

LEGAL NOTICE NO. 5

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>
Novolin® N PenFill Suspension for Injection 100 IU/ml, 3 ml Cartridge (Change of Package Insert)	Novo Nordisk A/S	Denmark	Third Schedule
Novolin® N Suspension for Injection 100 IU/ml, 10 ml Vial (Change of Package Insert)	do.	do.	do.
NovoMix® 30 FlexPen® 100 IU/ml, 3 ml Pre-Filled Pen Suspension for Injection (Change of Artwork Design and Update to Package Insert)	do.	do.	do.
NovoRapid® Flex Pen® 3ml Pre-filled Pen 100IU/ml, Solution for Injection (Update to Packaging Insert)	do.	do.	do.
Bisolvon Cough with Mucus Tablets 8 mg (Change of Artwork Design, Primary Packaging, Formulation, Source and Trade Name)	Delpharm Reims	France	Freely
Combivir Film-Coated Tablets 150/300 mg (Additional Manufacturing Site)	GlaxoSmithKline Pharmaceuticals SA	Poland	Third Schedule

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>
HAVRIX Junior 720 (Suspension for Injection) (Change of Formulation)	GlaxoSmithKline Biologicals S.A.	Belgium	Third Schedule
HAVRIX 1440 (Suspension for Injection) (Change of Formulation)	do.	do.	do.
Sandimmun Neoral Capsules 25 mg (Change of Source)	Catalent Germany Eberbach GmbH, Germany Packaged by: Novartis Pharma Stein AG, For Novartis Pharma AG Basle, Switzerland	Switzerland	do.
Sandimmun Neoral Capsules 100 mg (Change of Source)	do.	do.	do.
Pantecta P20 Tablets (Change of Name of Manufacturer and Change of Name of Packager)	Manufactured by: Takeda GmbH Germany Packaged by: Takeda Mexico S.A. De C.V. Mexico for Novartis Farmaceutica S.A., (AC) Guatemala	Mexico	do.
Pantecta 40 mg Tablets (Change of Name of Manufacturer and Change of Name of Packager)	do.	do.	do.
Pantecta IV Lyophilized Powder for Solution for Injection 40 mg (Change of Name of Manufacturer and Change of Name of Packager)	do.	do.	do.
Otrivin Nasal Drops Solution 0.1% – Adults (Change of Artwork Design of Primary and Secondary Packaging)	Novartis Consumer Health S.A.	Switzerland	Freely
Otrivin Metered Dose Nasal Spray 0.1% – Adults (Change of Artwork Design of Primary and Secondary Packaging)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Otrivin Nasal Spray Nebuliser Solution 0.1%-Adults (Change of Artwork Design of Primary and Secondary Packaging)	Novartis Consumer Health S.A.	Switzerland	Freely
Otrivin Nasal Gel 0.1%-Adults (Change of Artwork Design of Primary and Secondary Packaging)	do.	do.	do.
Otrivin Nasal Drops Solution 0.05% - Children (Change of Artwork Design of Primary and Secondary Packaging)	do.	do.	do.
Otrivin Metered Dose Nasal Spray 0.05%-Children (Change of Artwork Design of Primary and Secondary Packaging)	do.	do.	do.
Byetta 5 mcg/dose Solution for Injection Prefilled Pen (Change of Packaging Site and New Indication)	Manufactured for: Baxter Pharmaceutical Solutions LLC USA Packed by: Enestia Belgium Pen Assembly by: Sharp Corporation USA Holder: AstraZeneca Camcar S.A. Panama	Belgium	Third Schedule
Byetta 10 mcg/dose Solution for Injection Pre-filled Pen (Change of Packaging Site and New Indication)	do.	do.	do.
Epilim 200 Gastro-Resistant Tablets (Change of Manufacturing Site)	Sanofi-Aventis, S.A.	Spain	do.
Epilim Chrono 200 Controlled Release Tablets (Change of Manufacturing Site)	Sanofi Winthrop Industrie	France	do.
Epilim Chrono 300 Controlled Release Tablets (Change of Manufacturing Site)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Epilim Chrono 500 Controlled Release Tablets (Change of Manufacturing Site)	Sanofi Winthrop Industrie	France	Third Schedule
Norvasc Tablets 5 mg (Change of Name of Manufacturing Site)	R-Pharm Germany GmbH	Germany	do.
Norvasc Tablets 10 mg (Change of Name of Manufacturing Site)	do.	do.	do.
Vfend Film Coated Tablets 200 mg (Change of Name of Packager and New Indication)	Manufacturer: Pfizer Italia S.r.l. Italy Packager: R-Pharm Germany GmbH	Germany	do.
Vfend Powder for Solution for Infusion 200 mg (Change of Name of Packager and New Indication)	Manufacturer: Pharmacia & Upjohn Co. USA Packager: Fareva Amboise	France	do.
Ponstan Capsules 250 mg (Change of Name of Manufacturing Site)	Pfizer Manufacturing Deutschland GmbH	Germany	do.
Ponstan Forte Film Coated Tablets 500 mg (Change of Name of Manufacturing Site and Change of Artwork Design)	do.	do.	do.
Diflucan Capsules 150 mg (Change of Name of Manufacturing Site)	Manufacturer: Fareva Amboise License Holder: Pfizer Holding France	France	do.
Celebrex Capsules 200 mg (Change of Name of Manufacturing Site)	Manufacturer: Neolpharma Inc. Puerto Rico, USA Packager: R-Pharm Germany GmbH	Germany	do.
Glynase® Prestab® Tablets 3 mg (Change of Name of Manufacturing Site)	Manufacturer: Neolpharma Inc.	USA	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Glynase® Prestab® Tablets 6 mg (Change of Name of Manufacturing Site)	Manufacturer: Neolpharma Inc. USA Packager: Pharmacia & Upjohn Company	USA	Third Schedule
Cytotec 200 mcg Tablets (Change of Source and Change of Artwork Design)	Piramal Healthcare UK Limited	UK	do.
Claritine 10 mg Tablets (Change of Marketing Authorization Holder and Change of Artwork Design)	Manufactured & Packaged by: Schering-Plough Labo NV For: Bayer S.A., Guatemala	Belgium	Freely
Claritine Syrup (Alcohol Free) 1 mg/ml (Change of Marketing Authorization Holder and Change of Artwork Design)	do.	do.	do.
Angeliq Film Coated Tablets 2 mg/1 mg (Change of Name of Marketing Authorization Holder, Change of Manufacturing Site and Change of Artwork Design)	Manufactured by: Bayer Weimar GmbH und Co. KG Germany Packaged by: Schering do Brasil, Quimica e Farmaceutica Ltda. For: Bayer Pharma AG, Germany	Brazil	Third Schedule
Redoxon Vitamin C 2g Effervescent Tablets– Lemon Flavor (Change of Name of Manufacturer and Change of Primary & Secondary Artwork Design)	Manufactured by: Delpharm For: Bayer S.A. Guatemala	France	Freely
AriXtra Solution for Injection Pre-Filled Syringe with an Automatic Safety System 2.5 mg/0.5ml (Change of Name of Marketing Authorization Holder, Change of Manufacturing Site and Change of Artwork Design)	Manufactured & Packaged by: Aspen Notre Dame de Bondeville For: Aspen Labs S.A. De C.V. Mexico	do.	Third Schedule

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Tums Extra Strength 750 mg Chewable Antacid Tablets Assorted Fruit (Change of Name of Manufacturing Site and Change of Artwork Design)	Manufacturer: GlaxoSmithKline Consumer Healthcare Distributor: GlaxoSmithKline Consumer Healthcare USA	USA	Freely
Ketozal Shampoo (Change of Artwork Design and Change of Primary Packaging)	Manufactured by: Carlisle Laboratories Limited	Barbados	Third Schedule
Myleran Film-Coated Tablets 2 mg (Change of Name of Manufacturer)	Excella GmbH	Germany	do.
Puri-nethol Tablets 50 mg (Change of Name of Manufacturer)	do.	do.	do.
Imuran Tablets 50 mg (Change of Name of Manufacturer)	do.	do.	do.
Liquiband Optima/Tropical Skin Adhesive 0.5 g (Change of Packaging)	Advanced Medical Solutions (Plymouth) Limited	United Kingdom	Freely (Pharmacy ONLY)
Picoprep Powder For Oral Solution/Sachet 10 mg, 3.5 g, 12 g (Change of Artwork Design)	Ferring Pharmaceuticals (China) Co. Ltd.	China	Third Schedule
Pentasa Suppositories 1 g (Change of Manufacturing Site)	Ferring International Center S.A.	Switzerland	do.

Dated this 10th day of January, 2018

T. DEYALSINGH
Minister of Health