

LEGAL NOTICE NO. 119

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>
Apo-Mefloquine Tablets 250 mg	Apotex Inc.	Canada	Third Schedule
Apo-Dexamethasone Tablets USP 4 mg	do.	do.	do.
Apo-Carvedilol Tablets 25 mg	do.	do.	do.
Apo-Warfarin Tablets USP 5 mg	do.	do.	do.
Gardasil Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) Recombinant Vaccine	Merck & Co., Inc.	USA	do.
RotaTeq Rotavirus Vaccine, Live, Oral, Pentavalent	do.	do.	do.
Dolo-Neurobión XR Extended Release Tablets	Manufactured by Merck, S.A. de C.V. for Merck, S.A. de Guatemala Guatemala	Mexico	do.
Clotrimazole Merck 1% Topical Cream	Manufactured by Pacific Pharma- ceuticals Ltd. Distributed by Merck, S.A. Guatemala	New Zealand	do.
Bonviva Solution for i.v. Injection 3 mg/3 mL- Pre-Filled Syringe	Made for F. Hoffmann- La Roche Ltd., Switzerland by Vetter Pharma- Fertigung GmbH & Co. KG	Germany	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Children's Mylanta Chewable Tablets-Bubble Gum Flavor	Johnson & Johnson.Merck Consumer Pharmaceuticals Co.	USA	Freely
Flogozán Suspension 180 mg/100 mL	Manufactured by Merck, S.A. de C.V. for Merck, S.A. de Guatemala Guatemala	Mexico	Third Schedule
QuikClot 1st Response Advanced Clotting Sponge	Z-Medica Corporation	USA	Freely (For Use by Emergency Medical Technicians ONLY)
Vinorelbin "Ebewe" 10 mg/1 mL Concentrate for Solution for Infusion—10 mg	EBEWE Pharma Ges.m.b.H. Nfg.KG	Austria	Third Schedule
Vinorelbin "Ebewe" 50 mg/5 mL Concentrate for Solution for Infusion—50 mg	do.	do.	do.
Ubistesin Solution for Injection 4%	3M ESPE AG	Germany	do.
Ubistesin forte Solution for Injection 4%	do.	do.	do.
Calamine Lotion BP	Manufactured by L.C.M. Ltd. for Thornton & Ross Ltd., England	England	Freely
ErasmO-25 Film-Coated Tablets	Manufactured by NPI Co. for Mepha Ltd. Switzerland	Oman	Third Schedule
ErasmO-50 Film-Coated Tablets	do.	do.	do.
Truvada Film-Coated Tablets	Manufactured by Patheon Inc. for Gilead Sciences, Inc., USA	Canada	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Viread Film-Coated Tablets	Manufactured by Patheon Inc. for Gilead Sciences, Inc., USA	Canada	Third Schedule
Lucentis Solution for Injection 10 mg/mL	Manufactured by Novartis Pharma Stein AG for Novartis Pharma AG Switzerland	Switzerland	do.
Xolair Powder and Solvent for Solution for Injection 150 mg	do.	do.	do.
Postinor 2 SD Tablets	Gedeon Richter Ltd.	Hungary	do.
Verorab Purified Inactivated Rabies Vaccine, Prepared on Vero Cells, Powder and Diluent for Suspen- sion for Injection	Sanofi Pasteur SA	France	do.
Septanest with adrenaline 1/100,000 Solution for Injection	Septodont	do.	do.
Scandonest 3% Plain Solution for Injection	do.	do.	do.
Lignospan special Solution for Injection	do.	do.	do.
Panadol Multisymptom Cold & Flu Tablets	GlaxoSmithKline Panamá, S.A.	Panama	Freely
Cutter Advanced Insect Repellent	Made for Spectrum, Division of United Industries Corpora- tion, USA (Product of USA)	USA	do.
Toddler's Dimetapp Cold Drops Nasal Decongestant (Alcohol- Free)—Great Grape Taste	Wyeth Consumer Healthcare	do.	do.
Chlorhexidine Digluconate 0.2% w/v Antiseptic Mouthwash—Mint	Thornton & Ross Ltd.	UK	do.
Eloxatin Concentrate for Solution for Infusion 5 mg/mL—50 mg	Aventis Pharma Dagenham	United Kingdom	Third Schedule
Eloxatin Concentrate for Solution for Infusion 5 mg/mL—100 mg	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Lupride Depot Lyophilized Powder and Diluent for Injection 3.75 mg	Sun Pharmaceutical Ind. Ltd.	India	Third Schedule
Diflucan Capsules 150 mg (Change of Source)	Pfizer PGM	France	do.
Cymbalta Capsules 60 mg (New Indication)	Lilly S.A.	Spain	do.
Noroxin Tablets 400 mg (Change of Source)	Manufactured by Merck Sharp & Dohme Italia S.p.A. Italy Packaged by MERCK SHARP & DOHME MEXICO S.A. DE C.V.	Mexico	do.
MabThera Concentrate for Solution for Infusion 100 mg/10 mL (Additional Indication)	F. Hoffmann-La Roche Ltd	Switzerland	do.
MabThera Concentrate for Solution for Infusion 500 mg/50 mL (Additional Indication)	do.	do.	do.
Econopred plus Ophthalmic Suspension 1% (Change of Colour of Packaging)	Alcon Laboratories, Inc.	USA	do.
Altiva 120 Film-Coated Tablets 120 mg (Change of Formulation and Change of Name of Product)	Ranbaxy Laboratories Limited	India	do.
Altiva 180 Film-Coated Tablets 180 mg (Change of Formulation and Change of Name of Product)	do.	do.	do.
Norbactin Tablets 400 mg (Change of Packaging)	do.	do.	do.
Invoril-10 Tablets 10 mg (Additional Manufacturing Site)	do.	do.	do.
Invoril-20 Tablets 20 mg (Additional Manufacturing Site)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Fludara Powder for Solution for Injection (Change of Name of Manufacturer and Change of Source)	Manufactured by Intendis Manufacturing, S.p.A. Italy Packed by Schering AG	Germany	Third Schedule
Magnevist Solution for Injection 14.07 g (Additional Packaging Site)	Schering AG	do.	do.
Yasmin Film-Coated Tablets (Change of Source)	Schering do Brasil, Quimica e Farmacêutica Ltda.	Brazil	do.
Angeliq Film-Coated Tablets (Change of Source)	Manufactured by Schering GmbH & Co. Produktions KG Germany Packed by Schering do Brasil, Quimica e Farmacêutica Ltda.	do.	do.
Serevent Inhaler CFC-Free (Change of Artwork Design, Change of Formulation, Change of Source and Additional Indication)	Glaxo Wellcome Production	France	do.
Tamiflu Capsules 75 mg (Additional Indication)	Made for F. Hoffmann-La Roche Ltd., Switzerland by CENEXI SAS	do.	do.
Xeloda Film-Coated Tablets 500 mg (New Indication)	Made for F. Hoffmann-La Roche Ltd., Switzerland by Hoffmann-La Roche Inc.	USA	do.
Valium Solution for Injection 10 mg/2 mL (Additional Source)	Produtos Roche Quimicos e Farmacêuticos S.A.	Brasil	Controlled Drug
Centrum Silver Tablets (Change of Tablet Coating)	Marketed by Wyeth Consumer Healthcare USA (Product of USA)	USA	Freely

Dated this 28th day of May, 2007.

J. RAHAEL
Minister of Health