

LEGAL NOTICE No. 62

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
Neurorubine Forte Film-Coated Tablets (Change of Manufacturing and Packaging Sites; Reduction in Shelf Life; Change of Primary and Secondary Packaging Artwork; Update to the Patient Information Leaflet)	Acino Pharma AG	Switzerland	Freely
Olfen-50 Gastro-Resistant Tablets 50mg (Change of Manufacturing and Packaging Sites; Extension of Shelf Life; Change of Primary and Secondary Packaging Artwork; Update to the Patient Information Leaflet)	Acino Pharma AG	Switzerland	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
<p>Olfen-75 SR Prolonged-Release Tablets 75mg (Change of Manufacturing and Packaging Sites; Extension of Shelf Life; Change of Primary and Secondary Packaging Artwork; Update to the Patient Information Leaflet)</p>	Acino Pharma AG	Switzerland	Third Schedule
<p>Olfen-100 SR Prolonged-Release Capsules 100mg (Change of Manufacturing and Packaging Sites; Extension of Shelf Life; Change of Primary and Secondary Packaging Artwork; Update to the Patient Information Leaflet)</p>	do.	do.	do.
<p>Uvamin Retard Prolonged-Release Hard Capsules 100mg (Change of Manufacturing and Packaging Sites; Reduction of Shelf Life; Change of Primary and Secondary Packaging Artwork; Update to the Patient Information Leaflet)</p>	do.	do.	do.
<p>Decatylen Lozenges (Change of Manufacturing and Packaging Sites; Change of Primary and Secondary Packaging Artwork; Update to the Patient Information Leaflet)</p>	Acino Pharma AG	Switzerland	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Flamar-DP Tablets (Change of Importer)	Innova Captab For: Indoco Remedies Ltd., India	India	Third Schedule
Flamar-MX Tablets (Change of Importer)	do.	do.	do.
Otorex Ear Drops (Change of Importer; Change of Manufacturer)	Indoco Remedies Ltd.	India	Freely
Triz Syrup (Change of Importer)	do.	do.	Third Schedule
Triz Tablets (Change of Importer)	do.	do.	do.
Diabion Capsules (Change of Marketing Authorization Holder; Artwork Update; Change of Importer)	Gelcaps Exportadora De Mexico S.A. de C.V. For: Procter & Gamble Interaméricas de Guatemala LTDA, Guatemala	Mexico	Third Schedule
Iliadin LUB Nasal Decongestant with Lubricant Adult Spray Solution 0.05% (Change of Marketing Authorization Holder; Artwork Update; Change of Importer)	Merck, S.A. de C.V. For: Procter & Gamble Interaméricas de Guatemala LTDA, Guatemala	Mexico	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Vivera Probiotics Powder Sachets 2g (Change of Marketing Authorization Holder; Artwork Update; Change of Importer)	Probiotal S.p.A., Italy Packaged by: S.I.I.T, S.R.L, Servizio Internazionale For: Procter & Gamble Interaméricas de Guatemala LTDA, Guatemala	Italy	Freely
Jardiance Tablets 10mg (Additional Manufacturing and Packaging Site; Change of Name of Testing Site; Update to the In Process Control Weight for the Tablet Cores)	Manufactured & Packaged by: Boehringer Ingelheim Promeco S.A. De C.V.	Mexico	Third Schedule
Jardiance Tablets 25mg (Additional Manufacturing and Packaging Site; Change of Name of Testing Site; Update to the In Process Control Weight for the Tablet Cores)	do.	do.	do.
Spiriva Respimat Solution for Inhalation 2.5mcg (Change of Label; Update to Product Monograph and Package Insert)	Boehringer Ingelheim Pharma GmbH & Co. KG	Germany	Third Schedule
Simbrinza Eye Drops Suspension 10mg/ml + 2mg/ml (Change of Label; Change of Marketing Authorization Holder)	S.A. Alcon-Couvreur N.V. For: Novartis Pharma AG, Switzerland	Belgium	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Vigadexa Sterile Ophthalmic Solution 0.5% /0.1%, 2.5ml and 5ml (Change of Label)	Novartis Biociencias S.A. Sao Paula – SP	Brazil	Third Schedule
AA-Diltiaz Tablets 60mg (Change of Name; Change of Label; Change of Marketing Authorization Holder)	Apotex Inc. For: AA Pharma Inc., Canada	Canada	Third Schedule
Acetazolamide Tablets 250mg (Change of Name; Change of Label; Change of Marketing Authorization Holder)	do.	do.	do.
ISDN Isosorbide Dinitrate Tablets 10mg (Change of Name; Change of Label; Change of Marketing Authorization Holder)	do.	do.	do.
Trifluoperazine Tablets 5mg (Change of Name; Change of Label; Change of Marketing Authorization Holder)	do.	do.	do.
Trihexyphenidyl Tablets 2mg (Change of Name; Change of Label; Change of Marketing Authorization Holder)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Victoza Solution for Injection in a Pre-filled Pen 6mg/ml (Change of Indication; Update to the SmPC and Package Leaflet)	Novo Nordisk A/S	Denmark	Third Schedule
Stelara Solution for Injection in Pre-filled Syringe 90mg/1ml (New Indications)	Cilag AG For: Ethnor del Istmo S.A., Panamá	Switzerland	Third Schedule
Stelara I.V. 130mg Concentrate for Solution for Infusion 130mg/26ml (5mg/ml) (New Indications)	do.	do.	do.
Alimta Powder for Concentrate for Solution for Infusion 500mg (Additional Manufacturing Site)	Vianex S.A., Greece Packaged by: Lilly France	France	Third Schedule
Ibrance Capsules 100mg (Additional Secondary Packager; Change of License Holder; Extension of Shelf Life)	Manufactured & Packaged by: Pfizer Manufacturing Deutschland GmbH For: Pfizer Europe MA EEIG, Belgium	Germany	Third Schedule
Ibrance Capsules 125mg (Additional Secondary Packager; Change of License Holder; Extension of Shelf Life)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Ibrance Capsules 75mg (Additional Secondary Packager; Change of License Holder; Extension of Shelf Life)	Manufactured & Packaged by: Pfizer Manufacturing Deutschland GmbH For: Pfizer Europe MA EEIG, Belgium	Germany	Third Schedule
Celebrex Capsules 200mg (Change of Name of Packager)	Pfizer Pharmaceuticals LLC, Vega Baja, Puerto Rico Packaged by: Pfizer Manufacturing, Deutschland GmbH, Freiburg, Germany For: Pfizer Pharma PFE GmbH, Germany	Germany	Third Schedule
Eliquis Film-Coated Tablets 2.5mg (Additional Manufacturer; Additional Packager; Change of License Holder)	Pfizer Ireland Pharmaceuticals, Ireland Packaged by: Pfizer Manufacturing, Deutschland GmbH, Freiburg, Germany For: Bristol-Myers Squibb/ Pfizer EEIG Ireland	Germany	Third Schedule
Eliquis Film-Coated Tablets 5mg (Additional Manufacturer; Additional Packager; Change of License Holder)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Ambien Tablets 10mg (Change in Storage Conditions; Reduction of Shelf Life; Change of Packaging Site)	Manufactured & Packaged by: Sanofi Winthrop Industrie	France	Controlled Drug
Ambien CR Extended Release Tablets 12.5mg (Change in Storage Conditions; Extension of Shelf Life; Change of Packaging Site)	do.	do.	do.
Bengay Topical Analgesic Cream-Greaseless (Change of Name; Change of Primary and Secondary Label)	KIK Custom Products Distributed by: Johnson & Johnson Consumer Products Company Division of: Johnson & Johnson Consumer Companies, Inc., USA	Canada	Freely
Bengay Menthol 2.5% Topical Analgesic Cream - Vanishing Scent (Change of Name; Change of Primary and Secondary Label)	do.	do.	do.
Dogmatil Tablets 50mg (Change of Name of Manufacturing Site)	Delpharm Dijon	France	Third Schedule
Dogmatil Capsules 200mg (Change of Name of Manufacturing Site)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Faslodex Solution for Injection in a Pre-filled Syringe 250mg/5ml (Additional Indications; Change of Primary and Secondary Label)	Manufacturer and Primary packager: Vetter Pharma-Fertigung GmbH & Co. KG, Germany Secondary packager: AstraZeneca UK Limited	United Kingdom	Third Schedule
Forxiga Film Coated Tablets 5mg (New Indication; Monograph and Insert Update)	Manufactured and Packaged by: AstraZeneca Pharmaceuticals LP For: AstraZeneca CAMCAR S.A. Panama	United States of America	Third Schedule
Forxiga Film Coated Tablets 10mg (New Indication; Monograph and Insert Update)	do.	do.	do.
Toujeo SoloStar Solution for Subcutaneous Injection in Pre-filled Pen 300U/ml (Additional Indication)	Sanofi-Aventis Deutschland GmbH	Germany	Third Schedule
Xolair Powder and Solvent for Solution for Injection 150mg (Change of Manufacturing Site of Diluent; New Indication)	Manufactured & Packaged by: Novartis Pharma Stein AG, Switzerland Solvent/Diluent Manufactured by: Delpharm Dijon, France For: Novartis Pharma AG, Switzerland	Switzerland	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Moxiwar 400 Film Coated Tablets 400mg (Additional API Source & Extension of Shelf Life)	Aurobindo Pharma Ltd.	India	Third Schedule
Cortiment MMX Prolonged Release Tablets 9mg (Change in Artwork; Update in SPC and leaflet)	Manufacturer and Secondary Packaging Site: COSMO S.P.A. For Holder: Ferring International Centre SA, Switzerland	Italy	Third Schedule
Gonapeptyl Daily Solution for Injection 0.1mg/ml (Change of Marketing Authorization Holder; Change of Artwork; Update in SPC and leaflet; Update of the Container Closure System)	Manufacturer, Primary Packager and Marketing Authorization Holder: Ferring GmbH, Germany Secondary Packager: Ferring Léciva, a.s.	Czech Republic	Third Schedule
Pentasa Prolonged Release Granules Sachets 2g (Change in Artwork; Update in SPC, leaflet and drug product specification)	Manufactured and Packaged by: Ferring International Center SA, For Holder: Ferring AG, Switzerland	Switzerland	Third Schedule
Extraneal (7.5% Icodextrin) Peritoneal Dialysis Solution (Additional Manufacturing Site)	Baxter S.A. de C.V. Distributed by: Baxter Healthcare Corporation, USA	Mexico	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Holoxan 1g Dry Powder for I.V. Injection (Change of Manufacturer Mark; Change of Name of Manufacturing Site; Change of Marketing Authorization Holder; Artwork Update)	Baxter Oncology GmbH	Germany	Third Schedule
Holoxan 2g Dry Powder for I.V. Injection (Change of Manufacturer Mark; Change of Name of Manufacturing Site; Change of Marketing Authorization Holder; Artwork Update)	do.	do.	do.
Uromitexan 400mg Ampoules for I.V. Injection (Change of Manufacturer Mark; Change of Name of Manufacturing Site; Change of Marketing Authorization Holder; Artwork Update)	do.	do.	do.
Bupican Heavy 0.5% Bupivacaine Hydrochloride in Dextrose Injection USP (Change of Manufacturer Mark; Change of Name of Manufacturing Site; Change of Marketing Authorization Holder; Artwork Update)	Baxter Pharmaceuticals India Private Limited	India	Third Schedule
Diretif Furosemide Injection BP 10mg/ml (Change of Manufacturer Mark; Change of Name of Manufacturing Site; Change of Marketing Authorization Holder; Artwork Update)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Exomax Fluconazole Injection 2mg/ml (Change of Manufacturer Mark, Change of Name of Manufacturing Site; Change of Marketing Authorization Holder; Artwork Update)	Baxter Pharmaceuticals India Private Limited	India	Third Schedule
Levofloxacin Infusion I.V. 100ml (Change of Manufacturer Mark; Change of Name of Manufacturing Site; Change of Marketing Authorization Holder; Artwork Update)	do.	do.	do.
Provive 1% Propofol Intravenous Infusion 1% w/v (Change of Manufacturer Mark; Change of Name of Manufacturing Site; Change of Marketing Authorization Holder; Artwork Update)	do.	do.	do.
Amtas-5 Tablets 5mg (Additional Manufacturing Site; Change of Primary Packaging; Change of Label)	Intas Pharmaceuticals Ltd.	India	Third Schedule
Amtas-10 Tablets 10mg (Change of Formulation; Additional Manufacturing Site; Change of Primary and Secondary Label)	do.	do.	do.
Merex-50 Injection 50mg/2ml (Change of Formulation)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Mycofit 500 Film-coated Tablets 500mg (Change of Primary Packaging; Change of API Supplier)	Intas Pharmaceuticals Ltd.	India	Third Schedule
Enoxaparin 100mg/ml Sandoz Solution for Injection in Pre-Filled Syringe 20mg/0.2mL (Change of Name of Manufacturing Site; Change of Name of Packager; Change of Label)	Rovi Pharma Industrial Services, S.A. For: Sandoz Gmbh, Kundl, Austria	Spain	Third Schedule
Enoxaparin 100mg/ml Sandoz Solution for Injection in Pre-Filled Syringe 40mg/0.4mL (Additional Presentation; Change of Name of Manufacturing Site; Change of Name of Packager; Change of Label)	do.	do.	do.
Enoxaparin 100mg/ml Sandoz Solution for Injection in Pre-Filled Syringe 60mg/0.6mL (Additional Presentation; Change of Name of Manufacturing Site; Change of Name of Packager; Change of Label)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Enoxaparin 100mg/mL Sandoz Solution for Injection in Pre-Filled Syringe 80mg/0.8mL (Additional Presentation; Change of Name of Manufacturing Site; Change of Name of Packager; Change of Label)	Rovi Pharma Industrial Services, S.A. For: Sandoz Gmbh, Kundl, Austria	Spain	Third Schedule
Irbesartan 150mg Sandoz Film-coated Tablets (Change of Primary and Secondary Packaging Site; Change of Label)	Lek Pharmaceuticals d.d. For: Sandoz GmbH, Kundl, Austria	Slovenia	Third Schedule
Irbesartan 300mg Sandoz Film-coated Tablets (Change of Primary and Secondary Packaging Site; Change of Label)	do.	do.	do.
Rosustar® 10mg Film-coated Tablets (Change of Product Name; Change of Formulation; Change of Primary and Secondary Packaging Site; Change of Primary and Secondary Label)	do.	do.	do.
Rosustar® 20mg Film-coated Tablets (Change of Product Name; Change of Formulation; Change of Primary and Secondary Packaging Site; Change of Primary and Secondary Label)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Rosustar® 40mg Film-coated Tablets (Change of Product Name; Change of Formulation; Change of Primary and Secondary Packaging Site; Change of Primary and Secondary Label)	Lek Pharmaceuticals d.d. For: Sandoz GmbH, Kundl, Austria	Slovenia	Third Schedule
Buscopan Tablets 10mg (Change of Manufacturing Site; Change of Primary and Secondary Packaging)	Istituto de Angeli S.R.L. For: Sanofi-Aventis de Panamá, S.A., Panamá	Italy	Third Schedule
Buscopan Plus Film-coated Tablets 10/500mg (Change of Manufacturing Site; Change of Artwork)	Delpharm Reims For: Sanofi-Aventis Deutschland GmbH, Germany	France	Third Schedule
Dulcolax 5mg Gastro-resistant coated Tablet (Change of Manufacturing Site; Change of Primary and Secondary Label)	Delpharm Reims For: Sanofi-Aventis de Panamá, S.A., Panamá	France	Freely
Nasacort AQ Nasal Spray 55mcg/dose (Change of Name of Manufacturing Site; Change of Primary and Secondary Label)	Recipharm HC Limited	United Kingdom	Third Schedule
Enterogermina Oral Suspension 2 billion/5mL (Change of Name of Manufacturing Site; Change of Primary and Secondary Label)	Sanofi S.r.l.	Italy	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Pharmaton Kiddi Syrup (Change of Name of Manufacturing Site; Change of Primary and Secondary Label)	Soho Flordis International Switzerland S.A.	Switzerland	Freely
Erleada 60mg Film-coated Tablets (Additional Indication)	Janssen Ortho LLC For: Ethnor del Istmo S.A., Panama	Puerto Rico, USA	Third Schedule
Rekovele Solution for Injection in a pre-filled pen 12mcg/0.36ml (Addition of an alternative analytical method)	Vetter Pharma-Fertigung GmbH & Co. KG, Germany Packaged by: Ferring Controlled Therapeutics Ltd., For: Ferring GmbH, Germany	United Kingdom	Third Schedule
Rekovele Solution for Injection in a pre-filled pen 36mcg/1.08ml (Addition of an alternative analytical method)	do.	do.	do.
Rekovele Solution for Injection in a pre-filled pen 72mcg/2.16ml (Addition of an alternative analytical method)	do.	do.	do.
Depakote ER 250mg tablets (Change of Manufacturing Site; Change of Packaging Site; Change of Marketing Authorization Holder; Change of Packaging; Change of Presentation; Change of Shelf Life; Change of Label)	Abbott Laboratorios do Brasil Ltda	Brazil	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Depakote ER 500mg tablets (Change of Manufacturing Site; Change of Packaging Site; Change of Marketing Authorization Holder; Change of Packaging; Change of Presentation; Change of Shelf Life; Change of Label)	Abbott Laboratorios do Brasil Ltda	Brazil	Third Schedule
Grani-Denk 1mg/ml Ampoules - Concentrate for Solution for Injection or Infusion (Change of Manufacturer & Artwork Update)	Solupharm Pharmazeutische Erzeugnisse GmbH For: DENK PHARMA GmbH & Co. KG, Germany	Germany	Third Schedule
Humira AC 40mg/0.4ml Solution for Injection In Pre-Filled Pen (Change of Marketing Authorization Holder; New Indication & Artwork Update)	Vetter Pharma-Fertigung GmbH & Co. KG, Germany Secondary Packager & Marketing Authorization Holder: AbbVie Deutschland GmbH & Co. KG	Germany	Third Schedule
Venclexta Tablets 10mg (New Indication; Update to the Prescribing Information, Monograph and Insert)	AbbVie Ireland NL B.V., Ireland Packaged by: AbbVie Inc.	United States of America	Third Schedule
Venclexta Tablets 50mg (New Indication; Update to the Prescribing Information, Monograph and Insert)	do.	do.	do.
Venclexta Tablets 100mg (New Indication; Update to the Prescribing Information; Monograph and Insert)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Advil Cold & Sinus Caplets 200mg/30mg (Pouches) (Change of Marketing Authorization Holder; Addition of an Alternative Primary Packaging Site; Change of Distributor; Updated Artwork)	Wyeth Pharmaceuticals Company, Puerto Rico Packaged by: Reed-Lane, Inc For: GlaxoSmithKline Healthcare Holdings (US) LLC, USA	United States of America	Freely
Advil Cold & Sinus Caplets 200mg/30mg (Pouches) (Change of Marketing Authorization Holder; Change of Distributor; Updated Artwork)	do.	do.	do.
Advil Liqui-Gels Liquid Filled Capsules 200mg (Bottles) (Change of Marketing Authorization Holder; Change of Distributor; Updated Artwork)	Catalent Pharma Solutions, LLC, USA Packaged by: Fareva Richmond, Inc. For: GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, USA	United States of America	Freely
Advil Liqui-Gels Liquid Filled Capsules 200mg (Bottles) (Change of Marketing Authorization Holder; Change of Distributor; Updated Artwork)	Catalent Pharma Solutions, LLC, USA Packaged by: Wyeth Pharmaceuticals Company, Puerto Rico For: GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, USA	United States of America	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Advil Liqui-Gels Liquid Filled Capsules 200mg (Bottles) (Change of Marketing Authorization Holder; Addition of an Alternative Primary Packaging Site; Change of Distributor; Updated Artwork)	Catalent Pharma Solutions, LLC, USA Packaged by: Reed-Lane, Inc For: GlaxoSmithKline Healthcare Holdings (US) LLC, USA	United States of America	Freely
Advil Liqui-Gels Liquid Filled Capsules 200mg (Pouch) (Change of Marketing Authorization Holder; Change of Distributor; Updated Artwork)	Catalent Pharma Solutions, LLC, USA Packaged by: Fareva Richmond, Inc. For: GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, USA	United States of America	Freely
Advil Liqui-Gels Liquid Filled Capsules 200mg (Pouch) (Change of Marketing Authorization Holder; Addition of an Alternative Primary Packaging Site; Change of Distributor; Updated Artwork)	Catalent Pharma Solutions, LLC, USA Packaged by: Reed-Lane, Inc For: GlaxoSmithKline Healthcare Holdings (US) LLC, USA	United States of America	Freely
Advil Ibuprofen Tablets 200mg (Bottles) (Change of Marketing Authorization Holder; Addition of Alternate Method for the Coating Process and Product Composition; Change of Distributor; Addition of Alternate Primary Container Closure System; Updated Artwork)	Manufactured & Packaged by: Wyeth Pharmaceuticals Company, For: GlaxoSmithKline Healthcare Holdings (US) LLC, USA	United States of America	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Advil Ibuprofen Tablets 200mg (Pouch) (Change of Marketing Authorization Holder; Addition of Alternate Method for the Coating Process and Product Composition; Change of Distributor; Updated Artwork)	Wyeth Pharmaceuticals Company, Puerto Rico Packaged by: Fareva Richmond, Inc. For: GlaxoSmithKline Healthcare Holdings (US) LLC, USA	United States of America	Freely
Caltrate Tablets 600 + D3 (Change of Marketing Authorization Holder; Updated Artwork; Update of the Manufacturer Name)	Manufactured & Packaged by: Wyeth Pharmaceuticals Company, Puerto Rico For: GlaxoSmithKline Costa Rica S.A.	United States of America	Freely
Caltrate Tablets 600 + D3 Plus (Change of Marketing Authorization Holder; Updated Artwork; Update of the Manufacturer Name)	Manufactured & Packaged by: Wyeth Pharmaceuticals Company, Puerto Rico For: GlaxoSmithKline Costa Rica S.A.	United States of America	Freely
Canesten 1% Topic Cream (Additional Manufacturing and Packaging Site; Change of Name of Marketing Authorization Holder; Updated Artwork)	Manufacturer & Packager: GP Grenzach Produktions GmbH, For: Bayer, S.A., Guatemala	Germany	Third Schedule
Canesten V 1% Vaginal Cream (Additional Manufacturing and Packaging Site; Change of Name of Marketing Authorization Holder; Updated Artwork)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Canesten V 2% Vaginal Cream (Additional Manufacturing and Packaging Site; Change of Name of Marketing Authorization Holder; Updated Artwork)	Manufacturer & Packager: GP Grenzach Produktions GmbH, For: Bayer, S.A., Guatemala	Germany	Third Schedule
Centrum Tablets for Adults (Change of Marketing Authorization Holder; Change of Name of Manufacturer/Packager; Updated Artwork)	Manufacturer & Packager: PF Consumer Healthcare Canada ULC For: GlaxoSmithKline Costa Rica S.A.	Canada	Freely
Centrum Gender Men Tablets (Change of Marketing Authorization Holder; Change of Name of Manufacturer/Packager; Updated Artwork)	do.	do.	do.
Centrum Gender Women Tablets (Change of Marketing Authorization Holder; Change of Name of Manufacturer/Packager; Updated Artwork)	do.	do.	do.
Centrum Silver Vitamin and Mineral Coated Tablets (Change of Marketing Authorization Holder; Change of Name of Manufacturer/Packager; Updated Artwork)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Centrum + Energy Tablets (Change of Marketing Authorization Holder; Change of Name of Manufacturer/Packager; Change of Product Name; Updated Artwork)	Manufacturer & Packager: PF Consumer Healthcare Canada ULC For: GlaxoSmithKline Costa Rica S.A.	Canada	Freely
Phillips' Milk of Magnesia Original Liquid (Change of Marketing Authorization Holder; Updated Artwork)	Aspen Mexico, S. de R.L. de C.V. For: Aspen Labs S.A. de C.V. Mexico	Mexico	Freely
Phillips' Milk of Magnesia Mint Liquid (Change of Marketing Authorization Holder; Updated Artwork)	do.	do.	do.
Natele Soft Capsules (Change of Marketing Authorization Holder; Updated Artwork)	Berlimed, S.A. For: Bayer S.A. Guatemala	Spain	Freely
One Alpha Capsules 0.25mcg (Change in Name of the Marketing Authorization Holder; Updated Artwork)	LEO Pharma A/S For: CHEPLAPHARM Arzneimittel GmbH, Germany	Denmark	Third Schedule
One Alpha Capsules 1mcg (Change in Name of the Marketing Authorization Holder; Updated Artwork)	do.	do.	do.
Salazopyrin EN-Tabs Enteric Coated Tablets 500mg (Change of Manufacturer)	Recipharm Uppsala AB For: Pfizer AB, Sweden	Sweden	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Trental Film-Coated Tablets 400mg (Change of Marketing Authorization Holder; Updated Artwork)	Sanofi-aventis de Mexico S.A. de C.V. For: Dinafarma S.A. De C.V.	Mexico	Third Schedule
Tritace Tablets 2.5mg (Change of Marketing Authorization Holder; Updated Artwork)	do.	do.	do.
Tritace Tablets 5mg (Change of Marketing Authorization Holder; Updated Artwork)	do.	do.	do.
Valdure IM/IV 40mg/2ml Powder For Solution For Injection (Change of Name of the Manufacturer & Packager of the Powder)	Powder: Pharmacia & Upjohn Company LLC, USA Solvent: Pfizer Manufacturing Belgium NV, Belgium License Holder & Secondary Packager: Pfizer S.A. de C.V.	Mexico	Third Schedule
VFend Film Coated Tablets 200mg (Change of Packager)	Manufacturer & Packager: Pfizer Italia S.r.L.	Italy	Third Schedule
Xyntha Powder And Solvent For Solution for Injection 250 IU (New Indication; Modification of Current Indication; Manufacturing Process Update of Finished Product and Update of Excipients Specifications; Updated Artwork)	Powder: Wyeth Farma S.A., Spain Diluent: Vetter Pharma Fertigung GmbH, Germany Secondary Packager: Wyeth Farma S.A., Spain Licence Holder: Wyeth Pharmaceuticals Inc. USA	Spain	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Xyntha Powder And Solvent For Solution for Injection 500 IU (New Indication; Modification of Current Indication; Manufacturing Process Update of Finished Product and Update of Excipients Specifications; Updated Artwork)	Powder: Wyeth Farma S.A., Spain Diluent: Vetter Pharma Fertigung GmbH, Germany Secondary Packager: Wyeth Farma S.A., Spain Licence Holder: Wyeth Pharmaceuticals Inc. USA	Spain	Third Schedule
Cellcept 250mg Capsules (Addition of Alternate Primary and Secondary Packaging Site; Updated Artwork)	Manufacturer and Packager: Delpharm Milano S.r.L For: F.Hoffmann-La Roche Ltd, Switzerland	Italy	Third Schedule
Cellcept 500mg Film Coated Tablets (Addition of Alternate Primary and Secondary Packaging Site; Updated Artwork)	Manufacturer and Packager: Delpharm Milano S.r.L For: F.Hoffmann-La Roche Ltd, Switzerland	Italy	Third Schedule
Hemlibra Solution for Subcutaneous Injection 30mg/1ml (Modified Indication)	Chugai Pharma Manufacturing Co. Ltd., Japan Secondary Packager: F.Hoffmann-La Roche Ltd, Kaiseraugst For: F.Hoffmann-La Roche Ltd, Basel, Switzerland	Switzerland	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Hemlibra Solution for Subcutaneous Injection 60mg/0.4ml (Modified Indication)	Chugai Pharma Manufacturing Co. Ltd., Japan Secondary Packager: F.Hoffmann-La Roche Ltd., Kaiseraugst For: F.Hoffmann-La Roche Ltd., Basel, Switzerland	Switzerland	Third Schedule
Hemlibra Solution for Subcutaneous Injection 105mg/0.7ml (Modified Indication)	do.	do.	do.
Hemlibra Solution for Subcutaneous Injection 150mg/1ml (Modified Indication)	do.	do.	do.
Ocrevus Concentrate for Solution for Infusion 300mg/10ml (Additional Manufacturing Site; Artwork and Label Update)	F.Hoffmann-La Roche Ltd., Kaiseraugst For: F.Hoffmann-La Roche Ltd., Basel, Switzerland	Switzerland	Third Schedule
Tamiflu 75mg Capsules (Addition of Alternate Primary and Secondary Packaging Site; Updated Artwork)	Manufacturer, Primary and Secondary Packager: Delpharm Milano S.r.L For: F.Hoffmann-La Roche Ltd., Switzerland	Italy	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Tarceva 100mg Tablets (Addition of Alternate Primary and Secondary Packaging Site; Updated Artwork)	Manufacturer, Primary and Secondary Packager: Delpharm Milano S.r.L For: F.Hoffmann-La Roche Ltd., Switzerland	Italy	Third Schedule
Tarceva 150mg Tablets (Addition of Alternate Primary and Secondary Packaging Site; Updated Artwork)	do.	do.	do.
Tecentriq Concentrate for Solution For Infusion 1200mg/20ml (New Indication)	Roche Diagnostics GmbH, Mannheim, Germany Secondary Packager: F.Hoffmann-La Roche Ltd., Kaiseraugst For: F.Hoffmann-La Roche Ltd., Basel, Switzerland	Switzerland	Third Schedule
Xeloda Film-Coated Tablets 500mg (Addition of Alternate Primary and Secondary Packaging Site; Updated Artwork)	Manufacturer, Primary & Secondary Packager: Excella GmbH & Co. KG For: F.Hoffmann-La Roche Ltd., Switzerland	Germany	Third Schedule
Seretide Diskus Powder for Inhalation 250mcg/50mcg (Additional Manufacturing Site)	Glaxo Wellcome Production	France	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Seretide Diskus Powder for Inhalation 500mcg/50mcg (Additional Manufacturing Site)	Glaxo Wellcome Production	France	Third Schedule
Flixonase Aqueous Nasal Spray 50mcg (Additional Manufacturing and Packaging Site)	Glaxo Wellcome S.A.	Spain	Third Schedule
Zovirax Oral Suspension 200mg/5ml (Additional Manufacturing Site, Change in packaging)	Aspen Bad Oldesloe GmbH	Germany	Third Schedule
Ventolin Oral Solution 2mg/5ml (Additional Manufacturing Site, Change in packaging)	do.	do.	do.
Betnovate Cream 0.1% (Change of Name of Manufacturer)	GlaxoSmithKline Brasil LTDA	Brasil	Third Schedule
3TC Oral Solution 10mg/ml (Change of Name of Manufacturer)	Bora Pharmaceuticals Services Inc.	Canada	Third Schedule
Retrovir Oral Syrup 50mg/5ml (Change of Name of Manufacturer)	do.	do.	do.
Paxil CR Controlled Release Tablets 12.5mg (Change of Name of Manufacturer)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Paxil CR Controlled Release Tablets 25mg (Change of Name of Manufacturer)	Bora Pharmaceuticals Services Inc.	Canada	Third Schedule
Scanlux Solution for Injection 300mg I/ml (Change of Name of Manufacturer)	Sanochemia Pharmazeutika GmbH	Austria	Third Schedule
Wisdom Daily Enamel Protect Sensitive Mouthwash (Change of Label)	Wisdom Toothbrushes Ltd.	England	Freely
Wisdom Fresh Effect Alcohol Free Antibacterial Mouthwash (Change of Label & Change of Packaging)	do.	do.	do.
Wisdom Step by Step Cavity and Enamel Defence Alcohol Free Fluoride Mouthwash (Change of Label & Change of Packaging)	do.	do.	do.
Pacimol Tablets 500mg (Change of Importer)	IPCA Laboratories Limited	India	Freely
Xarelto Film Coated Tablets 15mg (New Indication)	Bayer AG	Germany	Third Schedule
Xarelto Film Coated Tablets 20mg (New Indication)	do.	do.	do.

Dated this 7th day of February, 2023.

T. DEYALSINGH  
*Minister of Health*