(Additional Packager,<br>Change of Artwork,<br>Change of Importer and<br>Change of Label) | do.  | do.               | do.               |

| Trade Name and Form  | Manufacturer   | Country of Origin | Condition of Sale |
|--|--|-------------------|-------------------|
| Mircera Solution for<br>Injection Pre-Filled<br>Syringes 200mcg/0.3ml<br>(Additional Packager,<br>Change of Artwork,<br>Change of Importer and<br>Change of Label) | F. Hoffmann-La Roche Ltd Basel, Switzerland Manufacturer: F. Hoffmann-La Roche Ltd Kaiseraugst, Switzerland Primary Packager: F. Hoffmann-La Roche Ltd Switzerland Secondary Packager: Roche Diagnostics GmbH, Germany | Germany           | Third Schedule    |
| Mabthera Concentrate<br>for Solution for<br>Infusion100mg/10ml<br>(Additional<br>Manufacturing Site)   | F. Hoffmann-La<br>Roche Ltd,<br>Basel, Switzerland<br>By:<br>Genentech Inc.,<br>Hillsboro,<br>Oregon, USA  | USA               | do.               |
| Mabthera Concentrate<br>for Solution for Infusion<br>500mg/50ml<br>(Additional<br>Manufacturing Site)  | do.  | do.               | do.               |

| Trade Name and Form  | Manufacturer  | Country of Origin | Condition of Sale |
|--|---|-------------------|-------------------|
| Tamiflu 75mg Capsules (Change of Manufacturer's Name and Address, Additional Secondary Packaging Site and Change of Importer)  | Delpharm Milano S.r.l., Italy Packed by: F. Hoffmann-La Roche Ltd., Switzerland For: F. Hoffmann-La Roche Ltd., Basel, Switzerland  | Switzerland       | Third Schedule    |
| Pulmozyme Solution for Inhalation 2500U (2.5mg) 2.5ml (Additional Primary Packaging Site, Additional Secondary Packaging Site, Change of Artwork, Change of Importer, Change of Packaging and Change of Label) | F. Hoffmann-La Roche Ltd Basel, Switzerland, By: Genentech Inc., South San Francisco, United States Packed by (Primary): Catalent Pharma Solutions, Woodstock, Illinois, United States Packed by (Secondary): F. Hoffmann-La Roche Ltd Kaiseraugst, Switzerland | do.               | do.               |

| Trade Name and Form  | Manufacturer   | Country of Origin | Condition of Sale |
|--|--|-------------------|-------------------|
| Pantecta Tablets P20<br>(Change of Marketing<br>Authorisation Holder,<br>Change of Artwork,<br>Additional Distributor<br>and Change of Label)                            | Takeda GmbH-<br>Lehnitzstrausse<br>Germany<br>Packaged by:<br>Takeda México<br>S.A. de C.V.,<br>Mexico<br>Distributor:<br>Aspen Panama<br>S.A.<br>Panama | Mexico            | Third Schedule    |
| Pantecta Tablets 40mg<br>(Change of Marketing<br>Authorisation Holder,<br>Change of Artwork,<br>Additional Distributor<br>and Change of Label)                           | do.  | do.               | do.               |
| Pantecta IV Lyophilized Powder for Solution for Injection 40mg (Change of Marketing Authorisation Holder, Change of Artwork, Additional Distributor and Change of Label) | do.  | do.               | do.               |
| Alevian Duo Capules<br>100mg/300mg<br>(Additional Distributor<br>and Change of Artwork)  | Gelcaps Exportadora de México Packaged by: Takeda México S.A. de C.V.  | do.               | do.               |

| Trade Name and Form   | Manufacturer  | Country of Origin | Condition of Sale |
|---|---|-------------------|-------------------|
| Diprivan 10mg/ml (1%) Emulsion for Injection or Infusion - Pre-Filled Syringe 50ml (Change in Marketing Authorisation Holder, Change of Artwork and Change of Label)  | Corden Pharma SpA Italy Packed by: AstraZeneca UK Ltd. For: Aspen Labs S.A. de C.V., Mexico | UK                | Third Schedule    |
| Diprivan 10mg/ml (1%) Emulsion for Injection or Infusion - Ampoules (Change of Marketing Authorisation Holder, Change of Artwork and Change of Label)   | do.   | do.               | do.               |
| Diprivan 20mg/ml (2%) Emulsion for Injection or Infusion - vials (Change of Marketing Authorisation Holder, Change of Artwork and Change of Label)  | do.   | do.               | do.               |
| Fraxiparine 2850IU AXA/0.3ml Solution for Injection (S.C.) in Pre- Filled Syringe (Change of Marketing Authorisation Holder, Change in Name of Manufacturing Site, Change of Artwork, Change of Importer and Change of Label) | Aspen Notre Dame de Bondeville, France For: Aspen Labs S.A. de C.V., Mexico                 | France            | do.               |

| Trade Name and Form   | Manufacturer   | Country of Origin | Condition of Sale |
|---|--|-------------------|-------------------|
| Fraxiparine 5700IU AXA/0.6ml Solution for Injection (S.C.) in Pre- Filled Syringe (Change of Marketing Authorisation Holder, Change in Name of Manufacturing Site, Change of Artwork, Change of Importer and Change of Label) | Aspen Notre Dame de Bondeville, France For: Aspen Labs S.A. de C.V., Mexico              | France            | Third Schedule    |
| Nimbex Solution for<br>Injection or Infusion<br>2mg/ml (5mg in 2.5ml)<br>(Change of Marketing<br>Authorisation Holder,<br>Change of Artwork,<br>Additional Presentation,<br>Change of Importer and<br>Change of Label)        | GlaxoSmithKline Manufacturing S.p.A., Pharma, Italy For: Aspen Labs S.A. de C.V., Mexico | Italy             | do.               |
| Nimbex Solution for<br>Injection or Infusion<br>2mg/ml (10mg in 5ml)<br>(Change of Marketing<br>Authorisation Holder,<br>Change of Artwork,<br>Additional Presentation<br>and Change of<br>Importer)                          | do.  | do.               | do.               |
| Mivacron Injection 2mg/ml (5mg/2.5ml) (Change of Marketing Authorisation Holder, Change of Artwork, Additional Presentation and Change of Importer)   | do.  | do.               | do.               |

|  | 1   |                   | 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - |
|--|---|-------------------|---|
| Trade Name and Form  | Manufacturer  | Country of Origin | Condition of Sale                       |
| Mivacron Injection<br>2mg/ml (10mg/5ml)<br>(Change of Marketing<br>Authorisation Holder,<br>Change of Artwork,<br>Additional Presentation,<br>Change of Importer and<br>Change of Label) | GlaxoSmithKline Manufacturing S.p.A., Pharma, Italy For: Aspen Labs S.A. de C.V., Mexico            | Italy             | Third Schedule                          |
| Phillips' Milk of Magnesia Original Liquid (Change of Manufacturing Site, Change of Artwork and Change of Label)   | Aspen Mexico S.de R.L de C.V., Mexico For: Aspen Caricam S.A. San Jose Costa Rica                   | Mexico            | Freely                                  |
| Phillips' Milk of<br>Magnesia Mint Liquid<br>(Change of<br>Manufacturing Site,<br>Change of Artwork and<br>Change of Label)  | do.   | do.               | do.                                     |
| Veterinary Products  |   |                   |   |
| Dectomax Injection 1%<br>(Change of Name of<br>Manufacturer)   | Inovat Industria Farmaceutica Ltda. Distributed by: Zoetis Industria de Productos Vereinarios Ltda. | Brazil            | Veterinary<br>Prescription Only         |
| Revolution Topical<br>Solution (for cats)<br>45mg/0.75ml<br>(Change of Name of<br>Manufacturer)  | Zoetis Inc.   | USA               | Veterinary<br>Prescription Only         |

| Trade Name and Form   | Manufacturer   | Country of Origin | Condition of Sale |
|---|--|-------------------|-------------------|
| Revolution Topical<br>Solution<br>(for dogs) 60mg/0.50ml<br>(Change of Name of<br>Manufacturer) | do.  | do.               | do.               |
| Revolution Topical<br>Solution (for dogs)<br>240mg/2.0ml<br>(Change of Name of<br>Manufacturer) | do.  | do.               | do.               |
| Zimecterin Gold Oral<br>Paste<br>(Change of Name of<br>Manufacturer)                            | Boehringer<br>Ingelheim Animal<br>Health do Brazil,<br>Ltda. | Brazil            | do.               |
| Imovec Injection<br>(Change of Name of<br>Manufacturer)   | do.  | do.               | do.               |
| Eqvalan Paste<br>(Change of Name of<br>Manufacturer)  | do.  | do.               | do.               |
| Recombitek C4<br>(Change of Name of<br>Manufacturer)  | Boehringer<br>Ingelheim Animal<br>Health USA Inc.            | USA               | do.               |
| Recombitek C6<br>(Change of Name of<br>Manufacturer)  | do.  | do.               | do.               |
| Recombitek C6/CV<br>(Change of Name of<br>Manufacturer)   | do.  | do.               | do.               |

| Trade Name and Form  | Manufacturer   | Country of Origin | Condition of Sale               |
|--|--|-------------------|---------------------------------|
| Heartgard Plus Chewables 68mcg Ivermectin and 57mg Pyrantel (Change of Name of Manufacturer)   | Boehringer<br>Ingelheim Animal<br>Health Puerto<br>Rico LLC. | USA               | Veterinary<br>Prescription Only |
| Heartgard Plus Chewables 136mcg Ivermectin and 114mg Pyrantel (Change of Name of Manufacturer) | do.  | do.               | do.                             |
| Heartgard Plus Chewables 272mcg Ivermectin and 227mg Pyrantel (Change of Name of Manufacturer) | Boehringer<br>Ingelheim Animal<br>Health Puerto<br>Rico LLC. | USA               | do.                             |
| Nexgard Chewable Tablets 11.3mg (Change of Name of Manufacturer)                               | Boehringer<br>Ingelheim Animal<br>Health do Brazil<br>Ltda.  | Brazil            | do.                             |
| Nexgard Chewable Tablets 28.3mg (Change of Name of Manufacturer)                               | do.  | do.               | do.                             |
| Nexgard Chewable<br>Tablets 68mg<br>(Change of Name of<br>Manufacturer)                        | do.  | do.               | do.                             |

| Trade Name and Form  | Manufacturer   | Country of Origin | Condition of Sale               |
|--|--|-------------------|---------------------------------|
| Nexgard Chewable Tablets 136mg (Change of Name of Manufacturer)  | Boehringer<br>Ingelheim Animal<br>Health do Brazil<br>Ltda.                                | Brazil            | Veterinary<br>Prescription Only |
| End of Veterinary<br>Medicine  |  |                   |                                 |
| Heparin Injection BP<br>5000IU/5ml<br>(Additional<br>Manufacturing Site)   | Gland Pharma<br>Limited  | India             | Third Schedule                  |
| Heparin Injection BP<br>25000IU/5ml<br>(Additional<br>Manufacturing Site)  | do.  | do.               | do.                             |
| Cerumol Ear Drops<br>(Change of Importer)  | Thornton and<br>Ross Limited<br>UK   | UK                | Freely                          |
| Seven Seas Cod Liver Oil Plus Omega Fish Oil 150ml, 170ml, 300ml, 450ml (Change of Manufacturing and Packaging Site) | Laleham Health<br>and Beauty<br>Limited  | United Kingdom    | do.                             |
| Dolo-Neurobion XR Extended Release Film Coated Tablets (Change of Marketing Authorization Holder)                    | Merck S.A. de C.V. Mexico For: Procter & Gamble Interamericas de Guatemala LTDA, Guatemala | Mexico            | Third Schedule                  |

| Trade Name and Form   | Manufacturer   | Country of Origin | Condition of Sale |
|---|--|-------------------|-------------------|
| Dolo-Neurobion N Film<br>Coated Tablets<br>(Additional Indication<br>and Change of<br>Marketing<br>Authorization Holder)        | Merck S.A. de C.V. Mexico For: Procter & Gamble Interamericas de Guatemala LTDA, Guatemala | Mexico            | Third Schedule    |
| Neurobion Film Coated Tablets (Change of Marketing Authorization Holder)  | do.  | do.               | do.               |
| Dolo-Neurobion Injection - Dual Chamber Pre-Filled Syringe (Change of Marketing Authorization Holder and Additional Indication) | do.  | do.               | do.               |
| Iliadian Nasal Decongestant Solution Pediatric Drops 0.01% (Change of Marketing Authorization Holder)                           | do.  | do.               | Freely            |
| Cosopt Ophthalmic<br>Solution 2%/0.5%<br>(Change of Artwork and<br>Change of Marketing<br>Authorization Holder)                 | Laboratories<br>Merck Sharp &<br>Dohme - Chibert   | France            | Third Schedule    |
| Trusopt Ophthalmic<br>Solution 2%<br>(Change of Marketing<br>Authorization Holder)  | do.  | do.               | do.               |

| Trade Name and Form   | Manufacturer   | Country of Origin | Condition of Sale |
|---|--|-------------------|-------------------|
| Timoptic Ophthalmic<br>Solution 0.5%<br>(Change of Marketing<br>Authorization Holder)   | Laboratories<br>Merck Sharp &<br>Dohme - Chibert           | France            | Third Schedule    |
| Timoptic XE Ophthalmic Solution 0.5% (Change of Marketing Authorization Holder)   | do.  | do.               | do.               |
| Saflutan Eye Drop<br>Solution 15mcg/ml<br>(Change of Marketing<br>Authorization Holder)   | Laboratoire<br>Unither                                     | do.               | do.               |
| Victoza Solution for<br>Injection in a Pre-filled<br>Pen 6mg/ml<br>(Additional Indications<br>and Additional<br>Packaging Site) | Novo Nordisk A/S   | Denmark           | do.               |
| Levemir FlexPen Solution for Injection 100U/ml, 3ml pre-filled pen (Additional Manufacturing Site)                              | Novo Nordisk<br>Produção<br>Farmacêutica do<br>Brasil Ltda | Brazil            | do.               |
| NovoRapid FlexPen<br>Solution for Injection<br>100U/ml, 3ml pre-filled<br>pen<br>(Additional<br>Manufacturing Site)             | do.  | do.               | do.               |

| Trade Name and Form  | Manufacturer  | Country of Origin | Condition of Sale |
|--|---|-------------------|-------------------|
| NovoMix 30 FlexPen<br>Solution for Injection<br>100U/ml, 3ml pre-filled<br>pen<br>(Additional<br>Manufacturing Site) | Novo Nordisk<br>Producão<br>Farmacêutica do<br>Brasil Ltda. | Brazil            | Third Schedule    |
| Novolin 70/30 Penfill Suspension for Injection, 100U/ml, 3ml cartridge (Additional Manufacturing Site)               | do.   | do.               | do.               |
| Trajenta Tablets 5mg<br>(Additional Indications)   | Boehringer<br>Ingelheim<br>Promeco, S.A. de<br>C.V.         | Mexico            | do.               |
| Twynsta 80/5mg Tablets (Additional Packaging Site)   | Rottendorf<br>Pharma GmbH                                   | Germany           | do.               |
| Twynsta 80/10mg Tablets (Additional Packaging Site)  | do.   | do.               | do.               |
| Spiriva Respimat<br>Solution for Inhalation<br>2.5mcg<br>(Additional Indication)                                     | Boehringer<br>Ingelheim Pharma<br>GmbH & Co. KG             | do.               | do.               |
| Pepto Bismol Liquid<br>(Change of Formulation<br>and Change of Label)  | The Procter & Gamble Company                                | USA               | Freely            |

| Trade Name and Form  | Manufacturer   | Country of Origin | Condition of Sale |
|--|--|-------------------|-------------------|
| ProVisc Ophthalmic<br>Viscosurgical Device<br>(Additional<br>Manufacturing Site)                                 | Lifecore Biomedical, LLC, For Alcon Laboratories Inc. USA              | USA               | Third Schedule    |
| Viscoat Ophthalmic Viscosurgical Device (Change of Name of Product and Additional Manufacturing Site)            | do.  | do.               | do.               |
| Buscopan Tablets 10mg<br>(Change of Distributor<br>and Marketing<br>Authorization Holder<br>and Change of Label) | Boehringer Ingelheim Promeco S.A. de C.V. For Sanofi-Aventis de Panama | Mexico            | do.               |

Dated this 29th day of July, 2020.

T. DEYALSINGH

Minister of Health