

LEGAL NOTICE No. 73

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
Xaroban Coated Tablets 10 mg	Farmacéutica Paraguaya S.A. Waldino Ramon Lovera y del Carmen, Fernando de la Mora, Republica del Paraguay Marketing Authorization Holder: Monte Verde S.A. Argentina	Republic of Paraguay	Third Schedule
Xaroban Coated Tablets 15 mg	do.	do.	do.
Xaroban Coated Tablets 20 mg	do.	do.	do.
Aldomet Film Coated Tablets 250 mg	Aspen SA Operations (PYT) Ltd. Corner Fairclough Road & Gibaud Road, Korsten Gqeberha, 6020, Republic of South Africa	South Africa	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
VILZERMET® Film-Coated Tablets 50 mg/500 mg	Monte Verde S.A. Ruta Nacional No.40 s/n esq. Calle 8 Departamento de Pocito Provincia de San Juan, Republica de Argentina	Argentina	Third Schedule
Summer's Eve Simply Sensitive Daily Gentle Wash (Change of Name of Product; Minor Change in Formula; Artwork Update)	C.B. Fleet Company, Inc. 4615 Murray Place, Lynchburg VA 24502, United States of America	United States of America	Freely
Summer's Eve Fragrance Free Daily Gentle Wash (Change of Name of Product; Minor Change in Formula; Artwork Update)	do.	do.	do.
Summer's Eve Sheer Floral Daily Refreshing Wash (Change of Name of Product; Minor Change in Formula; Artwork Update)	do.	do.	do.
Summer's Eve Lavender Night-Time Daily Refreshing Wash (Change of Name of Product; Minor Change in Formula; Artwork Update)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Summer's Eve Delicate Blossom Daily Refreshing Wash (Change of Name of Product; Minor Change in Formula; Artwork Update)	C.B. Fleet Company, Inc. 4615 Murray Place, Lynchburg VA 24502, United States of America	United States of America	Freely
Summer's Eve Blissful Escape Daily Refreshing Wash (Change of Name of Product; Minor Change in Formula; Artwork Update)	do.	do.	do.
Summer's Eve Aloe Love Daily Gentle Wash (Change of Name of Product; Minor Change in Formula; Artwork Update)	do.	do.	do.
Summer's Eve Island Splash Daily Refreshing Wash (Change of Name of Product; Minor Change in Formula; Artwork Update)	do.	do.	do.
Summer's Eve Island Splash Daily Refreshing Cloths (Change of Name of Product; Artwork Update)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Summer's Eve Fragrance Free Daily Gentle Cloths (Change of Name of Product; Artwork Update)	C.B. Fleet Company, Inc. 4615 Murray Place, Lynchburg VA 24502, United States of America	United States of America	Freely
Summer's Eve Simply Sensitive Daily Gentle Cloths (Change of Name of Product; Artwork Update)	do.	do.	do.
Summer's Eve Sheer Floral Daily Refreshing Cloths (Change of Name of Product; Artwork Update)	do.	do.	do.
Summer's Eve Blissful Escape Daily Refreshing Cloths (Change of Name of Product; Artwork Update)	do.	do.	do.
Summer's Eve Ultra Daily Performance Spray (Change of Name of Product; Artwork Update)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Summer's Eve Island Splash Daily Refreshing Spray (Change of Name of Product; Artwork Update)	C.B. Fleet Company, Inc. 4615 Murray Place, Lynchburg VA 24502, United States of America	United States of America	Freely
Summer's Eve Baby Powder Daily Gentle Spray (Change of Name of Product; Artwork Update)	do.	do.	do.
Puri-Nethol Tablets 50 mg (Additional Manufacturing Site; Artwork Update to reflect change)	Aspen SA Operations (PTY) Ltd. Corner of Fairclough Road & Gibaud Road Korsten Gqeberha 6020, Republic of South Africa	South Africa	Third Schedule
Imuran® Film Coated Tablets 50 mg (Change of Legal Entity of Manufacturer; Change of City Name of Manufacturer; Artwork Update to reflect changes)	do.	do.	do.
Panadol Woman Tablets 500 mg/65 mg (Additional Primary Packaging Material)	GlaxoSmithKline Panama, S.A. Urbanización Industrial Juan Diaz, Calle A y B, Panama City, Republic of Panama	Panama	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Panadol Ultra Caplets 500 mg/65 mg (Additional Primary Packaging Material)	GlaxoSmithKline Panama, S.A. Urbanización Industrial Juan Díaz, Calle A y B, Panama City, Republic of Panama	Panama	Freely
Panadol Rapid Film Coated Tablets 500 mg (Change of Name of Product; Artwork Update; Change of Composition of Finished Product; Additional Primary Packaging Material; Additional Commercial Presentation)	GlaxoSmithKline Dungarvan Ltd Knockbrack, Dungarvan, X35 RY76, Ireland Packaged by: GlaxoSmithKline Panama, S.A. Urbanización Industrial Juan Díaz, Calle A y B, Panama City, Republic of Panama	do.	do.
Norgesic Tablets 450 mg/35 mg (Change of Marketing Authorization Holder; Artwork and Labelling Update; Change of Distributor)	Quimica y Farmacia, S.A. de C.V. Blvd Ind Automatriz No. 3045 Fracc IIC.P. 25900, Ramos Arizpe Coahuila, Mexico	Mexico	Third Schedule
Norgesic Tablets 450 mg/35 mg (Additional Manufacturer; Change of Packaging; Artwork Update to reflect changes)	Grimann, S.A de C.V. Circuito Nemesio Diez Riega No. 11 Parque Industrial El Cerrillo IIC.P. 52000 Lerma, Mexico	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Trental Extended Release Film Coated Tablets 400 mg (Change of Name of Product; Artwork Update)	Grimann, S.A de C.V. Circuito Nemesio Diez Riega No. 11 Parque Industrial El Cerrillo IIC.P. 52000 Lerma Mexico	Mexico	Third Schedule
Alimta Powder for Concentrate for Solution for Infusion 500 mg (Change of Licence Holder; Primary and Secondary Artwork Update)	Vianex S.A., Plant C, 16 <sup>th</sup> km Marathonos Avenue, Pallini Attiki, 15 51, Greece Packaged by: Lilly France S.A.S. 2 rue du Colonel Lilly 67640 Fegersheim, France	France	do.
Xeloda Film Coated Tablets 500 mg (Change of Product License Holder; Artwork Update to reflect changes)	Excella GmbH & Co. KG Nurberger Str. 12 90537 Feucht, Germany	Germany	do.
Bondronat Concentrate for Solution for Infusion 6 mg/6 mL (Change of Manufacturing Site; Additional Secondary Packager; Minor Change of Manufacturing Process and Replacement of Test Procedures; Intro of Batch Size within	Universal Farma, S.L. Calle Del Tejido, 2, Azuqueca De Henares (Gusdalajara) E-19200 Spain Packaged by: Manantial Integra SLU Poligono Industrial Neinor-Henares E-3, Local 23 Y 24, Meco, Madrid, E-28880, Spain	Spain	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Approved Range; Change of Packaging of Final Product)			
Canesten V 1% Vaginal Cream (Artwork Update)	GP Grenzach Produktions GmbH Emil-Barell-Strasse 7 79639 Grenzach-Wyhlen, Germany	Germany	Third Schedule
Canesten V 2% Vaginal Cream (Artwork Update)	do.	do.	do.
Canesten V 1 Day Vaginal Ovule 500 mg (Artwork Update)	Berlimed S.A. C/ Francisco Alonso no. 7 Poligono Industriual Santa Rosa, Alcalá de Henares, 28806. Madrid, Spain Packaged by: GP Grenzach Produktions GmbH Emil-Barell-Strasse 7 79639 Grenzach-Wyhlen, Germany	do.	do.
Canesten V Vaginal Ovules 100 mg (Artwork Update; Change in Dimensions of Secondary Packaging)	Catalent Argentina S.A.I.C Avenida Márquez 654/91, (Código postal 1657), de la Ciudad de Villa Loma Hermosa, Provincia de Buenos Aires, Argentina	Guatemala	Freely



TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Packaged by: Bayer S.A., Km. 14.5 Carretera Roosevelt, Zona 3 Mixco, Guatemala		
Canesten V Vaginal Ovules 200 mg (Artwork Update; Change in Dimensions of Secondary Packaging)	Catalent Argentina S.A.I.C Avenida Márquez 654/91, (Código postal 1657), de la Ciudad de Villa Loma Hermosa, Provincia de Buenos Aires, Argentina Packaged by: Bayer S.A., Km. 14.5 Carretera Roosevelt, Zona 3 Mixco, Guatemala	Guatemala	Freely
Dormicum Ampoules IV, IM and Rectal Solution for Injection 15 mg/3 mL (Change of Marketing Authorization Holder; Artwork Update to reflect change)	Cenexi SAS 52, rue Marcel et Jacques Gaucher 94120 Fontenay-sous-Bois, France Marketing Authorization Holder: Laboratorios, Siegfried, S.A., Panamá	France	Controlled
Dormicum Ampoules IV, IM and Rectal Solution for Injection 50 mg/10 mL (Change of Marketing Authorization Holder; Artwork Update to reflect change)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Yasmin Film Coated Tablets 3 mg/300 mcg (Change of Name of Manufacturer and Packaging Site; Artwork Update to reflect changes)	União Química Internacional Ltda Rua Cancioneiro De Evora, No. 255 Santo Amaro São Paulo SP, Brazil	Brazil	Third Schedule
Yaz Film Coated Tablets 3 mg/0.02 mg (Change of Name of Manufacturer and Packaging Site; Artwork Update to reflect changes)	do.	do.	do.
Angeliq Film Coated Tablets 2 mg/1 mg (Change of Name of Manufacturer and Packaging Site; Artwork Update to reflect changes)	Bayer Weimar GmbH und Co. KG Dobereinerstrasse 20 99427 Weimar, Germany Packaged by: União Química Internacional Ltda., Rua Cancioneiro De Evora, No. 255 Santa Amaro São Paulo SP, Brazil	do.	do.
Mesigyna Solution for IM Injections 50 mg and 5 mg/1 mL (Change of Name of Manufacturer Address)	Bayer de México S.A. de C.V. Av. Reforma No.46, Porterillo, C.P., 94450, Ixtaczoquitlan, Veracruz, Mexico	Mexico	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Firialta® Film Coated Tablets 10 mg (Indication Update; Update of Monograph and Leaflet based on EU-SmPC)	Bayer AG Kaiser-Wilhelm-Allee 51368 Leverkusen, Germany	Germany	Third Schedule
Firialta® Film Coated Tablets 20 mg (Indication Update; Update of Monograph and Leaflet based on EU-SmPC)	do.	do.	do.
Xarelto Film Coated Tablets 2.5 mg (Artwork Update of Secondary Packaging)	Bayer AG Kaiser-Wilhelm-Allee 51368 Leverkusen, Germany	do.	do.
Nexavar Film Coated Tablets 200 mg (Artwork Update)	do.	do.	do.
Yasmin Film Coated Tablets 3 mg/30 mcg (Additional Manufacturing and Packaging Sites; Additional Primary Packaging Material; Artwork Update to reflect changes; Update to Leaflet and Monograph)	Bayer Weimar GmbH und Co. KG Dobereinerstrasse 20 99427 Weimar, Germany Packaged by: Bayer AG Mullerstrasse 178, 13353 Berlin, Germany	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Angeliq Film Coated Tablets 2 mg/1 mg (Additional Manufacturing and Packaging Sites; Artwork Update to reflect changes)	Bayer Weimar GmbH und Co. KG Dobereinerstrasse 20 99427 Weimar, Germany Packaged by: Bayer AG Mullerstrasse 178, 13353 Berlin, Germany	Germany	Third Schedule
Relpax Tablets 40 mg (Change of License Holder; Artwork Update to reflect change)	Pfizer S.A. de C.V. Km 63 Carretera Mexico Toluca Zona Industrial C.P. 50140, Toluca, Mexico	Mexico	do.
Progynova Coated Tablets 1 mg (Artwork Update; Form Inclusion of Tablet to Coated Tablet)	Bayer Weimar GmbH und Co. KG Dobereinerstrasse 20 99427 Weimar, Germany	Germany	do.
Ponstan Forte Film Coated Tablets 500 mg (Artwork Update)	Pfizer Manufacturing Deutschland GmbH Mooswaldallee 1 D- 79090 Freiburg, Germany	do.	do.
Nubeqa Film Coated Tablets 300 mg (New Indication; Secondary Artwork Update)	Orion Corporation, Orion Pharma Orionintie 1 02200 Espoo Finland	Finland	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Packaged by: Orion Corporation, Orion Pharma Joensuukatu 7 24100 Salo, Finland		
Humulin® N, NPH Isophane Insulin Human Suspension U100; 100 units/mL (Artwork Update, Change of Name of Product)	Manufactured and Packaged by: Eli Lilly and Company Indianapolis, IN 46285, United States of America For: Asofarma S.A. Guatemala	United States of America	Third Schedule
Dulera Inhalation Aerosol 100 mcg/5 mcg (Change of Name of Packaging Site)	Kindeva Drug Delivery Limited Derby Road Loughborough Leicestershire LE11 5SF, United Kingdom Packaged by: Merck Sharp & Dohme LLC 4633 Merck Road, Wilson, NC 27893, United States of America	do.	do.
Dulera Inhalation Aerosol 200 mcg/5 mcg (Change of Name of Packaging Site)	do.	do.	do.
Xigduo™ XR 5 mg/1000 mg Extended Release Film Coated Tablets	AstraZeneca Pharmaceuticals LP 4601 Highway 62 East Mount Vernon IN 47620,	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
(New Indication; Artwork Update to reflect change)	United States of America		
Xigduo™ XR 10 mg/1000 mg Extended Release Film Coated Tablets (New Indication; Artwork Update to reflect change)	AstraZeneca Pharmaceuticals LP 4601 Highway 62 East Mount Vernon IN 47620, United States of America	United States of America	Third Schedule
Arcoxia Tablets 60 mg (Additional Primary and Secondary Packager of Final Product; Artwork Update to reflect change)	Rovi Pharma Industrial Services S.A. Via Complutense 140, 28805 Alcalá de Henares, Madrid, Spain Packaged by: Schering Plough S.A. de C.V. A.16 de Septiembre. 301 16090 Xochimilco, Mexico D.F. For: Organon Pharma, S.de R.L. Panama	Mexico	do.
Arcoxia Tablets 90 mg (Additional Primary and Secondary Packager of Final Product; Artwork Update to reflect change)	Rovi Pharma Industrial Services S.A. Via Complutense 140, 28805 Alcalá de Henares, Madrid, Spain Packaged by: Schering Plough S.A. de C.V. A.16 de Septiembre. 301 16090 Xochimilco, Mexico D.F.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	For: Organon Pharma, S.de R.L. Panama		
Arcoxia Tablets 120 mg (Additional Primary and Secondary Packager of Final Product; Artwork Update to reflect change)	Rovi Pharma Industrial Services S.A. Via Complutense 140, 28805 Alcalá de Henares, Madrid, Spain Packaged by: Schering Plough S.A. de C.V. A.16 de Septiembre. 301 16090 Xochimilco, Mexico D.F. For: Organon Pharma, S.de R.L. Panama	Mexico	Third Schedule
Nexium Gastro-Resistant Granules for Oral Suspension, Sachet 10 mg (Artwork Update)	AstraZeneca AB Gartunavagen, Sodertalje, SE-152 57, Sweden Primary & Secondary Packager: AstraZeneca, S.A. de C.V. Super Avenida Lomas Verdes No. 67 Fraccionamiento Lomas C.P. 53120 Naucalpan de Juarez, Mexico	do.	do.
Singulair Oral Granules 4 mg (Change of Name of Packaging Site)	Patheon Manufacturing Services LLC 5900 Martin Luther King Jr Highway Greenville NC, 27834, United States of America	United States of America	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Packaged by: Merck Sharp & Dohme LLC 4633 Merck Road, Wilson NC 27893, United States of America		
Zocor Tablets 20 mg (Change of Name of Manufacturer; Change of Name of Marketing Authorization Holder & Packaging Site; Change of Distributor; Artwork Update to reflect changes)	Organon Pharma (UK) Limited Shotton Lane, Cramlington, NE23 3JU, United Kingdom Packaged by: Organon Farmacéutica Ltda, Rua Treze De Maio No. 1161 Campinas São Paulo, Brazil	Brazil	Third Schedule
Zocor Tablets 40 mg (Change of Name of Manufacturer; Change of Name of Marketing Authorization Holder & Packaging Site; Change of Distributor; Artwork Update to reflect changes)	do.	do.	do.
Synvisc Injectable Intra-articular Synovial Fluid Supplement (Hylan G-F-20 16 mg) (Change of Name of Manufacturer and Holder; Change of Storage Conditions; Artwork Update to reflect changes)	Genzyme Corporation 1125 Pleasantview Terrace Ridgefield N.J., United States of America 07657	United States of America	do.



TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Symbicort Rapihaler Pressurized Inhalation Suspension 80/2.25 mcg	AstraZeneca Dunkerque Production 224 avenue de la Dordogne 59640 Dunkerque, France	France	Third Schedule
Listerine Original Antiseptic Mouthwash (Change of Name of Distributor; Change of Claim)	Johnson & Johnson Consumer Inc. 400 W. Lincoln Ave., Lititz, PA 17543, United States of America	United States of America	Freely
Listerine Cool Mint Antiseptic Mouthwash	do.	do.	do.
Listerine Total Care Fresh Mint Anticavity Fluoride Mouthwash	do.	do.	do.
Puritan's Pride Vitamin B-12 500 mcg Ener-B® Tablets	Puritan's Pride, Inc., 2100 Smithtown Ave, Ronkonkoma, NY, United States of America 11779	do.	do.
Risdone-1 Tablets 1 mg	Intas Pharmaceuticals Ltd. Plot Numbers 457, 458 & 191/218P, Sarkhej-Bavla Highway, Matoda, Sanand, Ahmedabad, Gujarat, IN- 382210, India	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Uxigril® 10 mg Film-Coated Tablets	Manufacturer: Lek S.A., 16 Podlipie Street, 95-010 Stryków, Poland Packaged by: Lek S.A. ul. Domaniewska 50c, 02-672, Warszawa, Poland Marketing Authorization Holder: Sandoz GmbH, Kundl- Austria	Poland	Third Schedule
Fulvestrant Sandoz Solution for Injection 250 mg/5 mL	Fareva Unterach GmbH, Mondseetraße 11, 4866 Unterach am Attersee, Austria	Austria	do.
Revolade® Film-Coated Tablets 25 mg (Change of Manufacturer; Change of Origin; Update of Label and Product Leaflet)	Siegfried Barbera, S.L. Ronda de Santa Maria, 158 08210 Barberà del Vallès Barcelona, Spain Marketing Authorization Holder: Novartis Pharma AG Basel, Switzerland	Spain	do.
Revolade® Film-Coated Tablets 50 mg (Change of Manufacturer; Change of Origin; Update of Label and Product Leaflet)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Votrient® Film-Coated Tablets 200 mg (Change of Marketing Authorization Holder; Change of Manufacturer; Change of Packager; Change of Country of Origin; Artwork Update)	Siegfried Barbera, S.L. Ronda de Santa Maria, 158 08210 Barberà del Vallès Barcelona, Spain Packaged by: Lek Pharmaceuticals d.d. Verovškova ulica 57, Ljubljana, 1526, Slovenia Marketing Authorization Holder: Novartis Pharma AG Basel, Switzerland	Slovenia	Third Schedule
Votrient® Film-Coated Tablets 400 mg (Change of Marketing Authorization Holder; Change of Manufacturer; Change of Packager; Change of Country of Origin; Artwork Update)	do.	do.	do.
Uxigril® Chewable Tablets 4 mg (Change of Manufacturer; Change of Packager; Change of Country of Origin; Artwork Update)	Manufacturer: Lek S.A. 16 Podlipie Street, 95-010 Stryków, Poland Packaged by: Lek S.A. ul. Domaniewska 50c, 02-672 Warszawa, Poland Marketing Authorization	Poland	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Holder: Sandoz GmbH, Kundl- Austria		
Uxigril® Chewable Tablets 5 mg (Change of Manufacturer; Change of Packager; Change of Country of Origin; Artwork Update)	Lek S.A. 16 Podlipie Street, 95-010 Stryków, Poland Packaged by: Lek S.A. ul. Domaniewska 50c, 02-672 Warszawa, Poland Marketing Authorization Holder: Sandoz GmbH, Kundl- Austria	Poland	Third Schedule
Enterogermina® Oral Suspension 2 billion/5 mL (Change of the Name of the Manufacturer; Change of Artwork)	Opella Healthcare Italy SRL Viale Europa, 11 21040 Origgio (Va), Italy Marketing Authorization Holder: Opella Healthcare Panama S.A., Panama	Italy	Freely
KTD-XL Tablets	Veko Care Private Limited ARC-3, Amarpark Apt., Shirole Road, Pune - 411004, Maharashtra, India	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Auriko Ear Drops 5 mg/10 mg	Veko Care Private Limited ARC-3, Amarpark Apt., Shirole Road, Pune - 411004, Maharashtra, India	India	Third Schedule
Axaban-Denk Film Coated Tablets 2.5 mg (Change of Primary Packaging from Bottle to Blisters; Change of Storage Condition)	Combino Pharm Malta Ltd HF60 Hal Far Industrial Estate Hal Far BBG3000, Malta	Malta	do.
Axaban-Denk Film Coated Tablets 5.0 mg (Change of Primary Packaging from Bottle to Blisters; Change of Storage Condition)	do.	do.	do.
Clotri-Denk 100 Vaginal Tablets 100 mg (Primary and Secondary Packaging Update; Minor Text Update of Leaflet and SmPC)	Artesan Pharma GmbH & Co. KG Wendlandstrasse 1 D-29439 Lüchow, Germany	Germany	do.
Ena-Denk 10 Tablets 10 mg (Additional Primary and Secondary Packager of Final Product; Artwork Update to reflect change)	DENK PHARMA GmbH & Co. KG, Göllstr. 1 84529 Tittmoning, Germany Additional Packager: Swiss Caps GmbH, Grassingerstr. 9 83043 Bad Aibling, Germany	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Ena-Denk 20 Tablets 20 mg (Additional Primary and Secondary Packager of Final Product; Artwork Update to reflect change)	DENK PHARMA GmbH & Co. KG, Göllstr. 1 84529 Tittmoning, Germany Additional Packager: Swiss Caps GmbH, Grassingerstr. 9 83043 Bad Aibling, Germany	Germany	Third schedule
Panto-Denk Gastro-Resistant Tablets 20 mg (Additional Manufacturer; Minor Change in Manufacturing Process; Text Update)	Advance Pharma GmbH Wallenroder Straße 8-14 13435 Berlin, Germany Or allphamed PHARBIL Arzneimittel GmbH Hildebrandstr. 10-12 37081 Göttingen, Germany	do.	do.
Panto-Denk Gastro-Resistant Tablets 40 mg (Additional Manufacturer; Minor Change in Manufacturing Process; Text Update)	do.	do.	do.
Humira AC 40 mg/0.4 mL Solution for Injection in Pre-Filled Pen (Additional Manufacturing Site; Additional Secondary Packaging Site)	Vetter Pharma-Fertigung GmbH & Co. KG, Schützenstr. 87 und 99-101, 88212 Ravensburg, Germany or	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	AbbVie Biotechnology Ltd., Road No. 2, Km 59.2, Barceloneta, Puerto Rico (PR) 00617, United States of America Secondary Packager: AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Germany		
Humira AC 40 mg/0.4 mL Solution for Injection in Pre-Filled Pen (Additional Secondary Packaging Site)	Vetter Pharma-Fertigung GmbH & Co. KG Schützenstr. 87 und 99-101, 88212 Ravensburg, Germany Secondary Packager: AbbVie SRL., S.R. 148 Pontina Km 52 Snc, Campoverde di Aprilia, 04011 Aprilia (LT), Italy	Italy	do.
Humira AC 40 mg/0.4 mL Solution for Injection in Pre-Filled Pen  (Additional Manufacturing Site; Additional Secondary Packaging Site)	Vetter Pharma-Fertigung GmbH & Co. KG Schützenstr. 87 und 99-101, 88212 Ravensburg, Germany Or AbbVie Biotechnology Ltd., Road No. 2, Km 59.2, Barceloneta, Puerto Rico (PR) 00617, United States of America	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Secondary Packager: AbbVie SRL., S.R. 148 Pontina Km 52 Snc, Campoverde di Aprilia, 04011 Aprilia (LT), Italy		
Ogivri (Trastuzumab) Lyophilized Powder for Injection for I.V. Infusion 440 mg (Change of Name and Address of Marketing Authorization Holder; Change of Name of Manufacturer)	Biocon Biologics Ltd Block No. B1, B2, B3, Q13 of Q1 and W20 & Unit S18, 1st Floor, Block B4, Special Economic Zone, Plot No. 2, 3, 4 & 5, Phase IV, Bommasandra-Jigani Link Road, Bommasandra Post, Bengaluru-560 099, India	India	Third Schedule
Fulphila (Pegfilgrastim) Injection in a Pre-Filled Syringe 6 mg/0.6 mL (Change of Name and Address of Marketing Authorization Holder; Change of Name of Manufacturer)	do.	do.	do.
Semglee (Insulin Gargine) Solution for Subcutaneous Injection in Pre-Filled Pen 100 units/mL (Change of Name and Address of Marketing Authorization Holder)	Biocon SDN. BHD. No. 1, Jalan Bioteknologi 1, Kawasan Perindustrian SILC 79200- Iskandar Puteri, Johor, Malaysia	Malaysia	do.



TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Semglee (Insulin Glargine) Solution for Subcutaneous Injection in Vial 100 units/mL (Change of Name and Address of Marketing Authorization Holder)	Biocon SDN. BHD. No. 1, Jalan Bioteknologi 1, Kawasan Perindustrian SILC 79200- Iskandar Puteri, Johor, Malaysia	Malaysia	Third Schedule
Avonex 30 µg/0.5 mL Solution for Injection (Change of Marketing Authorization Holder)	Vetter Pharma-Fertigung GmbH & Co. KG Eisenbahnstrasse 2-4 88085 Langenargen Germany Packaged by: Fujifilm Diosynth Biotechnologies Denmark Aps Biotek Allé 1, Hillerod 3400, Denmark	Denmark	do.
Lamictal Dispersible/Chewable Tablets 25 mg (Change of Name of Manufacturer; Change of Artwork)	Delpharm Poznań S.A. ul. Grunwaldzka 189 60-332 Poznań, Poland	Poland	do.
Lamictal Dispersible/Chewable Tablets 50 mg (Change of Name of Manufacturer; Change of Artwork)	do.	do.	do.

<b>TRADE NAME AND FORM</b>	<b>MANUFACTURER</b>	<b>COUNTRY OF ORIGIN</b>	<b>CONDITION OF SALE</b>
Lamictal Dispersible/Chewable Tablets 100 mg (Change of Name of Manufacturer; Change of Artwork)	Delpharm Poznań S.A. ul. Grunwaldzka 189 60-332 Poznań, Poland	Poland	Third Schedule
Lamictal Dispersible/Chewable Tablets 5 mg (Change of Name of Manufacturer; Change of Artwork)	do.	do.	do.
Anoro Ellipta Inhalation Powder 62.5/25 mcg (Alternative Manufacturing Site; Change of Artwork)	GlaxoSmithKline LLC 1011 North Arendell Avenue Zebulon North Carolina 27597, United States of America	United States of America	do.
Backup Plan Onestep Tablets 1.5 mg	Apotex Inc. 150 Signet Drive, Toronto, ON Canada	Canada	do.
Apo-Sitagliptin Malate Tablets 100 mg	do.	do.	do.
Apo-Sitagliptin Malate/Metformin Hydrochloride Tablets 50 mg/500 mg	do.	do.	do.
Apo-Sitagliptin Malate/Metformin Hydrochloride Tablets 50 mg/1000 mg	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Apo-Zolpidem 10 mg Tablets	Apotex Inc. 150 Signet Drive, Toronto, ON Canada	Canada	Controlled
Jamieson Vitamin D3 1000 IU Chewable Tablets	Jamieson Laboratories 4025 Rhodes Drive, Windsor, Canada	do.	Freely
Jamieson Women's Probiotic Complex Capsules	do.	do.	do.
Jamieson Women's Multi Gummies	do.	do.	do.
Jamieson B12 2500 mcg Fast Melt Tablets	do.	do.	do.
Jamieson Effervescent C 1000 mg Tablets	do.	do.	do.
Jamieson Vitamin D3 1000 IU Gummies	do.	do.	do.
Cimetidine Tablets USP 300 mg (Change of Marketing Authorization Holder; Label Update; Change of Name)	Apotex Inc. for AA Pharma Inc. 1165 Creditstone Road, Unit #1. Vaughan, ON, L4K 4N7, Canada	do.	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Pentoxifylline Sustained-Release Tablets 400 mg (Change of Marketing Authorization Holder; Label Update; Change of Name)	Apotex Inc. for AA Pharma Inc. 1165 Creditstone Road, Unit #1. Vaughan, ON, L4K 4N7, Canada	Canada	Third Schedule
Diazepam Tablets USP 5 mg (Change of Marketing Authorization Holder; Label Update; Change of Name)	do.	do.	Controlled
Diazepam Tablets USP 10 mg (Change of Marketing Authorization Holder; Label Update; Change of Name)	do.	do.	do.
EspritVita Magnesium Glycinate Capsules 400 mg	Pharma Natural Inc 14500 NW 60th Ave Miami Lakes, FL33014 United States of America For: Esprit Vita, 8336 NW 68th Street Miami FL 33166, United States of America	United States of America	Freely
Nifedipine Slow Release Tablets 20 mg (Nifelat Retard)	Cipla C.O. Meditab Specialities Pvt. Ltd.	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
(Change of Manufacturing Site and Font Update of Primary and Secondary Packaging)	352 Kundaim Industrial Estate, Kundaim, GOA, India		
Firmagon 80 mg Powder and Solvent for Solution for Injection (Change of Marketing Authorization Holder and Carton)	Powder Manufacturer, Solvent Manufacturer and P L Holder: Ferring GmbH Wittland 11, 24109 Kiel, Germany Packaging: Ferring Léciva a.s. Ke Skále 455 252 42 Vestec u Prahy, Czech Republic Or Ferring International Center S.A. Chemin de la Vergognausaz 50, CH-1162 St. Prex, Switzerland Marketing Authorization Holder: Ferring GmbH Wittland 11, 24109 Kiel, Germany	Czech Republic	Third Schedule
Bell Lifestyle Blood Pressure Formulation Combo Capsules	Bell Lifestyle Products Inc. 3155 Pepper Mill Ct #4, Mississauga, ON L5L 4X4, Canada	Canada	Freely
Bell Lifestyle Shark Cartilage for Joint Relief Capsules	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Platol Cisplatin Injection B.P 50 mg/ 50 mL for IV Infusion	Venus Remedies Limited Hill Top Estate, Jharmajri EPIP, Phase-1 (Extn.), Bhatoli Kalan, Baddi Dist. Solan, Himachal Pradesh-173205, India	India	Third Schedule
Paxol (Paclitaxel Injection USP 100 mg/16.7 mL) for IV Use Only	do.	do.	do.
Cabazither-60 (Cabazitaxel) Liquid Injection 60 mg/6 mL	TherDose Pharma Pvt. Ltd Plot No.: 118, 119 & 120, Survey No.: 342, Road No.: 6, ALEAP Industrial Estate, Opp. JNTU, Pragathi Nagar, Kukatpally, Hyderabad - 500 090, Telangana, India	do.	do.
Abiraterone Acetate Tablets USP 250 mg	do.	do.	do.
NEOMOL (Paracetamol Injectable Solution 10 mg/mL) for Infusion 100 mL	Unique Pharmaceuticals Laboratories (A Div. of J.B. Chemicals & Pharmaceuticals Ltd) Plot No. 4, Phase IV GIDC Industrial Estate City Panoli, Dist. Bharuch Gujarat 394116, India	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Probiotic XL Capsules (Change of Indication; Change of Artwork)	Deerland Probiotics and Enzymes Inc. 3800 Cobb International Blvd Kennesaw, GA 3015, United States of America	United States of America	Freely
Heart XL Softgels 420 mg (Change of Name of Product; Change of Indication; Change of Artwork)	Elevate Health Sciences 3421 Sierra Vista Way, Provo UT 84606, United States of America	do.	do.
Turmeric XL Capsules (Change of Indication; Change of Artwork)	do.	do.	do.
Vitamin XL D3 Softgels 5000 IU (Change of Name of Product; Change of Indication; Change of Artwork)	Arizona Nutritional Supplements 14700 NW 60th Ave, Miami Lakes, FL 33014, United States of America	do.	Third Schedule
Paxlovid 150 mg/100 mg Film-Coated Tablets	Manufacturer of Nirmatrelvir 150 mg Film-Coated Tablets: Pfizer Manufacturing Deutschland GmbH Mooswaldallee 1 79090 Freiburg, Germany Manufacturer of Ritonavir 100 mg Film Coated Tablets: Hetero Labs Limited Plot No 22 - 110 Unit 3	Italy	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Formulation Industrial Development Area, Jeedimetia, Hyderabad 500055, India Packager of Paxlovid 150 mg + 100 mg Film Coated Tablets: Pfizer Italia S.r.L. Localita Marino del Tronto Ascoli Piceno 63100, Italy		

Dated this 18th day of April, 2024.

T. DEYALSINGH  
*Minister of Health*