

LEGAL NOTICE No. 367

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
Simparica Trio Chewable Tablets 72 mg/1.44 mg/300 mg	Corden Pharma GmbH, Otto-Hahn-Strasse, Plankstadt, Baden-Wuerttemberg, 68723, Germany	Germany	Veterinary Use Only
Simparica Trio Chewable Tablets 12 mg/0.24 mg/50 mg	Corden Pharma GmbH, Otto-Hahn-Strasse, Plankstadt, Baden-Wuerttemberg, 68723, Germany	Germany	Veterinary Use Only
Simparica Trio Chewable Tablets 3 mg/0.06 mg/12.5 mg	Corden Pharma GmbH, Otto-Hahn-Strasse, Plankstadt, Baden-Wuerttemberg, 68723, Germany	Germany	Veterinary Use Only
Avodart Soft Capsules 0.5 mg (Change in the Name of Manufacturer; Artwork Update)	Delpharm Poznań, S.A., Poznań, Poland	Poland	Third Schedule
Ziagen Film-Coated Tablets 300 mg (Change in the Name of Manufacturer; Artwork Update)	Delpharm Poznań, S.A., Poznań, Poland	Poland	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Combivir Film-Coated Tablets 150 mg/300 mg (Change in the Name of Manufacturer; Artwork Update)	Delpharm Poznań, S.A., Poznań, Poland	Poland	Third Schedule
Triumeq 50 mg/600 mg/300 mg Film-Coated Tablets (Change in the Name of Manufacturer; Artwork Update)	Delpharm Poznań, S.A., Poznań, Poland	Poland	Third Schedule
Kivexa Film-Coated Tablets 600 mg/300 mg (Change in the Name of Manufacturer)	Manufacturer: Delpharm Poznań, S.A., Poznań, Poland Packaged by: Glaxo Wellcome S.A., Aranda de Duero, Spain	Spain	Third Schedule
Tivicay Film-Coated Tablets 50 mg (Change in the Name of Manufacturer)	Manufactured & Packaged by: Delpharm Poznań, S.A., Poznań, Poland	Poland	Third Schedule
Cutivate Cream 0.05% (Change of Manufacturer)	GlaxoSmithKline Brasil Limitada, Rio de Janeiro – Brazil	Brazil	Third Schedule
Invega Sustenna Prolonged Release Suspension for Intramuscular Injection 25 mg (Change of Manufacturing Site; Change in Country of Origin; Change of Artwork)	Manufacturer: Cilag AG, Schaffhausen, Switzerland For: Ethnor del Istmo S.A., Panamá	Switzerland	Third Schedule
Invega Sustenna Prolonged Release Suspension for Intramuscular Injection 50 mg (Change of Manufacturing Site; Change in Country of Origin; Change of Artwork)	Manufacturer: Cilag AG, Schaffhausen, Switzerland For: Ethnor del Istmo S.A., Panamá	Switzerland	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Invega Sustenna Prolonged Release Suspension for Intramuscular Injection 75 mg (Change of Manufacturing Site; Change in Country of Origin; Change of Artwork)	Manufacturer: Cilag AG, Schaffhausen, Switzerland For: Ethnor del Istmo S.A., Panamá	Switzerland	Third Schedule
Invega Sustenna Prolonged Release Suspension for Intramuscular Injection 100 mg (Change of Manufacturing Site; Change in Country of Origin; Change of Artwork)	Manufacturer: Cilag AG, Schaffhausen, Switzerland For: Ethnor del Istmo S.A., Panamá	Switzerland	Third Schedule
Invega Sustenna Prolonged Release Suspension for Intramuscular Injection 150 mg (Change of Manufacturing Site; Change in Country of Origin; Change of Artwork)	Manufacturer: Cilag AG, Schaffhausen, Switzerland For: Ethnor del Istmo S.A., Panamá	Switzerland	Third Schedule
Pharmaton® GERIATRIC 50+ Capsules (Change in Name and Address of Marketing Authorization Holder; Artwork Update)	Catalent Brasil, Ltda, Brazil For: Opella HealthCare Panamá S.A., Panama	Brazil	Freely
Zyceva 150 Erlotinib Tablets 150 mg	Zydus Lifesciences Limited, Gujarat State, India	India	Third Schedule
Zimagliv 100 Imatinib Mesilate Tablets 100 mg	Zydus Lifesciences Limited, Gujarat State, India	India	Third Schedule
Zimagliv 400 Imatinib Mesilate Tablets 400 mg	Zydus Lifesciences Limited, Gujarat State, India	India	Third Schedule
Methorex 2.5 Methotrexate Tablets USP 2.5 mg	Zydus Lifesciences Limited, Gujarat State, India	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Strabin (Fulvestrant) Injection 250 mg/5 mL (50 mg/mL)	Zydus Lifesciences Limited, Gujarat State, India	India	Third Schedule
Ivazyd 5 Ivabradine Tablets 5 mg	Zydus Lifesciences Limited, Kundaim Industrial Estate, Kundaim GOA, India	India	Third Schedule
Ivazyd 7.5 Ivabradine Tablets 7.5 mg	Zydus Lifesciences Limited, Kundaim Industrial Estate, Kundaim GOA, India	India	Third Schedule
10D Glucose Intravenous Infusion BP (100 g/L)	Otsuka Pharmaceutical India Private Limited, Tal - Sanand Dist - Ahmedabad, India	India	Third Schedule
IMMUNOREL 5G (Human Normal Immunoglobulin for Intravenous Administration BP 5% Solution)	Reliance Life Sciences Pvt Ltd	India	Third Schedule
Avance Desloratadine 5 (Desloratadine Coated Tablets USP 5 mg)	Artura Pharmaceuticals Pvt Ltd	India	Third Schedule
Avance Chlorhexidine (Chlorhexidine Mouthwash BP)	ICPA Health Products Limited	India	Freely
Avance Bisoprolol Fumarate 2.5 (Bisoprolol Fumarate Coated Tablets USP 2.5 mg)	Ciron Drugs and Pharmaceutical Pvt Ltd	India	Third Schedule
Avance Desloratadine 2.5 (Desloratadine Syrup 2.5 mg/5 ml)	Sanpras Healthcare Pvt. Ltd	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Avance Lactulose Solution 3.35 (Lactulose Solution USP 3.5 mg/5 ml)	Sanpras Healthcare Pvt. Ltd	India	Third Schedule
Avance Vit B (Vitamin B1, B6, & B12 Soft Gelatin Capsules)	Ocean Healthcare Pvt. Ltd	India	Third Schedule
Alerchek 0.2% (Olopatadine Hydrochloride Ophthalmic Solution USP 0.2%) (Change in Distributor)	Indoco Remedies Limited, India	India	Third Schedule
Prolyte Oral Rehydration Salts BP Lime (Change in the Name of Manufacturer)	Cipla Health Ltd, India	India	Freely
Prolyte Oral Rehydration Salts BP Orange (Change in the Name of Manufacturer)	Cipla Health Ltd, India	India	Freely
Neubria® Charge Energy Capsules	Lifeplan Products Limited, Lutterworth, United Kingdom	United Kingdom	Freely
Neubria® Spark Memory Capsules	Lifeplan Products Limited, Lutterworth, United Kingdom	United Kingdom	Freely
Neubria® Shine Mood Capsules	Lifeplan Products Limited, Lutterworth, United Kingdom	United Kingdom	Freely
Neubria® Krill Oil Omega-3 Capsules 500 mg	Lifeplan Products Limited, Lutterworth, United Kingdom	United Kingdom	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Neubria® Edge Focus Capsules	Lifepan Products Limited, Lutterworth, United Kingdom	United Kingdom	Freely
Neubria® Drift Sleep Capsules	Lifepan Products Limited, Lutterworth, United Kingdom	United Kingdom	Freely
Dexamethasone PANPHARMA Solution for Injection 4 mg/ml (Change in the Name of Product; Change in the Name of Manufacturer; Change in Artwork)	PANPHARMA GmbH	Germany	Third Schedule
Metronidazol PANPHARMA Solution for Infusion 5 mg/ml (Change in the Name of Product; Change in the Name of Manufacturer; Change in Artwork)	PANPHARMA GmbH	Germany	Third Schedule
Fluphenazine PANPHARMA Solution for Injection 25 mg/ml (Change in the Name of the Product; Change in the Name of Manufacturer; Change in Artwork)	PANPHARMA GmbH	Germany	Third Schedule
Pancuroniumbromid PANPHARMA Solution for Injection 2 mg/ml (Change in the Name of the Product; Change in the Name of Manufacturer; Change in Artwork)	PANPHARMA GmbH	Germany	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Hydrocortisone PANPHARMA Solution for Injection 100 mg (Change in the Name of Product; Change in the Name of Manufacturer; Change in Country of Origin; Change in Artwork)	PANPHARMA	France	Third Schedule
Dimenhydrinat PANPHARMA Solution for Injection 50 mg/ml (Change in the Name of Product; Change in the Name of Manufacturer; Change in Artwork)	PANPHARMA GmbH	Germany	Third Schedule
Dobugen-PFV (Dobutamine Injection USP 12.5 mg/ml, 20 ml Vial)	SGPharma Pvt. Ltd	India	Third Schedule
PRANOSOL-P (Propranolol Injection B.P. 1 mg/ml, 1 ml Ampoule)	SGPharma Pvt. Ltd	India	Third Schedule
Dabigatran Etexilate Capsules 110 mg	Hetero Labs Limited	India	Third Schedule
Gefitinib Tablets 250 mg	Hetero Labs Limited	India	Third Schedule
Levofloxacin Tablets 500 mg	Hetero Labs Limited	India	Third Schedule
Tadalafil Tablets USP 20 mg	Hetero Labs Limited	India	Third Schedule
Tadalafil Tablets USP 5 mg	Hetero Labs Limited	India	Third Schedule
Moxifloxacin Hydrochloride Tablets 400 mg	Hetero Labs Limited	India	Third Schedule
Sugammadex Injection 200 mg/2 mL	Aspiro Pharma Limited	India	Third Schedule
ResinSodio® Powder for Oral Suspension 400 mg	Laboratorios Rubió, S.A., Castellbisbal- Barcelona, Spain.	Spain	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Sun Chlorella® Tablets 500 mg	Qualitech Pharma Co. Ltd., Shiga-Ken, Japan For: Sun Chlorella Corp., Kyoto, Japan	Japan	Freely
Tacroz 0.03% w/w (Tacrolimus ointment)	Glenmark Pharmaceuticals Ltd	India	Third Schedule
Varilrix Lyophilised Vaccine + Diluent for Injection (Additional Route of Administration; Artwork Update)	Manufacturer: GlaxoSmithKline Vaccines, Marietta, United States of America Packaged by: GlaxoSmithKline Biologicals S.A., Wavre, Belgium	Belgium	Third Schedule
Valtrex 500 mg Film-Coated Tablets (Change of Packaging Site)	Manufacturer: Glaxo Wellcome S.A., Aranda de Duero, Spain Packaged by: GlaxoSmithKline Brasil Ltda., Rio de Janeiro, Brasil	Brazil	Third Schedule
Systane® Complete Lubricant Eye Drops	Alcon Research LLC, Fort Worth Texas, United States of America	United States of America	Freely
Invega Hafyera™ Prolonged-Release Suspension 700 mg	Manufacturer: Janssen Pharmaceutica NV, Belgium For: Ethnor del Istmo, S.A., Panama	Belgium	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Invega Hafyera™ Prolonged-Release Suspension 1000 mg	Manufacturer: Janssen Pharmaceutica NV, Belgium For: Ethnor del Istmo, S.A., Panama	Belgium	Third Schedule
Exjade® Dispersible Tablets 125 mg (Change of Manufacturing Site; Change of Country of Origin; Change in Artwork)	Manufacturer: Sandoz S.R.L. Targu Mures, Romania For: Novartis Pharma AG, Basle, Switzerland	Romania	Third Schedule
Exjade® Dispersible Tablets 250 mg (Change of Manufacturing Site; Change of Country of Origin; Change in Artwork)	Manufacturer: Sandoz S.R.L. Targu Mures, Romania For: Novartis Pharma AG, Basle, Switzerland	Romania	Third Schedule
Exjade® Dispersible Tablets 500 mg (Change of Manufacturing Site; Change of Country of Origin; Change in Artwork)	Manufacturer: Sandoz S.R.L. Targu Mures, Romania For: Novartis Pharma AG, Basle, Switzerland	Romania	Third Schedule
Femara® Film-Coated Tablets 2.5 mg (Change of Primary and Secondary Packaging Site; Change of Country of Origin; Reduction of Shelf-life; Artwork Update)	Manufacturer: Novartis Pharma Stein AG, Stein Switzerland Packaged by: Novartis Farma S.P.A., Italy	Italy	Third Schedule
Aclasta® Solution for Infusion 5 mg (Change of Marketing Authorization Holder;	Manufacturer: Fresenius Kabi Austria GmbH, Graz, Austria	Slovenia	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Change of Secondary Packaging Site; Change in Country of Origin; Artwork Update)	Secondary Packager: Lek Pharmaceuticals d.d., Slovenia For: Sandoz Pharmaceuticals d.d., Slovenia		
Baxter Lactated Ringer's Injection USP (Additional Manufacturing Site; Change in Country of Origin)	Baxter, S.A. de C.V., Mexico	Mexico	Third Schedule
5% Dextrose Injection USP 250 mL/500 mL (Additional Manufacturing Site; Change in Country of Origin)	Baxter, S.A. de C.V., Mexico	Mexico	Third Schedule
VILZERMET® Film-Coated Tablets 50 mg/850 mg	Monte Verde S.A.	Argentina	Third Schedule
VILZERMET® Film-Coated Tablets 50 mg/1000 mg	Monte Verde S.A.	Argentina	Third Schedule
NOVOCAL Drinkable Ampoules	Ha Noi CPC1 Pharmaceutical Joint Stock Company, Ha Noi City, Vietnam	Vietnam	Freely
Beejuvit Appetite Drinkable Ampoules	Ha Noi CPC1 Pharmaceutical Joint Stock Company, Ha Noi City, Vietnam	Vietnam	Freely
Nature Foreyes Drinkable Ampoules	Ha Noi CPC1 Pharmaceutical Joint Stock Company, Ha Noi City, Vietnam	Vietnam	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Actiso Viet Drinkable Ampoules	Ha Noi CPC1 Pharmaceutical Joint Stock Company, Ha Noi City, Vietnam	Vietnam	Freely
ProBioGen® Men's Vitality Spore Probiotic Vegetarian Capsules	Nutritional Manufacturing Services (NMS), Arizona, United States of America	United States of America	Freely
DAFASGLIT 10 (Dapfliflozin Tablets 10 mg)	APL Healthcare Limited, Andhra Pradesh, India	India	Third Schedule
DUTABIT PLUS Capsules 0.5/0.4 (Dutasteride and Tamsulosin Hydrochloride Capsules 0.5 mg and 0.4 mg)	Aurobindo Pharma Ltd, Telangana State, India	India	Third Schedule
ONEGABA 300 (Gabapentin Capsules 300 mg)	Aurobindo Pharma Ltd, Telangana State, India	India	Third Schedule
Valabin 1000 Valaciclovir Hydrochloride Tablets 1000 mg	Aurobindo Pharma Ltd, Telangana State, India	India	Third Schedule
Trilagavit® Film-Coated Tablets	Lagap SA, Vezia, Switzerland	Switzerland	Freely
Hemarexin Oral Solution	Stellapharm Joint Venture Company Limited - Branch 1, Binh Duong, Vietnam	Vietnam	Freely
PENTASA® Slow Release Tablets 500 mg (Change in Marketing Authorization Holder; Artwork Update; Leaflet Update;	Ferring International Center SA, St-Prex, Switzerland	Switzerland	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Addition of ADRs in SPC and Leaflet; Addition of Storage Information)			
PENTASA® Prolonged Release Granules Sachets 2 g (Change of Marketing Authorization Holder; Change of Secondary Packaging; Addition of ADRs in SPC and Leaflet; Change in Artwork)	Ferring International Center SA, St-Prex, Switzerland	Switzerland	Third Schedule
PENTASA® Suppositories 1 g (Change of Marketing Authorization Holder; Secondary Packaging Labelling Update; Addition of ADRs in SPC and Leaflet)	Ferring International Center SA, St-Prex, Switzerland	Switzerland	Third Schedule
Renacet Film-Coated Tablets 475 mg (Change of Primary and Secondary Packaging; Artwork Update; Change in blister foil and size, carton box and PIL the number of tablets per blister)	Artesan Pharma GmbH & Co. KG, Lüchow, Germany For: RenaCare NephroMed GmbH, Huttenberg, Germany	Germany	Third Schedule
GLYPRESSIN® Powder and Solvent for Solution for Injection 1 mg/5 ml (Change of Marketing Authorization Holder; Change of Artwork; Change of Leaflet)	Manufacturer: Ferring GmbH Wittland, Germany For: Ferring GmbH, Germany	Germany	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Minirin® Nasal Spray Solution 0.1 mg/ml (Change of Marketing Authorization Holder; Change of Secondary Packager; Change in Artwork)	Manufacturer: Ferring GmbH, Kiel, Germany Packager: Ferring International Center SA, St-Prex, Switzerland For: Ferring GmbH, Kiel, Germany	Switzerland	Third Schedule
Nature's Way Alive!® Men's Multivitamin Gummy	Nature's Way Brands, LLC, Green Bay, Wisconsin, United States of America	United States of America	Freely
Nature's Way Alive!® Kids Multivitamin Gummy	Nature's Way Brands, LLC, Green Bay, Wisconsin, United States of America	United States of America	Freely
Nature's Way Alive!® Women's 50+ Multivitamin Gummy	Nature's Way Brands, LLC, Green Bay, Wisconsin, United States of America	United States of America	Freely
Nature's Way Alive!® Women's Multivitamin Gummy	Nature's Way Brands, LLC, Green Bay, Wisconsin, United States of America	United States of America	Freely
Nature's Way Blood Sugar Manager Capsules	Nature's Way Brands, LLC, Green Bay, Wisconsin, United States of America	United States of America	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Bio-Strath® + Zinc Immune Health Tablets	Manufacturer: Soho Flordis International Switzerland, Bioggio, Switzerland Packaged by: Bio-Strath AG, Herrliberg, Switzerland	Switzerland	Freely
Puritan's Pride C-1000 mg with Bioflavonoids and Wild Rose Hips Coated Caplets	Puritan's Pride, Inc., Ronkonkoma, NY, United States of America	United States of America	Freely
Puritan's Pride Zinc Caplets 50 mg	Puritan's Pride, Inc., Ronkonkoma, NY, United States of America	United States of America	Freely
Puritan's Pride Vitamin E-180 mg (400 IU) Rapid Release Softgels	Puritan's Pride, Inc., Ronkonkoma, NY, United States of America	United States of America	Freely
Puritan's Pride Co-Q-10 Rapid Release Softgels 200 mg	Puritan's Pride, Inc., Ronkonkoma, NY, United States of America	United States of America	Freely
Puritan's Pride Vitamin E 450 mg (1000 IU) Rapid Release Softgels	Puritan's Pride, Inc., Ronkonkoma, NY, United States of America	United States of America	Freely
Puritan's Pride Omega-3 Fish Oil Rapid Release Softgels 950 mg	Puritan's Pride, Inc., Ronkonkoma, NY, United States of America	United States of America	Freely
Puritan's Pride Maximum Strength Triple Omega 3-6-9 Fish, Flax & Borage Oils Rapid Release Softgels	Puritan's Pride, Inc., Ronkonkoma, NY, United States of America	United States of America	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Puritan's Pride Ultra Woman™ Collagen Support Rapid Release Capsules	Puritan's Pride, Inc., Ronkonkoma, NY, United States of America	United States of America	Freely
Puritan's Pride Sunvite® Mega-Potency Vitamin D3 Rapid Release Softgels 125 mcg (5000 IU)	Puritan's Pride, Inc., Ronkonkoma, NY, United States of America	United States of America	Freely
Puritan's Pride Odorless Garlic Extract Rapid Release Softgels 1000 mg	Puritan's Pride, Inc., Ronkonkoma, NY, United States of America	United States of America	Freely
Puritan's Pride Methylcobalamin B-12 5000 mcg Microlozenges	Puritan's Pride, Inc., Ronkonkoma, NY, United States of America	United States of America	Freely
Puritan's Pride C-500 mg with Wild Rose Hips	Puritan's Pride, Inc., Ronkonkoma, NY, United States of America	United States of America	Freely
Puritan's Pride 7 Day Formula Glucosamine, Chondroitin, MSM, Boswellia Extract Coated Caplets	Puritan's Pride, Inc., Ronkonkoma, NY, United States of America	United States of America	Freely
Puritan's Pride Youth Guard™ DHEA (dehydroepiandrosterone) Tablets 50 mg	Puritan's Pride, Inc., Ronkonkoma, NY, United States of America	United States of America	Freely
Valdoxan® Film-Coated Tablets 25 mg (Additional Indication)	Les Laboratoires Servier Industrie, Gidy, France	France	Third Schedule
Celebrex® Capsules 200 mg (Change in the Name of License Holder; Artwork and Labelling Update)	Manufacturer: Pfizer Pharmaceuticals LLC, Veja Baja, Puerto Rico	Germany	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Packager: Pfizer Manufacturing Deutschland GmbH, Germany For: Pfizer OFG Germany GmbH, Germany		
Alburex® Solution for Infusion 25% (Additional Secondary Packaging Site)	Manufacturer: CSL Behring AG, Bern, Switzerland Additional Secondary Packager: CSL Behring AG, Bolligenstrasse 93, 3006 Bern, Switzerland	Switzerland	Third Schedule
Nebido Solution for Injection 1000 mg/4 mL (Change of Marketing Authorization Holder; Change in Artwork Design)	Manufacturer: Bayer AG, Germany For: Grünenthal S.A., Panama	Germany	Third Schedule
Evrysdi Powder for Oral Solution 0.75 mg/mL (New Indication; New Commercial Presentation; Primary and Secondary Artwork Update)	F. Hoffmann-La Roche Ltd., Basel, Switzerland Packaged by: F. Hoffmann-La Roche Ltd., Kaiseraugst, Switzerland	Switzerland	Third Schedule
Nimbex™ Solution for Injection 2 mg/mL (5 mg in 2.5 mL) (Change in the Name of the Manufacturing Site;	Aspen SA Sterile Operations (Pty) Ltd., Gqeberha, South Africa	South Africa	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Change in the Name of the City where the Site is Located; Artwork Update)			
Nimbex™ Solution for Injection 2 mg/mL (10 mg in 5 mL) (Change in the Name of the Manufacturing Site; Change in the Name of the City where the Site is Located; Artwork Update)	Aspen SA Sterile Operations (Pty) Ltd., Gqeberha, South Africa	South Africa	Third Schedule
Zoloft® Tablets of 100 mg (Change in License Holder; Artwork Update; Distributor Update)	Pfizer S.A. De C.V., Toluca, Mexico	Mexico	Third Schedule
Zoloft® Tablets 50 mg (Change in License Holder; Artwork Update; Distributor Update)	Pfizer S.A. De C.V., Toluca, Mexico	Mexico	Third Schedule
Panadol Extra Strength 500 mg Tablets (Addition of Alternative Primary Packaging Material)	GlaxoSmithKline Panama, S.A., Panama	Panama	Freely
Evra Transdermal Patches 6.00 mg/0.6 mg (Change of Marketing Authorization Holder; Addition of Secondary Packaging and Release Site; Artwork Update)	Manufacturer: LTS Lohmann Therapie-Systeme AG, Germany Packaged and Released by: Gedeon Richter Plc., Budapest, Hungary	Hungary	Third Schedule
EUTEBROL® DUO Capsules 28 mg/10 mg	Monte Verde S.A., Argentina	Argentina	Third Schedule
EUTEBROL® DUO Capsules 14 mg/10 mg	Monte Verde S.A., Argentina	Argentina	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
NURTEC™ ODT Orally Disintegrating Tablets 75 mg	Manufacturer & Primary Packager: Catalent UK Swindon Zydis Limited, Blagrove Swindon, United Kingdom Secondary Packager: Millmount Healthcare Limited, Ireland	Ireland	Third Schedule
Wakunaga Kyolic® Aged Garlic Extract™ Cholesterol Health Lecithin Formula 104 Capsules	Wakunaga of America Co., Ltd, California, United States of America	United States of America	Freely
Wakunaga Kyolic® Aged Garlic Extract™ Blood Pressure Health Formula 109 Capsules	Wakunaga of America Co., Ltd, California, United States of America	United States of America	Freely
Wakunaga Kyolic® Aged Garlic Extract™ Total Heart Health Formula 108 Capsules	Wakunaga of America Co., Ltd, California, United States of America	United States of America	Freely
Jamieson Apple Cider Vinegar + Chromium Gummies	Sirio Healthcare (Anhui) Co., Ltd, Anhui, China For: Jamieson Laboratories Ltd/ Nutricorp International, Ontario, Canada	Canada	Freely
Jamieson Omega-3 Gummies	Sirio Healthcare (Anhui) Co., Ltd, Anhui, China	Canada	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	For: Jamieson Laboratories Ltd./ Nutricorp International, Ontario, Canada		
Jamieson Ginkgo Biloba Caplets 4,000 mg	Body Plus Nutritional Products Inc., Ontario, Canada For: Jamieson Laboratories Ltd./ Nutricorp International, Ontario, Canada	Canada	Freely
Jamieson Zinc Lozenges with Echinacea, Vitamins C & D - Honey Lemon	Jamieson Laboratories Ltd./ Nutricorp International, Ontario, Canada	Canada	Freely
Jamieson Zinc Lozenges with Echinacea, Vitamins C & D - Wild Cherry	Jamieson Laboratories Ltd./ Nutricorp International, Ontario, Canada	Canada	Freely
Jamieson Zinc Lozenges with Echinacea, Vitamins C & D - Lemon and Menthol	Jamieson Laboratories Ltd./ Nutricorp International, Ontario, Canada	Canada	Freely
Jamieson Advanced Multi Vitamin + Energy Support Caplets	Jamieson Laboratories Ltd./ Nutricorp International, Ontario, Canada	Canada	Freely
Jamieson Multi Vitamin and Mineral Supplement for Kids Chewable Tablets	Jamieson Laboratories Ltd./ Nutricorp International, Ontario, Canada	Canada	Freely
Jamieson Chewable C+D ₃ Tablets 500 mg/500 IU	Jamieson Laboratories Ltd./ Nutricorp International, Ontario, Canada	Canada	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Jamieson Fast Dissolving Melatonin Max Strength Tablets 10 mg	Jamieson Laboratories Ltd./ Nutricorp International, Ontario, Canada	Canada	Freely
Jamieson Omega-3 Select Softgels	Jamieson Laboratories Ltd./ Nutricorp International, Ontario, Canada	Canada	Freely
Jamieson Echinacea Extra Strength Capsules 1200 mg	Jamieson Laboratories Ltd./ Nutricorp International, Ontario, Canada	Canada	Freely
Jamieson 100% Complex Chewable Multivitamin for Adults	Jamieson Laboratories Ltd./ Nutricorp International, Ontario, Canada	Canada	Freely
Jamieson Cranberry Complex	Jamieson Laboratories Ltd./ Nutricorp International, Ontario, Canada	Canada	Freely
Jamieson Gummies C Tangy Orange	Jamieson Laboratories Ltd./ Nutricorp International, Ontario, Canada	Canada	Freely
Ovima Tablets 0.15 mg/ 0.03 mg	Laboratorios Leon Farma S.A., Leon, Spain For: Apotex Inc., Ontario, Canada	Canada	Third Schedule
Apo-Perindopril-Indapamide Tablets 4 mg/1.25 mg	Apotex Inc., Ontario, Canada	Canada	Third Schedule
Apo-Ramipril Capsules 5 mg	Apotex Inc., Ontario, Canada	Canada	Third Schedule
Apo-Darunavir Tablets 600 mg	Apotex Inc., Ontario, Canada	Canada	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Apo-Gabapentin Capsules 100 mg	Apotex Inc., Ontario, Canada	Canada	Third Schedule
Apo-Gefitinib Tablets 250 mg	Apotex Inc., Ontario, Canada	Canada	Third Schedule
Apo-Desvenlafaxine ER Tablets 50 mg	Apotex Research Private Limited, Bommasandra Industrial Area, India For: Apotex Inc., Ontario, Canada	Canada	Third Schedule
Apo-Donepezil Tablets 10 mg	Apotex Research Private Limited, Bommasandra Industrial Area, India For: Apotex Inc., Ontario, Canada	Canada	Third Schedule
COVONIA ALL-IN-ONE Chesty Cough, Cold & Flu Relief Oral Solution (Change in the Name of Product; Change in Artwork)	Thornton & Ross Limited, Huddersfield, United Kingdom	United Kingdom	Freely
Phanadyl Paracetamol Tablets 500 mg	New GPC Inc. Guyana.	Guyana	Freely
Berberine Plus Capsules 625 mg	Natural Vitamins Laboratory Corporation	United States of America	Freely

Dated this 15th day of November, 2023.

T. DEYALSINGH
Minister of Health