

LEGAL NOTICE NO. 217

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
Travatan Eye Drops Solution 40mcg/ml (Change of name, change of label and change of Marketing Authorisation Holder)	S.A. Alcon-Couvreur N.V., Belgium For: Novartis Pharma AG, Basel, Switzerland	Belgium	Third Schedule
Buscopan Plus Film-coated Tablets 10/500mg (Change of packaging, change of label and change of Marketing Authorisation Holder)	Boehringer Ingelheim Promeco, S.A. de C.V.	Mexico	do.
Trajenta Tablets 5mg (Additional indication and change of packaging)	West-Ward Columbus Inc.	USA	do.
Trajenta Tablets 5mg (Additional indication and change of packaging)	Boehringer Ingelheim Promeco, S.A. de C.V.	Mexico	do.
Flucess Capsule 150mg (Change of Manufacturer and Manufacturing Site and change of label)	Manufactured by: SALUTAS Pharma GmbH, Germany For: Sandoz GmbH, Austria	Germany	do.
Flucess Capsule 200mg (Change of Manufacturer and Manufacturing Site and change of label)	do.	do.	do.
Mycota Powder (Change of packaging)	Manufactured by: Laboratoria Smeets N. V., Belgium For: Thornton & Ross Limited, U. K.	Belgium	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Allegra D Extended Release Film-coated Tablets (Change of name of Packager, change of name and address of Product Holder)	Manufacturer: Sanofi-Winthrop Industrie, France Packager: Sanofi Medley Farmac�utica Ltda.	Brazil	Third Schedule
Allegra Pediatric Suspension 30mg/5mL (Change of name of Manufacturer, Change of name and address of Product Holder and change of Condition of Sale)	Sanofi Medley Farmac�utica Ltda.	do.	Freely
Allegra Film-coated Tablets 120mg (Change of name of Manufacturer, change of name and address of Product Holder and change of Condition of Sale)	do.	do.	do.
Allegra Film-coated Tablets 180mg (Change of name of Manufacturer, change of name and address of Product Holder)	do.	do.	Third Schedule
Tykerb Film-coated Tablets 250mg (Change of label, additional Manufacturer and change of Marketing Authorisation Holder)	Manufacturer: S.C. Sandoz S.R.L., Rom�nia For: Distributor/Marketing Authorisation Holder: Novartis Pharma AG, Basel, Switzerland	Romania	do.
Tivicay Film-coated Tablets 50mg (Additional Manufacturing Site)	Manufactured and Packaged by: GlaxoSmithKline Pharmaceuticals S.A., Poland	Poland	do.
Lamictal Dispersible/Chewable Tablets 5mg (Additional Packaging Site and change of packaging)	do.	do.	do.
Lamictal Dispersible/Chewable Tablets 25mg (Additional Packaging Site)	do.	do.	do.
Lamictal Dispersible/Chewable Tablets 50mg (Additional Packaging Site)	do.	do.	do.
Lamictal Dispersible/Chewable Tablets 100mg (Additional Packaging Site)	do.	do.	do.
Choragon Powder and Solvent for Injection/Vial 5000IU (Additional Secondary Packager)	Marketing Authorisation Holder and Powder Manufacturer: Ferring GmbH, Germany Solvent Manufacturer: Haupt Pharma W�lfing GmbH, Germany Packaged by: Ferring-L�civa, a.s., Czech Republic	Czech Republic	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Duratocin Solution for Injection 100mcg/ml (Change of indications, change of packaging)	Manufactured by: Ferring GmbH, Germany Packaged by: Ferring-Léciva a.s., Czech Republic	Czech Republic	Third Schedule (For Specialist Use Only)
Gonapeptyl Daily Solution for Injection 0.1mg/ml (Change of name, additional Secondary Packager and change of packaging)	Manufactured by: Ferring GmbH, Germany Secondary Packager: Ferring-Léciva a.s., Czech Republic Marketing Authorisation Holder: Ferring GmbH, Germany	do.	Third Schedule
Pentasa Slow Release Tablets 500mg (Change of packaging)	Manufactured by: Ferring International Center SA, Switzerland	Switzerland	do.
Pentasa Prolonged Release Granules Sachets 2g (Change of packaging)	do.	do.	do.
Vaxigrip Tetra, Suspension for Injection in Pre-Filled Syringe, Quadrivalent Influenza Vaccine (Split virion, inactivated) 15mcg (New indication)	Sanofi Pasteur	France	do.
Cifran Tablet 250mg (Change of Manufacturing Site)	Sun Pharmaceutical Industries Limited	India	do.
Cifran Tablet 500mg (Change of Manufacturing Site)	do.	do.	do.
Panto-Denk 20 Gastro-Resistant Tablets 20mg (Change of API Manufacturer)	Manufactured by: Advance Pharma GmbH Distributed by: Denk Pharma GmbH & Co. KG	Germany	do.
Panto-Denk 40 Gastro-Resistant Tablets 40mg (Change of API Manufacturer)	do.	do.	do.
Zoledro-Denk Concentrate for Solution for Infusion 4mg/5ml (Change of name of Manufacturing Site)	Manufactured by: Siegfried Hameln GmbH Distributed by: Denk Pharma GmbH & Co. KG	do.	do.
Nizoral Gel Shampoo 2% (Change of Marketing Authorisation Holder and change of artwork)	Janssen-Cilag S.A de C.V.	Mexico	do.
Prograf Capsules 1mg (Change of label)	Astellas Ireland Co., Limited	Ireland	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Prograf Capsules 5mg (Change of label)	Astellas Ireland Co., Limited	Ireland	Third Schedule
Darzalex Concentrate for Solution for Infusion 100mg/5mL (Additional indications)	Cilag AG	Switzerland	do.
Darzalex Concentrate for Solution for Infusion 400mg/20ml (Additional indications)	do.	do.	do.
Pantoprazol Gastro-Resistant Capsules 40mg (Change of Manufacturing Site, change of artwork and change of label)	Farmalabor S.A (Bulk Manufacturer, Batch control/testing) and Atlantic Pharma S.A.	Portugal	do.
Clopicor Film-coated Tablets 75mg (Change of Manufacturer and change of artwork)	Atlantic Pharma S.A.	do.	do.
Talliton Tablets 6.25mg (Change of packaging and change of artwork)	Egis Pharmaceuticals PLC Budapest	Hungary	do.
Talliton Tablets 12.5mg (Change of packaging and change of artwork)	do.	do.	do.
Talliton Tablets 25mg (Change of packaging and change of artwork)	do.	do.	do.
Exforge Film-coated Tablets 5/320mg (Additional Manufacturer and new Manufacturing Site)	Manufactured by: Lek Pharmaceuticals d.d., Ljubljana, Slovenia For: Novartis Pharma S.A. (AC), Guatemala	Slovenia	do.
Exforge Film Coated Tablets 10/320mg (Additional Manufacturer and new Manufacturing Site)	do.	do.	do.
Kadcyla Powder For Concentrate For Solution For Infusion 100mg (Additional indication and change of name of Manufacturer)	Patheon Manufacturing Services LLC, NC, USA For: F. Hoffmann-La Roche Ltd., Basel, Switzerland	USA	do.
Kadcyla Powder For Concentrate For Solution For Infusion 160mg (Additional indication and change of name of Manufacturer)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Kadcyla Powder For Concentrate For Solution For Infusion 100mg (Additional indication)	F. Hoffmann-La Roche Ltd., Kaiseraugst, Switzerland For: F. Hoffmann-La Roche Ltd., Basel, Switzerland	Switzerland	Third Schedule
Kadcyla Powder For Concentrate For Solution For Infusion 160mg (Additional indication)	do.	do.	do.
Tecentriq Concentrate For Solution For Infusion 1200mg/20ml (Additional indications, additional Manufacturing Site, change of label and artwork update)	do.	do.	do.
Avastin Concentrate For Solution For Infusion 100mg/4ml (Additional Manufacturing Site)	Genentech Inc., Hillsboro, Oregon, USA Packed by (secondary): F. Hoffmann-La Roche Ltd., Kaiseraugst, Switzerland For: F. Hoffmann-La Roche Ltd., Basel, Switzerland	do.	do.
Avastin Concentrate For Solution For Infusion 100mg/4ml (Change in Sourcing Statement)	F. Hoffmann-La Roche Ltd., Kaiseraugst, Switzerland For: F. Hoffmann-La Roche Ltd., Basel, Switzerland	do.	do.
Avastin Concentrate For Solution For Infusion 400mg/16ml (Change in Sourcing Statement)	do.	do.	do.
Avastin Concentrate For Solution For Infusion 400mg/16ml (Additional Manufacturing Site)	Genentech Inc., Hillsboro, Oregon, USA Packed by (secondary): F. Hoffmann-La Roche Ltd., Kaiseraugst, Switzerland For: F. Hoffmann-La Roche Ltd., Basel, Switzerland	do.	do.
Norvase Tablet 10mg (Additional Manufacturing Site, change of Packaging Site and artwork update)	Manufacturer: Pfizer Pharmaceuticals, LLC Vega Baja, Puerto Rico Packager: Pfizer Manufacturing Deutschland GmbH, Freiburg, Germany License Holder: Pfizer Pharma PFE GmbH, Link Strasse Berlin, Germany	Germany	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Norvasc Tablet 5mg (Additional Manufacturing Site, change of Packaging Site and artwork update)	Manufacturer: Pfizer Pharmaceuticals, LLC Vega Baja, Puerto Rico Packager: Pfizer Manufacturing Deutschland GmbH, Freiburg, Germany License Holder: Pfizer Pharma PFE GmbH, Link Strasse Berlin, Germany	Germany	Third Schedule
Panadol Children Syrup 160mg/5ml (Change of packaging, change of Distributor, change of Manufacturing Site, change of label and artwork update)	Manufactured by: Pharmetique S.A., Colombia License Holder: GlaxoSmithKline Costa Rica S.A., Costa Rica	Colombia	Freely
Panadol Babies Solution 100mg/ml (Change of name, change of Distributor, change of Manufacturing Site, change of packaging, change of label and artwork update)	do.	do.	do.
Xarelto Film-coated Tablets 2.5mg (Additional indication)	Manufactured by: Bayer AG, Leverkusen, Germany For: Bayer AG, Germany	Germany	Third Schedule
OMNIPAQUE™ Solution for injection/infusion IOHEXOL 300mg l/ml (Change of label, change of Importer and Distributor, change of Manufacturer, change of Marketing Authorisation Holder and change of Country of Origin)	Manufactured by: GE Healthcare Distributed by: Soluna Company Limited	Ireland	do.
OMNIPAQUE™ Solution for injection/infusion IOHEXOL 350mg l/ml (Change of label, change of Importer and Distributor, change of Manufacturer, change of Marketing Authorisation Holder and change of Country of Origin)	do.	do.	do.
Leponex Tablets 25mg (Change of packaging, change of label and change of Marketing Authorisation Holder)	Manufactured by: Novartis Unrunleri, Turkey For: Mylan Pharma GmbH, Switzerland	Turkey	do.
Leponex Tablets 100mg (Change of packaging, change of label and change of Marketing Authorisation Holder)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Enbrel Solution for Injection in Pre-Filled Syringe 50mg (Change in Secondary Packaging Site, change of label and artwork update)	Manufacturer, Primary and Secondary Packager: Pfizer Manufacturing Belgium NV, Puurs, Belgium, License Holder: Pfizer Europe MA EEIG, Belgium	Belgium	Third Schedule
RhoGAM Ultra-Filtered Plus, Solution for Injection, 300µg Dose (1500IU) (Change of Manufacturing Site)	Manufactured by: Kedrion Biopharma Inc.	USA	do.
Zocon Eye Drops 0.3% w/v (Change of Distributor)	FDC Limited	India	do.
Zoxon Eye/Ear Drops 0.3% w/v (Change of Distributor)	do.	do.	do.
Allerrom Eye Drops 2% (Change of Distributor)	do.	do.	do.
Biofreeze Pain Relieving Gel (Change of Manufacturing Site)	Manufactured by: Span Packaging Services DBA For: Performance Health, LLC	USA	Freely
Biofreeze Pain Relieving Roll-On (Change of Manufacturing Site)	do.	do.	do.
Biofreeze Pain Relieving Spray 10% Menthol (Change of Manufacturing Site)	do.	do.	do.
Genhydrate Oral Rehydration Salts, Grape Flavored, Powder (Change of Formulation)	Bpi Genetics Limited	Trinidad and Tobago	do.
0.9% Sodium Chloride Injection USP (Additional Manufacturer and Manufacturing Site)	Baxter S.A. de C.V.	Mexico	Third Schedule
Safebul Tablets 8mg (Change of name and change of label)	Lek Pharmaceuticals d.d. For: Sandoz GmbH, Austria	Slovenia	do.
Safebul Tablets 16mg (Change of name and change of label)	do.	do.	do.
Safebul Tablets 32mg (Change of name and change of label)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
VETERINARY PRODUCTS			
Recombitek C8 Injection (Change of Marketing Authorisation Holder and Change of name of Manufacturing Site)	Marketing Authorisation Holder: Boehringer Ingelheim Vetmedica GmbH Manufacturer: Boehringer Ingelheim Animal Health USA Inc.	USA	Veterinary Prescription Only
Apoquel Film-coated Tablets 3.6mg (Change of Manufacturer and change of Manufacturing Site)	Zoetis Inc.	do.	do.
Apoquel Film-coated Tablets 5.4mg (Change of Manufacturer and change of Manufacturing Site)	do.	do.	do.
Apoquel Film-coated Tablets 16mg (Change of Manufacturer and change of Manufacturing Site)	do.	do.	do.
END OF VETERINARY PRODUCTS			

Dated this 12th day of August, 2021.

T. DEYALSINGH
Minister of Health