

LEGAL NOTICE NO. 125

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>
Amaryl M SR Prolonged-Release Film-Coated Tablets 2 mg/500 mg	Handok Pharmaceuticals Co., Ltd.	Korea	Third Schedule
Amaryl M Film-Coated Tablets 2 mg/1000 mg	Manufactured by: Laboratorios Silanes, S.A de C.V. for sanofi-aventis de México S.A. de C.V. Mexico	Mexico	do.
Theraflu AL Pediatric Allergy & Cold Syrup—Orange Flavor	Novartis Consumer Health Inc.	USA	Freely
Theraflu Severe Cold & Cough Night Powder for Oral Solution—Sachets	do.	do.	do.
Now Calcium & Magnesium Tablets	Now Foods	do.	do.
Ventab XL 75 Extended-Release Tablets	Intas Pharmaceuticals Ltd.	India	Third Schedule
Sandoz Paroxetine Film-Coated Tablets 20 mg	Manufactured by: Salutas Pharma GmbH for Sandoz GmbH, Austria	Germany	do.
Delmed Dextrose 5% Solution for Injection	Laboratorios Biogalenic, S.A. DE C.V.	El Salvador	do.
Natrol Tonalin CLA Softgels 1200 mg	Natrol Inc.	USA	Freely

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Exforge Film-Coated Tablets 5 mg/320 mg	Manufactured by: Novartis Pharma Stein AG for Novartis Farmacéutica S.A. (AC) Guatemala	Switzerland	Third Schedule
Exforge HCT Film-Coated Tablets 5 mg/160 mg/12.5 mg	Manufactured by: Novartis Pharma Stein AG for Novartis Pharma AG, Switzerland	do.	do.
Exforge HCT Film-Coated Tablets 10 mg/160 mg/12.5 mg	do.	do.	do.
Rasilez HCT Film-Coated Tablets 150 mg/25 mg	Manufactured by: Novartis Farma S.p.A. for Novartis Pharma AG, Switzerland	Italy	do.
Onbrize Breezhaler Inhalation Powder Hard Capsules 150 mcg with Inhaler	Manufactured by: Novartis Pharma Stein AG for Novartis Pharma AG, Switzerland	Switzerland	do.
Onbrize Breezhaler Inhalation Powder Hard Capsules 300 mcg with Inhaler	do.	do.	do.
Alevian duo Capsules 100 mg/300 mg	Manufactured by: Gelcaps Exportadora de México S.A. de C.V. Mexico for Nycomed S.A. de C.V., Mexico Packaged by: Nycomed S.A. de C.V.	Mexico	do.
Sebivo Oral Solution 20 mg/ml	Manufactured by: Novartis Pharma SAS for Novartis Pharma AG, Switzerland	France	do.
Foseal-800 Film-Coated Tablets	Emcure Pharmaceuticals Ltd.	India	do.
Cerumol Ear Drops	Thornton & Ross Ltd.	United Kingdom	Freely

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Gonapepty I 0.1 mg Daily Solution for Injection	Manufactured by: Ferring GmbH Germany Packaged by: Ferring International Center S.A. PL Holder: Ferring AG Switzerland	Switzerland	Third Schedule
Hycamtin Capsules 0.25 mg	GlaxoSmithKline Manufacturing S.p.A.	Italy	do.
Hycamtin Capsules 1 mg	do.	do.	do.
Chloraseptic Sore Throat Spray—Menthol	Distributed by: Medtech Products Inc. USA (Product of USA)	USA	Freely
Chloraseptic Sore Throat Spray—Cherry	do.	do.	do.
Chloraseptic Sore Throat Spray—Soothing Citrus	do.	do.	do.
Kids Chloraseptic Sore Throat Spray—Grape	do.	do.	do.
Caduet Tablets 5 mg/10 mg	Manufactured by: Gödecke GmbH Germany Packed by: Pfizer, S.A. de C.V.	Mexico	Third Schedule
Sterile Concentrate for Cardioplegia Infusion—Ampoules	Martindale Pharmaceuticals	United Kingdom	do.
Iron Sucrose Injection USP I.V.—Ampoules	Gland Pharma Limited	India	do.
Tylenol Extra Strength PM Caplets	Distributed by: McNeil Consumer Healthcare, DIVISION OF MCNEIL-PPC, INC. USA (Product of USA)	USA	Freely
Nature's Plus Liquid Bone Power with Boron—Vegetarian (Orange Cream Flavour)	Natural Organics Laboratories, Inc.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Pact-500 IP Tablets 500 mg	Vance & Health Pharmaceuticals Pvt. Ltd.	India	Freely
Pact Suspension	do.	do.	do.
Dricoril-C Syrup	do.	do.	do.
Diamicron MR Tablets 60 mg	Les Laboratoires Servier Industrie	France	Third Schedule
Cebión Minis Vitamin C Chewable Tablets 100mg— Multiflavours	Merck, S.A.	Colombia	Freely
Sandoz Omeprazole Capsules 40 mg	Manufactured by: Lek Pharmaceuticals d.d. for Sandoz GmbH, Austria	Slovenia	Third Schedule
Topaz-25 Film-Coated Tablets 25 mg	Intas Pharmaceuticals Ltd.	India	do.
Topaz-50 Film-Coated Tablets 50 mg	do.	do.	do.
Topaz-100 Film-Coated Tablets 100 mg	do.	do.	do.
Sandoz Zarzio Solution for Injection or Infusion in Pre-Filled Syringe 30 MU/ 0.5 ml	IDT Biologika GmbH	Germany	do.
Sandoz Binocrit Solution for Injection in a Pre-Filled Syringe 4,000 IU/0.4 ml	do.	do.	do.
Sandoz Binocrit Solution for Injection in a Pre-Filled Syringe 10,000 IU/1 ml	do.	do.	do.
Centrum Performance Multivitamin/Multimineral Supplement Tablets (Change of Formulation)	Marketed by: Wyeth Consumer Healthcare USA (Product of USA)	USA	Freely
Infanrix Suspension for Injection—Prefilled Syringe (Change of Formulation)	GlaxoSmithKline Biologicals s.a.	Belgium	Third Schedule
FluaRIX Suspension for Injection—Prefilled Syringe (Change of Strain)	GlaxoSmithKline Biologicals, Branch of SB Pharma GmbH & Co. KG	Germany	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Maximum Strength Comtrex Day and Night Severe Cold and Sinus Coated Caplets (Change of Manufacturer and Change of Formulation)	Novartis Consumer Health Inc.	USA	Freely
Valixa Film-Coated Tablets 450 mg (Change of Artwork Design, Additional Information on Package Insert and Extension of Indication)	Made for F. Hoffmann- La Roche Ltd. Switzerland by Patheon Inc.	Canada	Third Schedule
Pantecta Tablets (Change of Name of Manufacturer)	Manufactured by: Nycomed Oranienburg GmbH Germany Packaged by: Nycomed S.A. de C.V. for Novartis Farmacéutica S.A. Guatemala	Mexico	do.
Pantecta I.V. Lyophilized Powder for Solution for Injection 40 mg (Change of Name of Manufacturer and Additional Source)	do.	do.	do.
Aclasta Solution for Infusion 5 mg (Additional Indication)	Manufactured by: Novartis Pharma Stein AG for Novartis Pharma AG, Switzerland	Switzerland	do.
Bisolvon Elixir—Sugar-Free (Change of Manufacturing Site and Change of Formulation)	Boehringer Ingelheim S.A.	Colombia	Freely
Mencevax ACWY Vaccine (Change of Name of Manufacturer and Change of Formulation)	GlaxoSmithKline Biologicals s.a.	Belgium	Third Schedule
Infanrix IPV+Hib Lyophilisate and Solvent in a Pre-Filled Syringe for Injection (Change of Formulation)	do.	do.	do.
Alyvir Film-Coated Tablets 500 mg	Ranbaxy Laboratories Limited	India	do.

Approval in Respect of New Drugs

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Pristiq Extended-Release Tablets 50 mg	Wyeth Pharmaceuticals Company	Puerto Rico	Third Schedule
Relcer Gel	Glenmark Pharmaceuticals Ltd.	India	Freely
Coveram Tablets 5 mg/10 mg	Servier (Ireland) Industries Ltd.	Ireland	Third Schedule
Stalevo Film-Coated Tablets 75 mg/18.75 mg/200 mg	Manufactured by: Orion Corporation for Novartis Pharma AG Switzerland	Finland	do.
Stalevo Film-Coated Tablets 125 mg/31.25 mg/200 mg	do.	do.	do.
Stalevo Film-Coated Tablets 200 mg/50 mg/200 mg	do.	do.	do.

Dated this 5th day of March, 2012.

F. KHAN
Minister of Health