Legal Notice No. 153

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
Anzavir-R Tablets 300mg/100mg	Mylan Laboratories Ltd.	India	Third Schedule
Ritonavir Tablets 100mg	do.	do.	do.
Abacavir Sulfate Tablets 60mg	do.	do.	do.
Abacavir Sulfate/Lamivudine Tablets 60mg/30mg	do.	do.	do.
Abacavir Sulfate/Lamivudine Tablets 600mg/300mg	do.	do.	do.
Lopinavir/Ritonavir Film- Coated Tablets 200mg/50mg (Change of Name of Manufacturer and Change of Process for Premix)	do.	do.	do.
Lucentis Solution for Injection 10mg/ml (Additional Indication)	Manufactured by: Novartis Pharma Stein AG, for: Novartis Pharma AG Switzerland	Switzerland	do.
Ciproxina Solution for Infusion 0.2g (Change of Packaging Site and Change of Mass)	Bayer Pharma AG	Germany	do.

Trade Name and Form	Manufacturer	Country of Origin	Condition of Sale
Ciproxina Solution for Infusion 0.4g (Change of Packaging Site and Change of Mass)	Bayer Pharma AG	Germany	Third Schedule
Humira 40mg/0.8ml pre-filled pen (Change of Name of Manufacturer, Additional Source and New Indications)	Abbvie	USA	do.
Humira 40mg/0.8ml pre-filled syringe (Change of Name of Manufacturer, Additional Source and New Indications)	do.	do.	do.
Gadovist Solution for Injection 1.0mmol/ml (Change of Name of Marketing Authorisation Holder, Manufacturer and Packager and Addition of a New Indication)	Bayer AG	Germany	do.
Actemra Concentrate for Solution for Infusion 20mg/ml (80mg/4ml) (Additional Indications)	Manufactured by: Chugai Pharma Manufacturing Co. Ltd. for: F. Hoffmann- La Roche Ltd. Switzerland	Japan	do.
Actemra Concentrate for Solution for Infusion 20mg/ml (200mg/10ml) (Additional Indications)	do.	do.	do.
Actemra Concentrate for Solution for Infusion 20mg/ml (400mg/20ml) (Additional Indications)	do.	do.	do.
Cervarix Vaccine Suspension for Injection (Change in Dosage and Change in Indication)	GlaxoSmithKline Biologicals S.A.	Belgium	do.

Trade Name and Form	Manufacturer	Country of Origin	Condition of Sale
Triplixam Film-Coated Tablets 10mg/2.5mg/10mg	Servier (Ireland) Industries Ltd (SII) for: Les Laboratoires Servier France	Ireland	Third Schedule
Triplixam Film-Coated Tablets 5mg/1.25mg/5mg	do.	do.	do.
Triplixam Film-Coated Tablets 10mg/2.5mg/5mg	do.	do.	do.
Triplixam Film-Coated Tablets 5mg/1.25mg/10mg	do.	do.	do.
Dixisol Injection B.P. 250mcg/ml, 1ml Ampoule	SGPharma Pvt. Ltd.	India	do.
Digoxin Tablets USP 0.25mg	do.	do.	do.
Avastin Concentrate for Solution for Infusion 100mg/4ml (New Indication)	Manufactured by: Roche Diagnostics GmbH for: F. Hoffmann- La Roche Ltd., Switzerland	Germany	do.
Avastin Concentrate for Solution for Infusion 400mg/16ml (New Indication)	do.	do.	do.
Revolade Film-Coated Tablets 25mg (Additional Indication)	Glaxo Operations UK Limited, UK Packed by: Glaxo Wellcome S.A.	Spain	do.
Revolade Film-Coated Tablets 50mg (Additional Indication)	do.	do.	do.
Preva–75 Film-Coated Tablets (Change of Formulation)	Intas Pharmaceuticals Ltd.	India	do.
Perjeta Concentrate for Solution for Infusion 420mg/14ml (New Indication)	Roche Diagnostics GmbH, Mannheim	Germany	do.

Trade Name and Form	Manufacturer	Country of Origin	Condition of Sale
Avastin Concentrate for Solution for Infusion 100mg/4ml (New Indication)	Roche Diagnostics GmbH Mannheim	Germany	Third Schedule
Avastin Concentrate for Solution for Infusion 400mg/16ml (New Indication)	do.	do.	do.
Enbrel Powder and Solvent for Solution for Injection 25mg (New Indication)	Boehringer Ingelheim Pharma, KG Birkendorfer, Germany Secondary Packager: Wyeth Pharmaceuticals, New Lane, Havant	United Kingdom	do.
Enbrel Solution for Injection in Pre-filled Syringe 50mg (New Indication)	Pfizer Ireland Pharmaceuticals, Grange Castle Business Park, Ireland Packaged by: Vetter Pharma- Fertigung GmbH & Co. KG, Langenargen Germany Secondary Packager: Wyeth Pharmaceuticals, New Lane, Havant	do.	do.
Prevenar 13® Pnuemococcal 13–Valent Conjugate Vaccine (Diphtheria CRM197 Protein) (New Indication)	Pfizer Ireland Pharmaceuticals, Grange Castle Business Park, Ireland Secondary Packager: Wyeth Pharmaceuticals, New Lane, Havant	do.	do.
Stivarga Film-Coated Tablets 40mg (New Indication)	Bayer AG	Germany	do.
Herceptin Injection 440mg (Change of Additional Manufacturing Site)	Genentech Inc. Hillsboro, Oregon	USA	do.

Trade Name and Form	Manufacturer	Country of Origin	Condition of Sale
Trade Ivanie and Form	manufacturer	Country of Origin	Condition of Sale
Lamictal Dispersible/Chewable Tablets 2mg	Manufacturer: GlaxoSmithKline LLC, USA Packaged by: GlaxoSmithKline Pharmaceuticals S.A.	Poland	Third Schedule
Genotropin Lyophilized Powder and Solvent for Injection 16 IU (5.3mg)–Two Chamber Cartridge and Pre-filled Pen Go Quick (Change of Product Name, Change of Manufacturer, Change of Importer, Addition of Presentation, Change of Shelf Life and Change of Artwork Design)	Pfizer Manufacturing Belgium N.V. for: Pfizer S.A., Belgium	Belgium	do.
Genotropin Lyophilized Powder and Solvent for Injection 36 IU (12mg)–Two Chamber Cartridge and Pre-filled Pen Go Quick (Change of Product Name, Change of Manufacturer, Change of Importer, Addition of Presentation, Change of Shelf Life and Change of Artwork Design)	do.	do.	do.
Simponi Solution for Injection in Pre-filled Pen 50mg/0.5ml (Additional Indication)	Baxter Pharmaceutical Solutions LLC, USA Packaged by: Cilag AG	Switzerland	do.
Simponi Solution for Injection in Pre-filled Pen 100mg/1ml (Additional Indication)	do.	do.	do.
Lamictal Dispersible/Chewable Tablets 5mg	Manufacturer: GlaxoSmithKline Pharmaceuticals S.A., Poland Packaged by: GlaxoSmithKline S.A. de C.V.	Mexico	do.

Trade Name and Form	Manufacturer	Country of Origin	Condition of Sale
Myborte Bortezomib for Injection 3.5mg/vial	Dr. Reddy's Laboratories Ltd.	India	Third Schedule
Podoxred Pemetrexed for Injection 100mg/vial	do.	do.	do.
Docetere 80 Docetaxel Injection USP 80mg/4ml	do.	do.	do.
Docetere 20 Docetaxel Injection USP 20mg/ml	do.	do.	do.
Eranfu Fulvestrant Injection 250mg/5ml (50mg/ml)	do.	do.	do.
Covonia Chesty Cough Sugar Free Syrup	Thornton and Ross Ltd.	UK	Freely
Ocrevus Concentrate for Solution for Infusion 300mg/10ml	Roche Diagnostics GmbH, Mannheim Germany for: F. Hoffmann- La Roche Ltd., Basel, Switzerland Packed by: (Secondary) F. Hoffmann- La Roche Ltd., Kaiseraugst	Switzerland	Third Schedule
Tecentriq Concentrate for Solution for Infusion 1200mg/20ml	do.	do.	do.
Alecensa Hard Capsules 150mg	Excella GmbH, Feucht, Germany for: F. Hoffmann- La Roche Ltd., Basel, Switzerland Packed by: Delpharm Milano S.r.l., Segrate, Milan	Italy	do.

Trade Name and Form	Manufacturer	Country of Origin	Condition of Sale
Cotellic Film Coated Tablets 20mg	F. Hoffmann- La Roche Ltd., Basel, Switzerland Packed by: Delpharm, Milano S.r.l. Segrate, Milan	do.	Third Schedule
Hemlibra Solution for Subcutaneous Injection 30mg/1ml	Chugai Pharma Manufacturing Co. Ltd., Utsunomiya- city for: F. Hoffmann- La Roche Ltd., Basel, Switzerland	Japan	do.
Hemlibra Solution for Subcutaneous Injection 60mg/0.4ml	do.	do.	do.
Hemlibra Solution for Subcutaneous Injection 105mg/0.7ml	do.	do.	do.
Hemlibra Solution for Subcutaneous Injection 150mg/1ml	do.	do.	do.
Canesten V Vaginal Ovules 100mg	Catalent Argentina S.A.I.C., Argentina for: Bayer S.A. Guatemala Packaged by: Bayer S.A.	Guatemala	Freely
Canesten V Vaginal Ovules 200mg	do.	do.	do.
Abasaglar Solution for Injection in a pre-filled pen KwikPen 100 units/mL	Manufactured and Packaged by: Lilly France S.A.S., Fergersheim	France	Third Schedule
Zyprexa Coated Tablets 5mg	Lilly S.A., Alcobendas, Madrid	Spain	do.

Trade Name and Form	Manufacturer	Country of Origin	Condition of Sale
Centrum Gender Men Tablets	Holder/ Manufacturer & Packager: Pfizer Canada Inc.	Canada	Freely
Centrum Gender Women Tablets	do.	do.	do.
Apo-Deferasirox Dispersible Tablets for Oral Suspension 500mg	Apotex Inc.	do.	Third Schedule
Apo-Deferasirox Dispersible Tablets for Oral Suspension 250mg	do.	do.	do.
Apo-Deferasirox Dispersible Tablets for Oral Suspension 125mg	do.	do.	do.
Apo-Atorvastatin Tablets 80mg	do.	do.	do.
Apo-Olopatadine Ophthalmic Solution USP 0.2%w/v	do.	do.	do.
Apo-Emtricitabine-Tenofovir Tablets 200mg/300mg	do.	do.	do.
Apo-Travoprost Z Ophthalmic Solution USP 0.004% w/v	do.	do.	do.
Apo-Erlotinib Tablets 150mg	do.	do.	do.
Apo-Methylphenidate ER Tablets 36mg	do.	do.	do.
Apo-Methylphenidate ER Tablets 18mg	do.	do.	do.
Apo-Duloxetine Delayed Release Capsules USP 60mg	do.	do.	do.
Apo-Domperidone Tablets 10mg	do.	do.	do.

Trade Name and Form	Manufacturer	Country of Origin	Condition of Sale
Apo-Tenofovir Tablets 300mg	Apotex Inc.	Canada	Third Schedule
Apo-Tadalafil Tablets 5mg	do.	do.	do.
Apo-Sildenafil Tablets 25mg	do.	do.	do.
Cortiment MMX Prolonged Release Tablets 9mg	Cosmo S.P.A. for: Ferring International Centre SA, Switzerland	Italy	do.
Rekovelle Solution for Injection in a pre-filled pen 12mcg/0.36ml	Vetter Pharma- Fertigung GmbH & Co. KG, Germany Packaged by: Ferring Controlled Therapeutics Ltd. for: Ferring GmbH, Germany	UK	do.
Rekovelle Solution for Injection in a pre-filled pen 36mcg/1.08ml	do.	do.	do.
Rekovelle Solution for Injection in a pre-filled pen 72mcg/2.16ml	do.	do.	do.
Menopur Powder and Solvent for Solution for Injection 600 UI/IU	Ferring GmbH, Germany Packaged by: Ferring International Centre SA	Switzerland	do.
Menopur Powder and Solvent for Solution for Injection 1200 UI/IU	do.	do.	do.
Triumeq Film-Coated Tablets 50mg/600mg/300mg	Glaxo Operations UK Ltd., UK Packed by: Glaxo Wellcome S.A.	Spain	do.

Trade Name and Form	Manufacturer	Country of Origin	Condition of Sale
Tivicay Film-Coated Tablets 10mg	Glaxo Operations UK Ltd., UK Packed by: Glaxo Wellcome S.A.	Spain	Third Schedule
Tivicay Film-Coated Tablets 25mg	do.	do.	do.
Keppra Film-Coated Tablets 500mg	UCB Pharma S.A.	Belgium	do.
Keppra Film-Coated Tablets 1000mg	do.	do.	do.
Wisdom Step By Step Cavity and Enamel Defence Alcohol Free Fluoride Mouthwash	Wisdom Toothbrushes Ltd.	England	Freely
Wisdom Daily Enamel Protect Sensitive Mouthwash	do.	do.	do.
Wisdom Fresh Effect Alcohol Free Antibacterial Mouthwash	do.	do.	do.
Wisdom UV Pro Whitening Expert Alcohol Free Mouthwash	do.	do.	do.
Wisdom Smokers Anti-Stain Alcohol Free Antibacterial Mouthwash	do.	do.	do.
Care Chlorhexidine Digluconate Antiseptic Mouthwash Aniseed Flavour 0.2% w/v	Thornton and Ross Ltd.	do.	do.
Simbrinza Eye Drops Suspension 10mg/ml + 2mg/ml	Alcon-Couvreur for: Novartis Europharm Limited, UK	Belgium	Third Schedule
Spiolto Respimat Solution for Inhalation 2.5mcg/2.5mcg	Boehringer Ingelheim Pharma GmbH & Co. KG	Germany	do.

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Trade Name and Form	Man	ufacturer	Country of Origin	Condition of Sale
Natrol Complete Balance Menopause Relief Capa		LLC	USA	Freely
Olfen Patch 140mg	for: A	maceutical .cino .cerland	Japan	Third Schedule
Paraconica Plus Film Co Tablets 500mg/150mg	Labo for: A Phar	ratories Ltd. .cino ma AG, zerland	India	Freely
Jamieson Omega–3 + Tu Softgels 500mg/20mg		on ratories Ltd.	Canada	do.
Jamieson Gentle Iron Vegetarian Capsules 2	8mg	do.	do.	do.
Jamieson Curcumin Tur Vegetarian Capsules 5		do.	do.	do.
Jamieson CoQ 10 with Omega–3 Softgels 100mg/450mg		do.	do.	do.
Jamieson Hair, Skin and Fast Melt Tablets Biot 5000mcg		do.	do.	do.
Lenzetto Transdermal S Solution 1.53mg	Roma for: C	n Richter ania S.A. dedeon er Plc., gary	Romania	Third Schedule
Toujeo SoloStar Solution Subcutaneous Injectior Pre-filled pen 300U/ml	n in Deut	Aventis schland H	Germany	do.

Trade Name and Form	Manufacturer	Country of Origin	Condition of Sale
Vymada Film-Coated Tablets 50mg (24mg/26mg)	Novartis Singapore Pharmaceutical Manufacturing Private Ltd. Singapore Packaged by: Novartis Farma S.p.A. Torre Annunziata for: Novartis Pharma AG, Basel, Switzerland	Italy	Third Schedule
Vymada Film-Coated Tablets 100mg (49mg/51mg)	do.	do.	do.
Vymada Film-Coated Tablets 200mg (97mg/103mg)	do.	do.	do.
Cataflam Liquid Soft Capsules 50mg	Catalent Germany Eberbach GmbH, Germany Packaged by: Novartis Farma S.p.A., for: Novartis Pharma AG, Basel, Switzerland	do.	do.
Tagrisso Film-Coated Tablets 40mg	AstraZeneca AB	Sweden	do.
Tagrisso Film-Coated Tablets 80mg	do.	do.	do.
Brillinta Film-Coated Tablets 60mg	do.	do.	do.
Xigduo XR Extended Release Film Coated Tablets 5mg/1000mg	AstraZeneca Pharmaceuticals LP, Mt. Vernon Indiana, for: AstraZeneca CAMCAR S.A., Panama	USA	do.
Xigduo XR Extended Release Film Coated Tablets 10mg/1000mg	do.	do.	do.

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Trade Name and Form	Manufacturer	Country of Origin	Condition of Sale
Imfinzi Injection for Intraveneous Use 50mg/ml (120mg/2.4ml & 500mg/10ml)	Catalent Indiana LLC USA Secondary Packager: AstraZeneca AB	Sweden	Third Schedule
Keytruda Injection for Intravenous Infusion 25mg/ml	Manufactured by: Merck Sharp & Dohme Corp. At: MSD Ireland County Carlow, Ireland a subsidiary of Merck & Co. Inc. USA Packaging & Final Release: Merck Sharp & Dohme Corp.	USA	do.
Gardasil 9–Human papillomavirus 9–Valent Vaccine, Recombinant Suspension for Intramuscular Injection 0.5ml Vial	Manufactured by: Merck, Sharp & Dohme Corp., USA Secondary Packager: Merck Sharp & Dohme B.V., Haarlem	The Netherlands	do.
Gardasil 9–Human papillomavirus 9–Valent Vaccine, Recombinant Suspension for Intramuscular Injection 0.5ml Pre-filled Syringe	do.	do.	do.
Esmeron Solution for Injection 10mg/ml	Manufactured by: Hameln Pharmaceuticals GmbH, Hameln, Germany Packaged by: N.V. Organon Kloosterstraat	do.	do.
Bridion Solution for Injection 100mg/ml (200mg/2ml & 500mg/5ml)	Manufactured and Packaged by: N.V. Organon Kloosterstraat	do.	do.

Trade Name and Form	Manufacturer	Country of Origin	Condition of Sale
Odontocaina Injectable Solution 3%	New Stetic S.A., for: Productora y Comercializadora Odontologica New Stetic S.A. Colombia	Colombia	Third Schedule
Artheek Injectable Solution 4%	do.	do.	do.
Tremfya 100mg/ml Solution for Injection in pre-filled syringe	Cilag AG	Switzerland	do.
Kisqali 200mg Film-Coated Tablets	Novartis Singapore Pharmaceutical Manufacturing Pte. Ltd., Singapore Packaged by: Novartis Pharma Produktions GmbH	Germany	do.
Scapho 150mg Powder for Solution for Injection	Novartis Pharma Stein AG	Switzerland	do.
Invega Trinza 175mg Prolonged-Release Suspension for Intramuscular Injection	Janssen Pharmaceutica NV	Belgium	do.
Invega Trinza 263mg Prolonged-Release Suspension for Intramuscular Injection	do.	do.	do.
Invega Trinza 350mg Prolonged-Release Suspension for Intramuscular Injection	do.	do.	do.
Invega Trinza 525mg Prolonged-Release Suspension for Intramuscular Injection	do.	do.	do.
Erleada 60mg Film-Coated Tablets	Janssen Ortho LLC	USA	do.
Mekinist 0.5mg Film-Coated Tablets	GlaxoSmithKline Manufacturing S.p.A.	Italy	do.

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Trade Name and Form	Manufacturer	Country of Origin	Condition of Sale
Mekinist 2mg Film-Coated Tablets	GlaxoSmithKline Manufacturing S.p.A.	Italy	Third Schedule
Ziverel Oral Solution	O.F.I. S.p.A. Officina Farmaceutica Italian for: Apharm S.r.l. Italy	do.	Freely
Intaq SR 50 Sustained Release Tablets	Intas Pharmaceuticals Ltd.	India	Third Schedule
Intaq SR 200 Sustained Release Tablets	do.	do.	do.
Intaq SR 300 Sustained Release Tablets	do.	do.	do.
PEGKine PFS 6mg/0.6ml Injection	do.	do.	do.
Polyride Fe Capsules	Seaford Pharmaceuticals Inc.	Canada	Freely
Polyride Fe Ultra Capsules	do.	do.	do.
Ranitidine Solution for Injection USP 25mg/ml	SG Pharma Pvt. Ltd.	India	Third Schedule
Phenytoin Capsules B.P. 100mg	do.	do.	do.
Tranexamic Acid Solution for Intravenous Injection B.P. 100mg/ml	do.	do.	do.
Propylthiouracil Tablets B.P. 50mg	do.	do.	do.
Menactra Meningococcal (Groups A, C, Y, and W–135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine Injectable Solution for Intramuscular Use 4mcg/vial	Sanofi Pasteur, Inc.	USA	do.

Trade Name and Form	Manufacturer	Country of Origin	Condition of Sale
Vaxigrip Tetra Quadrivalent Influenza Vaccine (split virion, inactivated) Suspension for Injection in Pre-filled Syringe 15mcg	Sanofi Pasteur	France	Third Schedule
Pedialyte Advance Care Tropical Fruit Electrolyte Solution	Abbott Nutrition	USA	Freely
Pamdol–370 Injectable Solution 370mg/ml	Unique Pharmaceuticals Laboratories	India	Third Schedule
Pamdol–300 Injectable Solution 300mg/ml	do.	do.	do.
Lopinavir 200mg and Ritonavir 50mg Tablets USP	Macleods Pharmaceuticals Ltd.	do.	do.
Lamivudine 150mg, Zidovudine 300mg and Nevirapine 200mg Tablets	do.	do.	do.
Efavirenz 600mg, Emtricitabine 200mg and Tenofovir Disoproxil Fumarate 300mg Tablets	do.	do.	do.
Clopidogrel Film-Coated Tablets USP 75mg	do.	do.	do.
Aminoven 10% Solution for Infusion	Fresenius Kabi Austria GmbH	Austria	do.
Nitroglycerin Solution for Injection 50mg/10ml	Laboratorio Sanderson S.A.	Chile	do.
Haloperidol Solution for Injection 5mg/1ml	do.	do.	do.
Trozet Tablets USP 2.5mg	Fresenius Kabi Oncology Limited	India	do.
Irinotel Injection 100mg/5ml (20mg/ml)	do.	do.	do.
Irinotel Injection 40mg/2ml (20mg/ml)	do.	do.	do.

Trade Name and Form	Manufacturer	Country of Origin	Condition of Sale
Cabita 500 Tablets USP 500mg	Getwell Pharmaceuticals	India	Third Schedule
Zoldron Concentrate Solution for Infusion (Zoledronic Acid for Injection) 4mg	do.	do.	do.
Pacliwel Concentrate Solution for Infusion (Paclitaxel Injection USP) 100mg/16.7ml (6mg/ml)	do.	do.	do.
5D Glucose Intravenous Infusion BP (50g/l)	Otsuka Pharmaceutical India Private Limited	do.	do.
NS Sodium Chloride Intravenous Infusion BP (0.9% w/v)	do.	do.	do.
RL Compound Sodium Lactate Intravenous Infusion BP	do.	do.	do.
SuperAmp (Sterilised Water for Injections BP)	do.	do.	do.
Irbesartan Tablets USP 300mg	Macleods Pharmaceuticals Ltd.	do.	do.
Irbesartan Tablets USP 150mg	do.	do.	do.
Emtricitabine 200mg and Tenofovir Disoproxil Fumarate 300mg Tablets	do.	do.	do.
Cardiamin Multivitamin Softgel Capsules with Omega–3	Coreceuticals, Nephroceuticals LLC	USA	Freely
ProRenal + D Multivitamin Tablets	Nephroceuticals LLC	do.	do.
ProRenal + D Multivitamin Softgel Capsules with Omega–3	do.	do.	do.

Trade Name and Form	Manufacturer	Country of Origin	Condition of Sale
Lonsurf Film-Coated Tablets 15mg/6.14mg	Taiho Pharmaceutical Co. Ltd. Japan Packed by: Les Laboratoires Servier Industrie for: Les Laboratoires Servier, France	France	Third Schedule
Lonsurf Film-Coated Tablets 20mg/8.19mg	do.	do.	do.
Daflon 1000mg Film-Coated Tablets	Les Laboratoires Servier Industrie for: Les Laboratoires Servier, France	do.	do.
Triveram Film-Coated Tablets 20mg/5mg/5mg	do.	do.	do.
Triveram Film-Coated Tablets 20mg/10mg/5mg	do.	do.	do.
Triveram Film-Coated Tablets 40mg/10mg/10mg	do.	do.	do.
Stelara 130mg Concentrate for Solution for Infusion 130mg/26ml	Cilag AG, for: Ethnor del Istmo S.A., Panama	Switzerland	do.
Darzalex 100mg/5ml Concentrate for Solution for Infusion	do.	do.	do.
Darzalex 400mg/20ml Concentrate for Solution for Infusion	do.	do.	do.
Mavenclad Tablets 10mg	NerPharMa S.R.L., for: Merck S.A., Guatemala	Italy	do.

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Trade Name and Form	Manufacturer	Country of Origin	Condition of Sale
Zytiga Film-Coated Tablets 500mg	Patheon France S.A.S., France Packed by: Janssen Cilag S.p.A. for: Ethnor del Istmo S.A. Panama	Italy	Third Schedule
Vivera Probiotics Powder Sachets 2g	Probiotical S.p.A. Italy Packed by: S.I.I.T. S.R.L. Servizio Internationale, for: Merck S.A., Guatemala	do.	Freely
Eutirox 112 Tablets 112mcg	Merck, S.A. de C.V.	Mexico	Third Schedule
Eutirox 88 Tablets 88mcg	do.	do.	do.
Neuroipran Coated Tablets 20mg	Laboratorios Recalcine, S.A.	Chile	do.
Neuroipran Coated Tablets 10mg	do.	do.	do.
Dium Capsules 75mg	do.	do.	do.
Louten Sterile Ophthalmic Emulsion Latanoprost 0.005%	Laboratorios Poen S.A.C.I.F.I.	Argentina	do.
Brimopress T Sterile Ophthalmic Solution Brimonidine Tartrate 0.2%/Timolol 0.5%	do.	do.	do.
Neagel Ophthalmic Gel Ganciclovir 0.15%	do.	do.	do.
Closporil 0.1% Sterile Ophthalmic Solution Cyclosporine 0.1%	do.	do.	do.
Fotorretin Sterile Ophthalmic Solution Tropicamide 0.5%/Phenylephrine HCl 5%	do.	do.	do.

Trade Name and Form	Manufacturer	Country of Origin	Condition of Sale
Louten T Sterile Ophthalmic Solution Latanoprost 0.005%/ Timolol 0.5%	Laboratorios Poen S.A.C.I.F.I.	Argentina	Third Schedule
Ciclopentolato Poen 1% Sterile Ophthalmic Solution Cyclopentolate Hydrochloride 1%	do.	do.	do.
Capecitabine 500mg Sandoz Film-Coated Tablets	Hetero Labs Limited, for: Sandoz GmbH Austria	India	do.
Fabrazyme 35mg Powder for Concentrate for Solution for Infusion	Genzyme Ireland Limited	Ireland	do.
Mycophenolate Intas 360 Gastro Resistant Tablets	Intas Pharmacueticals Ltd.	India	do.
Recipro 500 Film-Coated Tablets BP 500mg	Aurobindo Pharma Ltd.	do.	do.
Onchofin 250 Tablets 250mg	do.	do.	do.
Moxiwar 400 Film-Coated Tablets 400mg	do.	do.	do.
Kyo-Dophilus 9 Capsules	Wakunaga of America Co. Ltd.	USA	Freely
Kyo-Dophilus with Enzymes Capsules	do.	do.	do.
Kyolic Omega 3 Capsules	do.	do.	do.
Efavir 600 Tablets 600mg	Cipla Ltd.	India	Third Schedule
Dabigatran Etexilate Capsules 150mg	Hetero Labs Limited	do.	do.
Valgovir 450 Tablets USP 450mg	do.	do.	do.

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Trade Name and Form	Manufacturer	Country of Origin	Condition of Sale
Oseltamivir Phosphate Capsules USP 75mg	Hetero Labs Limited	India	Third Schedule
Lithium Carbonate Capsules USP 300mg	do.	do.	do.
Lavuzid Tablets 150mg/300mg	do.	do.	do.
Zidovudine Oral Solution USP 50mg/5ml	do.	do.	do.
Zidovudine Tablets USP 300mg	do.	do.	do.
Procarbazine Hydrochloride Capsules 50mg	SG Pharma Pvt. Ltd.	do.	do.
Norethisterone Enanthate Solution for Injection 200mg/ml	do.	do.	do.
Norethisterone Enanthate and Estradiol Valerate Solution for Injection 50mg + 5mg/ml	do.	do.	do.
Furosemide Solution for Injection USP 20mg/2ml (10mg/ml)	do.	do.	do.
Riopan Gel 80mg/10mg/1ml	Takeda Mexico, S.A. de C.V. Distributed by: Aspen Panama S.A., Panama	Mexico	Freely
Ibrance Capsules 75mg	Pfizer Manufacturing Deutschland GmbH, Germany Packaged by: Pfizer Pharmaceuticals LLC, Puerto Rico for: Pfizer Inc. USA	USA	Third Schedule
Ibrance Capsules 100mg	do.	do.	do.
Ibrance Capsules 125mg	do.	do.	do.

Trade Name and Form	Manufacturer	Country of Origin	Condition of Sale
Zovanta Pantoprazole Sodium for Injection 40mg (Lyophilized)	Dr. Reddy's Laboratories Ltd.	India	Third Schedule
Podoxred Pemetrexed for Injection 500mg/vial	do.	do.	do.
Scanlux Solution for Injection 300mg l/ml	Sanochemia Pharmazeutika AG	Austria	do.
Pentasa Enema Rectal Suspension 1g/100ml	Ferring Leciva, A.S.	Czech Republic	do.
Praxbind Solution for Intravenous Injection/ Infusion 50mg/mL	Boehringer Ingelheim Pharma GmbH & Co. KG	Germany	do.
Jardiance Tablets 10mg	do.	do.	do.
Jardiance Tablets 25mg	do.	do.	do.
Tresiba FlexTouch 100U/mL Solution for Injection in Pre-filled Pen	NOVO Nordisk A/S	Denmark	do.
Aciclovir Solution for Intravenous Infusion 25mg/ml	SG Pharma Pvt. Ltd.	India	do.
Sterile Potassium Chloride Concentrate Solution B.P. for Intravenous Infusion 150mg/ml	do.	do.	do.
Turbocaina Articaine HCl 4% Epinephrine Injection	Laboratorios Zeyco S.A. de C.V.	Mexico	do.
Propofol Fresenius 1% mit MCT Emulsion for Injection or Infusion	Fresenius Kabi Austria GmbH	Austria	do.
Taxewell Concentrate with Solvent for Injection 80mg/ 2ml (40mg/ml)	Getwell Pharmaceuticals	India	do.
Fulphila (Pegfilgrastim) Injection in a Pre-filled Syringe 6mg/0.6ml	Biocon Limited for: Mylan Pharmaceuticals Private Limited, India	do.	do.

Trade Name and Form	Manufacturer	Country of Origin	Condition of Sale
Iliadin LUB Nasal Decongestant with Lubricant Adult Spray Solution 0.05%	Merck, S.A. de C.V.	Mexico	Freely
Diaris Capsules	Laboratorios Poen S.A.C.I.F.I.	Argentina	do.
Brixia Sterile Ophthalmic Solution Azelastine Hydrochloride 0.05%	do.	do.	Third Schedule
Arduus Tablets 20mg	Sandoz Ilaç San. Ve Tic. A.S. for: Sandoz GmbH, Austria	Turkey	do.
Bortezomib 3.5mg Sandoz Lyophilisate Powder for Injection	S.C. Sindan- Pharma S.R.L. for: Sandoz GmbH, Austria	Romania	do.
Simcard–40 Tablets USP 40mg	Cipla Ltd.	India	do.
Oncodox-50 Powder for	do.	do.	do.

do.

Pharmaceuticals d.d. for; Sandoz GmbH Austria

do.

MSN Laboratories

Private Limited

do.

Lek

do.

Slovenia

do.

India

do.

do.

do.

do.

do.

do.

Reconstitution for Injection

Reconstitution for Injection

Pantoprazole Sandoz Gastro-

Pantoprazole Sandoz Gastro-

Resistant Tablets 20mg

Pregasafe 75 Capsules 75mg

Pregasafe 150 Capsules 150mg

Resistant Tablets 40mg

Oncodox-10 Powder for

USP 50mg

USP 10mg

Trade Name and Form	Manufacturer	Country of Origin	Condition of Sale
VETERINARY PRODUCTS			
Recombitek C8 Injection	Merial Inc.	USA	Veterinary Prescription Only
Nobivac: Canine 1–DAPPv + L4 Injection	Intervet Inc.	do.	do.
Nobivac: Canine 1–DAPPvL2 + Cv Injection	do.	do.	do.
Nobivac: Feline 1–HCPCh Injection	do.	do.	do.
Nobivac: Feline 1–HCPCh + FeLV Injection	do.	do.	do.
Bravecto Chews 112.5mg	Intervet GesmbH	Austria	do.
Bravecto Chews 250mg	do.	do.	do.
Bravecto Chews 500mg	do.	do.	do.
Bravecto Chews 1000mg	do.	do.	do.
Bravecto Chews 1400mg	do.	do.	do.
Vanguard Plus 5 Injection	Zoetis Inc.	USA	do.
RespiSure1ONE Intramuscular Injection	do.	do.	do.
RespiSure Intramuscular Injection	do.	do.	do.
Bronchicine CAe Subcutaneous Injection	do.	do.	do.
Cerenia 10mg/mL Injectable Solution	Fareva AMBOISE	France	do.
Apoquel Film-Coated Tablets 3.6mg	Pfizer Italia S.R.L.	Italy	do.

Trade Name and Form	Manufacturer	Country of Origin	Condition of Sale		
Apoquel Film-Coated Tablets 5.4mg	Pfizer Italia S.R.L.	Italy	Veterinary Prescription Only		
Apoquel Film-Coated Tablets 16mg	do.	do.	do.		
Quest Plus Oral Gel 20mg/ 125mg/ml	Manufactured by: Zoetis Manufacturing & Research Spain, S.L. Distributed by: Zoetis Inc., USA	Spain	do.		
Rimadyl Chewable Tablets 25mg	Zoetis Inc.	USA	do.		
Rimadyl Chewable Tablets 100mg	do.	do.	do.		
END OF VETERINARY MEDICINE					
Alerchek 0.2% (Olopatadine Hydrochloride Ophthalmic Solution USP 0.2%)	Indoco Remedies Limited	India	Third Schedule		
Venclexta Tablets 100mg	AbbVie Ireland NL B.V., Ireland Packager: AbbVie Inc., for: AbbVie Inc., USA	USA	do.		
Venclexta Tablets 10mg	do.	do.	do.		
Venclexta Tablets 50mg	do.	do.	do.		
Venclexta Tablets Starting Pack (with or including 10mg, 50mg & 100mg)	do.	do.	do.		
Colgate Total Pro-shield Peppermint Blast Mouthwash/Liquid 0.075%	Colgate Palmolive Company	do.	Freely		

Trade Name and Form	Manufacturer	Country of Origin	Condition of Sale
Colgate Total Pro-shield Spearmint Surge Mouthwash/Liquid 0.075%	Colgate Palmolive Company	USA	Freely
Colgate Kids Minions Anticavity Fluoride Rinse Bello Bubble Fruit/Liquid 0.02%	Kleen Test Products Corporation	do.	do.
ProBioGen Daily Digestive Balance Probiotic Capsules	Nutritional Manufacturing Services, LLC for: WR Group USA	do.	Freely
Natrol Kids' Multi Gummies	Natrol LLC	do.	do.
Melphalan Tablets USP 2mg	SGPharma Pvt. Ltd.	India	Third Schedule
Methyldopa Tablets USP 250mg	do.	do.	do.
Alive Women's 50+ Multi- Vitamin Tablets	Nature's Way Brand LLC	USA	Freely
Alive Men's Energy Multi- Vitamin Tablets	do.	do.	do.
Alive Women's Energy Multi- Vitamin Tablets	do.	do.	do.
Alive Men's 50+ Multi-Vitamin Tablets	do.	do.	do.
EfaGold Flax Oil Softgels 1300mg	do.	do.	do.
EfaGold Krill Oil 500mg Softgels	do.	do.	do.
Probiotic Pearls Acidophilus Softgels 1 billion CFU	do.	do.	do.
Primadophilus Original Vegetarian Capsules 5 billion CFU	do.	do.	do.

Trade Name and Form	Manufacturer	Country of Origin	Condition of Sale
ProBioGen Stress and Mood Balance Probiotic Capsules	Nutritional Manufacturing Services, LLC for: WR Group USA	USA	Freely
Foligain Stimulating Supplement for Thinning Hair Caplets	do.	do.	do.
Kyolic Aged Garlic Extract Candida Cleanse & Digestion Formula 102 Capsules	Wakunaga of America Co. Ltd.	do.	do.
Kyolic Aged Garlic Extract Circulation Formula 106 Capsules	do.	do.	do.

Dated this 23rd day of August, 2019.

T. DEYALSINGH Minister of Health