

LEGAL NOTICE No. 113

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
Intimate Rose Myo and D-Chiro Inositol Capsules	Aviva Natural Supplements LLC 26 Van Dyke Avenue, New Brunswick, New Jersey, United States of America Manufactured for: Plus EV Holdings Inc. DBA Intimate Rose, North Kansas City, Missouri, United States of America	United States of America	Third Schedule
Caniverm Tablets	Laboratorios Tornel S.A. Venustiano Carranza No. 24 Colonia Naucalpan Centro, Naucalpan, Edo. De México CP 5300	Mexico	Third Schedule (Veterinary Use Only)

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Natrol Relax + Ultimate Calm Capsules	Natrol LLC Chatsworth, CA 91311, United States of America	United States of America	Freely
Hemotin-Epo Injection 4000 IU/mL (Change of Packaging)	Shenyang Sunshine Pharmaceutical Co. Ltd No.3 A 1, Road 10, Economy and Technology Development Zone, Shenyang, PR, China	China	Third Schedule
Olfen™-75 SR Prolonged Release Tablets (Change of Shelf Life; Update to Analytical Procedures)	Acino Pharma AG Birsweg 2 4253 Liesberg, Switzerland	Switzerland	Third Schedule
Bactiflox™ Neo Film Coated Tablets 500 mg (Change of Manufacturer & Manufacturing Site; Artwork Update to reflect change)	Acino Pharma AG Birsweg 2 4253 Liesberg, Switzerland	Switzerland	Third Schedule
Neurorubine™ IM Ampoule for Injection (Change of Manufacturer & Manufacturing Site; Artwork Update to reflect change)	Haupt Pharma Wülfing GmbH Bethelber Landstrasse 18, 31028 Gronau/Leine, Germany	Germany	Third Schedule
Vitabiotics Immunace Original Tablets	Vitabiotics Ltd. 1 Apsley Way, London NW2 7HF, England	United Kingdom	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Vitabiotics Wellman 70+ Tablets	Vitabiotics Ltd. 1 Apsley Way, London NW2 7HF, England	United Kingdom	Freely
Vitabiotics Wellwoman 70+ Tablets	Vitabiotics Ltd. 1 Apsley Way, London NW2 7HF, England	United Kingdom	Freely
Vitabiotics Wellteen Him Tablets	Vitabiotics Ltd. 1 Apsley Way, London NW2 7HF, England	United Kingdom	Freely
Hyland's Seasonal Allergy Relief Quick Dissolving Tablets	Standard Homeopathic Company PO Box 61067, Los Angeles, CA 90061, United States of America	United States of America	Freely
Hyland's Stress Busters Vegan Gummies	Standard Homeopathic Company PO Box 61067, Los Angeles, CA 90061, United States of America	United States of America	Freely
Dabur Nature4U Amla Vegetarian Capsules	Dabur India Limited Plot No. 22 Site-4, Sahibabad District- Ghaziabad State-U. P, India	India	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORGIN	CONDITION OF SALE
Dabur Nature4U Ashwagandha Vegetarian Capsules	Dabur India Limited Plot No. 22 Site-4, Sahibabad District- Ghaziabad State-U. P, India	India	Freely
Dabur Nature4U Brahmi Vegetarian Capsules	Dabur India Limited Plot No. 22 Site-4, Sahibabad District- Ghaziabad State-U. P, India	India	Freely
Dabur Nature4U Neem Vegetarian Capsules	Dabur India Limited Plot No. 22 Site-4, Sahibabad District- Ghaziabad State-U. P, India	India	Freely
Dabur Nature4U Arjuna Vegetarian Capsules	Dabur India Limited Plot No. 22 Site-4, Sahibabad District- Ghaziabad State-U. P, India	India	Freely
Dabur Nature4U Shilajit Vegetarian Capsules	Dabur India Limited Plot No. 22 Site-4, Sahibabad District- Ghaziabad State-U. P, India	India	Freely
Bell Lifestyle Supreme Immune Booster Capsules	Acenzia Inc. 1580 Rossi Drive, Oldcastle, Ontario N9G 0B8, Canada	Canada	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORGIN	CONDITION OF SALE
Fluticasone Nasal Spray 50 mcg/spray	Jewim Pharmaceutical (Shandong) Co., Ltd. Taian Hi-Tech Industrial Development Zone, Shandong, China	China	Third Schedule
Myonit (Nitroglycerin Injection USP 5 mg/mL) Injection	Troikaa Pharmaceuticals Limited C-1, Sara Industrial Estate, Selaqui, Dehradun-248197, Uttarakhand, India	India	Third Schedule
TACHYBAN (Adenosine Injection Ampoules USP 3 mg)	Troikaa Pharmaceuticals Limited C-1, Sara Industrial Estate, Selaqui, Dehradun-248197, Uttarakhand, India	India	Third Schedule
Bupitroy Heavy (Bupivacaine Hydrochloride in Dextrose Injection USP 5 mg/ml) Solution for Injection	Troikaa Pharmaceuticals Limited C-1, Sara Industrial Estate, Selaqui, Dehradun-248197, Uttarakhand, India	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORGIN	CONDITION OF SALE
Doparis (Dopamine Hydrochloride USP 40 mg/ml) Solution for IV Infusion	Troikaa Pharmaceuticals Limited C-1, Sara Industrial Estate, Selaqui, Dehradun-248197, Uttarakhand, India	India	Third Schedule
Isotroy 100 (Isoflurane USP) Liquid for Inhalation	Troikaa Pharmaceuticals Limited C-1, Sara Industrial Estate, Selaqui, Dehradun-248197, Uttarakhand, India	India	Third Schedule
Narcotan (Naloxone Hydrochloride Injection USP 400 mcg/ml)	Troikaa Pharmaceuticals Limited C-1, Sara Industrial Estate, Selaqui, Dehradun-248197, Uttarakhand, India	India	Third Schedule
Zygem 200 (Gemcitabine for Injection USP 200 mg/vial)	Zydus Hospira Oncology Pvt. Ltd. Plot 3, Pharmez SEZ, Sarkhej Bavla Road, Sanand, Ahmedabad, Gujarat 382213, India	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORGIN	CONDITION OF SALE
Zygem 1000 (Gemcitabine for Injection USP 1000 mg/vial)	Zydus Hospira Oncology Pvt. Ltd. Plot 3, Pharmez SEZ, Sarkhej Bavla Road, Sanand, Ahmedabad, Gujarat 382213, India	India	Third Schedule
Oxalizyd 50 (Oxaliplatin Injection USP 50 mg/10 ml)	Zydus Hospira Oncology Pvt. Ltd. Plot 3, Pharmez SEZ, Sarkhej Bavla Road, Sanand, Ahmedabad, Gujarat 382213, India	India	Third Schedule
Oxalizyd 100 (Oxaliplatin Injection USP 100 mg/20 ml)	Zydus Hospira Oncology Pvt. Ltd. Plot 3, Pharmez SEZ, Sarkhej Bavla Road, Sanand, Ahmedabad, Gujarat 382213, India	India	Third Schedule
Proteoz (Bortezomib for Injection 3.5 mg/vial)	Zydus Hospira Oncology Pvt. Ltd. Plot 3, Pharmez SEZ, Sarkhej Bavla Road, Sanand, Ahmedabad, Gujarat 382213, India	India	Third Schedule
Iohexol Injection 300 mg/ml	Beijing Beilu Pharmaceutical Co., Ltd. No. 3, Shuiyuan West Road, Miyun District, Beijing, China	China	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORGIN	CONDITION OF SALE
Metformin Film Coated Tablets USP 500 mg	Laurus Labs Limited Plot No: 19, 20 & 21, Western Sector, APSEZ, Gurajapalem Village, Rambilli Mandal, Anakapalli District-531011, Andhra, Pradesh, India	India	Third Schedule
Sorafenib Tablets USP 200 mg	YBAO Pharmaceutical Co., Ltd. 97 Kechuang East, 6 <sup>th</sup> Street, BDA, Beijing 10111, China	China	Third Schedule
ATEKEN 50 (Atenolol Tablets USP 50 mg)	Pell Tech Health Care Pvt Ltd Plot No. 20B, Tansa Farm Estate, Village Met, Gonsai, Bhiwandi-Wada, Thane 421312 Maharashtra State, India	India	Third Schedule
Alfa Vitamins Elderberry Plus C-Zinc Gummies Adult	Alfa Vitamins Laboratories, Inc. 4701 N.W. 77 <sup>th</sup> Avenue, Miami FL 33166, United States of America	United States of America	Freely



TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Alfa Vitamins Multi Women Tablets	Alfa Vitamins Laboratories, Inc. 4701 N.W. 77 <sup>th</sup> Avenue, Miami FL 33166, United States of America	United States of America	Freely
Alfa Vitamins Multi Men Tablets	Alfa Vitamins Laboratories, Inc. 4701 N.W. 77 <sup>th</sup> Avenue, Miami FL 33166, United States of America	United States of America	Freely
Alfa Vitamins Zinc Gluconate Tablets 50 mg	Alfa Vitamins Laboratories, Inc. 4701 N.W. 77 <sup>th</sup> Avenue, Miami FL 33166, United States of America	United States of America	Freely
Alfa Vitamins Zinc Vitamin C & D Caplets	Alfa Vitamins Laboratories, Inc. 4701 N.W. 77 <sup>th</sup> Avenue, Miami FL 33166, United States of America	United States of America	Third Schedule
Zejula Film-Coated Tablets 100 mg	Catalent Greenville Inc. 1240 Sugg Parkway Greenville, NC 27834, United States of America	Ireland	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORGIN	CONDITION OF SALE
	Packaged by: PCI Pharma Services Dublin (doing business as Millmount Healthcare Limited) Unit 4, Donore Road Industrial Estate, Drogheda, A92 X2FR, Ireland	Ireland	Third Schedule
Arabitro Film-Coated Tablets 250 mg	Glenmark Pharmaceuticals Ltd. Plot No. B-25, M.I.D.C., Shendra, Aurangabad - 431210, Maharashtra, India	India	Third Schedule
Arabitro Film-Coated Tablets 500 mg	Glenmark Pharmaceuticals Ltd. Plot No. B-25, M.I.D.C., Shendra, Aurangabad - 431210, Maharashtra, India	India	Third Schedule
Apo-Metformin ER Tablets 500 mg	Apotex Inc. 150 Signet Drive, Toronto, ON Canada, M9L 1T9	Canada	Third Schedule
Apo-Levofloxacin Tablets 500 mg	Apotex Inc. 150 Signet Drive, Toronto, ON Canada, M9L 1T9	Canada	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Apo-Bisoprolol Tablets 10 mg	Apotex Inc. 150 Signet Drive, Toronto, ON Canada, M9L 1T9	Canada	Third Schedule
Apo-Lamotrigine Tablets 25 mg	Apotex Inc. 150 Signet Drive, Toronto, ON Canada, M9L 1T9	Canada	Third Schedule
Apo-Lamotrigine Tablets 100 mg	Apotex Inc. 150 Signet Drive, Toronto, ON Canada, M9L 1T9	Canada	Third Schedule
Apo-Atorvastatin Tablets 10 mg	Apotex Inc. 150 Signet Drive, Toronto, ON Canada, M9L 1T9	Canada	Third Schedule
Apo-Atorvastatin Tablets 20 mg	Apotex Inc. 150 Signet Drive, Toronto, ON Canada, M9L 1T9	Canada	Third Schedule
Apo-Anastrozole Tablets 1 mg	Apotex Inc. 150 Signet Drive, Toronto, ON Canada, M9L 1T9	Canada	Third Schedule
Apo-Mycophenolic Acid Delayed Release Tablets 360 mg	Apotex Inc. 150 Signet Drive, Toronto, ON Canada, M9L 1T9	Canada	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORGIN	CONDITION OF SALE
Apo-Lamivudine Tablets 150 mg	Apotex Inc. 150 Signet Drive, Toronto, ON Canada, M9L 1T9	Canada	Third Schedule
Apo-Metformin ER Tablets 1000 mg	Apotex Inc. 150 Signet Drive, Toronto, ON Canada, M9L 1T9	Canada	Third Schedule
Pradaxa Hard Capsules 75 mg (Change of Product Monograph; Change of Package Insert; Change of Artwork)	Boehringer Ingelheim Pharma GmbH & Co. KG Binger Strasse 173, 55216 Ingelheim am Rhein, Germany	Germany	Third Schedule
Pradaxa Hard Capsules 110 mg (Change of Product Monograph; Change of Package Insert; Change of Artwork)	Boehringer Ingelheim Pharma GmbH & Co. KG Binger Strasse 173, 55216 Ingelheim am Rhein, Germany	Germany	Third Schedule
Pradaxa Hard Capsules 150 mg (Change of Product Monograph; Change of Package Insert; Change of Artwork)	Boehringer Ingelheim Pharma GmbH & Co. KG Binger Strasse 173, 55216 Ingelheim am Rhein, Germany	Germany	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Spiolto Respimat Solution for Inhalation 2.5 µg/2.5 µg (Change of Product Monograph; Change of Package Insert; Change of Printed Packaging Material; Change of Piercing Element of Device)	Boehringer Ingelheim Pharma GmbH & Co. KG Binger Strasse 173, 55216 Ingelheim am Rhein, Germany	Germany	Third Schedule
Systane® Ultra PF Lubricant Eye Drops	Alcon Research LLC 6201 South Freeway, Fort Worth, TX 76134, United States of America	United States of America	Freely
Colpermin Gastro-Resistant Capsules 187 mg (Change of Manufacturer; Update of Artwork)	Tillotts Pharma AG Hauptstrasse 27, 4417 Ziefen, Switzerland	Switzerland	Freely
Sandostatin® Solution for Injection or Infusion 0.1 mg/ml (Change in Manufacturer; Change in Country of Origin; Change in Artwork)	Delpharm Dijon 6 boulevard de l'Europe, 21800 Quetigny, France For: Novartis Pharma AG Basel, Switzerland	France	Third Schedule
Sandostatin® Solution for Injection or Infusion 0.05 mg/ml (Change in Manufacturer; Change in Country of Origin; Change in Artwork)	Delpharm Dijon 6 boulevard de l'Europe, 21800 Quetigny, France For: Novartis Pharma AG Basel, Switzerland	France	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Sandostatin® LAR® Powder and Solvent for Suspension for Injection 20 mg (Change in Packager; Change in Country of Origin; Change in Artwork)	Sandoz GmbH Schaftenau, Biochemiestrasse 10, 6336 Langkampfen, Austria Packaged by: Abbott Biologicals B.V. Veerweg 12, 8121 AA Olst, Netherlands For: Novartis Pharma AG Basel, Switzerland	Netherlands	Third Schedule
Mekinist™ Film-Coated Tablets 0.5 mg (New Indication; Change in Manufacturer; Change in Country of Origin; Change in Artworks)	Novartis Pharma Stein AG Schaffhauserstrasse, 4332, Stein, Switzerland Packaged by: Lek Pharmaceuticals d.d. Verovškova ulica 57, Ljubljana, 1526, Slovenia For: Novartis Pharma AG Basel, Switzerland	Slovenia	Third Schedule
Mekinist™ Film-Coated Tablets 2 mg (New Indication; Change in Manufacturer; Change in Country of Origin; Change in Artworks)	Novartis Pharma Stein AG Schaffhauserstrasse, 4332, Stein, Switzerland	Slovenia	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Packager: Lek Pharmaceuticals d.d. Verovškova ulica 57, Ljubljana, 1526, Slovenia For: Novartis Pharma AG Basel, Switzerland	Slovenia	Third Schedule
Jakavi® Tablets 5 mg (New Indication; Update of Product Insert)	Novartis Pharma Stein AG Schaffhauserstrasse, 4332 Stein, Switzerland For: Novartis Pharma AG Basel, Switzerland	Switzerland	Third Schedule
Jakavi® Tablets 15 mg (New Indication; Update of Product Insert)	Novartis Pharma Stein AG Schaffhauserstrasse, 4332 Stein, Switzerland For: Novartis Pharma AG Basel, Switzerland	Switzerland	Third Schedule
Kisqali® Film-Coated Tablets 200 mg (Change in Manufacturer; Change in Primary and Secondary Packager; Change in Country of Origin; Change in Artworks)	Lek Pharmaceuticals d.d. Verovškova ulica 57, Ljubljana, 1526, Slovenia For: Novartis Pharma AG Basel, Switzerland	Slovenia	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Simponi® Solution for Injection in Prefilled Pen (Smartject®) 50 mg/0.5 ml (Additional Manufacturing Site)	Cilag AG Hochstrasse 201, 8200 Schaffhausen, Switzerland For: Ethnor del Istmo S.A. Panama	Switzerland	Third Schedule
Glivec® Film-Coated Tablets 400 mg (Change in Manufacturing Site; Change in Packager; Change in Country of Origin; Change in Artworks)	Novartis Pharma Produktions GmbH Öflinger Strasse 44, 79664 Wehr, Germany Packaged by: Lek Pharmaceuticals d.d. Trimlini 2D, Lendava/Lendva, 9220, Slovenia For: Novartis Pharma AG Basel, Switzerland	Slovenia	Third Schedule
Bell's Healthcare Children's Cough Syrup Honey & Lemon Flavour 0.75 g/5 ml	Bell, Sons & Co (Druggists) Limited Gifford House, Slaidburn Crescent, Southport, PR9 9AL, United Kingdom	United Kingdom	Freely
Cataflam Oral Suspension 1.8 mg/mL (Artwork Update)	Delpharm Huningue S.A.S. 26 rue de la Chapelle, Huningue, 68330, France	France	Third Schedule



TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	For: Novartis Farmaceutica S.A. (AC), Guatemala	France	Third Schedule
Cataflam 50 Coated Tablets 50 mg (Update of Artwork Design)	Novartis Ürunleri Yenisehir Mah. Ihlara Vadisi Sok. No:2 34912 Pendik Istanbul, Turkey For: Novartis Pharma AG, Switzerland	Turkey	Third Schedule
Detrusitol SR Prolonged Release Capsules 2 mg (Change in Dimensions of Packaging; Change in Address of the Marketing Authorisation Holder)	Catalent Pharma Solutions LLC 1100 Enterprise Drive, Winchester, KY 40391, United States of America Packaged by: Pfizer Italy S.r.l Via Anna Maria, Mozzoni, 12, 20152, Milano MI, Italy For: Upjohn US 2 LLC, United States of America	United States of America	Third Schedule
Detrusitol SR Prolonged Release Capsules 4 mg (Change in Artwork and Dimensions of Packaging; Change in Address of the Marketing Authorisation Holder)	Catalent Pharma Solutions LLC 1100 Enterprise Drive, Winchester, KY 40391, United States of America	United States of America	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Packaged by: Pfizer Italy S.r.l Via Anna Maria, Mozzoni, 12, 20152, Milano MI, Italy For: Upjohn US 2 LLC, United States of America	United States of America	Third Schedule
Dilantin Extended Release Oral Capsules 100 mg (Change in Artwork; Change in the Marketing Authorisation Holder; Change of Leaflet and Monograph)	Pfizer Pharmaceuticals LLC Road 689 Km 1.9, Vega Baja, Puerto Rico 00693 For: Viatris Speciality LLC, United States of America	United States of America	Third Schedule
Dilantin- 125 Oral Suspension USP 125 mg/5 ml (Change in Artwork; Change in the Marketing Authorisation Holder)	Pharmacia & Upjohn Company LLC 7000 Portage Road, Kalamazoo, MI 49001, United States of America For: Viatris Speciality LLC, United States of America	United States of America	Third Schedule
Epamin® Solution for Injection 50 mg/ml (Change in the Marketing Authorisation Holder;	Pfizer Manufacturing Belgium NV Rijksweg 12, 2870 Puurs-Sint-Amands, Belgium	Belgium	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORGIN	CONDITION OF SALE
Artwork and Labelling; Update to Manufacturer's Address)	For: Mylan Österreich GmbH, Austria	Belgium	Third Schedule
Rozlytrek Hard Capsules 100 mg (Change in Primary and Secondary Packaging; Shelf Life Extension)	Mayne Pharma Inc 1240 Sugg Parkway Greenville, NC 27834, United States of America Packaged by: F. Hoffmann-La Roche Ltd. Wurmisweg, 4303 Kaiseraugst, Switzerland For: F. Hoffmann-La Roche Ltd. Basel, Switzerland	Switzerland	Third Schedule
Rozlytrek Hard Capsules 200 mg (Change in Primary and Secondary Packaging; Shelf Life Extension)	Mayne Pharma Inc 1240 Sugg Parkway Greenville, NC 27834, United States of America Packaged by: F. Hoffmann-La Roche Ltd. Wurmisweg, 4303 Kaiseraugst, Switzerland For: F. Hoffmann-La Roche Ltd. Basel, Switzerland	Switzerland	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Elocom® Cream 0.1% (Change of Name of Manufacturer and Packager; Artwork Update to reflect change; Change of Name of Marketing Authorization Holder)	Organon Heist bv Industriepark 30B-2220, Heist-op-den-Berg, Belgium Marketing Authorization Holder: Organon Pharma S. de R.L., Panama	Belgium	Third Schedule
Elocom® Ointment 0.1% (Change of Name of Manufacturer and Packager; Artwork Update to reflect change; Change of Name of Marketing Authorization Holder)	Organon Heist bv Industriepark 30B-2220, Heist-op-den-Berg, Belgium	Belgium	Third Schedule
Humulin R Regular 100 units/ml Insulin Human Injection (Change in Artwork and Package Insert)	Eli Lilly and Company Indianapolis, IN 46285, United States of America For: Asofarma S.A., Guatemala	United States of America	Third Schedule
Humulin® 70/30 100 units/ml Human Insulin Isophane Suspension and Human Insulin Injection (Change in Label, Carton and Insert)	Eli Lilly and Company Indianapolis, IN 46285, United States of America For: Asofarma S.A., Guatemala	United States of America	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Ibrance Palbociclib Film-Coated Tablets 75 mg (Change in Name of the Product; Artwork and Leaflet Update)	Pfizer Manufacturing Deutschland GmbH Betriebsstätte Freiburg, Mooswaldallee 1 79090 Freiburg, Germany For: Pfizer Europe MA EEIG, Belgium	Germany	Third Schedule
Ibrance Palbociclib Film-Coated Tablets 100 mg (Change in Name of the Product; Artwork and Leaflet Update)	Pfizer Manufacturing Deutschland GmbH Betriebsstätte Freiburg, Mooswaldallee 1 79090 Freiburg, Germany For: Pfizer Europe MA EEIG, Belgium	Germany	Third Schedule
Ibrance Palbociclib Film-Coated Tablets 125 mg (Change in Name of the Product; Artwork and Leaflet Update)	Pfizer Manufacturing Deutschland GmbH Betriebsstätte Freiburg, Mooswaldallee 1 79090 Freiburg, Germany For: Pfizer Europe MA EEIG, Belgium	Germany	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Verzenio Film-Coated Tablets 50 mg (Change of Marketing Authorisation Holder; Additional Indication; Change of the Primary and Secondary Packaging)	Lilly del Caribe, Inc. 12.6 KM 65 <sup>th</sup> Infantry Road (PR01), Carolina, Puerto Rico (PR) 00985, United States of America Packaged by: Lilly, S.A. Avda. De la industria 30, 28108 Alcobendas, Madrid, Spain	Spain	Third Schedule
Verzenio Film-Coated Tablets 100 mg (Change of Marketing Authorisation Holder; Additional Indication; Change of the Primary and Secondary Packaging)	Lilly del Caribe, Inc. 12.6 KM 65 <sup>th</sup> Infantry Road (PR01), Carolina, Puerto Rico (PR) 00985, United States of America Packaged by: Lilly, S.A. Avda. De la industria 30, 28108 Alcobendas, Madrid, Spain	Spain	Third Schedule
Verzenio Film-Coated Tablets 150 mg (Change of Marketing Authorisation Holder; Additional Indication; Change of the Primary and Secondary Packaging)	Lilly del Caribe, Inc. 12.6 KM 65 <sup>th</sup> Infantry Road (PR01), Carolina, Puerto Rico (PR) 00985, United States of America	Spain	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Packaged by: Lilly, S.A. Avda. De la industria 30, 28108 Alcobendas, Madrid, Spain	Spain	Third Schedule
Erbix Solution for Infusion 5 mg/mL (Additional Indication)	Merck Healthcare KGaA, Frankfurter Strasse 250, 64293 Darmstadt, Germany	Germany	Third Schedule
Forxiga™ Film-Coated Tablets 5 mg (New Indication; Update of the Monograph and Insert)	AstraZeneca Pharmaceuticals LP Mount Vernon, IN 47620, United States of America For: AstraZeneca Camcar S.A., Panama	United States of America	Third Schedule
Forxiga™ Film-Coated Tablets 10 mg (New Indication; Update of the Monograph and Insert)	AstraZeneca Pharmaceuticals LP Mount Vernon, IN 47620, United States of America For: AstraZeneca Camcar S.A., Panama	United States of America	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Janumet® XR Extended Release Tablets 50/1000 mg (Change in the Name and Address of the Marketing Authorisation Holder)	MSD international GmbH (Puerto Rico Branch) LLC Pridco Indus park, SR 183, Las Piedras, Puerto Rico 00771 Packaged by: Merck Sharp & Dohme, B.V. Waarder Weg 39, Haarlem 2031 BN, Netherlands For: Merck Sharp & Dohme LLC	Netherlands	Third Schedule
Janumet® XR Extended Release Tablets 100/1000 mg (Change in the Name and Address of the Marketing Authorisation Holder)	MSD international GmbH (Puerto Rico Branch) LLC Pridco Indus park, SR 183, Las Piedras, Puerto Rico 00771 Packaged by: Merck Sharp & Dohme, B.V. Waarder Weg 39, Haarlem 2031 BN, Netherlands For: Merck Sharp & Dohme LLC	Netherlands	Third Schedule
Fasenra™ Solution for Injection in Pen 30 mg/1 ml (Change in the Name and Ownership of Secondary Packaging Site)	Manufactured and Primary Packaging (Prefilling) by: Catalent Indiana, LLC 1300 South Bloomington, In 47403, United States of America	United States of America	Third Schedule



TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Assembled and Packaged by: Resilience US, Inc. 8814 Trade Port Drive, West Chester, Ohio 45071, United States of America For: AstraZeneca AB, Sweden	United States of America	Third Schedule
Fasenra™ Solution for Injection in Pre-Filled Syringe 30 mg/1 ml (Change in the Name and Ownership of Secondary Packaging Site)	Manufactured and Primary Packaging (Prefilling) by: Catalent Indiana, LLC 1300 South Bloomington, In 47403, United States of America Assembled and Packaged by: Resilience US, Inc. 8814 Trade Port Drive, West Chester, Ohio 45071, United States of America For: AstraZeneca AB, Sweden	United States of America	Third Schedule
M-M-R II Measles, Mumps and Rubella Virus Vaccine Live 0.5 ml Vials - Single-Dose (Change in Name of Marketing Authorisation Holder; Change in Manufacturer,	Merck Sharp & Dohme LLC 770 Sumneytown Pike, West Point, PA 19486, United States of America	United States of America	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Primary and Secondary Packager Name; Change in Distributor)	For: Merck Sharp & Dohme LLC Rahway, NJ 07065, United States of America	United States of America	Third Schedule
Wakunaga Kyolic® Aged Garlic Extract™ Blood Sugar Support Formula 112 Capsules	Wakunaga of America Co., Ltd. 23501 Madero Mission Viejo, California 92691, United States of America	United States of America	Freely

Dated this 24th day of June, 2024.

T. DEYALSINGH  
*Minister of Health*