

LEGAL NOTICE NO. 34

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>
Pregabid-150 Hard Gelatin Capsules 150 mg	Intas Pharmaceuticals Ltd.	India	Third Schedule
Zoryl-2 Tablets 2 mg	do.	do.	do.
O-Plat 50 Powder for Injection 50 mg/Vial	do.	do.	do.
Iritop Injection 20 mg/mL	do.	do.	do.
Firmagon 80 mg Powder and Solvent for Solution for Injection	Manufacturer: Powder: Rentschler Biotechnologie GmbH Germany Solvent: Hameln Pharmaceuticals GmbH Germany Packaged by: Ferring International Centre S.A. Marketing Authorization Holder: Ferring AG Switzerland	Switzerland	do.
Firmagon 120 mg Powder and Solvent for Solution for Injection	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Clopicor Film-Coated Tablets 75 mg	West Pharma-Produções de Especialidades Farmacêuticas, S.A.	Portugal	Third Schedule
Glyree-M1 Tablets	Ipca Laboratories Ltd.	India	do.
Glyree-M2 Tablets	do.	do.	do.
Efcure-600 Film-Coated Tablets 600 mg	Emcure Pharmaceuticals Ltd.	do.	do.
Apo-Gliclazide MR Modified Release Tablets 30 mg	Apotex Inc.	Canada	do.
Apo-Amiodarone Tablets BP 200 mg	do.	do.	do.
Apo-Bicalutamide Tablets 50 mg	do.	do.	do.
Simtas 40 Film-Coated Tablets USP 40 mg	Intas Pharmaceuticals Ltd.	India	do.
Veltam 0.4 Modified Release Tablets 0.4 mg	do.	do.	do.
Pregabid-75 Hard Gelatin Capsules 75 mg	do.	do.	do.
Gabapin-300 Capsules 300 mg	do.	do.	do.
Takfa 0.5 Capsules 0.5 mg	do.	do.	do.
Takfa 1 Capsules 1 mg	do.	do.	do.
Takfa 5 Capsules 5 mg	do.	do.	do.
Diclofenac Potassium Tablets 50 mg	Ranbaxy Laboratories Limited	do.	do.
Felotensil Film-Coated Tablets 5 mg	Manufactured by: Aurochem Laboratories (I) Pvt. Ltd. Marketed by: Trinpharm Company Ltd. Trinidad and Tobago	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Cancan Tablets USP 200 mg	Manufactured by: Aurochem Laboratories (I) Pvt. Ltd. Marketed by: Trinpharm Company Ltd. Trinidad and Tobago	India	Third Schedule
Trinvas-10 Film-Coated Tablets 10 mg	do.	do.	do.
Trinvas-20 Film-Coated Tablets 20 mg	do.	do.	do.
Trin-Brite Cream	do.	do.	do.
Trinbrite-F Cream	do.	do.	do.
Alcof-D Cough Syrup	do.	do.	Freely
Rumifen-800 Film-Coated Tablets BP 800 mg	do.	do.	Third Schedule
Muzle-DP Tablets	Vance & Health Pharmaceuticals Pvt. Ltd.	do.	do.
Preterax Film-Coated Tablets 10 mg/2.5 mg	Servier (Ireland) Industries Ltd.	Ireland	do.
Coveram Tablets 10 mg/5 mg	do.	do.	do.
Coveram Tablets 10 mg/10 mg	do.	do.	do.
Gemcitabine Lyophilized Powder for Solution for Injection USP 200 mg	Sun Pharmaceutical Ind. Ltd.	India	do.
Gemtaz Lyophilized Powder for Solution for Injection USP 1 g	do.	do.	do.
Carbopa-150 Injection 150 mg/15 ml-Single Use Vial	Intas Pharmaceuticals Ltd.	do.	do.
Carbopa-450 Injection 450 mg/45 ml-Single Use Vial	do.	do.	do.
Epira Injection 10 mg/5 mL- Vial	do.	do.	do.
Epira Injection 50 mg/25 mL- Vial	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Sandoz Binocrit Solution for Injection in a Pre-Filled Syringe 2000 IU/1 ml	IDT Biologilca GmbH	Germany	Third Schedule
Pantecta P20 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.
Genotropin Powder and Solvent for Injection 5.3 mg-Two Chamber Cartridge (Change of Manufacturer and Additional Indication)	Manufactured by: Vetter Pharma- Fertigung GmbH & Co., KG, Germany Packaged by: Manufacturing Belgium NV	Belgium	do.
Genotropin Powder and Solvent for Injection 12 mg-Two Chamber Cartridge (Change of Manufacturer and Additional Indication)	do.	do.	do.
Gemibine 200 Lyophilized Powder for Injection USP 200 mg	Intas Pharmaceuticals Ltd.	India	do.
Gemibine 1000 Lyophilized Powder for Injection USP 1000 mg	do.	do.	do.
Losar-Denk 100 Film-Coated Tablets	DENK PHARMA GmbH Co. KG	Germany	do.
Pantopral Gastro-Resistant Tablets 40 mg	West Pharma- Produções de Especialidades Farmacêuticas, S.A.	Portugal	do.
Sandoz Tacrolimus Capsules 5 mg	Manufactured by: Sandoz Private Limited for Sandoz GmbH Austria	India	do.
Anti-Kalium Na, Granules	MEDICE Arzneimittel Pütter GmbH & Co. KG	Germany	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Ovidrel Solution for Injection 250 micrograms/0.5 ml in a Pre-Filled Syringe	Merck Serono S.p.A.	Italy	Third Schedule
Glucophage Powder for Oral Solution 1000 mg-Sachets	Manufactured by: Merck, S.L. for Merck Santé France	Spain	do.
Glucophage Film-Coated Tablets 500 mg	Merck Santé s.a.s.	France	do.
Glucophage Film-Coated Tablets 1000 mg	do.	do.	do.
Jalra M Film-Coated Tablets 50 mg/500 mg	Manufactured by: Novartis Pharma Stein AG for Merck, S.A., Guatemala	Switzerland	do.
Jalra M Film-Coated Tablets 50 mg/850 mg	do.	do.	do.
Jalra M Film-Coated Tablets 50 mg/1000 mg	do.	do.	do.
Atacand Plus Tablets 32/12.5 mg	Manufactured by: AstraZeneca AB, Sweden Packed and Distributed by: AstraZeneca, S.A. de C.V. for AstraZeneca AB, Sweden	Mexico	do.
RasilAmlo Film-Coated Tablets 150/5 mg	Manufactured by: Novartis Pharma Stein AG for Novartis Pharma AG, Switzerland	Switzerland	do.
RasilAmlo Film-Coated Tablets 150/10 mg	do.	do.	do.
RasilAmlo Film-Coated Tablets 300/5 mg	do.	do.	do.
RasilAmlo Film-Coated Tablets 300/10 mg	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Co-Diovan Film-Coated Tablets 320/12.5 mg	Manufactured by: Novartis Farma S.p.A. for Novartis Pharma AG, Switzerland	Italy	Third Schedule
Co-Diovan Film-Coated Tablets 320/25 mg	do.	do.	do.
Cialis Film-Coated Tablets 5 mg	Lilly S.A.	Spain	do.
Actos Tablets 30 mg	Manufactured by: Takeda Pharmaceutical Company Limited Japan Packaged by: Eli Lilly y Compañía de México, S.A. de C.V.	Mexico	Third Schedule (For Specialists ONLY)
Viagra Jet Chewable Tablets 50 mg	Pfizer S.A. de C.V.	do.	Third Schedule
Viagra Jet Chewable Tablets 100 mg	do.	do.	do.
Invega Sustenna Prolonged Release Suspension for Intramuscular Injection 25 mg	Janssen Pharmaceutica N.V.	Belgium	do.
Listerine Smart Rinse Anticavity Fluoride Rinse- Mint Shield	Distributed by: Johnson & Johnson Healthcare Products DIVISION OF McNEIL-PPC, INC. USA (Product of USA)	USA	Freely
Listerine Smart Rinse Anticavity Fluoride Rinse- Berry Shield	do.	do.	do.
Sandoz Escitalopram Film- Coated Tablets 10 mg	Manufactured by: Sandoz Private Limited for Sandoz GmbH Austria	India	Third Schedule

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Pradox Hard Capsules 150 mg	Distributed by: Boehringer Ingelheim (Canada) Ltd. Canada (Product of Germany)	Germany	Third Schedule
Norbit Injection USP 4 mg/ 2 mL	Celon Laboratories Ltd.	India	do.
Aremed 1 Film-Coated Tablets 1 mg	Remedica Ltd.	Cyprus	do.
Concor AM Tablets 5 mg/5 mg	Manufactured by: EGIS Pharmaceuticals PLC for Merck KGaA, Germany	Hungary	do.
Concor AM Tablets 5 mg/10 mg	do.	do.	do.
Concor AM Tablets 10 mg/5 mg	do.	do.	do.
Concor AM Tablets 10 mg/10 mg	do.	do.	do.
Glucophage Powder for Oral Solution 500 mg-Sachets	Manufactured by: Merck, S.L. for Merck Santé France	Spain	do.
Glucophage Powder for Oral Solution 850 mg-Sachets	do.	do.	do.
Glucophage Film-Coated Tablets 850 mg	Merck Santé s.a.s.	France	do.
Ismigen Sublingual Tablets 50 mg	Manufactured by: Bruschettini S.R.L. for Lallemand Pharma AG, Switzerland Distributed by: Merck, S.A., Guatemala	Italy	do.
Actos Tablets 15 mg	Manufactured by: Takeda Pharmaceutical Company Limited Japan Packaged by: Eli Lilly y Compañía de México, S.A. de C.V.	Mexico	Third Schedule (For Specialists ONLY)

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Actos Tablets 45 mg	Manufactured by: Takeda Pharmaceutical Company Limited Japan Packaged by: Eli Lilly y Compañía de México, S.A. de C.V.	Mexico	Third Schedule (For Specialists ONLY)
Celtax 30 Injection USP 30 mg/5 mL	Celon Laboratories Ltd.	India	Third Schedule
Celtax 100 Injection USP 100 mg/16.7 mL	do.	do.	do.
Cel Carb 150 Injection BP 150 mg/15 mL	do.	do.	do.
Cel Carb 450 Injection BP 450 mg/45 mL	do.	do.	do.
5 Flucel 500 Injection USP 500 mg/10 mL- Ampoules	do.	do.	do.
IRNOCEL 100 Injection 100 mg/5 mL	do.	do.	do.
Doxyld 10 Lyophilized Powder for Solution for Injection USP 10 mg-Vials	do.	do.	do.
Doxyld 50 Lyophilized Powder for Solution for Injection USP 50 mg-Vials	do.	do.	do.
Rubilon 10 Lyophilized Powder for Solution for Injection 10 mg-Vials	do.	do.	do.
Rubilon 50 Lyophilized Powder for Solution for Injection 50 mg-Vials	do.	do.	do.
Glypressin Injection Powder and Solvent for Solution for Injection (Change of Name of Solvent Manufacturer)	Powder Manufacturer: Ferring GmbH, Germany Solvent Manufacturer: Haupt Pharma Wülfing GmbH, Germany Packager: Ferring International Center SA, Switzerland PL Holder: Ferring AG, Switzerland	Switzerland	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Bravelle Powder and Solvent for Solution for Injection 75 IU (Change of Name of Solvent Manufacturer)	Powder Manufacturer: Ferring GmbH, Germany Solvent Manufacturer: Haupt Pharma Wülfing GmbH, Germany Packager: Ferring International Center SA, Switzerland PL Holder: Ferring AG, Switzerland	Switzerland	Third Schedule
Asomex-2.5 Tablets (Change of Importer/Local Agent)	Emcure Pharmaceuticals Ltd.	India	do.
Asomex-5 Tablets (Change of Importer/Local Agent)	do.	do.	do.
Pentasa Sachets 2 g Prolonged-Release Granules (Change of Formulation)	Manufactured by: Ferring International Center S.A. PL Holder: Ferring AG Switzerland	Switzerland	do.
Vinelbine Injection USP 10 mg/1 ml-Single Dose Vial (Change of Name of Manufacturer)	Fresenius Kabi Oncology Ltd.	India	do.
Intaxtel Injection USP 30 mg/5 ml-Multi Dose Vial (Change of Name of Manufacturer)	do.	do.	do.
Rocaltrol Capsules 0.25 µg (Change of Artwork Design)	Made for: F. Hoffmann- La Roche Ltd. Switzerland by R.P. Scherer GmbH & Co. KG	Germany	do.
Valium Solution for Injection 10 mg/2 ml -Ampoules (Change of Artwork Design)	Produtos Roche Químicos E Farmacêuticos S.A.	Brasil	Controlled Drug

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Viracept Film-Coated Tablets 250 mg (Change of Artwork Design)	Made for: F. Hoffmann- La Roche Ltd. Switzerland by Roche Farma SA	Spain	Third Schedule
Tarceva Film-Coated Tablets 100 mg (Change of Name of Manufacturer)	Made for: F. Hoffmann- La Roche Ltd. Switzerland by Kremers Urban Pharmaceuticals Inc.	USA	do.
Tarceva Film-Coated Tablets 150 mg (Change of Name of Manufacturer)	do.	do.	do.
Tarceva Film-Coated Tablets 100 mg (New Indication)	Made for: F. Hoffmann- La Roche Ltd. Switzerland by Roche S.p.A.	Italy	do.
Tarceva Film-Coated Tablets 150 mg (New Indication)	do.	do.	do.
Centrum Multivitamin/Multimineral Supplement Tablets (Change of Source, Change of Formulation and Change of Artwork Design)	Pfizer Canada Inc.	Canada	Freely
Centrum Performance Multivitamin/Multimineral Supplement Tablets (Change of Source, Change of Formulation and Change of Artwork Design)	do.	do.	do.
Centrum Select 50+ Multivitamin/Multimineral Supplement Tablets (Change of Source, Change of Formulation and Change of Artwork Design)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Avelox I.V. Solution for Intravenous Infusion 400 mg-Vial (Change of Packaging Site)	Bayer Schering Pharma AG	Germany	Third Schedule
Ciproxina Solution for Infusion 0.2 g-Vial (Change of Packaging Site)	do.	do.	do.
Ciproxina Solution for Infusion 0.4 g-Vial (Change of Packaging Site)	do.	do.	do.
Invega Extended-Release Tablets 3 mg (Additional Source)	Manufactured by: Janssen Cilag Manufacturing LLC Puerto Rico Packaged and Released by: Janssen-Cilag S.p.A., Via C. Janssen	Italy	do.
Invega Extended-Release Tablets 9 mg (Additional Source)	do.	do.	do.
Arcalion 200 Coated Tablets (Change of Packaging, Change of Artwork Design and Change in Manufacturing Process)	Les Laboratoires Servier Industrie	France	do.
Atacand Tablets 32 mg (Change of Packaging Site)	Manufactured by: AstraZeneca AB, Sweden Packed and Distributed by: AstraZeneca, S.A. de C.V.	Mexico	do.
Crestor Coated Tablets 10 mg (Additional Indication)	Manufactured by: IPR Pharmaceutical Inc. Puerto Rico Packed and Distributed by: AstraZeneca, S.A. de C.V.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Crestor Coated Tablets 20 mg (Additional Indication)	Manufactured by: IPR Pharmaceutical Inc. Puerto Rico Packed and Distributed by: AstraZeneca, S.A. de C.V.	Mexico	Third Schedule
Nexium Film-Coated Tablets 20 mg (Change of Artwork Design)	Made by: AstraZeneca AB Sweden Packed and Distributed by: AstraZeneca, S.A. de C.V.	do.	do.
Nexium Film-Coated Tablets 40 mg (Change of Artwork Design)	do.	do.	do.
Avastin Concentrate for Solution for Injection 100 mg/4 ml (New Indication)	Made for: F. Hoffmann- La Roche Ltd Switzerland by Roche Diagnostics GmbH	Germany	do.
Avastin Concentrate for Solution for Injection 400 mg/16 ml (New Indication)	do.	do.	do.
Cialis Film-Coated Tablets 10 mg (Change of Packaging)	Lilly S.A.	Spain	do.
Cialis Film-Coated Tablets 20 mg (Change of Packaging)	do.	do.	do.
Strattera Hard Capsules 10 mg (Change of Packaging)	Manufactured by: Lilly del Caribe Inc. Puerto Rico Packaged by: Lilly S.A.	do.	do.
Strattera Hard Capsules 18 mg (Change of Packaging)	do.	do.	do.
Strattera Hard Capsules 25 mg (Change of Packaging)	do.	do.	do.
Strattera Hard Capsules 40 mg (Change of Packaging)	do.	do.	do.
Strattera Hard Capsules 60 mg (Change of Packaging)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Diflucan Capsules 150 mg (Change of Colour of Capsules and Change of Formulation)	Pfizer PGM	France	Third Schedule
Glucobay 50 Tablets 50 mg (Change of Marketing Authorization Holder and Change of Packaging)	Bayer Schering Pharma AG	Germany	do.
Glucobay Tablets 100 mg (Change of Marketing Authorization Holder and Change of Packaging)	do.	do.	do.
Mirena Intrauterine System 20 µg/24 h (Change of Name of Manufacturer and Change of Packaging)	Bayer OY	Finland	do.
Progynova Tablets 1 mg (Change of Artwork Design and Change of Name of Marketing Authorization Holder)	Manufactured by: Delpharm Lille S.A.S., France Packaged by: Schering do Brasil, Química e Farmacêutica Ltda.	Brazil	do.
Progynova Tablets 2 g (Change of Artwork Design and Change of Name of Marketing Authorization Holder)	do.	do.	do.
Qlaira Film-Coated Tablets (New Indication)	Schering GmbH & Co. Produktions KG	Germany	do.
Gadovist Solution for Injection 1 mmol/ml (Change of Artwork Design)	Bayer Schering Pharma AG	do.	do.
Urografin 76% Solution for Injection and Infusion (Change of Name of Marketing Authorization Holder and Change of Artwork Design)	Berlimed S.A.	Spain	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Ultravist-300 mg 1/ml Solution for Injection and Infusion (Change of Artwork Design and Change of Packaging)	Bayer Schering Pharma AG	Germany	Third Schedule
Ultravist-370 mg 1/ml Solution for Injection and Infusion (Change of Artwork Design and Change of Packaging)	do.	do.	do.
Betaferon Powder and Solvent for Solution for Injection 250 microgram/ml (Additional Source)	Powder Manufactured by: Boehringer Ingelheim Pharma GmbH and Co. KG, Germany Solvent Manufactured by: Bayer Schering Pharma AG, Germany Packaged by: Bayer Schering Pharma AG	do.	do.
3TC Film-Coated Tablets 150 mg (Additional Source, Addition of Score on Tablet and Change of Artwork Design)	Made by: Glaxo Operations UK Ltd. Trading as Glaxo Wellcome Operations United Kingdom for Viiv Healthcare UK Limited United Kingdom Packed by: GlaxoSmithKline Pharmaceuticals SA	Poland	do.
Eprex 4000 Injectable Solution 4000 IU/0.4 ml Prefilled Syringe with Needle Guard (PROTECS™) (Change of Artwork Design and Change of Packaging)	Cilag AG	Switzerland	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Ciproxina 500 Film-Coated Tablets (Change of Name of Manufacturer and Change of Artwork Design)	Bayer Schering Pharma AG	Germany	Third Schedule
Nimotop Film-Coated Tablets (Change of Manufacturer and Change of Artwork Design)	do.	do.	do.
Listerine Essential Care [®] Fluoride Anticavity Toothpaste Original Gel -Powerful Mint Gel (Change of Distributor)	Distributed by: Johnson and Johnson Healthcare Products DIVISION OF McNEIL-PPC, INC. USA (Product of USA)	USA	Freely
Listerine Essential Care [®] Fluoride Anticavity Toothpaste Original Paste -Powerful Mint Paste (Change of Distributor)	do.	do.	do.
Pradox Hard Capsules 75 mg (Change of Distributor and Change of Name of Product)	Distributed by: Boehringer Ingelheim (Canada) Ltd. Canada (Product of Germany)	Germany	Third Schedule
Pradox Hard Capsules 110 mg (Change of Distributor, New Indication and Change of Name of Product)	do.	do.	do.
JointFlex Pain Relieving Cream	SmartScience Laboratories Inc.	USA	Freely
Purim Tablets	The Himalaya Drug Company	India	do.

Dated this 14th day of January, 2013.

F. KHAN
Minister of Health