

## LEGAL NOTICE NO. 126

## REPUBLIC OF TRINIDAD AND TOBAGO

## 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 of Health signifies his approval in respect of the following new drugs:

| <i>Trade Name and Form</i>                     | <i>Manufacturer</i>                                                                                       | <i>Country of Origin</i> | <i>Condition of Sale</i> |
|------------------------------------------------|-----------------------------------------------------------------------------------------------------------|--------------------------|--------------------------|
| Privigen Solution for Infusion 2.5 g           | CSL Behring AG                                                                                            | Switzerland              | Third Schedule           |
| Privigen Solution for Infusion 5 g             | do.                                                                                                       | do.                      | do.                      |
| Privigen Solution for Infusion 10 g            | do.                                                                                                       | do.                      | do.                      |
| Erbix Solution for Infusion 5 mg/mL            | Boehringer Ingelheim Pharma GmbH & Co. KG                                                                 | Germany                  | do.                      |
| Prezista Film-Coated Tablets 400 mg            | Manufactured by: Janssen Ortho LLC<br>Puerto Rico<br>Packaged by: Janssen-Cilag S.p.A.,<br>Via C. Janssen | Italy                    | do.                      |
| Prezista Film-Coated Tablets 600 mg            | do.                                                                                                       | do.                      | do.                      |
| Simva-Denk 20 Film-Coated Tablets 20 mg        | DENK PHARMA GmbH & Co. KG                                                                                 | Germany                  | do.                      |
| Simva-Denk 40 Film-Coated Tablets 40 mg        | do.                                                                                                       | do.                      | do.                      |
| Amlo-Denk 5 Tablets 5 mg                       | do.                                                                                                       | do.                      | do.                      |
| Amlo-Denk 10 Tablets 10 mg                     | do.                                                                                                       | do.                      | do.                      |
| Glimepiride Denk 2 Tablets                     | do.                                                                                                       | do.                      | do.                      |
| Glimepiride Denk 3 Tablets                     | do.                                                                                                       | do.                      | do.                      |
| Clopidogrel Winthrop Film-Coated Tablets 75 mg | Sanofi Winthrop Industrie                                                                                 | France                   | do.                      |
| Zerodol Film-Coated Tablets 100 mg             | Ipsa Laboratories Ltd.                                                                                    | India                    | do.                      |

| <i>Trade Name and Form</i>                                                                                               | <i>Manufacturer</i>                                                                                                  | <i>Country of Origin</i> | <i>Condition of Sale</i> |
|--------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------------|
| Mofilet-500 Film-Coated Tablets 500 mg                                                                                   | Emcure Pharmaceuticals Ltd.                                                                                          | India                    | Third Schedule           |
| Panimun Bioral Soft Gelatin Capsules 25 mg                                                                               | Panacea Biotec Ltd.                                                                                                  | do.                      | do.                      |
| Panimun Bioral Soft Gelatin Capsules 50 mg                                                                               | do.                                                                                                                  | do.                      | do.                      |
| Panimun Bioral Soft Gelatin Capsules 100 mg                                                                              | do.                                                                                                                  | do.                      | do.                      |
| Mycept-250 Hard Gelatin Capsules 250 mg                                                                                  | do.                                                                                                                  | do.                      | do.                      |
| Sports Balm Ultra with Capsicum—Stick Applicator                                                                         | Genethics Pharmaceuticals Ltd.                                                                                       | Trinidad and Tobago      | Freely                   |
| Baby Chest Rub Nighttime                                                                                                 | do.                                                                                                                  | do.                      | do.                      |
| Afinitor Tablets 5 mg                                                                                                    | Manufactured by:<br>Novartis Pharma Stein AG for<br>Novartis Pharma AG<br>Switzerland                                | Switzerland              | Third Schedule           |
| Afinitor Tablets 10 mg                                                                                                   | do.                                                                                                                  | do.                      | do.                      |
| Tasigna Capsules 200 mg                                                                                                  | do.                                                                                                                  | do.                      | do.                      |
| Gonapeptyl Depot Powder for Solution for Injection—Pre-Filled Syringe                                                    | Manufactured by:<br>Ferring GmbH<br>Germany<br>Packed by:<br>Ferring International<br>Centre S.A.                    | do.                      | do.                      |
| Rumifen-600 Film-Coated Tablets BP 600 mg                                                                                | Manufactured by:<br>Aurochem Laboratories (I) Pvt. Ltd.<br>Marketed by:<br>Trinpharm Co. Ltd.<br>Trinidad and Tobago | India                    | do.                      |
| Gofen 400 Softgel Capsules                                                                                               | Mega Lifesciences Ltd.                                                                                               | Thailand                 | do.                      |
| Mab Thera Concentrate for Solution for Infusion 100 mg/10 ml (New Indication, Change of Packaging and Additional Source) | Made for F. Hoffmann-La Roche Ltd.,<br>Switzerland by<br>Roche Diagnostics GmbH                                      | Germany                  | do.                      |
| Mab Thera Concentrate for Solution for Infusion 500 mg/50 ml (New Indication, Change of Packaging and Additional Source) | do.                                                                                                                  | do.                      | do.                      |

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| <i>Trade Name and Form</i>                                                                                  | <i>Manufacturer</i>                                                                          | <i>Country of Origin</i> | <i>Condition of Sale</i> |
|-------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------|--------------------------|--------------------------|
| Xeloda Film-Coated Tablets<br>500 mg (New Indication,<br>Additional Source and<br>Change of Artwork Design) | Made for F. Hoffmann-<br>La Roche Ltd.,<br>Switzerland by<br>Productos Roche<br>S.A. DE C.V. | Mexico                   | Third Schedule           |
| Lasix Tablets 40 mg<br>(Additional Source)                                                                  | sanofi-aventis<br>Farmacêutica<br>Ltda.                                                      | Brazil                   | do.                      |

Dated this 5th day of March, 2012.

F. KHAN  
*Minister of Health*