

LEGAL NOTICE No. 188

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
Bharat Biotech BBV152 COVAXIN® COVID-19 Vaccine Suspension for Injection 0.5mL/Single-dose Vial	Bharat Biotech International Limited, Genome Valley, Hyderabad	India	Pandemic Use/ Emergency Use Authorisation/ Individual 18 years and above
Bharat Biotech BBV152 COVAXIN® COVID-19 Vaccine Suspension for Injection 2.5mL/Multi-dose Vial	do.	do.	do.
Bharat Biotech BBV152 COVAXIN® COVID-19 Vaccine Suspension for Injection 5mL/Multi-dose Vial	do.	do.	do.
Bharat Biotech BBV152 COVAXIN® COVID-19 Vaccine Suspension for Injection 10mL/Multi-dose Vial	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Scapho® 150mg Powder for solution for injection (Change of Marketing Authorisation Holder; New Indication)	Manufactured & Packaged by: Novartis Pharma Stein AG, Stein, Switzerland For: Novartis Overseas Investments AG, Switzerland	Switzerland	Third Schedule (Specialist Use Only)
Actemra® 20 mg/ml (80 mg / 4 ml) concentrate for solution for infusion (Additional packaging site; New Indication)	Chugai Pharma Manufacturing Co., Ltd., Utsunomiya-city, Japan Packaged by: F. Hoffmann-La Roche Ltd., Kaiseraugst, Switzerland For: F. Hoffmann-La Roche Ltd., Basel, Switzerland	do.	do.
Actemra® 20 mg/ml (200 mg / 10 ml) concentrate for solution for infusion (Additional packaging site; New Indication)	do.	do.	do.
Pristiq® 50 mg Extended-Release Tablets (Change in packaging material)	Pfizer Ireland Pharmaceuticals, Ireland Packaged by: Pfizer Pharmaceuticals LLC, Ireland	Ireland	Third Schedule
Pristiq® 100 mg Extended-Release Tablets (Change in packaging material)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
BeneFix® 250IU Powder and Solvent for Solution for Injection (Change of manufacturing process)	<u>POWDER:</u> Wyeth Farma, S.A., Madrid, Spain <u>SOLVENT:</u> Vetter Pharma-Fertigung GmbH & Co., KG, Langenargen, Germany Packaged by: Wyeth Farma, S.A., Madrid, Spain For: Pfizer Europe MA EEIG, Belgium	Spain	Third Schedule
BeneFix® 500IU Powder and Solvent for Solution for Injection (Change of manufacturing process)	do.	do.	do.
Rinetason® 50mcg Nasal Spray Suspension (Change of name of product; Artwork update)	Lek Pharmaceuticals d.d., Slovenia For: Sandoz GmbH, Kundl-Austria	Slovenia	do.
Safebul® HCT 16mg/12.5mg Tablets (Change of name of product; Artwork update)	do.	do.	do.
Safebul® HCT 32mg/12.5mg Tablets (Change of name of product; Artwork update)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Safebul® HCT 32mg/25mg Tablets (Change of name of product; Artwork update)	Lek Pharmaceuticals d.d., Slovenia For: Sandoz GmbH, Kundl-Austria	Slovenia	Third Schedule
Uxigril® 4mg chewable tablets (Change of name of product; Change of name of manufacturer; Artwork update)	Genveon İlaç Sanayi Ve Ticaret A.S., Gebze-Kocaeli, Turkey For: Sandoz GmbH, Kundl-Austria	Turkey	do.
Uxigril® 5mg chewable tablets (Change of name of product; Change of name of manufacturer; Artwork update)	do.	do.	do.
Uxigril® 10mg film-coated tablets (Change of name of product; Change of name of manufacturer; Artwork update)	do.	do.	do.
Forxiga™ 5mg film-coated tablets (New Indications)	Manufactured & Packaged by: AstraZeneca Pharmaceuticals LP, USA For: AstraZeneca CAMCAR S.A., Panamá	USA	do.
Forxiga™ 10mg film-coated tablets (New Indications)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Andrews Salts Orange Sparkling Salts	Manufactured & Packaged by: GlaxoSmithKline Argentina, S.A., Carlos Cásares No. 3690, Buenos Aires, Argentina For: GlaxoSmithKline Costa Rica, S.A., Costa Rica	Argentina	Freely
COVERAM® 3.5mg/2.5mg Tablets	Servier (Ireland) Industries Ltd, Gorey Road-Arklow-Co. Wicklow Ireland For: Les Laboratoires Servier- France	Ireland	Third Schedule
Synthroid® 200 mcg Tablet	AbbVie Ireland NL B.V., Ireland Packaged by: Abbott Laboratorios do Brasil LTD., Brasil For: Abbott Laboratorios Limitada, Guatemala	Brazil	do.
Synthroid® 150 mcg Tablet	do.	do.	do.
Synthroid® 125 mcg Tablet	do.	do.	do.
Synthroid® 112 mcg Tablet	do.	do.	do.
Synthroid® 100 mcg Tablet	do.	do.	do.
Synthroid® 88 mcg Tablet	do.	do.	do.
Synthroid® 75 mcg Tablet	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Synthroid® 50 mcg Tablet	AbbVie Ireland NL B.V., Ireland Packaged by: Abbott Laboratorios do Brasil LTD., Brasil For: Abbott Laboratorios Limitada, Guatemala	Brazil	Third Schedule
Synthroid® 25 mcg Tablet	do.	do.	do.
NUBEQA® 300 mg Film coated tablets	Orion Corporation, Espoo, Finland Packaged by: Orion Corporation, Salo, Finland For: Bayer AG, Leverkusen, Germany	Finland	do.
Xeljanz® XR 11 mg Extended Release Tablets	Pfizer Pharmaceuticals LLC, Barceloneta, Puerto Rico, USA Packaged by: Pfizer Pharmaceuticals LLC, Vega Baja, Puerto Rico, USA For: Pfizer Inc., USA	USA	do.
IBRANCE® 75 mg Film-coated tablets	Manufactured & Packaged by: Pfizer Manufacturing Deutschland GmbH, Freiburg, Germany For: Pfizer Europe MA EEIG, Belgium	Germany	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
IBRANCE® 100 mg Film-coated tablets	Manufactured & Packaged by: Pfizer Manufacturing Deutschland GmbH, Freiburg, Germany For: Pfizer Europe MA EEIG, Belgium	Germany	Third Schedule
IBRANCE® 125 mg Film-coated tablets	do.	do.	do.
Microdacyn® 60 Hydrogel	Oculus Technologies of México, S.A. de C.V., Zapopan, Jalisco, México For: Aerobal, S.A. de C.V., Lerma, México	Mexico	Freely
Pentoxifylline 400 mg Extended release film- coated tablets	Manufactured & Packaged by: Grimann, S.A. de C.V., Lerma, Mexico For: Dinafarma, S.A. de C.V., Lerma, Mexico	do.	Third Schedule
Alka-Seltzer® Boost EFFERVESCENT TABLETS	Bayer de México S.A. de C.V., México For: Bayer S.A., Guatemala	do.	Freely
Ibuprofen MK® Liqui-Gels® 600 mg capsules	Catalent, Argentina S.A.I.C. Packaged by: Corporación Bonima S.A. de C.V., El Salvador For: Corporación Bonima S.A. de C.V., El Salvador	El Salvador	Third Schedule
Verquvo® 2.5 mg Film-coated tablet	Bayer AG, Leverkusen- Germany	Germany	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Verquvo® 5 mg Film-coated tablet	Bayer AG, Leverkusen- Germany	Germany	Third Schedule
Verquvo® 10 mg Film-coated tablet	do.	do.	do.
EPAMIN® 50 mg/mL Solution for injection	Manufacturer & Packager: Pfizer Manufacturing Belgium NV, Belgium For: Pfizer Corporation Austria GmbH, Austria	Belgium	do.
TAMSULON® DUO 0.5/0.4 mg hard capsules	ASOFARMA S.A.I. y C., Argentina Distributed by: ASOFARMA S.A., Guatemala	Argentina	do.
LEBRINA® 0.5 mg hard capsules	do.	do.	do.
Tramadol Denk 100 mg/2 ml Solution for injection or infusion	Solpharm Pharmazeutische Erzeugnisse GmbH, Germany For: DENK PHARMA GmbH & Co. KG, Germany	Germany	do.
Losar-Denk 50 film coated tablets	DENK PHARMA GmbH & Co. KG, Göllstr. 1, 84529 Tittmoning, Germany For: DENK PHARMA GmbH & Co. KG, München, Germany	do.	do.



TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
TriLipix® 135 mg Delayed Release Capsules	Fournier Laboratories Ireland Limited, Ireland Packaged by: Abbott Laboratories de México, S.A. de C.V., México For: Abbott Laboratories de México, S.A. de C.V., México	Mexico	Third Schedule
Scapho® 150 mg/mL Solution for injection in pre- filled SensoReady® pen	Novartis Pharma Stein AG, Stein, Switzerland For: Novartis Overseas Investments AG, Basel, Switzerland	Switzerland	Third Schedule (Specialist Use Only)
Leponex® 100 mg Tablets	Madaus GmbH, Germany For: Mylan Pharma GmbH Switzerland	Germany	Third Schedule
DARZALEX™ FASPRO 1,800 mg/15ml solution for injection	Manufactured & Packaged by: Cilag AG Switzerland For: Ethnor del Istmo S.A., Panama	Switzerland	do.
STÉRiMAR™ NOSE HYGIENE baby nasal spray	Church & Dwight UK LTD-Wear Bay Road, Folkestone, UK For: SOFIBEL-Laboratoires Fumouze 110-114, rue Victor Hugo 92686 Levallois-Perret Cedex - FRANCE	UK	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
STÉRiMAR™ NOSE HYGIENE AND COMFORT nasal spray	Church & Dwight UK LTD-Wear Bay Road, Folkestone, UK For: SOFIBEL-Laboratoires Fumouze 110-114, rue Victor Hugo 92686 Levallois-Perret Cedex - FRANCE	UK	Freely
BREZTRI AEROSPHERE™ Pressurised inhalation, suspension 160 µg / 9 µg / 5 µg	AstraZeneca Dunkerque Production., Dunkerque, France For: AstraZeneca AB., Sweden	France	Third Schedule
Skyrizi (Risankizumab Injection) 150 mg/mL Sterile Solution for Subcutaneous Injection in Single-Use PEN	Manufacturer & Primary Packager - Abbvie Biotechnology LTD, PR, USA Secondary Packager – Abbvie Deutschland GmbH & Co. KG, Ludwigshafen, Germany For: Abbvie Deutschland GmbH & Co. KG, Ludwigshafen, Germany	Germany	do.
Natele® Stage 2 Softgel Capsules	Catalent Brasil LTDA, Brazil For: Bayer S.A., Guatemala	Brazil	do.
Redoxon® Triple Action Effervescent tablets	Bayer S.A., Argentina For: Bayer S.A., Guatemala	Argentina	Freely
Bactrim® 400/80 mg for intravenous infusion	Roemmers, S.A.I.C.F- Argentina For: Laboratorios Siegfried, S.A.- Panamá	do.	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Canesten® V 1 Day Vaginal Ovule	Berlimed S.A., Spain Packaged by: GP Grenzach Produktions GmbH, Germany For: Bayer S.A., Guatemala	Germany	Third Schedule
Ziextenzo® 6 mg/0.6 mL Solution for injection in pre-filled syringe	Sandoz GmbH, Langkampfen- Austria For: Sandoz GmbH, Kundl-Austria	Austria	do.
NexGard SPECTRA® 9.375mg/1.875mg Flavored Chewable Tablets For Dogs 2 - 3.5kg	Boehringer Ingelheim Animal Health, do Brasil Ltda., Brazil For: Boehringer Ingelheim Vetmedica GmbH, Germany	Brazil	Veterinary Use Only
NexGard SPECTRA® 18.75mg/3.75mg Flavored Chewable Tablets For Dogs 3.6 - 7.5kg	do.	do.	do.
NexGard SPECTRA® 75mg/15mg Flavored Chewable Tablets For Dogs 15.1 - 30kg	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
NexGard SPECTRA® 150mg/30mg Flavored Chewable Tablets For Dogs 30.1 - 60kg	Boehringer Ingelheim Animal Health, do Brasil Ltda., Brazil For: Boehringer Ingelheim Vetmedica GmbH, Germany	Brazil	Veterinary Use Only

Dated this 14th day of September, 2022.

T. DEYALSINGH  
*Minister of Health*