

LEGAL NOTICE NO. 28

REPUBLIC OF TRINIDAD AND TOBAGO

FOOD AND DRUGS ACT, CHAP. 30:01

NOTIFICATION

NOTICE OF 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>
Vicks VapoRub Ointment (Change of Artwork Design, Change of Name of Manufacturer, Change of Marketing Authorisation Holder and Change of Distributor)	Procter & Gamble Manufacturing Mexico, S. de R.L. de C.V. for: Procter & Gamble International Operations S.A., Panama	Mexico	Freely
Firmagon Powder and Solvent for Solution for Injection 80mg (Change of Marketing Authorization Holder, Change of Manufacturing Site, Change of Artwork Design and Shelf Life Extension)	FERRING GmbH, Germany Packager: Ferring International Center S.A.	Switzerland	Third Schedule
Firmagon Powder and Solvent for Solution for Injection 120mg (Change of Marketing Authorization Holder, Change of Manufacturing Site, Change of Artwork Design and Shelf Life Extension)	do.	do.	do.
Tractocile Solution for Injection 7.5mg/ml (Change of Marketing Authorization Holder, Change of Manufacturing Site and Change of Packaging and Artwork Design)	FERRING GmbH, Germany Packager: FERRING S.A. de C.V.	Mexico	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Tractocile Concentrate for Solution for Infusion 7.5mg/ml (Change of Marketing Authorization Holder, Change of Manufacturing Site and Change of Packaging and Artwork Design)	FERRING GmbH, Germany Packager: FERRING S.A. de C.V.	Mexico	Third Schedule
SULZINE (SULFADIAZINE Tablets USP 500mg)	SG Pharma Pvt. Ltd.	India	do.
Safetelmi H Tablets 40mg/12.5mg	MSN Laboratories Private Ltd.	do.	do.
Eppone 25 Tablets 25mg	do.	do.	do.
Eppone 50 Tablets 50mg	do.	do.	do.
Lactacyd® Pro-Bio Femina	Sanofi-Aventis Farmaceutica Ltda.	Brazil	Freely
Lactacyd® Pro-Bio Delicata	do.	do.	do.
Lactacyd® Pro-Bio Breeze	do.	do.	do.
Fertilaid For Men	Arizona Nutritional Supplements	USA	do.
Motility Boost Capsule	do.	do.	do.
Dexorange® Plus Hematinic Syrup of Iron, Folic Acid and Vitamin B12	Wardex Pharmaceuticals Pvt. Ltd for: Franco-Indian Pharmaceuticals Pvt. Ltd. India	India	do.
Cloxabix Capsules 100mg	Atlantic Pharma - Produções Farmacéuticas S.A.	Portugal	Third Schedule
Cloxabix Capsules 200mg	do.	do.	do.
Accentrix Solution for Injection 10mg/ml (Change of Product Name, Change of Marketing Authorisation Holder, Additional Presentation)	Novartis Pharma Stein AG for: Alcon de Centroamerica S.A., Costa Rica	Switzerland	do.
Meftal-500 Tablets 500mg (Change of Name of Manufacturer)	Blue Cross Laboratories Pvt. Ltd.	India	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Meftal-Spas Tablet 250/10mg (Change of Name of Manufacturer)	Blue Cross Laboratories Pvt. Ltd.	India	Third Schedule
Meftal-Spas DS Tablet 500/20mg (Change of Name of Manufacturer)	do.	do.	do.
Cebran-500 Tablet 500mg (Change of Name of Manufacturer)	do.	do.	do.
Diclotal-Forte Tablet 50/500mg (Change of Name of Manufacturer)	do.	do.	do.
Zeet Expectorant Liquid (Change of Name of Manufacturer)	Alembic Pharmaceuticals Ltd.	do.	Freely
Brozeet Liquid (Change of Name of Manufacturer)	do.	do.	do.
Duratocin Solution for Injection 100mcg/ml (Addition of Room Temperature Stable Presentation and Extension of Shelf Life)	Ferring GmbH, Germany Packaged by: Ferring S.A. de C.V.	Mexico	Third Schedule
Menopur Powder and Solvent for Solution for Injection 75 IU (Change of Marketing Authorisation Holder, Addition of Secondary Packager, Change of Storage Conditions and Extension of Solvent Shelf Life)	do.	do.	do.
Privigen Solution for Infusion 2.5g (Additional Indication)	CSL Behring AG	Switzerland	do.
Privigen Solution for Infusion 5g (Additional Indication)	do.	do.	do.
Privigen Solution for Infusion 10g (Additional Indication)	do.	do.	do.
Avelox 400mg Solution for Infusion (Change of Marketing Authorisation Holder and Change of Name of Manufacturing and Packaging Site)	Bayer AG	Germany	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Gazyva Concentrate for Solution for Infusion 1000mg/40ml (Additional Indication and Change of Country of Origin)	Roche Diagnostics GmbH for: F. Hoffmann-La Roche Ltd., Switzerland	Germany	Third Schedule
Actemra Solution 162mg/0.9ml Solution for Subcutaneous Injection (Additional Indication)	Vetter Pharmafertigung GmbH & Co. KG for: F. Hoffmann-La Roche Ltd., Switzerland	do.	do.
Genotropin Lyophilized Powder and Solvent for Injection 16 IU (5.3mg) - Pre-filled Pen Go Quick (Change of Product Name, Change of Manufacturer, Change of Importer, Change of Presentation, Change of Shelf Life and Change of Artwork Design)	Pfizer Manufacturing Belgium N.V. for: Pfizer S.A., Belgium	Belgium	do.
Genotropin Lyophilized Powder and Solvent for Injection 35 IU (12mg) - Pre-filled Pen Go Quick (Change of Product Name, Change of Manufacturer, Change of Importer, Change of Presentation, Change of Shelf Life and Change of Artwork Design)	do.	do.	do.
Eylia Solution for Injection 40mg/ml (Additional Indication and Change of Name of Marketing Authorisation Holder and Secondary Packager)	Regeneron Pharmaceuticals Inc., USA Primary packaging/filled by: Vetter Pharmafertigung GmbH & Co. KG, Germany Secondary packaging: Bayer AG for: Bayer AG, Germany	Germany	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Iressa Tablets 250mg (Change of Manufacturer)	NIPRO Pharma Corporation, Japan Packed by: AstraZeneca UK Limited	UK	Third Schedule
Isentress Tablets 400mg (Additional Manufacturing Site)	MSD International GmbH (Ballydine), Ireland Packaged by: Merck, Sharp & Dohme B.V.	The Netherlands	do.
Sinemet-275 Tablets (Change of Manufacturing Site, Change of Presentation, Change of Artwork Design, Change of Country of Origin and Change of Importer)	Savio Industrial S.L.R	Italy	do.
Sinemet Plus Tablets 25mg/100mg (Change of Manufacturing Site, Change of Presentation, Change of Artwork Design, Change of Country of Origin and Change of Importer)	do.	do.	do.
Voltaren® Retard Coated Tablets 100mg (Change of Manufacturer and Change of Country of Origin)	Novartis Farma S.p.A. for: Novartis Pharma AG, Switzerland	do.	do.
Voltaren® Solution for Injection 75mg/3ml (Change of Manufacturer and Change of Country of Origin)	Lek Pharmaceuticals d.d. for: Novartis Pharma AG, Switzerland	Slovenia	do.
Pneumovax® 23 Vaccine Pre-filled Syringe 25mcg (Additional Presentation and Change of Product Name)	Merck, Sharp & Dohme Corp.	USA	do.
M-M-R II Measles, Mumps and Rubella Virus Vaccine Live 0.5ml Vials - Single-Dose (Additional Manufacturing Site)	do.	do.	do.
Imbruvica Capsules 140mg (New Indications)	Catalent CTS, LLC	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Vigorton 2 Tonic Liquid (Change of Distributor)	Federated Pharmaceutical	Jamaica	Freely
Fedbutamol Expectorant Syrup 2mg/100mg in 10ml (Change of Distributor)	do.	do.	do.
Fedbutamol Syrup 2mg/5ml (Change of Distributor)	do.	do.	do.
Federgel Antacid Tablets 270mg/75mg (Change of Distributor)	do.	do.	do.
Hemafed Iron & Vitamin Supplement Capsules of Distributor)	do.	do.	do.
Tropivite Vitamin Drops 15ml (Change of Distributor)	do.	do.	do.
Ubistesin forte Solution for Injection 4% (Change of Name of Manufacturer)	3M Deutschland GmbH	Germany	Third Schedule
Trajenta 5mg Tablets (Change of Manufacturer)	Boehringer Ingelheim Promeco, S.A. de C.V., Mexico for: Boehringer Ingelheim (Canada) Limited	Canada	do.
NovoRapid® FlexPen® 3ml Pre-filled pen 100IU/ml, Solution for Injection (New Indication and Extension of Storage Conditions	Novo Nordisk A/S	Denmark	do.
Levemir® FlexPen® Pre- filled Pen, Solution for Injection 100IU/ml (New Indication and Extension of Storage Conditions)	do.	do.	do.
Pradaxa 75mg Capsules (Change of Colour of Capsules)	Boehringer Ingelheim Pharma GmbH & Co. KG, Germany for: Boehringer Ingelheim (Canada) Limited	Canada	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Pradaxa 110mg Capsules (Change of Colour of Capsules)	Boehringer Ingelheim Pharma GmbH & Co. KG, Germany for: Boehringer Ingelheim (Canada) Limited	Canada	Third Schedule
Pradaxa 150mg Capsules (Change of Colour of Capsules)	do.	do.	do.
Bisolvon Elixir-Sugar-Free 8mg/5ml (Change of Marketing Authorisation Holder and Change of Artwork Design)	Pharmetique S.A. for: Sanofi-Aventis de Panamá, S.A., Panama	Colombia	Freely
Bisolvon Elixir-Pediatric-Strawberry (Sugar-Free) 4mg/5ml (Change of Marketing Authorisation Holder and Change of Artwork Design)	do.	do.	do.
Synflorix Suspension for Injection (Additional Indication, Change of Product Name and Change of Importer)	GlaxoSmithKline Biologicals S.A.	Belgium	Third Schedule
Ziagen Film-Coated Tablets 300mg (Additional Manufacturing Site and Change of Importer)	GlaxoSmithKline Pharmaceuticals S.A.	Poland	do.
Infanrix hexa™ Powder and Suspension for Suspension for Injection in a Pre-filled Syringe (Additional Packaging Site, Change of Dosage, Change of Importer and Change of Product Name)	GlaxoSmithKline Biologicals S.A., Belgium Packaged by: GlaxoSmithKline Biologicals	France	do.
Cervarix Suspension for Injection - Pre-filled Syringe (New Indication, Additional Manufacturing Site and Change of Importer)	GlaxoSmithKline Biologicals S.A.	Belgium	Third Schedule
Varilix Lyophilised Vaccine + Diluent for Injection (Additional Manufacturing Site and Change of Importer)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Priorix Lyophilisate and Solvent for Injection (Additional Manufacturing Site and Change of Importer)	GlaxoSmithKline Biologicals S.A.	Belgium	Third Schedule
Depakote ER 250mg Tablets (Change of Marketing Authorisation Holder, Change of Packaging Site, Change of Country of Origin and Change of Artwork Design)	AbbVie Ltd., Puerto Rico Packaged by: Abbott Laboratories Argentina S.A.	Argentina	Third Schedule
Depakote ER 500mg Tablets (Change of Marketing Authorisation Holder, Change of Packaging Site, Change of Country of Origin, Change of Artwork Design and Extension of Shelf Life)	do.	do.	do.
Humira™ AC 40mg/0.4ml Solution for Injection in Pre-filled Pen (Change of Formulation, Additional Indications, Change of Artwork Design and Change of Importer)	Vetter Pharma-Fertigung GmbH & Co. KG, Germany Secondary Packager: AbbVie Deutschland GmbH & Co. KG	Germany	do.
Acyclovir Denk 5% Cream 50mg/g (Change of Manufacturer, Change of Package Size and Change of Importer)	RubiePharm Arzneimittel GmbH for: Denk Pharma GmbH & Co. KG, Germany	do.	do.
Cipro-Denk 500 Film-Coated Tablets 500mg (Additional API Manufacturer and Change of Importer)	Allphamed Pharmed Arzneimittel GmbH for: Denk Pharma GmbH & Co. KG, Germany	do.	do.
Olfen-75 IM Ampoules 75 mg (Change of Manufacturer, Extended Shelf Life and Change of Artwork Design)	Haupt Pharma Wülfig GmbH for: Acino Pharma AG, Switzerland	do.	do.
Simepar Capsules (Change of Artwork Design)	Acino Pharma AG	Switzerland	do.
Bactiflox™ 500mg Film-Coated Tablets (Change of Manufacturer, Change of Formulation, Change of Artwork Design and Change of Product Name)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Gasec-20 Gastrocaps 20mg (Change of Manufacturing Site, Change of Formulation, Change of Artwork Design and Extended Shelf Life)	Acino Pharma AG for: Acino AG, Germany	Switzerland	Third Schedule
Enterogermina Oral Solution 4 billion/5ml (Additional Strength)	Sanofi S.p.A.	Italy	Freely
Enapril-10 Tablets USP 10mg (Change of Manufacturer and Change of Importer)	Intas Pharmaceuticals Limited	India	Third Schedule
Temintas 100 Capsules (Additional Manufacturing Site)	do.	do.	do.
Temintas 140 Capsules (Additional Manufacturing Site)	do.	do.	do.
Simponi Solution for Injection in Pre-filled Pen 50mg/0.5ml (Additional Indication)	Baxter Pharmaceutical Solutions LLC, USA Packaged by: Cilag AG	Switzerland	do.
Simponi Solution for Injection in Pre-filled Pen 100mg/0.5ml (Additional Indication)	do.	do.	do.
Hexi-Cream (Change of Name and Address of Manufacturer)	Bpi Genethics Limited	Trinidad and Tobago	Freely
Genethics Diphenhydramine Elixir (Change of Name and Address of Manufacturer)	do.	do.	do.
Salve Concentrate (Hospital Strength) (Change of Name and Address of Manufacturer)	do.	do.	do.
Genethics Gravogen Liquid (Change of Name and Address of Manufacturer)	do.	do.	do.
Hexi-Scrub Liquid (Change of Name and Address of Manufacturer)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Genethics Sports Balm Ultra with Capsicum - Stick Applicator (Change of Name and Address of Manufacturer and Change of Product Name)	Bpi Genethics Limited	Trinidad and Tobago	Freely
Hexitane (Change of Name and Address of Manufacturer and Change of Product Name)	do.	do.	do.
Genhydrate Oral Rehydration Salts Original Flavor (Change of Name and Address of Manufacturer and Change of Product Name)	do.	do.	do.
Genhydrate Oral Rehydration Salts - Grape Flavored (Change of Name and Address of Manufacturer and Change of Product Name)	do.	do.	do.
Genhydrate Oral Rehydration Salts - Orange Flavored (Change of Name and Address of Manufacturer and Change of Product Name)	do.	do.	do.
Imbruvica Capsules 140mg (Additional Manufacturing Site)	Cilag AG	Switzerland	Third Schedule
Fempro Tablets Letrozole Tablets USP 2.5mg (Change of Formulation)	Cipla Limited	India	do.
Verasol (VERAPAMIL HYDROCHLORIDE Injection USP 2.5mg/2ml, 2ml Ampoule)	SG Pharma Pvt. Ltd	do.	do.
Cordasol (Sterile Amiodarone Concentrate B.P. 50mg/ml, 3ml Ampoule)	do.	do.	do.
Naloxone Hydrochloride Injection USP 0.4mg/ml, 1ml Ampoule	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Xafen Tablets 180mg	Medreich Limited for: Mylan Pharmaceuticals Pvt. Ltd. India	India	Third Schedule
Xafen Tablets 120mg	do.	do.	do.
Cetriwina Tablets 10mg	Akriti Pharmaceuticals Pvt. Ltd.	do.	do.
Q Gel Mega 100 Coenzyme Q10 100mg Softsules	Tishcon Corp.	USA	Freely
Unitinib 100mg Capsules	United Biotech (P) Ltd.	India	Third Schedule
Unitinib 400mg Capsules	do.	do.	do.
ILet 2 Tablets 2mg/500mg	MSN Laboratories Private Ltd.	do.	do.

Dated this 30th day of January, 2019

T. DEYALSINGH
Minister of Health