LEGAL NOTICE NO. 196

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
Glendes (Desloratadine Tablets 5 mg)	Glenmark Pharmaceuticals Ltd. Plot No. S-7 Colvale Industrial Estate, Colvale Bardez-Goa, 403513, India	India	Third Schedule
Glemont IR 10 (Montelukast Tablets 10 mg)	Glenmark Pharmaceuticals Ltd. Plot No. S-7 Colvale Industrial Estate, Colvale Bardez-Goa, 403513, India	India	Third Schedule
Pregabalin Denk Hard Capsules 150 mg	Temmler Pharma GmbH Temmlerstraβe 2 35039 Marburg, Germany For: Denk Pharma GmbH & Co. KG Prinzregentenstr. 79, 81675 Munchen, Germany	Germany	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Bemabix Concentrate for Solution for Infusion 100 mg/4 mL	Universal Farma, S.L. C/Del Tejido, 2, Azuqueca de Henares, 19200 Guadalajara, Spain	Spain	Third Schedule
Bemabix Concentrate for Solution for Infusion 400 mg/16 mL	Universal Farma, S.L. C/Del Tejido, 2, Azuqueca de Henares, 19200 Guadalajara, Spain	Spain	Third Schedule
Fingolimod Capsules 0.5 mg	Pharmascience Inc. 100 Boul De L'Industrie, Candiac, Quebec Canada, J5R 1J1 Packager: Pharmascience Inc. 6111 Royalmount Ave 100 Montreal, Quebec, Canada, II4P 2T4	Canada	Third Schedule
Heptral™ Gastro-Resistant Tablets 500 mg	Abbvie S.R.L S.R. 148 Pontina km 52 Snc-Campoverde Di Aprilia (loc. Aprilia) 04011 Aprilia (LT), Italy	Italy	Third Schedule
Micardis® Plus Tablets 80 mg/12.5 mg (Change of Manufacturer of the Finished Product; Change of Country of Origin; Addition of an Alternative Manufacturing Site for the	Boehringer Ingelheim International GmbH Binger Strasse 173, D-55216 Ingelheim am Rhein, Germany Alternative Manufacturer:	Germany	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Finished Product; Addition of an Alternative Primary and Secondary Packaging Site of the Drug Product; Addition of an Alternative Method for the Determination of the Water Content for the Finished Product; Change of the Name of the Analytical Testing Site for the Drug Product)	Rottendorf Pharma GmbH Ostenfelder Straβe 51-61, 59320 Ennigerloh, Germany Primary and Secondary Packager: Rottendorf Pharma GmbH Am Fleigendahl 3, 59320 Ennigerloh, Germany		
Micardis® Plus Tablets 80 mg/25 mg (Addition of an Alternative Manufacturing Site for the Finished Product; Addition of an Alternative Primary and Secondary Packaging Site of the Drug Product; Addition of an Alternative Method for the Determination of the Water Content for the Finished Product; Change of the Name of the Analytical Testing Site for the Drug Product)	Boehringer Ingelheim International GmbH Binger Strasse 173, D-55216 Ingelheim am Rhein, Germany Alternative Manufacturer: Rottendorf Pharma GmbH Ostenfelder Straβe 51-61, 59320 Ennigerloh, Germany Primary and Secondary Packager: Rottendorf Pharma GmbH Am Fleigendahl 3, 59320 Ennigerloh, Germany	Germany	Third Schedule
Synjardy® Film-Coated Tablets 12.5 mg/850 mg (Addition of an Alternative Manufacturing Site; Update to the Secondary Artwork and Package Insert to reflect the change)	Boehringer Ingelheim Hellas Single Member S.A. 5th km, Paiania-Markopoulo, Koropi Attiki, 19441, Greece	Greece	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Synjardy® Film-Coated Tablets 12.5 mg/1000 mg (Addition of an Alternative Manufacturing Site; Update to the Secondary Artwork and Package Insert to reflect the change)	Boehringer Ingelheim Hellas Single Member S.A. 5th km, Paiania-Markopoulo, Koropi Attiki, 19441, Greece	Greece	Third Schedule
Glyxambi® Film-Coated Tablets 25 mg/5 mg (Addition of Alternate Manufacturing, Primary Packaging and Secondary Packaging Site for the Drug Product; Deletion of Alternate Secondary Packaging and Labelling Sites)	Rottendorf Pharma GmbH Am Fleigendahl 3 59320 Ennigerloh, Germany	Germany	Third Schedule
NovoSeven® RT 1 mg/Vial (50 KIU) Powder and Solvent for Solution for Injection (Prefilled Syringe) (Addition of a New Therapeutic Indication; Update to the Summary of Product Characteristics and Package Insert)	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Denmark	Denmark	Specialist Use Only
Ultrox Film Coated Tablets 20 mg	Nobel İlaç Sanayii Ve Ticaret A.Ş. Sancaklar Mah. Eski Akçakoca, Cad. No: 299, 81100 Duzce/Turkey	Turkey	Third Schedule
Alzancer EasyTab Orodispersible Tablets 5 mg	Nobel İlaç Sanayii Ve Ticaret A.Ş. Sancaklar Mah. Eski	Turkey	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Akçakoca, Cad. No: 299, 81100 Duzce/Turkey		
Alzancer EasyTab Orodispersible Tablets 10 mg	Nobel İlaç Sanayii Ve Ticaret A.Ş. Sancaklar Mah. Eski Akçakoca, Cad. No: 299, 81100 Duzce/Turkey	Turkey	Third Schedule
Lipidra Film Coated Tablets 20 mg	Nobel İlaç Sanayii Ve Ticaret A.Ş. Sancaklar Mah. Eski Akçakoca, Cad. No: 299, 81100 Duzce/Turkey	Turkey	Third Schedule
Pulcet Enteric Coated Tablets 40 mg	Nobel İlaç Sanayii Ve Ticaret A.Ş. Sancaklar Mah. Eski Akçakoca, Cad. No: 299, 81100 Duzce/Turkey	Turkey	Third Schedule
Novothym Forte Drinkable Ampoules	Ha Noi CPC 1 Pharmaceutical Joint Stock Company Ha Binh Phuong Industrial Zone, Van Binh Commune, Thuong Tin District, Hanoi City, Vietnam	Vietnam	Freely
Aerius® 5 mg Tablets (Change of Name of Manufacturer and Packager;	Organon Heist bv Industriepark 30, 2220	Belgium	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Artwork Update to reflect change)	Heist-op-den Berg, Belgium		
Nature's Way Calcium Mag & Zinc Capsules	Schwabe North America, Inc. 825 Challenger Drive Green Bay, WI, 54311, United States of America	United States of America	Freely
Nature's Way Goldenseal Herb Capsules	Schwabe North America, Inc. 825 Challenger Drive Green Bay, WI, 54311, United States of America	United States of America	Freely
Aquarest™ (Saccharomyces Boulardii-Lyophilized) Sachets	Sai Mirra Innopharm Pvt Ltd 288 & 289 Sidco Estate, Ambattur, Chennai 600 098, India For: Virchow Healthcare Private Limited 901, DLH Park, S.V. Road, Goregaon (W), Mumbai - 400 062, India	India	Freely
VOXAPARIN 60 (Enoxaparin Sodium Injection IP 60 mg/0.6 ml)	Virchow Biotech Private Limited Survey No. 172 part, Gagillapur, Dundigal-Gandimaisamma Mandal, Medchal-Malkajgiri District- 500 043, Telangana State, India For:	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Virchow Healthcare Private Limited 901, DLH Park, S.V. Road, Goregaon (W), Mumbai - 400 062, India		
Solaray Cran Actin Urinary Tract Health Capsules 400 mg	Nutraceutical International Corporation 550W Second Street, BDO Build 2A, 2B, 2C Ogden, Utah 84404, United States of America	United States of America	Freely
Solaray Enhanced Absorption Calcium, Magnesium, Zinc Capsules	Nutraceutical International Corporation 550W Second Street, BDO Build 2A, 2B, 2C Ogden, Utah 84404, United States of America	United States of America	Freely
Solaray High Potency Selenium Vegetarian Capsules 200 mcg	Nutraceutical International Corporation 550W Second Street, BDO Build 2A, 2B, 2C Ogden, Utah 84404, United States of America	United States of America	Freely
Erleada Film-Coated Tablets 60 mg (Change of Primary and Secondary Packager; Change of the Country of Origin; Change of Primary and Secondary Artwork)	Janssen Ortho LLC State Road 933, KM 0.1, Mamey Ward, Gurabo Puerto Rico PR 00778, United States of America Packager: Janssen-Cilag S.p.A. Via	Italy	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	C. Janssen Borgo San Michele 04100 Latina, Italy		
Systane® Complete PF Lubricant Eye Drops	Alcon Research LLC 6201 South Freeway, Fort Worth, TX 76134, United States of America	United States of America	Freely
Immunity Vitamin C & Zinc Effervescent Tablets 1000 mg	Natural Vitamins Laboratory Corp 4400 NW 133rd. Opa Locka, Florida, 33054, United States of America	United States of America	Freely
Nature's Truth Just 4 Kidz Multivitamins + Probiotic Gummies	Nature's Truth, LLC 3900 Veterans Memorial Highway, Bohemia, NY 11716, United States of America	United States of America	Freely
Gonapeptyl Depot 3.75 mg Powder and Solvent for Suspension for Injection (Change of Marketing Authorization Holder; Change of Secondary Artwork)	Ferring GmbH Wittland 11, D-24109 Kiel, Germany	Germany	Third Schedule
Glypressin Powder and Solvent for Injection 1 mg/5 ml (Change of PA Holder; Change of Packaging; Change of Primary and Secondary Artwork)	Powder Manufacturer: Ferring GmbH Wittland 11 24109 Kiel, Germany Solvent Manufacturer: Haupt Pharma Wülfing GmbH - Bethelner Landstraβe 18, 31028	Czech Republic	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Gronau/Leine, Germany Secondary Packager: Ferring-Léčiva, a.s. - areál spol ECP, a.s., Ke Skále 455, Vestec u Prahy, 25242, Czech Republic PA Holder: Ferring GmbH Wittland 11 24109 Kiel, Germany		
Bell Lifestyle Prostate Ezee Flow Tea	Trans-Herbe Inc. 1090 rue Parent St-Bruno de Montarville, Quebec, J3V 6L8, Canada	Canada	Freely
Bell Lifestyle Kidney Cleanse & Function Tea	Trans-Herbe Inc. 1090 rue Parent St-Bruno de Montarville, Quebec, J3V 6L8, Canada	Canada	Freely
Bell Eroxil Capsules for Men	Bell Lifestyle Products Inc. 3155 Pepper Mill Court, Unit 4, Mississauga, ON L5L 4X7, Canada	Canada	Freely
Supramol 500 (Paracetamol Tablets BP 500 mg)	Pell Tech Health Care Pvt. Ltd. Plot No. 20B, Tansa Farm Estate, Village Met, Gonsai, Bhiwandi-Wada, Thane 421312 Maharashtra State, India For:	India	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Kenheal Healthcare PVT Ltd Ahmedabad, India		
Tenofovir Disoproxil Fumarate, Lamivudine and Efavirenz Tablets 300 mg/300 mg/600 mg	Mylan Laboratories Limited Plot No. 11, 12 & 13, Indore Sez, Pharma Zone, Phase-11, Sector-111, Pithampour - 454775, Dist.- Dhar (MP) India	India	Third Schedule
Carvil 25 (Carvedilol) Film Coated Tablets 25 mg	Zydus Lifesciences Ltd. Survey No. 417, 419 & 420, Sarkhej- Bavla National Highway No. 8A, Village- 13 Moraiya, Taluka-Sanand, Dist- Ahmedabad- 382 210, Gujarat State, India	India	Third Schedule
Carvil 6.25 (Carvedilol) Film Coated Tablets 6.25 mg	Zydus Lifesciences Ltd. Survey No. 417, 419 & 420, Sarkhej- Bavla National Highway No. 8A, Village- 13 Moraiya, Taluka-Sanand, Dist- Ahmedabad- 382 210, Gujarat State, India	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Xarid 10 (Rivaroxaban) Tablets 10 mg	Zydus Lifesciences Ltd. Survey No. 417, 419 & 420, Sarkhej- Bavla National Highway No. 8A, Village- 13 Moraiya, Taluka- Sanand, Dist- Ahmedabad- 382 210, Gujarat State, India	India	Third Schedule
Xarid 15 (Rivaroxaban) Tablets 15 mg	Zydus Lifesciences Ltd. Survey No. 417, 419 & 420, Sarkhej- Bavla National Highway No. 8A, Village- 13 Moraiya, Taluka- Sanand, Dist- Ahmedabad- 382 210, Gujarat State, India	India	Third Schedule
Xarid 20 (Rivaroxaban) Tablets 20 mg	Zydus Lifesciences Ltd. Survey No. 417, 419 & 420, Sarkhej- Bavla National Highway No. 8A, Village- 13 Moraiya, Taluka- Sanand, Dist- Ahmedabad- 382 210, Gujarat State, India	India	Third Schedule
Hyland's 4 Kids Cold 'n Cough Nighttime Liquid	Hyland's Consumer Health Inc	United States of America	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	13301 South Main Street, Los Angeles, CA, United States of America		
Hyland's 4 Kids Cold & Cough Daytime Liquid	Hyland's Consumer Health Inc 13301 South Main Street, Los Angeles, CA, United States of America	United States of America	Freely
Quad-D-Tox Hepatic Stimulant and Tonic Liquid	Quadragen Vethealth Private Limited 1/1, 1st Floor, Akka Complex, 14th Cross, 5th Main, RMV 2nd Stage, Dollars Colony, Bangalore- 560094 Karnataka, India	India	Freely
Olumiant Film-Coated Tablets 2 mg	Lilly del Caribe, Inc. 12.6 km 65th 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 For: Asofarma, S.A., Guatemala	Spain	Third Schedule
Olumiant Film-Coated Tablets 4 mg	Lilly del Caribe, Inc. 12.6 km 65th Infantry Road (PR01) Carolina,	Spain	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Puerto Rico (PR) 00985, United States of America Packaged by: Lilly S.A. Avda. De la Industria 30, 28108 Alcobendas, Madrid, Spain For: Asofarma, S.A., Guatemala		
Natele Prenatal Soft Gel Capsules (Change of Name of Product; Change of Wording in Composition; Parabens Elimination from Capsule Shell)	Berlimed, S.A. C/Francisco Alonso, 7-Polígono Industrial Sta. Rosa., 28806 Alcalá de Henares Madrid, Spain	Spain	Freely
Yaz Film Coated Tablets 3 mg/0.02 mg	Bayer Weimar GmbH und Co. KG Döbereiner Str. 20, 99427 Weimar, Germany	Germany	Third Schedule
Evrysdi Powder for Oral Solution 0.75 mg/1 ml (Addition of a Manufacturing Site; Artwork Update to reflect Additional Manufacturing Site)	F. Hoffmann-La Roche AG Wurmisweg Kaiseraugst, 4303 Switzerland	Switzerland	Third Schedule
Kovaltry Recombinant Antihemophilic Factor (rFVIII) (Octocog alfa) Lyophilized Powder for Solution for Injection 250 IU	Bayer HealthCare LLC 800 Dwight Way, Berkeley, California (CA) 94710, United States of America (USA) Compounding and Filling of the	United States of America	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Prefilled Syringe with Diluent: Vetter Pharma - Fertigung (LOC-100022677) GmbH & Co. KG Vetter Pharma - Fertigung (LOC-100021106) Elsenbahnstr. 2-4 88085 Langenargen, Germany		
Kovaltry Recombinant Antihemophilic Factor (rFVIII) (Octocog alfa) Lyophilized Powder for Solution for Injection 500 IU	Bayer HealthCare LLC 800 Dwight Way, Berkeley, California (CA) 94710, United States of America (USA) Compounding and Filling of the Prefilled Syringe with Diluent: Vetter Pharma - Fertigung (LOC-100022677) GmbH & Co. KG Vetter Pharma - Fertigung (LOC-100021106) Elsenbahnstr. 2-4 88085 Langenargen, Germany	United States of America	Third Schedule
Kovaltry Recombinant Antihemophilic Factor (rFVIII) (Octocog alfa) Lyophilized Powder for Solution for Injection 1000 IU	Bayer HealthCare LLC 800 Dwight Way, Berkeley, California (CA) 94710, United States of America (USA)	United States of America	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Compounding and Filling of the Prefilled Syringe with Diluent: Vetter Pharma - Fertigung (LOC-100022677) GmbH & Co. KG Vetter Pharma - Fertigung (LOC-100021106) Elsenbahnstr. 2-4 88085 Langenargen, Germany		
Clarityne Cort Tablets	Eurofarma Argentina S.A. Av. San Martín 4450, Lomas del Mirador, Province of Buenos Aires Argentine Republic For: Bayer S.A. Guatemala	Argentina	Third Schedule
Viagra Film Coated Tablets 50 mg (Change of Name of Product License Holder; Artwork and Labelling Update to reflect rebranding; Update of Distributor)	Pfizer, S.A. de C.V. Km. 63 Carretera México-Toluca, Col. Zona Industrial, C.P. 50140, Toluca, Mexico For: Upjohn Export BV Sucursal Costa Rica, Costa Rica	Mexico	Third Schedule
Viagra Film Coated Tablets 100 mg (Change of Name of Product License Holder; Artwork and	Pfizer, S.A. de C.V. Km. 63 Carretera México-Toluca,	Mexico	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Labelling Update to reflect rebranding; Update of Distributor)	Col. Zona Industrial, C.P. 50140, Toluca, Mexico For: Upjohn Export BV Sucursal Costa Rica, Costa Rica		
Lipitor Coated Tablets 10 mg (Change of Product License Holder; Artwork Update to reflect change)	Pfizer Pharmaceuticals LLC Km. 1.9, Road 689, Vega Baja, PR 00693 Puerto Rico/ United States of America Packaged by: Pfizer Manufacturing Deutschland GmbH Betriebsstätte Freiburg Mooswaldallee 1 79090 Freiburg, Germany For: Viatris Pharma GmbH Germany	Germany	Third Schedule
Lipitor Coated Tablets 80 mg (Change of Product License Holder; Artwork Update to reflect change)	Pfizer Pharmaceuticals LLC Km. 1.9, Road 689, Vega Baja, PR 00693 Puerto Rico/ United States of America Packaged by: Pfizer Manufacturing Deutschland GmbH Betriebsstätte Freiburg Mooswaldallee 1 79090 Freiburg, Germany For: Viatris Pharma GmbH Germany	Germany	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Neurontin® Capsules 100 mg (Change of Marketing Authorization Holder; Change of the Legal Entity Name of the Manufacturing Site)	Viatris Pharmaceuticals LLC Road 689 Km 1.9, Vega Baja, Puerto Rico 00693 For: Viatris Specialty LLC United States of America	United States of America	Third Schedule
Neurontin® Capsules 300 mg (Change of Marketing Authorization Holder; Change of the Legal Entity Name of the Manufacturing Site)	Viatris Pharmaceuticals LLC Road 689 Km 1.9, Vega Baja, Puerto Rico 00693 For: Viatris Specialty LLC United States of America	United States of America	Third Schedule
Norvasc 5 mg Tablets (Change of Product License Holder; Change of Secondary Artwork)	Pfizer Pharmaceuticals LLC Road 689, KM 1.9 Barrio Carmelita Vega Baja, Puerto Rico 00693 Packaged by: Pfizer Manufacturing Deutschland GmbH Betriebsstätte Freiburg Mooswaldallee 1 79090 Freiburg, Germany For: Viatris Pharma GmbH Germany	Germany	Third Schedule
Detrusitol SR Prolonged Release Capsules 2 mg (Change of Surelease Excipient Composition; Addition of an	Catalent Pharma Solutions LLC 1100 Enterprise Drive, Winchester, Kentucky (KY) 40391,	Italy	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Alternative Enzymatic Dissolution Method; Addition of Alternative Primary Packaging)	United States of America Packaged by: Pfizer Italia S.r.l. Ascoli Piceno, Italy For: Upjohn US 2 LLC United States of America		
Celebrex Capsules 200 mg (Change of Product License Holder; Artwork Update of Secondary Packaging to reflect change)	Pfizer Pharmaceuticals, LLC Road 689, Km. 1.9 Barrio Carmelita Vega Baja, Puerto Rico 00693 Packaged by: Pfizer Manufacturing Deutschland GmbH Mooswaldallee 1 79090 Freiburg Im Breisgau, Germany For: Viatris Pharma GmbH Germany	Germany	Third Schedule
PROGYNOVA® Tablets 1 mg (Change of Marketing Authorization Holder; Change of Design, Colour, Logo and Layout of Primary and Secondary Packaging)	Bayer Weimar GmbH und Co. KG Dobereinerstraβe 20, 99427 Weimar, Germany For: Amdipharm Limited 3 Burlington Road, Dublin 4, Ireland	Germany	Third Schedule
PROGYNOVA® Tablets 2 mg (Change of Marketing Authorization Holder; Change	Bayer Weimar GmbH und Co. KG Dobereinerstraβe 20, 99427 Weimar,	Germany	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
of Design, Colour, Logo and Layout of Primary and Secondary Packaging)	Germany For: Amdipharm Limited 3 Burlington Road, Dublin 4, Ireland		
Neubria Neu Kid Soft Chews	Vitux AS Hamnegata 71 No-8480 Andenes, Norway For: Neubria Ltd Hamilton House, Church Street, Altrincham, WA14 4DR, United Kingdom	Norway	Freely
Neubria Neu Him Tablets	Lifeplan Products Limited Elizabethan Way, Lutterworth LE17 4ND, United Kingdom For: Neubria Ltd Hamilton House, Church Street, Altrincham, WA14 4DR, United Kingdom	United Kingdom	Freely
Neubria Neu Her Tablets	Lifeplan Products Limited Elizabethan Way, Lutterworth LE17 4ND, United Kingdom For: Neubria Ltd Hamilton House, Church Street, Altrincham, WA14 4DR, United Kingdom	United Kingdom	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Neubria Neu Phase Tablets	Lifeplan Products Limited Elizabethan Way, Lutterworth LE17 4ND, United Kingdom For: Neubria Ltd Hamilton House, Church Street, Altrincham, WA14 4DR, United Kingdom	United Kingdom	Freely
Neubria Neu Beauty Tablets	Lifeplan Products Limited Elizabethan Way, Lutterworth LE17 4ND, United Kingdom For: Neubria Ltd Hamilton House, Church Street, Altrincham, WA14 4DR, United Kingdom	United Kingdom	Freely
Neubria Neu Mum Softgels	Power Health Products Limited Pocklington Airfield Industrial Estate Pocklington York YO42 1NR, United Kingdom	United Kingdom	Freely
Mayzent Film Coated Tablets 2 mg (Addition of Primary and Secondary Packager; Update of Artwork to reflect change; Update of Patient Leaflet to	Novartis Pharma Stein AG Schaffhauserstrasse 4332 Stein, Switzerland	Switzerland	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
reflect Amendment to the National Prescribing Information)			
Mayzent Film Coated Tablets 0.25 mg (Addition of Primary and Secondary Packager; Update of Artwork to reflect change; Update of Patient Leaflet to reflect Amendment to the National Prescribing Information)	Novartis Pharma Stein AG Schaffhauserstrasse 4332 Stein, Switzerland	Switzerland	Third Schedule
Scapho 150 mg Powder for Solution for Injection (New Indication)	Novartis Pharma Stein AG Schaffhauserstrasse 4332 Stein, Switzerland	Switzerland	Third Schedule
Scapho Solution for Injection in Pre-Filled SensoReady Pen 150 mg/ml (New Indication)	Novartis Pharma Stein AG Schaffhauserstrasse 4332 Stein, Switzerland	Switzerland	Third Schedule
Scapho Solution for Injection in Pre-Filled SensoReady Pen 300 mg/2 ml (New Indication)	Novartis Pharma Stein AG Schaffhauserstrasse 4332 Stein, Switzerland	Switzerland	Third Schedule
Xolair Powder and Solvent for Solution for Injection 150 mg (Addition of a Packaging Site; Change of Secondary Artwork)	Novartis Pharma Stein AG Schaffhauserstrasse 4332 Stein, Switzerland	Switzerland	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
RotaTeq® Pentavalent Oral Live Virus Vaccine Against Rotavirus Solution (Change of Marketing Authorization Holder; Update of the Name and Address of the Manufacturer, Primary Packager and Secondary Packager; Change of Distributor; Update of Artwork and Package Insert to reflect changes)	Merck Sharp & Dohme LLC 770 Sumneytown Pike, West Point, PA, 19486, United States of America	United States of America	Third Schedule
Edistride 10 mg Film Coated Tablets (Indication Update; Update of Monograph and Insert)	AstraZeneca Pharmaceuticals LP 4601 Highway 62 East, Mount Vernon, IN 47620, United States of America	United States of America	Third Schedule
Cancidas Powder for Concentrate for Solution for Infusion Single Dose Vial 70 mg (Change of Name and Address of the Marketing Authorization Holder; Artwork Design Update; Artwork Update (Bilingual version); Labelling Change from FDA to EMA Leaflet)	Fareva Mirabel Route De Marsat Riom, Clermont Ferrand Cedex 9, 63963, France	France	Third Schedule
Cancidas Powder for Concentrate for Solution for Infusion Single Dose Vial 50 mg (Change of Name and Address of the	Fareva Mirabel Route De Marsat Riom, Clermont Ferrand Cedex 9, 63963, France	France	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Marketing Authorization Holder; Artwork Design Update; Artwork Update (Bilingual version); Labelling Change from FDA to EMA Leaflet)			
Listerine Ultraclean Antiseptic Cool Mint Mouthwash (Addition of Claim on label; Change of Name of Distributor; Artwork Update to reflect the change)	Johnson & Johnson Consumer Inc. 400 W. Lincoln Ave., Lititz, PA 17543, United States of America	United States of America	Freely
Imodium Multi-Symptom Relief Caplets (Change of Manufacturing Site; Change of Distributor; Change of Secondary Artwork)	JNTL Consumer Health (France) SAS Domaine De Maigremont Val De Reuil, Eure 27100, France	France	Freely
Imfinzi Injection for Intravenous Use 120 mg/2.4 ml (New Indications)	Catalent Indiana, LLC Bloomington Indiana 47403, United States of America Secondary Packager: AstraZeneca AB Forskargatan 18, Sodertalje 151 36, Sweden	Sweden	Third Schedule
Imfinzi Injection for Intravenous Use 500 mg/10 ml (New Indications)	Catalent Indiana, LLC Bloomington Indiana 47403, United States of America Secondary Packager: AstraZeneca AB Forskargatan 18, Sodertalje	Sweden	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	151 36, Sweden		
Lynparza Film Coated Tablets 100 mg (New Indication; Update to Prescribing Information and Leaflet to reflect the change)	AbbVie Limited KM 58 Carretera 2 Cruce Davilia, Barceloneta, Puerto Rico 00617, United States of America Packaged by: Astrazeneca UK Limited Silk Road Business Park, Macclesfield, Chesire SK 102NA, United Kingdom For: Astrazeneca AB SE-151 85 Sodertalje, Sweden	United Kingdom	Third Schedule
Femiane® Coated Tablets 75 mcg/20 mcg (Change of Product License Holder; Change of Manufacturer Legal Entity Name; Change of Primary and Secondary Artwork)	Uniao Quimica Internacional Ltda Rua Cancioneiro de Evora, No 255, Santo Amaro, Sao Paulo, Brazil	Brazil	Third Schedule
Tenoretic® Film-Coated Tablets 50 mg/12.5 mg (Change of Marketing Authorization Holder; Change of Manufacturer of the Finished Product; Change of Packaging, Quality Control Testing and Batch Release Site; Artwork Update to reflect changes of Marketing Authorization Holder, Logo and Manufacturing Site)	Corden Pharma GmbH Otto-Hahn-Strasse 1, 68723, Plankstadt, Germany	Germany	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Tenoretic® Film-Coated Tablets 100 mg/25 mg (Change of Marketing Authorization Holder; Change of Manufacturer of the Finished Product; Change of Packaging, Quality Control Testing and Batch Release Site; Artwork Update to reflect changes of Marketing Authorization Holder, Logo and Manufacturing Site)	Corden Pharma GmbH Otto-Hahn-Strasse 1, 68723, Plankstadt, Germany	Germany	Third Schedule
Tenormin Film-Coated Tablets 50 mg (Change of Marketing Authorization Holder; Change of Manufacturer of the Finished Product; Change of Packaging, Quality Control Testing and Batch Release Site; Artwork Update to reflect changes of Marketing Authorization Holder, Logo and Manufacturing Site)	Corden Pharma GmbH Otto-Hahn-Strasse 1, 68723, Plankstadt, Germany	Germany	Third Schedule
Tenormin Film-Coated Tablets 100 mg (Change of Marketing Authorization Holder; Change of Manufacturer of the Finished Product; Change of Packaging, Quality Control Testing and Batch Release Site; Artwork Update to reflect changes of Marketing Authorization Holder, Logo and Manufacturing Site)	Corden Pharma GmbH Otto-Hahn-Strasse 1, 68723, Plankstadt, Germany	Germany	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Zestril Tablets 10 mg (Change of Marketing Authorization Holder; Addition of Drug Substance Manufacturer; Addition of Finished Product Manufacturing Site; Addition of Primary and Secondary Packaging Site; Addition of Quality Control Testing Site and Batch Testing Site; Downscaling of Finished Product Batch Size; Minor change of Manufacturing Process; Change of Secondary Artwork)	Rovi Pharma Industrial Services SA VIA Complutense 140, Alcala De Henares (Madrid), E- 28805, Spain	Spain	Third Schedule
Zestril Tablets 20 mg (Change of Marketing Authorization Holder; Addition of Drug Substance Manufacturer; Addition of Finished Product Manufacturing Site; Addition of Primary and Secondary Packaging Site; Addition of Quality Control Testing Site and Batch Testing Site; Downscaling of Finished Product Batch Size; Minor change of Manufacturing Process; Change of Secondary Artwork)	Rovi Pharma Industrial Services SA VIA Complutense 140, Alcala De Henares (Madrid), E- 28805, Spain	Spain	Third Schedule
Zestoretic Tablets 20/12.5 mg (Change of Marketing Authorization Holder; Addition of Drug Substance	Rovi Pharma Industrial Services SA VIA Complutense 140, Alcala De Henares (Madrid), E- 28805, Spain	Spain	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Manufacturer; Addition of Finished Product Manufacturing Site; Addition of Primary and Secondary Packaging Site; Addition of Quality Control Testing Site and Batch Testing Site; Downscaling of Finished Product Batch Size; Minor change of Manufacturing Process; Change of Secondary Artwork)			
Lynparza Film Coated Tablets 150 mg (New Indication; Update to Prescribing Information and Leaflet to reflect the change)	AbbVie Limited KM 58 Carretera 2 Cruce Davilia, Barceloneta, Puerto Rico 00617, United States of America Packaged by: Astrazeneca UK Limited Silk Road Business Park, Macclesfield, Chesire SK 102NA, United Kingdom For: Astrazeneca AB SE-151 85 Sodertalje, Sweden	United Kingdom	Third Schedule
Radomex Film Coated Tablets 90 mg	Micro Labs Limited Plot No.: S - 155 to S - 159 & N1, Verna Industrial Estate, Phase III & Phase IV, Verna Salcette, Goa 403 722, India	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Radomex Film Coated Tablets 120 mg	Micro Labs Limited Plot No.: S - 155 to S - 159 & N1, Verna Industrial Estate, Phase III & Phase IV, Verna Salcette, Goa 403 722, India	India	Third Schedule
Rivaroxaban Tablets 20 mg	Emcure Pharmaceuticals Limited Hinjawadi, Pune - 411057, India	India	Third Schedule

Dated this 21st day of October, 2024.

T. DEYALSINGH
Minister of Health

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