LEGAL NOTICE NO. 130

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
Hyland's Leg Cramps Quick Dissolving Tablets	Hyland's Consumer Health Inc. 13301 South Main Street, Los Angeles, CA, United States of America	United States of America	Freely
Hyland's Calms Forte Sleep Aid Tablets	Hyland's Consumer Health Inc. 13301 South Main Street, Los Angeles, CA, United States of America	United States of America	Freely
Ultra Magnesium Tablets	Vitabiotics Ltd 1 Apsley Way, London, NW2 7HF, England	United Kingdom	Freely
Perfectil Tablets	Vitabiotics Ltd 1 Apsley Way, London, NW2 7HF, England	United Kingdom	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Dabur Honitus Herbal Lozenges Orange Flavour	Lozen Pharma Pvt Ltd Raghav Estate KSSIDC Industrial Estate, Shiggaon Road, Savanur-584 118, India	India	Freely
Dabur Honitus Herbal Lozenges Mint Flavour	Lozen Pharma Pvt Ltd Raghav Estate KSSIDC Industrial Estate, Shiggaon Road, Savanur-584 118, India	India	Freely
Dabur Honitus Herbal Lozenges Lemon Flavour	Lozen Pharma Pvt Ltd Raghav Estate KSSIDC Industrial Estate, Shiggaon Road, Savanur-584 118, India	India	Freely
Dabur Honitus Herbal Lozenges Honey Flavour	Lozen Pharma Pvt Ltd Raghav Estate KSSIDC Industrial Estate, Shiggaon Road, Savanur-584 118, India	India	Freely
Dabur Honitus Herbal Lozenges Ginger Flavour	Lozen Pharma Pvt Ltd Raghav Estate KSSIDC Industrial Estate, Shiggaon Road, Savanur-584 118, India	India	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
ALBOVET-N Albendazole and Niclosamide Oral Suspension	International Health Care Limited D.No. 40-9-60, GFD, Kohinoor Apartments, Kalanagar, Opp: Trust Hospital, Near Benz circle, Vijayawada-520 010, A.P.-520010, India	India	Third Schedule (Veterinary Use Only)
IOMECT-R Ivermectin and Rafoxanide Oral Suspension	International Health Care Limited D.No. 40-9-60, GFD, Kohinoor Apartments, Kalanagar, Opp: Trust Hospital, Near Benz circle, Vijayawada- 520 010, A.P-520010, India	India	Freely (Veterinary Use Only)
I-PLEX DS Animal Feed Supplement	International Health Care Limited D.No. 40-9-60, GFD, Kohinoor Apartments, Kalanagar, Opp: Trust Hospital, Near Benz circle, Vijayawada- 520 010, A.P-520010, India	India	Third Schedule (Veterinary Use Only)
Super Endurance Oral Solution	Laboratories Tornel S.A de C.V Venustiano Carranza 24, Naucalpan de Juarez Centro,	Mexico	Freely (Veterinary Use Only)

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Naucalpan de Juarez, Mexico, C.P. 53000		
Sarna Sana Oily Solution	Laboratories Tornel S.A de C.V Venustiano Carranza 24, Naucalpan de Juarez Centro, Naucalpan de Juarez, Mexico, C.P. 53000	Mexico	Freely (Veterinary Use Only)
Minvit Forte Liquid 2.5%	Advance Aqua Bio Technologies India Private Limited "AABT HOUSE" Plot No. 62, P&T Colony-ll near Sai Baba Temple, Vijaywada-520008 Krishna District, A.P., India	India	Freely (Veterinary Use Only)
Super Vitamina B12 5500 Injectable Solution	Laboratorios Tornel S.A. De C.V Venustiano Carranza 24, Naucalpan de Juarez Centro, Naucalpan de Juarez, Mexico, C.P 53000	Mexico	Third Schedule (Veterinary Use Only)
Urolix Diuretico Injectable Solution	Laboratorios Tornel S.A. De C.V Venustiano Carranza 24, Naucalpan de Juarez Centro, Naucalpan de Juarez, Mexico, C.P 53000	Mexico	Third Schedule (Veterinary Use Only)

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Vitamin B12 3000 Injectable Solution	Laboratorios Tornel S.A. De C.V Venustiano Carranza 24, Naucalpan de Juarez Centro, Naucalpan de Juarez, Mexico, C.P 53000	Mexico	Third Schedule (Veterinary Use Only)
Buta-fenil Injectable Solution	Laboratorios Tornel S.A. De C.V Venustiano Carranza 24, Naucalpan de Juarez Centro, Naucalpan de Juarez, Mexico, C.P 53000	Mexico	Third Schedule (Veterinary Use Only)
Probio-50 Probiotic Capsules 650 mg	GB International 10651 N Kendall Drive Suite, 118 Miami Florida, 33176, United States of America	United States of America	Freely
Berberine 600 Enhanced with PQQ Capsules 600 mg	GB International 10651 N Kendall Drive Suite, 118 Miami Florida, 33176, United States of America	United States of America	Freely
Ashwagandha Capsules 500 mg	GB International 10651 N Kendall Drive Suite, 118 Miami Florida, 33176, United States of America	United States of America	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
T-XCEL Stamina Capsules 705 mg	GB International 10651 N Kendall Drive Suite, 118 Miami Florida, 33176, United States of America	United States of America	Freely
Omega ES Capsules 625 mg	GB International 10651 N Kendall Drive Suite, 118 Miami Florida, 33176, United States of America	United States of America	Freely
Atorvastatin Tablets 40 mg	Hetero Labs Limited Unit-V, Sy. No. 439, 440, 441 & 458, TSIIC Formulation SEZ, Polepalle Village, Jadcherla Mandal, Mahabubnagar District, Pincode 509301, Telangana State, India	India	Third Schedule
Fexofenadine Hydrochloride Tablets 180 mg	Hetero Labs Limited Unit-V, Sy. No. 439, 440, 441 & 458, TSIIC Formulation SEZ, Polepalle Village, Jadcherla Mandal, Mahabubnagar District, Pincode 509301, Telangana State, India	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Irbesartan Tablets 75mg	Hetero Labs Limited Unit-V, Sy. No. 439, 440, 441 & 458, TSIIC Formulation SEZ, Polepalle Village, Jadcherla Mandal, Mahabubnagar District, Pincode 509301, Telangana State, India	India	Third Schedule
Irbesartan Tablets 150 mg	Hetero Labs Limited Unit-V, Sy. No. 439, 440, 441 & 458, TSIIC Formulation SEZ, Polepalle Village, Jadcherla Mandal, Mahabubnagar District, Pincode 509301, Telangana State, India	India	Third Schedule
Irbesartan Tablets 300 mg	Hetero Labs Limited Unit-V, Sy. No. 439, 440, 441 & 458, TSIIC Formulation SEZ, Polepalle Village, Jadcherla Mandal, Mahabubnagar District, Pincode 509301, Telangana State, India	India	Third Schedule
Quetiapine Fumarate Tablets 100 mg	Hetero Labs Limited Unit-V, Sy. No. 439, 440, 441 & 458, TSIIC Formulation SEZ, Polepalle Village,	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Jadcherla Mandal, Mahabubnagar District, Pincode 509301, Telangana State, India		
Quetiapine Fumarate Tablets 200 mg	Hetero Labs Limited Unit-V, Sy. No. 439, 440, 441 & 458, TSIIC Formulation SEZ, Polepalle Village, Jadcherla Mandal, Mahabubnagar District, Pincode 509301, Telangana State, India	India	Third Schedule
Quetiapine Fumarate Tablets 300 mg	Hetero Labs Limited Unit-V, Sy. No. 439, 440, 441 & 458, TSIIC Formulation SEZ, Polepalle Village, Jadcherla Mandal, Mahabubnagar District, Pincode 509301, Telangana State, India	India	Third Schedule
Valacyclovir Hydrochloride Tablets 500 mg	Hetero Labs Limited Unit-V, Sy. No. 439, 440, 441 & 458, TSIIC Formulation SEZ, Polepalle Village, Jadcherla Mandal, Mahabubnagar District, Pincode 509301, Telangana State, India	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Valacyclovir Hydrochloride Tablets 1000 mg	Hetero Labs Limited Unit-V, Sy. No. 439, 440, 441 & 458, TSIIC Formulation SEZ, Polepalle Village, Jadcherla Mandal, Mahabubnagar District, Pincode 509301, Telangana State, India	India	Third Schedule
Irbesartan and Hydrochlorothiazide Tablets 300 mg/25 mg	Hetero Labs Limited Unit-V, Sy. No. 439, 440, 441 & 458, TSIIC Formulation SEZ, Polepalle Village, Jadcherla Mandal, Mahabubnagar District, Pincode 509301, Telangana State, India	India	Third Schedule
Sertraline Film Coated Tablets 100 mg	Hetero Labs Limited Unit-V, Sy. No. 439, 440, 441 & 458, TSIIC Formulation SEZ, Polepalle Village, Jadcherla Mandal, Mahabubnagar District, Pincode 509301, Telangana State, India	India	Third Schedule
Sertraline Film Coated Tablets 50 mg	Hetero Labs Limited Unit-V, Sy. No. 439, 440, 441 & 458, TSIIC Formulation SEZ,	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Polepalle Village, Jadcherla Mandal, Mahabubnagar District, Pincode 509301, Telangana State, India		
Donepezil Hydrochloride Tablets 5 mg	Hetero Labs Limited Unit-V, Sy. No. 439, 440, 441 & 458, TSIIC Formulation SEZ, Polepalle Village, Jadcherla Mandal, Mahabubnagar District, Pincode 509301, Telangana State, India	India	Third Schedule
Empagliflozin Tablets 10 mg	Annora Pharma Private Limited Sy. No 261, Annaram Village, Gummadidala Mandal, Sangareddy District, Pincode 502313, Telangana State, India	India	Third Schedule
Empagliflozin Tablets 25 mg	Annora Pharma Private Limited Sy. No 261, Annaram Village, Gummadidala Mandal, Sangareddy District, Pincode 502313, Telangana State, India	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Trihexyphenidyl Hydrochloride Tablets USP 2 mg	SGPharma Pvt. Ltd. 542, 3/10, Bhuta Niwas, Dr. Ambedkar Road, Matunga (E), Mumbai-400 019, India	India	Third Schedule
Bupivacaine Hydrochloride in Dextrose Injection, USP 5 mg + 80 mg/ml, 4 ml Vial	SGPharma Pvt. Ltd. 542, 3/10, Bhuta Niwas, Dr. Ambedkar Road, Matunga (E), Mumbai-400 019, India	India	Third Schedule
Chlorpromazine Hydrochloride Tablets USP 25 mg	SGPharma Pvt. Ltd. 542, 3/10, Bhuta Niwas, Dr. Ambedkar Road, Matunga (E), Mumbai-400 019, India	India	Third Schedule
Lidocaine Hydrochloride Injection USP 2% (20 mg/mL), (100 mg/5 ml)	Aspiro Pharma Limited Sy. No. 321, Biotech Park, Phase-III, Karkapatla Village, Markook Mandal, Siddipet District, Pincode 502281, Telangana State, India	India	Third Schedule
Imatinib Denk 400 mg Film-Coated Tablets	Haupt Pharma Amareg GmbH Donaustaufer Str. 378, 93055 Regensburg, Germany	Germany	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Imatinib Denk 100 mg Film-Coated Tablets	Haupt Pharma Amareg GmbH Donaustaufer Str. 378, 93055 Regensburg, Germany	Germany	Third Schedule
BETASERC®OD Modified Release Coated Tablets 48 mg	Abbott Laboratories de México, S.A de C.V. Calz de Tlalpan No.3092, COL. Ex Hacienda Coapa, C.P. 04980, Coyoacán, Ciudad de México, México For: Abbott Healthcare Costa Rica Sociedad Anonima, Costa Rica	Mexico	Third Schedule
Triam-Denk 40 Injection (Triamcinolone acetonide 40 mg/ml Suspension for Injection)	Fisiopharma S.R.L. Nucleo Industriale 84020 Palomonte (SA), Italy For: Denk Pharma GmbH & Co. KG Prinzregentenstr. 79 81675 München, Germany	Germany	Third Schedule
Tramadol Denk 50 mg Effervescent Tablets	Losan Pharma GmbH Otto-Hahn-Str. 13, 79395 Neuenburg, Germany	Germany	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
APREPITANT 125 mg and APREPITANT 80 mg Capsules	Pharmathen International S.A Block No. 5, Sapes Rodopi Prefecture, Industrial Park, Sapes 693 00, Greece	Greece	Third Schedule
Intimate Rose Boric Balance for Feminine Support Vaginal Suppositories	Aviva Natural Supplements LLC 26 Van Dyke Avenue, New Brunswick, NJ 08901, United States of America	United States of America	Freely
Imbruvica Film-Coated Tablets 140 mg	Cilag AG Hochstrasse 201, 8200 Schaffhausen, Switzerland Packaged by: Janssen-Cilag S.P.A Via C. Janssen, Loc Borgo S. Michele, 04100 Latina, Italy	Italy	Third Schedule
Imbruvica Film-Coated Tablets 420 mg	Cilag AG Hochstrasse 201, 8200 Schaffhausen, Switzerland Packaged by: Janssen-Cilag S.P.A Via C. Janssen, Loc Borgo S. Michele, 04100 Latina, Italy	Italy	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Imbruvica Film-Coated Tablets 560 mg	Cilag AG Hochstrasse 201, 8200 Schaffhausen, Switzerland Packaged by: Janssen-Cilag S.P.A Via C. Janssen, Loc Borgo S. Michele, 04100 Latina, Italy	Italy	Third Schedule
Simulect® 20 mg Powder for Solution for Injection/Infusion (Alternative Manufacturer; Alternative Packager; Change of Secondary Artwork; Change of Distributor)	Novartis Pharma Stein AG Schaffhauserstrasse 4332 Stein, Switzerland Alternative Manufacturer: Patheon Italia S.P.A. Viale G.B. Stucchi, 110-20900 Monza (MB), Italy Alternative Packager: Delpharm Dijon 6 Boulevard De L Europe Quetigny, 21800, France For: Novartis Pharma AG Basel, Switzerland	France	Third Schedule
Aerius® 0.5 mg/ml Syrup (Change of Name of Manufacturer and Packager; Artwork Update to reflect change)	Organon Heist bv Industriepark 30, 2220 Heist-op-den-Berg, Belgium	Belgium	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Calquence Film Coated Tablets 100 mg	AstraZeneca AB Gartunavagen, Sodertalje, 152 57, Sweden	Sweden	Third Schedule
Diprosalic Ointment 15 g (Change of Name of Marketing Authorization Holder, Manufacturer and Packager; Artwork Update to reflect change)	Organon Heist bv Industriepark 30, 2220 Heist-op-den-Berg, Belgium	Belgium	Third Schedule
Nasonex Aqueous Nasal Spray 0.05% - Scent Free (Change of Name of Marketing Authorization Holder, Manufacturer and Packager; Artwork Update to reflect change)	Organon Heist bv Industriepark 30, 2220 Heist-op-den-Berg, Belgium	Belgium	Third Schedule
Rilutek Film-Coated Tablets 50 mg (Update of Primary Artwork, Secondary Artwork and Patient Leaflet)	Opella Healthcare International SAS 56 route de Choisy au bac 60200 Compiegne, France	France	Third Schedule
Exforge HCT Film-Coated Tablets 5 mg/160 mg/12.5 mg (Additional Manufacturing and Packaging Site; Artwork Update to reflect change)	Siegfried Barbera, S.L. Ronda de Santa Maria 158 08210 BARBERÁ DEL VALLÉS (Barcelona) Additional Manufacturer and Packager: Novartis Farma S.p.A. Via Provinciale Schito 131, 80058 Torre	Italy	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Annunziata (NA), Italy		
Exforge HCT Film-Coated Tablets 5 mg/160 mg/25 mg (Additional Manufacturing and Packaging Site; Artwork Update to reflect change)	Siegfried Barbera, S.L. Ronda de Santa Maria 158 08210 BARBERÁ DEL VALLÉS (Barcelona) Additional Manufacturer and Packager: Novartis Farma S.p.A. Via Provinciale Schito 131, 80058 Torre Annunziata (NA), Italy	Italy	Third Schedule
Exforge HCT Film-Coated Tablets 10 mg/160 mg/12.5 mg (Additional Manufacturing and Packaging Site; Artwork Update to reflect change)	Siegfried Barbera, S.L. Ronda de Santa Maria 158 08210 BARBERÁ DEL VALLÉS (Barcelona) Additional Manufacturer and Packager: Novartis Farma S.p.A. Via Provinciale Schito 131, 80058 Torre Annunziata (NA), Italy	Italy	Third Schedule
Exforge HCT Film-Coated Tablets 10 mg/160 mg/25 mg (Additional Manufacturing and Packaging Site; Artwork Update to reflect change)	Siegfried Barbera, S.L. Ronda de Santa Maria 158 08210 BARBERÁ DEL VALLÉS (Barcelona) Additional Manufacturer and Packager: Novartis Farma S.p.A	Italy	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Via Provinciale Schito 131, 80058 Torre Annunziata (NA), Italy		
Exforge HCT Film-Coated Tablets 10 mg/320 mg/25 mg (Additional Manufacturing and Packaging Site; Artwork Update to reflect change)	Siegfried Barbera, S.L. Ronda de Santa Maria 158 08210 BARBERÁ DEL VALLÉS (Barcelona) Additional Manufacturer and Packager: Novartis Farma S.p.A. Via Provinciale Schito 131, 80058 Torre Annunziata (NA), Italy	Italy	Third Schedule
Imjudo 20 mg/ml (15 ml vial) Concentrate for Solution for Infusion	Vetter Pharma - Fertigung GmbH & Co. KG Mooswiesen 2, 88214 Ravensburg, Germany For: Astrazeneca AB Gartunavagen, Sodertalje 151 85, Sweden, Forkskargaten 18, Sodertalje 151 36, Sweden	Germany	Third Schedule
Imjudo 20 mg/ml (1.25 ml vial) Concentrate for Solution for Infusion	Vetter Pharma - Fertigung GmbH & Co. KG Mooswiesen 2, 88214 Ravensburg, Germany	Germany	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	For: Astrazeneca AB Gartunavagen, Sodertalje 151 85, Sweden, Forkskargaten 18, Sodertalje 151 36, Sweden		
LUMIGAN™ (Bimatoprost Ophthalmic Solution) 0.01% (Additional Manufacturer; Change of Marketing Authorization Holder; Change of Artwork)	Allergan Sales, LLC 8301 Mars Drive, Waco, TX 76712, United States of America Additional Manufacturer: Allergan Pharmaceuticals Ireland Castlebar Road, Westport, Co. Mayo, Ireland	Ireland	Third Schedule
PRED FORTE® Ophthalmic Suspension 1% (Additional Manufacturer; Change of Marketing Authorization Holder; Change of Artwork)	Allergan Sales, LLC 8301 Mars Drive, Waco, TX 76712, United States of America Additional Manufacturer: Allergan Pharmaceuticals Ireland Castlebar Road, Westport, Co. Mayo, Ireland	Ireland	Third Schedule
Alka AD Tablets 2 mg	Bayer S.A. 14.5 Carretera Roosevelt, zona 3, Mixco, Guatemala	Guatemala	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
VILZER (Vildagliptin) Tablets 50 mg	MONTE VERDE S.A. Ruta Nacional N° 40 s/n° esq. Calle 8, Departamento de Pocito, Provincia de San Juan, República Argentina Secondary Packager: Adium Pharma S.A. Ruta 6 KM 17.500 Local 320-Zona Franca Montevideo, Republica Oriental del, Uruguay	Uruguay	Third Schedule
Lyrica Capsules 25 mg (Update to Product's Monograph – New Indication)	Pfizer Manufacturing Deutschland GmbH Betriebsstatte Freiburg Mooswaldallee 1 79090 Freiburg, Germany	Germany	Third Schedule
Lyrica Capsules 300 mg (Update to Product's Monograph – New Indication)	Pfizer Manufacturing Deutschland GmbH Betriebsstatte Freiburg Mooswaldallee 1 79090 Freiburg, Germany	Germany	Third Schedule
Lyrica Capsules 150 mg (Update to Product's Monograph - New Indication)	Pfizer Manufacturing Deutschland GmbH Betriebsstatte Freiburg Mooswaldallee 1 79090 Freiburg, Germany	Germany	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Lyrica Capsules 75 mg (Update to Product's Monograph – New Indication)	Pfizer Manufacturing Deutschland GmbH Betriebsstatte Freiburg Mooswaldallee 1 79090 Freiburg, Germany	Germany	Third Schedule
Aldactone Tablets 100 mg (Packaging and Artwork Update)	Piramal Healthcare UK Limited Whalton Road, Morpeth, Northumberland, NE61 3YA, United Kingdom	United Kingdom	Third Schedule
Fanter Coated Tablets 10 mg	MONTE VERDE S.A Argentina Ruta Nacional N 40° s/n° Calle 8, Departamento de Pocito Provincia de San Juan, República Argentina	Argentina	Third Schedule
Febuday 40 (Febuxostat Tablets 40 mg)	MSN Laboratories Private Limited Formulations Division Unit-II, Sy. No. 1277 & 1319 to 1324, Nandigama (Village & Mandal), Telangana, India	India	Third Schedule
Febuday 80 (Febuxostat Tablets 80 mg)	MSN Laboratories Private Limited Formulations Division Unit-II, Sy. No. 1277 & 1319 to 1324,	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Nandigama (Village & Mandal), Telangana, India		
Bortezomib Powder for Solution for Injection 3.5 mg/vial	MSN Laboratories Private Limited Formulations Division Unit-II, Sy. No. 1277 & 1319 to 1324, Nandigama (Village & Mandal), Telangana, India	India	Third Schedule
Apixaban Tablets 2.5 mg	MSN Laboratories Private Limited Formulations Division Unit-II, Sy. No. 1277 & 1319 to 1324, Nandigama (Village & Mandal), Telangana, India	India	Third Schedule
Apixaban Tablets 5 mg	MSN Laboratories Private Limited Formulations Division Unit-II, Sy. No. 1277 & 1319 to 1324, Nandigama (Village & Mandal), Telangana, India	India	Third Schedule
Empagliflozin Tablets 10 mg	MSN Laboratories Private Limited Formulations Division Unit-II, Sy. No. 1277 & 1319 to 1324,	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Nandigama (Village & Mandal), Telangana, India		
Empagliflozin Tablets 25 mg	MSN Laboratories Private Limited Formulations Division Unit-II, Sy. No. 1277 & 1319 to 1324, Nandigama (Village & Mandal), Telangana, India	India	Third Schedule
Zoledronic Acid for Injection 4 mg	Caplin Point R.S. No. 85/3, Suthukeny Village, Mannadipet Commune Panchayat, Puducherry - 605502, India Laboratories Ltd, India Marketed by: Juvencia Lifesciences Ahmedabad-380060 Gujarat, India	India	Third Schedule
Labetalol Injection BP 5 mg/ml	Caplin Point R.S. No. 85/3, Suthukeny Village, Mannadipet Commune Panchayat, Puducherry - 605502, India Laboratories Ltd, India Marketed by:	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Juvencia Lifesciences Ahmedabad-380060 Gujarat, India		
Octreotide Solution for Injection 0.1 mg/ml	Caplin Point R.S. No. 85/3, Suthukeny Village, Mannadipet Commune Panchayat, Puducherry - 605502, India Laboratories Ltd, India Marketed by: Juvencia Lifesciences Ahmedabad-380060 Gujarat, India	India	Third Schedule
Azaglin 10 (Dapagliflozin Tablets 10 mg)	Emcure Pharmaceuticals Limited Hinjawadi, Pune - 411057, India	India	Third Schedule
Rivaroxaban Tablets 10 mg	Emcure Pharmaceuticals Limited Hinjawadi, Pune - 411057, India	India	Third Schedule
Rivaroxaban Tablets 15 mg	Emcure Pharmaceuticals Limited Hinjawadi, Pune - 411057, India	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Alfa Multivitamin Gummy Bears for Kids	Alfa Vitamins Laboratories Inc. 4701 N.W. 77th Avenue, Miami Fl 33166, United States of America	United States of America	Freely
Sandostatin LAR Powder and Solvent for Suspension for Injection 30 mg (Change of Manufacturer; Change of Packager; Change of Country of Origin; Update of Secondary Artwork to reflect changes)	Novartis Pharmaceutical Manufacturing GmbH Biochemistraße 10, 6336 Langkampfen, Austria Packaged by: Abbott Biologicals B.V. Veerweg 12, 8121 AA Olst, The Netherlands For: Novartis Pharmaceutical AG Basel, Switzerland	The Netherlands	Third Schedule
Rosustar® 10 mg Film-Coated Tablets (Change of Manufacturer; Change of Secondary Artwork)	Lek S.A. Podlipie Str. 16, 95-010 Stryków, Poland Packaged by: Lek Pharmaceuticals d.d. Trimlini 2D, 9220 Lendava, Slovenia For: Sandoz GmbH Biochemiestrasse 10, 6250 Kundl-Austria	Slovenia	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Rosustar® 20 mg Film-Coated Tablets (Change of Manufacturer; Change of Secondary Artwork)	Lek S.A. Podlipie Str. 16, 95-010 Stryków, Poland Packaged by: Lek Pharmaceuticals d.d. Trimlini 2D, 9220 Lendava, Slovenia For: Sandoz GmbH Biochemiestrasse 10, 6250 Kundl-Austria	Slovenia	Third Schedule
Rosustar® 40 mg Film-Coated Tablets (Change of Manufacturer; Change of Secondary Artwork)	Lek S.A. Podlipie Str. 16, 95-010 Stryków, Poland Packaged by: Lek Pharmaceuticals d.d. Trimlini 2D, 9220 Lendava, Slovenia For: Sandoz GmbH Biochemiestrasse 10, 6250 Kundl-Austria	Slovenia	Third Schedule
Zometa Concentrate for Solution for Infusion (Change of Packager; Change of Country of Origin; Change of Artwork to reflect changes)	Fresenius Kabi Austria GmbH Hafnerstrasse 36, A-8055 Graz, Austria Packaged by:	Switzerland	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Novartis Pharma Stein AG Schaffhauserstrasse, 4332 Stein, Switzerland For: Novartis Pharmaceutical AG Basel, Switzerland		
Allegra Pediatric 30 mg/5 ml Suspension	Sanofi Medley Farmaceutica Ltda. Rua Conde Domingos Papaiz, 413 Suzano, São Paulo, Brazil	Brazil	Freely
Dasatinib 70 mg Film-Coated Tablets	Remedica Ltd. Aharnon Street, Limassol Industrial Estate, 3056 Limassol, Cyprus For: Sandoz GmbH Kundl-Austria	Cyprus	Third Schedule
Dasatinib 100 mg Film-Coated Tablets	Remedica Ltd. Aharnon Street, Limassol Industrial Estate, 3056 Limassol, Cyprus For: Sandoz GmbH Kundl-Austria	Cyprus	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Taflinar® 75 mg Hard Capsules	Lek Pharmaceuticals d.d. Verovskova Ulica 57, Ljubljana, 1526, Slovenia For: Novartis Pharma AG Basel, Switzerland	Slovenia	Third Schedule
Femara Film Coated Tablets 2.5 mg (Change of Manufacturer and Packaging Site, Update of Secondary Artwork to reflect change)	Novartis Farma S.P.A Via Provinciale Schito 131-80058 Toree, Annunziata, Italy For: Novartis Pharma AG Basel, Switzerland	Italy	Third Schedule
EspritVita Berberine Capsules 600 mg	Pharma Natural Inc. 14500 NW 60th Ave Miami Lakes, FL33014, United States of America Manufactured for: EspritVita 8336 NW 68th Street Miami FL 33166, United States of America	United States of America	Freely
EspritVita Collagen Peptides & Hyaluronic Acid Capsules	Pharma Natural Inc. 14500 NW 60th Ave Miami Lakes, FL33014, United States of America Manufactured for: EspritVita	United States of America	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	8336 NW 68th Street Miami FL 33166, United States of America		
Evening Primrose Max Strength Softgels 1300 mg	Nature's Way 825 Challenger Dr, Green Bay, WI 54311 #318506, United States of America	United States of America	Freely
Sambucus Traditional Immune Syrup	Nature's Way 825 Challenger Dr, Green Bay, WI 54311 #318506, United States of America	United States of America	Freely
Sambucus Elderberry Immune Support Gummy	Nature's Way 825 Challenger Dr, Green Bay, WI 54311 #318506, United States of America	United States of America	Freely
Alive! Men's 50+ Multivitamin Gummy	Nature's Way 825 Challenger Dr, Green Bay, WI 54311 #318506, United States of America	United States of America	Freely
Bell Lifestyle Blood Sugar Metabolism Capsules	Acenzia Inc. 1580 Rossi Drive Oldcastle, Ontario N9G 0B8, Canada	Canada	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Bell Lifestyle Cholesterol Control Capsules	Acenzia Inc. 1580 Rossi Drive Oldcastle, Ontario N9G 0B8, Canada	Canada	Freely
Bell Lifestyle Allergy Relief Capsules	Bell Lifestyle Products Inc 3155 Pepper Mill Crt. Unit 4, Mississauga, ON L5L 4X7, Canada	Canada	Freely
MISOL Film Coated Tablets 50 mg	Nobel Ilac Sanayii ve Ticaret A.S. Sancaklar Mah. Eski Akcakoca Cad. No:229 81100 Duzce, Turkey	Turkey	Third Schedule
Puritan's Pride High Potency Magnesium 500 mg Tablets	Puritan's Pride, Inc. 2100 Smithtown Ave, Ronkonkoma, NY, United States of America 11779	United States of America	Freely
Puritan's Pride Super Strength Melatonin 10 mg Capsules	Puritan's Pride, Inc. 2100 Smithtown Ave, Ronkonkoma, NY, United States of America 11779	United States of America	Freely
Puritan's Pride Lutigold™ Lutein 20 mg Softgels	Puritan's Pride, Inc. 2100 Smithtown Ave, Ronkonkoma, NY,	United States of America	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	United States of America 11779		
Puritan's Pride L-Lysine 500 mg Caplets	Puritan's Pride, Inc. 2100 Smithtown Ave, Ronkonkoma, NY, United States of America 11779	United States of America	Freely
Puritan's Pride L-Carnitine 500 mg Caplets	Puritan's Pride, Inc. 2100 Smithtown Ave, Ronkonkoma, NY, United States of America 11779	United States of America	Freely
Benjie's Pain Relief Spray	V & S Pharmaceutical Ltd Lot 38 Frederick Settlement Industrial Park, Caroni, Trinidad	Trinidad and Tobago	Freely
ZYRISP 1 (Risperidone Tablets USP 1 mg)	Zydus Lifesciences Limited Kundaim Industrial Estate, Plot No. 203-213, Kundaim, Goa - 403 115, India	India	Controlled
ZYRISP 2 (Risperidone Tablets USP 2 mg)	Zydus Lifesciences Limited Kundaim Industrial Estate,	India	Controlled

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Plot No. 203-213, Kundaim, Goa - 403 115, India		
Parin-E (Enoxaparin Sodium Injection BP 60 mg/0.6 ml) Injection	Venus Remedies Limited Hill Top Industrial Estate, Jharmajri, EPIP Phase-1 (Extn), Bhatoli Kalan, Baddi, Distt, Solan, Himachal Pradesh, 173205, India	India	Third Schedule
Relvar Ellipta Inhalation Powder 200 mcg/25 mcg (Addition of an Alternate Manufacturing Site; Change in Secondary Artwork, Primary Artwork and Package Insert to reflect the change)	GlaxoSmithKline LLC 1011 North Arendell Avenue, Zebulon, North Carolina 27597, United States of America	United States of America	Third Schedule
Relvar Ellipta Inhalation Powder 100 mcg/25 mcg (Addition of an Alternate Manufacturing Site; Change in Secondary Artwork, Primary Artwork and Package Insert to reflect the change)	GlaxoSmithKline LLC 1011 North Arendell Avenue, Zebulon, North Carolina 27597, United States of America	United States of America	Third Schedule
Boostrix Suspension for Injection (Addition of an Additional Filling, Formulation and	GlaxoSmithKline Biologicals 637, rue des Aulnois,	France	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Packaging Site; Editorial Change to Summary Product Characteristics; Artwork Change - New GSK Logo)	Saint-Amand-Les-Eaux, 59230, France		
Paxil Coated Tablets 20 mg	Delpharm Poznań Spółka Akcyjna, 189 Grunwaldzka street, 60-322 Poznań, Poland	Poland	Third Schedule
Nature's Truth Restore and Unwind Ashwagandha Gummies 500 mg	Nature's Truth, LLC 3900 Veterans Memorial Highway, Bohemia, NY 11716, United States of America	United States of America	Freely
Nature's Truth Hair, Skin and Nails Biotin Gummies 2,500 mcg	Nature's Truth, LLC 3900 Veterans Memorial Highway, Bohemia, NY 11716, United States of America	United States of America	Freely
Nature's Truth Women's Multivitamin & Collagen Gummies	Nature's Truth, LLC 3900 Veterans Memorial Highway, Bohemia, NY 11716, United States of America	United States of America	Freely
Nature's Truth Apple Cider Vinegar Gummies 600 mg	Nature's Truth, LLC 3900 Veterans Memorial Highway, Bohemia, NY 11716, United States of America	United States of America	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Nature's Truth Essential Iron + B-Vitamins & Zinc Gummies 500 mg	Nature's Truth, LLC 3900 Veterans Memorial Highway, Bohemia, NY 11716, United States of America	United States of America	Freely
Ibuprofen Oral Suspension 100 mg/5 ml	THORPE LABORATORIES LIMITED Golf Road Industrial Estate, Mable Thorpe, LN1 21NB, United Kingdom	United Kingdom	Freely
Duo-2 Eye Drops	Hanuchem Laboratories Ind. Area, Plot No. 13, Sec-5, Parwanoo, Distt. Solan, (H.P.), India	India	Third Schedule
Joint Aid Capsules	Biotrex Nutraceuticals Survey No 419/4 Plot No 10/11 Radhe Industrial Estate Tajpur Road Changodar Ahmedabad, India	India	Freely
Amlopres-10 (Amlodipine Besilate) 10 mg Tablets (Addition of a Manufacturing Site)	Cipla Ltd Village Malpur, Baddi, Distt. Solan (H.P.), India	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Energy + Syrup (Multivitamin & Amino Acid Syrup)	Sanpras Healthcare Pvt. Ltd. Plot No.81, S.T.I.C.E, Musalgaon, Tal, Sinnar, Nashik – 422112, Maharashtra State, India	India	Freely
EZ Melts Calcium & Magnesium Oral Dissolvable Tablets (Change in Name of Product; Change in Commercial Presentation; Update to Primary Artwork to reflect changes)	Solara Labs 5105 Nw 159th St, Miami Lakes, Florida 33014, United States of America	United States of America	Freely
Menopur 75 IU Powder and Solvent for Solution for Injection (Addition of Alternative Solvent Manufacturer; Change of Secondary Artwork)	Powder Manufacturer and Marketing Authorization Holder: Ferring GmbH Wittland 11, D-24109, Kiel, Germany Solvent Manufacturer: Zentiva, k.s. U kabelovny 130, 102 37 Praha 10 - Dolní Měcholupy, Czech Republic and Haupt Pharma Wülfing GmbH, Bethelner Landstr.18, 31028 Gronau, Germany	Czech Republic	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Packaged by: Ferring Léčiva, a.s. Ke Skále 455, 252 50 Vestec, Czech Republic		
Choragon Powder and Solvent for Injection 5000 IU (Addition of Alternative Solvent Manufacturer; Change of Secondary Artwork)	Powder Manufacturer and Marketing Authorization Holder: Ferring GmbH Wittland 11, D-24109, Kiel, Germany Solvent Manufacturer: Zentiva, k.s. U kabelovny 130, 102 37 Praha 10 - Dolní Měcholupy, Czech Republic and Haupt Pharma Wülfing GmbH, Bethelner Landstr.18, 31028 Gronau, Germany Packaged by: Ferring Léčiva, a.s. Ke Skále 455, 252 50 Vestec, Czech Republic	Czech Republic	Third Schedule
Floravital (Bacillus Clausii Spores Suspension 2 Billion Spores/5 mL)	Aarmed Formulations PVT Ltd Survey No. 431/2 Plot No. 1 Steel town, Moraiva Tal Sanand Dist, Ahmedabad Gujarat state, India	India	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Natrol Glucosamine, Chondroitin & MSM Tablets	Natrol LLC Chatsworth, CA, 91311, United States of America For: NATROL LLC Sherman Oaks, CA 91403, United States of America	United States of America	Freely

Dated this 17th day of July, 2024.

T. DEYALSINGH
Minister of Health

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