

LEGAL NOTICE NO. 189

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 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>
Vitamin D Tablets 1,000 IU	Jamieson Laboratories	Canada	Freely
Tranox Capsules 100 mg	Manufactured by: Aurochem Laboratories (I) Pvt. Ltd. Marketed by: Trinpharm Co. Ltd. Trinidad & Tobago	India	Third Schedule
Auroplus Lotion	do.	do.	do.
Trosone Ointment BP 0.1% w/w	do.	do.	do.
Clobitrim Cream BP 0.05% w/w	do.	do.	do.
Kandicide-B Lotion	do.	do.	do.
Kandicide-V Vaginal Gel 2% w/w with Applicator	do.	do.	do.
Multisymptom Panadol Cold & Flu Non-Drowsy Tablets	Made by: GlaxoSmithKline (Dungarvan) Ltd. Ireland Packed by: GlaxoSmithKline Panamá, S.A.	Panama	Freely
Avamys™ Nasal Spray Suspension 27.5 micrograms/actuation— 120 Sprays	Glaxo Operations UK Limited	UK	Third Schedule

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Spiriva® Respimat® Solution for Inhalation 2.5 microgram	Manufactured by: Boehringer Ingelheim Pharma GmbH & Co. KG for Boehringer Ingelheim International GmbH Germany	Germany	Third Schedule
Health 2000 Risperidone 2 mg Film-Coated Tablets	Manufactured by: Meditab Specialities Pvt. Ltd. for Health 2000 Inc. Canada	India	do.
Health 2000 Alendronate 70 mg Tablets	do.	do.	do.
H2K Triamcinolone 40 mg/ml Injectable Suspension	do.	do.	do.
Mircera Solution for Injection 30 micrograms/ 0.3 ml-Pre-Filled Syringe	Made for: F. Hoffmann-La Roche Ltd. Switzerland by Roche Diagnostics GmbH	Germany	do
Mircera Solution for Injection 120 micrograms/0.3 ml- Pre-Filled Syringe	do.	do.	do.
Mircera Solution for Injection 360 micrograms/0.6 ml- Pre-Filled Syringe	do.	do.	do.
Mircera Solution for Injection 800 micrograms/0.6 ml- Pre-Filled Syringe	do.	do.	do.
Actemra Concentrate for Solution for Infusion 20 mg/ml (80 mg/4 ml)	Made for: F. Hoffmann-La Roche Ltd. Switzerland by Chugai Pharma Manufacturing Co., Ltd.	Japan	do.
Actemra Concentrate for Solution for Infusion 20 mg/ml (200 mg/10 ml)	do.	do.	do.
Actemra Concentrate for Solution for Infusion 20 mg/ml (400 mg/20 ml)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
AmbienCR Extended-Release Tablets 6.25 mg	sanofi-aventis U.S. LLC	USA	Third Schedule
AmbienCR Extended-Release Tablets 12.5 mg	do.	do.	do.
Valixa Powder for Oral Solution 50 mg/ml	Made for: F. Hoffmann-La Roche Ltd. Switzerland by Patheon Inc.	Canada	do.
Tamiflu Capsules 30 mg	Made by: F. Hoffmann-La Roche Licensor: Gilead Sciences, USA	Switzerland	do.
Batrafen S Shampoo 10 mg/g	Manufactured by: Dreiturm GmbH Germany Packed by: sanofi-aventis Deutschland, GmbH	Germany	do.
Pentasa Slow Release Tablets 500 mg	Manufactured by: Ferring International Center SA MA Holder: Ferring AG Switzerland	Switzerland	do.
Pentasa Sachets 2 grams Prolonged-Release Granules	do.	do.	do.
Pentasa Suppositories 1 g	Manufactured by: Pharbil Pharma GmbH Germany Packed by: Ferring International Center SA PL Holder: Ferring AG Switzerland	do	do.
Humira® Pen 40 mg/ 0.8 mL-Single Use Prefilled Pens	Abbott Laboratories	USA	do.
Pradaxa Hard Capsules 75 mg	Manufactured by: Boehringer Ingelheim Pharma GmbH & Co. KG for Boehringer Ingelheim International GmbH, Germany	Germany	do.
Pradaxa Hard Capsules 110 mg	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Efavir 200 Capsules	Cipla Ltd.	India	Third Schedule
Tenvir Film-Coated Tablets 300 mg	do.	do.	do.
Seroquel XR Extended-Release Tablets 50 mg	AstraZeneca UK Limited	United Kingdom	do.
Seroquel XR Extended-Release Tablets 200 mg	do.	do.	do.
Seroquel XR Extended-Release Tablets 300 mg	do.	do.	do.
Seroquel XR Extended-Release Tablets 400 mg	do.	do.	do.
Xarelto Film-Coated Tablets 10 mg	Bayer HealthCare AG	Germany	do.
Yaz Film-Coated Tablets 3 mg-0,02 mg	Manufactured by: Schering do Brasil, Química e Farmacêutica Ltda. Under Licence of: Bayer Schering Pharma AG Germany	Brazil	do.
Metpure-XL 12.5 Extended Release Tablets 12.5 mg	Emcure Pharmaceu- ticals Ltd.	India	do.
Metpure-XL 25 Extended-Release Tablets 25 mg	do.	do.	do.
Metpure-XL 50 Extended-Release Tablets 50 mg	do.	do.	do.
pms-Sertraline Capsules 100 mg	Pharmascience Inc.	Canada	do.
Thymoglobuline 25 mg Powder for Solution for Intravenous Infusion	Manufactured by: Genzyme Polyclonals S.A.S. France Packaged by: Genzyme Ltd. MAH: Genzyme Europe B.V. The Netherlands	United Kingdom	do.
Astrol-1 Film-Coated Tablets 1 mg	Intas Pharmaceuticals	India	do.
Bencogen Injection Solution USP 2 mg in 2 ml (1 mg/ml)	Manufactured by: SGPharma Pvt. Ltd. Distributed by: Puerto Rico Pharmaceutical, Inc. Puerto Rico, USA	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Flixotide® Suspension for Inhalation 50 mcg/dose-CFC Free (Change of Name of Manufacturer and Additional Source)	Glaxo Wellcome S.A.	Spain	Third Schedule
Flixotide® Suspension for Inhalation 125 mcg/dose-CFC Free (Change of Name of Manufacturer and Additional Source)	do	do.	do.
Flixotide® Suspension for Inhalation 250 mcg/dose-CFC Free (Change of Name of Manufacturer and Additional Source)	do	do.	do.
Retrovir® Capsules 100 mg (Change of Artwork Design)	SmithKline Beecham Pharmaceuticals	UK	do.
Mobic Tablets 7.5 mg (Change of Packaging)	Manufacturer: Boehringer Ingelheim Pharma GmbH & Co. KG for Boehringer Ingelheim International GmbH Germany	Germany	do.
Mobic Tablets 15 mg (Change of Packaging)	do.	do.	do.
Centrum Performance Multivitamin/Multimineral Supplement Tablets (Change of Formulation and Change of Packaging)	Marketed by: Wyeth Consumer Healthcare USA (Product of USA)	USA	Freely
Centrum Silver Multivitamin/Multimineral Supplement Tablets (Change of Formulation and Change of Packaging)	do.	do.	do.
Byetta 5 micrograms solution for injection, prefilled pen 5 g (Additional Source)	Lilly Pharma Fertigung und Distribution GmbH & Co. KG	Germany	Third Schedule

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Byetta 10 micrograms solution for injection, prefilled pen 10 g (Additional Source)	Lilly Pharma Fertigung und Distribution GmbH & Co. KG	Germany	Third Schedule
Aprovel Film-Coated Tablets 150 mg (Reduced Mass of Tablet)	Sanofi Winthrop Industrie	France	do.
Aprovel Film-Coated Tablets 300 mg (Reduced Mass of Tablet)	do.	do.	do.
Co Aprovel Film-Coated Tablets 150/12.5 mg (Reduced Mass of Tablet and Additional Indication)	do.	do.	do.
Co Aprovel Film-Coated Tablets 300/12.5 mg (Reduced Mass of Tablet and Additional Indication)	do.	do.	do.
Roferon-A Solution for Injection 3MIU /0.5ml s.c.-Prefilled Syringe (New Indication)	F. Hoffmann-La Roche Ltd.	Switzerland	do.
Valium Tablets 5 mg (Additional Source)	Made for: F. Hoffmann-La Roche Ltd. Switzerland by Roche Farma SA	Spain	Controlled Drug
Valium Tablets 10 mg (Additional Source)	do.	do.	do.
Rivotril Drops 2.5 mg/ml (New Indication)	Produtos Roche Químicos e Farmacêuticos S.A.	Brasil	do.
Protopic Ointment 0.03% (Additional Source)	Manufactured by: Astellas Toyama Co. Ltd. Marketed by: Astellas Pharma US, Inc. USA	Japan	Third Schedule
Protopic Ointment 0.1% (Additional Source)	do.	do.	do.
SASTid Soap (Change of Formulation)	Stiefel Mexicana, S.A. de C.V.	Mexico	Freely

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Loxof Film-Coated Tablets 500 mg (Change of Artwork Design)	Ranbaxy Laboratories Limited	India	Third Schedule
Lovir Cream 5% w/w (Additional Manufacturing Site)	do.	do.	do.
Vitalux® Plus Time Release Multivitamin/ Multimineral Coated Tablets with Lutein (Change of Artwork Design)	Manufactured by: NutriCorp International for Novartis Pharma AG Switzerland	Canada	Freely
Ketotrin Lotion	Manufactured by: U Square Lifescience Pvt. Ltd. for Trinpharm Co. Ltd. Trinidad & Tobago	India	Third Schedule
Excedrin Extra Strength Caplets	Distributed by: Novartis Consumer Health, Inc. USA (Product of USA)	USA	Freely
pms-Bicalutamide Tablets 50 mg	Pharmascience Inc.	Canada	Third Schedule
C-Flox 500 Film-Coated Tablets BP 500 mg	Intas Pharmaceu- ticals Ltd.	India	do.
Beclotis Inhaler BP 50 mcg per actuation— CFC Free (Change of Propellant)	Jewim Pharmaceu- tical (Shandong) Co., Ltd.	China	do.
Salbutis Inhalation Aerosol BP 100 mcg per actuation—CFC Free (Change of Propellant)	do.	do.	do.
Dr. Smith's Garlic Oil Capsules 0.25%	Cipla Ltd.	India	Freely

Dated this 10th day of August, 2009.

J. NARACE  
*Minister of Health*