

LEGAL NOTICE NO. 278

## REPUBLIC OF TRINIDAD AND TOBAGO

THE 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:

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Prevenar 13® Pneumococcal 13-Valent Conjugate Vaccine (Diphtheria CRM197 Protein) (Change of Secondary Packager, Change of Product License Holder and Change of Label)	Manufacturer and Primary Packager: Pfizer Ireland Pharmaceuticals, Ireland Secondary Packager: Pfizer Manufacturing Belgium NV, Belgium License Holder: Pfizer Europe MA EEIG, Belgium	Belgium	Third Schedule
VETERINARY PRODUCTS			
Zimecterin Gold Oral Paste (Change of Name of Manufacturer)	Boehringer Ingelheim Animal Health do Brazil, Ltda.	Brazil	Freely
Ivomec Injection (Change of Name of Manufacturer)	do.	do.	Veterinary Prescription Only
Eqvalan Paste (Change of Name of Manufacturer)	Boehringer Ingelheim Animal Health do Brazil, Ltda.	do.	Veterinary Prescription Only

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
END OF VETERINARY MEDICINE			
Vit-B-Denk Film Coated Tablets 100mg + 200mg  (Additional Packaging Site)	Denk Pharma GmbH & Co. KG, Germany	Germany	Freely
Clotri-Denk 1% Cream (Change of Manufacturer)	C.P.M. ContractPharma GmbH Germany	do.	Third Schedule
Para-Denk 125 Suppository, 125mg (Alternative Manufacturer and Change of Packaging)	bene-Arzneimittel GmbH Germany	do.	Freely
Para-Denk 250 Suppository, 250mg (Alternative Manufacturer and Change of Packaging)	do.	do.	do.
Amlo-Denk 5 Tablet 5mg (Additional Packaging Site)	Denk Pharma GmbH & Co. KG, Germany	do.	Third Schedule
Amlo-Denk 10 Tablet 10mg (Additional Packaging Site)	do.	do.	do.
Synagis Solution for Injection 100mg/ml (Change of Marketing Authorisation Holder)	Manufacturing Site: Boehringer Ingelheim Pharma GmbH & Co. KG Germany Secondary Packager: Abbvie S.r.L. Italy For: Abbvie & Co. KG Deutschland GmbH Germany	do.	do.
Lexapro® (Escitalopram) Film- Coated Tablets 20mg (Change of Marketing Authorisation Holder)	H. Lundbeck A/S, Valby, Denmark For: Lundbeck America Central, S.A., Panama City, Republic of Panama	Denmark	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Kalms Day 84 Tablets & 200 Tablets (Change of Formulation and Change of Label)	G.R. Lane Health Product Limited, United Kingdom	UK	Freely
Blopress Tablets 8mg (Change of Packaging and Change of Label)	Abbott Laboratories Argentina S.A., Argentina	Argentina	Third Schedule
Blopress Tablets 16mg (Change of Packaging and Change of Label)	do.	do.	do.
Blopress Plus Tablets 16mg/12.5mg (Change of Packaging and Change of Label)	Takeda Ireland Ltd., Ireland Packaged by: Abbott Laboratories, Argentina S.A., Argentina	do.	do.
Avonex 30mcg/0.5ml Solution for Injection (Change of Formulation, Change of Packaging, Change of Label and New Manufacturing Site)	Vetter Pharma-Fertigung, GmbH & Co. KG, Langenargen, Germany	Germany	do.
Cytax 30 Paclitaxel Injection USP Concentrate 30mg/5ml (Change of Packaging)	Intas Pharmaceuticals Limited	India	do.
Cytax 100 Paclitaxel Injection USP Concentrate 100mg/16.7ml (Change of Packaging)	do.	do.	do.
Cytax 300 Paclitaxel Injection USP Concentrate 300mg/50ml (Change of Packaging)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Accentrix Solution for Injection 10mg/ml (Change of Marketing Authorisation Holder, Change of Indications for Use and Change of Label)	Novartis Pharma Stein AG	Switzerland	Third Schedule
Voltaren Emulgel 1.16% (Change of Manufacturing Site Name and Change of Label)	Manufactured by: GSK Consumer Healthcare S.A., Switzerland For: GlaxoSmithKline Costa Rica, S.A., Costa Rica	do.	Third Schedule
Procto-Glyvenol Suppositories (Change of Product License Holder and Change of Label)	Manufactured by: Delpharm Huningue S.A.S, France For: GlaxoSmithKline, S.A., Costa Rica	France	do.
Procto-Glyvenol Cream (Change of Product License Holder, Change of Manufacturing Site Name and Change of Label)	Manufactured by: GSK Consumer Healthcare S.A., Switzerland For: GlaxoSmithKline Costa Rica, S.A., Costa Rica	Switzerland	do.
Lamisil Dermgel 1% (Change of Product License Holder, Change of Name of Manufacturing Site, Change of Packaging and Change of Label)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Lamisil Cream 1% (Change of Product License Holder, Change of Manufacturing Site Name and Change of Label)	Manufactured by: GSK Consumer Healthcare S.A., Switzerland For: GlaxoSmithKline Costa Rica, S.A., Costa Rica	Switzerland	Third Schedule
Lamisil Spray 1% (Change of Product License Holder and Change of Label)	Manufactured by: Delpharm Huningue S.A.S., France  For: GlaxoSmithKline Costa Rica, S.A., Costa Rica	France	Third Schedule
Otrivin Nasal Spray Nebulizer Solution 0.1% (Change of Name of Manufacturing Site and Change of Label)	Manufactured by: GSK Consumer Healthcare S.A., Nyon, Switzerland For: GlaxoSmithKline Costa Rica, S.A., Costa Rica	Switzerland	Freely
Otrivin Nasal Drops Solution 0.1% (Change of Name of Manufacturing Site and Change of Label)	do.	do.	do.
Otrivin Metered Dose Nasal Spray 0.1% (Change of Name of Manufacturer and Change in Primary Packaging and Change of Label)	do.	do.	do.
Otrivin Nasal Drops Solution 0.05% Children (Change of Name of Manufacturing Site and Change of Label)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Panadol Extra Strength with Optizorb Film Coated Tablets (Change of Name of Product, Change of Artwork and Change of Label)	Manufactured by: GlaxoSmithKline Dungarvan Ltd., Ireland Packed by: GlaxoSmithKline Panama S.A., Panama	Panama	Freely
Panadol Day Non-Drowsy Tablets (Change of Name of Product, Change of Artwork and Change of Label)	do.	do.	do.
Panadol Multi-Symptom Tablets (Change of Name of Product, Change of Artwork and Change of Label)	Manufactured by: GlaxoSmithKline Panama S.A., Panama	Panama	Freely
Panadol Sinus Tablets (Change of Name of Product, Change of Artwork and Change of Label)	do.	do.	do.
Panadol Woman Tablets (Change of Artwork and Change of Label)	do.	do.	do.
Andrews Salts Original Effervescent Powder (Additional Source, Change of Artwork and Change of Label)	Manufactured by: GlaxoSmithKline Argentina S.A., Argentina	Argentina	do.
Andrews Salts Lemon (Change of Formulation, Additional Source, Change of Artwork and Change of Label)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Benjamins Relief Diphenhydramine Elixir (Change of Name of Product, Change of Artwork and Change of Label)	Manufactured by: P.A. Benjamin Mfg. Co. Ltd. 97 East Street, Kingston, Jamaica	Jamaica	Freely
Benjamins Relief Diphenhydramine Elixir – Cherry Flavour, Sugar Free, Alcohol Free (Change of Name of Product, Change of Artwork and Change of Label)	do.	do.	do.
Benjamins Relief Diphenhydramine Elixir – Grape Flavour, Sugar Free, Alcohol Free (Change of Name of Product, Change of Artwork and Change of Label)	do.	do.	do.
Benjamins Relief Diphenhydramine Expectorant (Change of Name of Product, Change of Artwork, Change of Packaging and Change of Label)	Manufactured by: P.A. Benjamin Mfg. Co. Ltd. 97 East Street, Kingston, Jamaica	Jamaica	Freely
Benjamins Relief Diphenhydramine – Expectorant – Cherry Flavour, Sugar Free, Alcohol Free (Change of Name of Product, Change of Artwork, Change of Packaging and Change of Label)	do.	do.	do.
Benjamins Relief Diphenhydramine – Expectorant – Grape Flavour, Sugar Free, Alcohol Free (Change of Name of Product, Change of Artwork, Change of Packaging and Change of Label)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Kytril Film-Coated Tablets 1mg (Change of Marketing Authorisation Holder, Change of Name of Manufacturer, Change of Artwork, Change of Importer and Change of Label)	Manufactured by: Delpharm Milano S.r.l., Italy Packaged by: Ivers-Lee A.G., Switzerland For: Atnahs Pharma UK Limited UK	Switzerland	Third Schedule
Kytril 3mg/3ml I.V. Injectable Solution (Change of Marketing Authorisation Holder, Change of Artwork, Change of Importer and Change of Label)	Manufactured and Packaged by: Cenexi SAS, France For: Atnahs Pharma UK Limited, UK	France	do.
Bondronat Film-Coated Tablets 50mg (Change of Marketing Authorisation Holder, Change of Artwork, Additional Source, Change of Importer, Change of Packaging and Change of Label)	Manufacturer and Primary Packager: Penn Pharmaceutical Services Limited, Tredegar, UK Secondary Packager: Waymade PLC, UK For: Atnahs Pharma UK Limited, UK	UK	Third Schedule
Bondronat Concentrate for Solution for Infusion 6mg/6ml (Change of Marketing Authorisation Holder, Change of Artwork, Additional Packager, Change of Importer, Change of Packaging and Change of Label)	Manufacturer and Primary Packager: Roche Diagnostics GmbH, Germany Secondary Packager: Waymade PLC, UK For: Atnahs Pharma UK Limited, UK	UK	Third Schedule



TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Bonviva Solution for I.V. Injection 3mg/3ml – Pre-Filled Syringe (Change of Marketing Authorisation Holder, Change of Artwork, Change in Secondary Packager, Change of Importer, Change of Packaging and Change of Label)	Manufacturer and Primary Packager: Vetter Pharmaceutical Manufacturing GMBH & CO KG, Germany Secondary Packager: Waymade PLC, UK For: Atnahs Pharma UK Ltd., UK	UK	Third Schedule
Bonviva Film-Coated Tablets 150mg (Change of Marketing Authorisation Holder, Change of Artwork, Additional Packager, Change of Importer, Change of Packaging and Change of Label)	Manufacturer and Primary Packager: Penn Pharmaceutical Services Limited Tredegar, UK Secondary Packager: Waymade PLC, UK For: Atnahs Pharma UK Ltd., UK	do.	do.
Roswera 5mg Film-Coated Tablets	KRKA	Slovenia	Third Schedule
Roswera 10mg Film-Coated Tablets	do.	do.	do.
Roswera 20mg Film-Coated Tablets	do.	do.	do.
Emanera 20mg Gastro Resistant Capsules	do.	do.	do.
Emanera 40mg Gastro Resistant Capsules	do.	do.	do.
Yasnal Q-tab 5mg Orodispersable Tablets	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Yasnal Q-tab 10mg Orodispersable Tablets	KRKA	Slovenia	Third Schedule
Depakote 500mg Delayed-Release Tablets (Change of Manufacturing Site, Change of Name of Product, Change in Excipient Composition, Change of Manufacturing Process, Change in Process Testing, Change in Final Product Specifications, Change in Packaging Specifications, Change in Artwork Design and Change in Shelf Life)	Abbott Laboratories de México S.A. de C.V.	Mexico	do.
Depakote 250mg Delayed-Release Tablets (Change of Manufacturing Site, Change of Name of Product, Change in Excipient Composition, Change of Manufacturing Process, Change in Process Testing, Change in Final Product Specifications, Change in Packaging Specifications, Change in Artwork Design and Change in Shelf Life)	do.	do.	do
Doloforte Denk Film Coated Tablets 37.5mg/325mg	Denk Pharma GmbH & Co. KG	Germany	Third Schedule
Rosuvastatin Denk 20mg Film Coated Tablets 20mg	Pharmaceutical Works Polpharma S.A. for: Denk Pharma GmbH & Co. KG, Germany	Poland	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Abiratred Abiraterone Acetate Tablets USP 250mg	Dr. Reddy's Laboratories Ltd.	India	Third Schedule
Traparcin Tablets 37.5mg/325mg	Ferrer International S.A. for Acino Pharma AG, Germany	Spain	do.
Salmex Inhalation Powder 100µg/50µg	Celon Pharma S.A.	Poland	do.
Salmex Inhalation Powder 250µg/50µg	do.	do.	do.
Salmex Inhalation Powder 500µg/50µg	do.	do.	do.
Bortezomib W&H Powder for Solution for Injection 3.5mg	PharmIdea SIA for: William & Halls ehf., Iceland	Latvia	do.
Ossazol Zoledronic Acid Concentrate for Solution for Infusion 4mg/5ml	do.	do.	do.
Chlorpheniramine Maleate Solution for Injection USP 10mg/ml	SGPharma Pvt. Ltd.	India	Third Schedule
Darunavir Tablets 600mg	Hetero Labs Limited	do.	do.
Lopinavir and Ritonavir Tablets USP 200mg/50mg	do.	do.	do.
Trustiva Tablets 600mg/200mg/300mg	do.	do.	do.
Abacavir Sulfate and Lamivudine Tablets 600mg/300mg	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Digoxin Tablets USP 0.125mg	SGPharma Pvt. Ltd.	India	Third Schedule
Atropine Sulfate Solution for Injection USP 0.6mg/ml	do.	do.	do.
Lavuzid N Tablets 150mg/200mg/300mg	Hetero Labs Limited	do.	do.
Sevelamer Sandoz Film-Coated Tablets 800mg	Synthon Hispania, S.L. for: Sandoz GmbH, Austria	Spain	do.
Divenis Film-Coated Tablets 500mg	Kern Pharma S.L. for: Sandoz GmbH, Austria	do.	Third Schedule
Enoxaparin 100mg/ml Sandoz Solution for Injection in Pre-filled Syringe 20mg/0.2ml	Rovi Contract Manufacturing S.L. Spain Packed by: Frosst Iberica, S.A. for: Sandoz GmbH, Austria	do.	do.
Peppa Pig Multivitamin Gummies	Nutra Essential OTC, S.L.	Spain	Freely
HERBAL PRODUCTS			
Curamin Capsules 750mg	Europharm Inc.	USA	Freely
Senna Leaves Capsules 450mg	Nature's Way Brand LLC	do.	do.
Tumeric Standardized Tablets 500mg	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Maca Standardized Capsules 450mg	Nature's Way Brand LLC	USA	Freely
Eyebright Herb Capsules 430mg	do.	do.	do.
END OF HERBAL MEDICINE			
Microdacyn 60 Sterilizing and Strong Oxidizing Antiseptic Solution	Oculus Technologies of Mexico, S.A. de C.V.	Mexico	Freely
Diovan Film-Coated Tablets 320mg (Additional Source and Change in the Coating Composition, Tablet Shape and Appearance)	Novartis Farmacéutica S.A. Barbera del Valles For: Novartis Pharma AG, Basel Switzerland	Spain	Third Schedule
Tykerb Film-Coated Tablets 250mg (New Indication)	Manufactured by: Glaxo Operations UK Limited UK Packed by: Glaxo Wellcome S.A.	do.	do.
Microdacyn 60 Oropharynx Antiseptic Oropharynx Solution	Oculus Technologies of Mexico, S.A. de C.V. Mexico	Mexico	Freely
Bactigras Chlorhexidine Acetate Tulle Gras Dressing 0.5% (Additional Source)	Smith & Nephew Medical (Suzhu) Ltd	China	Freely

Dated this 22nd day of July, 2020.

T. DEYALSINGH  
*Minister of Health*