

LEGAL NOTICE NO. 201

REPUBLIC OF TRINIDAD AND TOBAGO

FOOD AND DRUGS ACT, CHAP. 30:01

NOTIFICATION

APPROVAL IN RESPECT OF NEW DRUGS

ISSUED by the Minister of Health 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 of Health signifies his approval in respect of the following new drugs listed hereunder:

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Xarelto Film-Coated Tablets 2.5 mg	Manufactured by: Bayer Pharma AG, Leverkusen for Bayer Pharma AG, Germany	Germany	Third Schedule
Stivarga Film-Coated Tablets 40 mg	Manufactured by: Bayer Pharma AG, Leverkusen	do.	do.
Viagra ODT® Orodispersible Tablets 50 mg	Manufactured by: Pfizer PGM, Licence Holder: Pfizer Limited UK	France	do.
BeneFIX Powder and Solvent for Solution for Injection 250 IU	Powder Manufacturer: Wyeth Farma, S.A., Spain Solvent Manufacturer: Vetter Pharma-Fertigung GmbH & Co. Germany Secondary Packager: Wyeth Farma, S.A., Licence Holder: Pfizer Limited United Kingdom	Spain	do.
BeneFIX Powder and Solvent for Solution for Injection 500 IU	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Lyrica 20 mg/ml Oral Solution	Manufactured & Packaged by: Pharmacia & Upjohn Co. License Holder: PF Prism USA	USA	Third Schedule
Enbrel Myclic Solution for Injection in Pre-Filled Pen 50 mg	Manufacturer: Pfizer Ireland Pharmaceuticals Ireland Primary Packager: Vetter Pharma Fertigung GmbH & Co. KG Germany Pen Assembly: Vetter Pharma Fertigung GmbH & Co. KG Germany Secondary Packager: Wyeth Pharmaceuticals	UK	do.
Beriate® Powder and Solvent for Solution for Injection for Infusion 250 IU	Manufactured by: CSL Behring GmbH	Germany	do.
Beriate® Powder and Solvent for Solution for Injection for Infusion 500 IU	do.	do.	do.
Beriate® Powder and Solvent for Solution for Injection for Infusion 1000 IU	do.	do.	do.
Alburex® Solution for Infusion 20%	Manufactured by: CSL Behring AG	Switzerland	do.
Alburex® Solution for Infusion 25%	do.	do.	do.
Erivedge Capsules 150 mg	Made for: F. Hoffmann-La Roche Ltd. Switzerland By: Patheon Inc.,	Canada	do.
Gazya Concentrate for Solution for Infusion 1000 mg/40 ml	Made for: F. Hoffmann-La Roche Ltd. Switzerland By: Roche Diagnostics GmbH	Germany	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Biofreeze Pain Relieving Spray 10% Menthol	Manufacturer: Span Packaging Services, LLC for: Performance Health, LLC United States of America	USA	Freely
Relvar Ellipta Inhalation Powder 100/25 mcg	Glaxo Operations UK Limited	United Kingdom	Third Schedule
Relvar Ellipta Inhalation Powder 200/25 mcg	do.	do.	do.
Himani Fast Relief Herbal Pain Relief Spray (Wintergreen Oil 20%) (Menthol 10%)	Rubion Formulations Pvt. Ltd.	India	Freely
Signifor 0.3 mg/1 ml Solution for Injection	Novartis Pharma Stein AG, for Novartis Pharma AG, Switzerland	Switzerland	Third Schedule
Signifor 0.6 mg/1 ml Solution for Injection	do.	do.	do.
Signifor 0.9 mg/1 ml Solution for Injection	do.	do.	do.
Jakavi Tablets 5 mg	do.	do.	do.
Jakavi Tablets 15 mg	do.	do.	do.
Jakavi Tablets 20 mg	do.	do.	do.
Seebri Breezhaler Inhalation Powder, Hard Capsules 50 mcg	do.	do.	do.
Neutrogena® T/Gel Therapeutic Shampoo Original Formula	Distributed by: Neutrogena Corporation	USA	Freely
Neutrogena® T/Sal Therapeutic Shampoo	do.	do.	do.
Neutrogena® Blackhead Eliminating Cleanser/Mask	Manufacturer: KIK Custom Products— Rexdale Plant Distributor: Neutrogena Corp. LA Canada	Canada	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Neutrogena® Rapid Clear Acne Eliminating Spot Gel	Manufacturer: Les Emballages Knowlton Inc. Distributor: Neutrogena Corp. LA USA	Canada	Freely
Clean & Clear Continuous Control® Acne Cleanser	Manufacturer: KIK Custom Products—Rexdale Plant Distributor: Johnson & Johnson Consumer Products Company Division of Johnson & Johnson Consumer Companies, Inc. USA	do.	do.
Clean and Clear® Advantage® Acne Control Moisturizer	do.	do.	do.
Visine AC® Astringent/Redness Reliever Eye Drops	Manufacturer: Janssen Pharmaceutica N.V. Distributor: Johnson & Johnson Healthcare Products Division of McNeil-PPC Inc., USA	Belgium	do.
EZ Melts Multi Vitamin Supplement Fast Melting Tablets	Solara Inc.	USA	do.
EZ Melts Joint Relief Complex Fast Melting Tablets	do.	do.	do.
EZ Melts Co Q10 Complex Fast Melting Tablets	do.	do.	do.
EZ Melts Bone Support Fast Melting Tablets	Solara Inc.	do.	do.
Synvisc One Liquid	Genzyme Biosurgery	do.	do.
Bronchicum Elixir	A. Nattermann & Cie. GmbH	Germany	do.
Anoro Ellipta Inhalation Powder 62.5/25 mcg	Glaxo Operations UK Limited	United Kingdom	Third Schedule

Approval in Respect of New Drugs

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<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Imbruvica Capsules 140 mg	Catalent CTS Inc.	USA	Third Schedule
Simponi One SmartJect® Autoinjector Solution for Injection in Pre-filled Pen 100 mg/ml	Manufactured by: Baxter Pharmaceuticals Solutions LLC USA Packaged by: Cilag, AG	Switzerland	do.
Omega-3 Brain™ Softgel Capsules 1000 mg	Jamieson Laboratories Ltd.	Canada	Freely
Omega-3 Calm™ Softgel Capsules 1000 mg	do.	do.	do.
Chewable Vitamin D Chocolate Tablets 1000 IU (25 mcg)	do.	do.	do.
Melatonin Tablets 5 mg	do.	do.	Third Schedule
Magnesium Tablets 50 mg	do.	do.	Freely
Potassium TR Tablets 100 mg	do.	do.	do.
CoQ10 Omega-3 Softgel Capsules 100/850 mg	do.	do.	do.
CoQ10 Softgel Capsules 120 mg	do.	do.	do.
Apo-Clopidogrel Tablets 75 mg	Apotex Inc.	do.	Third Schedule
Zoladex Depot 3.6 mg Implant—Prefilled Syringe (Update on Primary Packaging Material and Secondary Packaging Material in Bilingual Version)	AstraZeneca UK Limited	UK	do.
Zoladex La Depot Implant 10.8 mg, Prefilled Syringe Applicator (Update on Primary Packaging Material and Secondary Packaging Material in Bilingual Version)	do.	do.	do.
Insuman N 100 IU/ML Injectable Suspension (Update of Artwork Design of Secondary Packaging and Change of Name of Manufacturer)	sanofi-aventis Deutschland GmbH	Germany	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Insuman R 100 IU/ML Injectable Suspension (Update of Artwork Design of Secondary Packaging and Change of Name of Manufacturer)	sanofi-aventis Deutschland GmbH	Germany	Third Schedule
Plavix Film-Coated Tablets 75 mg (Update of Artwork Design of Secondary Packaging)	Sanofi Winthrop Industries	France	do.
Amaryl Film Coated Tablets 2 mg (Update of Artwork Design of Secondary Packaging)	sanofi-aventis Farmacêutica Ltda.	Brazil	do.
Amaryl Film Coated Tablets 4 mg (Update of Artwork Design of Secondary Packaging)	do.	do.	do.
Amaryl Film Coated Tablets 2/1000 mg (Update of Artwork Design of Secondary Packaging)	Manufactured in Mexico by: Laboratories Silanes, S.A. de C.V. for sanofi- aventis de Mexico S.A. de C.V. Mexico	Mexico	do.
Amaryl Film Coated Tablets 4/1000 mg (Update of Artwork Design of Secondary Packaging)	do.	do.	do.
Cataflam Oral Suspension 1.8 mg/ml (Additional Source)	Delpharm Huningue S.A.S	France	do.
Daivobet Gel (Change of Name of Marketing Authorization Holder)	Leo Laboratories Ltd. (Leo Pharma) for Leo Pharma A/S, Ireland	Ireland	do.
Daivobet Ointment 50 mcg/0.5 mg (Change of Name of Marketing Authorization Holder)	do.	do.	do.
One Alpha® Capsules 0.25 mcg (Change of Name of Marketing Authorization Holder)	Leo Pharmaceutical Products Ltd. A/S (Leo Pharma A/S) for Leo Pharma A/S, Denmark	Denmark	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
One Alpha® Capsules 1 mcg (Change of Name of Marketing Authorization Holder)	Leo Pharmaceutical Products Ltd. A/S (Leo Pharma A/S) for Leo Pharma A/S, Denmark	Denmark	Third Schedule
Heparin Leo 1000 I.U./ml (Change of Name of Marketing Authorization Holder, Storage Condition Statement and Change of Artwork Design)	do.	do.	do.
Heparin Leo 5000 I.U./ml (Change of Name of Marketing Authorization Holder, Storage Condition Statement and Change of Artwork Design)	do.	do.	do.
Redoxon Vitamin C 1000 mg Effervescent Tablets—Orange Flavor (Change in the Primary and Secondary Package Labelling, Change of Name of Manufacturer and Change in the Primary and Secondary Artwork Design)	Manufactured by: Delpharm Gaillard for: Bayer S.A. Guatemala	France	Freely
Ferrum Hausmann Oral Solution 100 mg/5 ml (Additional Manufacturing Site and Change of Artwork Design)	Abdi Ibrahim Ilac Sanayi ve TIC.A.S. for: Vifor (International) Inc., Switzerland	Turkey	do.
Risperdal Consta 25 mg Prolonged Suspension for Intramuscular Injection 25 mg (Change of Name of Manufacturer, Change of Diluent Manufacturer and Addition of Packager)	Manufacturer: Alkermes Incorporated USA, for Cilag AG, Switzerland Packager: Cilag AG	Switzerland	Third Schedule
Risperdal Consta 50 mg Prolonged Release Suspension for Intramuscular Injection 50 mg (Change of Name of Manufacturer, Change of Diluent Manufacturer and Addition of Packager)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Risperdal Consta 37.5 mg Prolonged Release Suspension for Intramuscular Injection 37.5 mg (Change of Name of Manufacturer, Change of Diluent Manufacturer and Addition of Packager)	Manufacturer: Alkermes Incorporated USA, for Cilag AG, Switzerland Packager: Cilag AG	Switzerland	Third Schedule
Oxitan Injection 50 mg/25 ml (Change of Name of Manufacturer)	Fresenius Kabi Oncology Limited	India	do.
Oxitan Injection 100 mg/50 ml (Change of Name of Manufacturer)	do.	do.	do.
Kemocarb Injection 150 mg/15 ml (Change of Name of Manufacturer)	do.	do.	do.
Kemocarb Injection 450 mg/45 ml (Change of Name of Manufacturer)	do.	do.	do.
Cisplatin Injection 10 mg/10 ml (Change of Name of Manufacturer)	do.	do.	do.
Cisplatin Injection 50 mg/50 ml (Change of Name of Manufacturer)	do.	do.	do.
Intaxel Injection Concentrate 100 mg (Change of Name of Manufacturer)	do.	do.	do.
Fivoflu Injection 500 mg (Change of Name of Manufacturer)	do.	do.	do.
Leucovorin Calcium Injection USP 50 mg/5 ml (Change of Name of Manufacturer)	do.	do.	do.
Vinlbine Injection 50 mg (Change of Name of Manufacturer)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Solvent for Docetaxel Injection Concentrate 20 mg (Change of Name of Manufacturer)	Fresenius Kabi Oncology Limited	India	Third Schedule
Cytarine Injection 500 mg/5 ml (Change of Name of Manufacturer)	do.	do.	do.
Cytarine Injection 100 mg/ml (Change of Name of Manufacturer)	do.	do.	do.
Zexate Injection USP 50 mg/2 ml (Change of Name of Manufacturer)	do.	do.	do.
Gynatam Tablets 20 mg (Change of Name of Manufacturer)	do.	do.	do.
Gynatam Tablets 10 mg (Change of Name of Manufacturer)	do.	do.	do.
Solvent for Docetaxel Injection Concentrate 80 mg (Change of Name of Manufacturer)	do.	do.	do.
Daxotel Injection Concentrate 80 mg (Change of Name of Manufacturer)	do.	do.	do.
Daxotel Injection Concentrate 20 mg (Change of Name of Manufacturer)	do.	do.	do.
Topotel Injection Concentrate 4 mg (Change of Name of Manufacturer)	do.	do.	do.
Cytarine Injection 1 g (Change of Name of Manufacturer)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Plendil Extended Release Tablets 5 mg (Additional Manufacturing Site, Additional Packaging Site, Change in Primary Packaging and Change of Artwork Design)	Manufactured by: AstraZeneca Pharmaceutical Co. Ltd., China Packed by: AstraZeneca do Brasil Ltda., for: AstraZeneca AB, Sweden	Brazil	Third Schedule
Plendil Extended Release Tablets 10 mg (Additional Manufacturing Site, Additional Packaging Site, Change in Primary Packaging and Change of Artwork Design)	do.	do.	do.
Synvisc Injectable Intra- Articular Synovial Fluid Supplement (Hylan G-F-20) (Change of Name of Product, Change of Name of Manufacturer, Change of Source and Change of Artwork Design)	Genzyme Biosurgery	USA	do.
Enzypride Coated Tablets Pancreatin 4NF (85% AI Potency) (Change of Name of Manufacturer)	Altea Farmaceutica S.A.	Colombia	do.
Zyrtec Oral Solution 1 mg/ml (Change of Name of Manufacturer)	Aesica Pharmaceuticals S.r.l.	Italy	do.
Zyrtec Oral Drop 10 mg/ml (Change of Name of Manufacturer)	do.	do.	do.
Chesteez Cough Syrup (Change of Artwork Design)	L'amar Natural Products Pvt. Ltd.	India	Freely
Mesigyna Solution for IM Injection 50 mg and 5 mg/1 ml (Change of Name of Marketing Authorisation Holder)	Manufactured by: Bayer de México, S.A. De C.V. for: Bayer Pharma AG, Germany	Mexico	Third Schedule

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Nexavar Film-Coated Tablets 200 mg (Change of Name of Marketing Authorisation Holder and Manufacturing Site)	Manufactured by: Bayer Pharma AG, Leverkusen for: Bayer Pharma AG, Germany	Germany	Third Schedule
Nexavar Film-Coated Tablets 200 mg (Change of Name of Marketing Authorisation Holder and Manufacturing Site and New Indication)	do.	do.	do.
Prevenar 13 [®] Pneumococcal 13-Valent Conjugated Vaccine (Diphtheria CRM ₁₉₇ Protein) (Additional Source, Change of Name of Product)	Manufacturer: Pfizer Ireland Pharmaceuticals, Ireland Packager: Wyeth Pharmaceuticals	United Kingdom	do.
Prevenar 13 [®] Pneumococcal 13-Valent Conjugated Vaccine (Diphtheria CRM ₁₉₇ Protein) (New Indication)	Wyeth Pharmaceuticals Inc., A Subsidiary of Pfizer Inc. USA	USA	do.
Dulera Inhalation Aerosol 200 mcg/5 mcg	3M HealthCare Ltd.	United Kingdom	do.
Dulera Inhalation Aerosol 100 mcg/5 mcg	do.	do.	do.
Simponi Injection 12.5 mg/ml	Cilag AG	Switzerland	do.
Ovol Drops 40 mg	Church & Dwight Canada Corp	Canada	Freely
Gravol Kids Liquid Syrup 15 mg/5 ml	do.	do.	do.
Orajel Regular Strength Gel For Teething	do.	do.	do.
Orajel Toothache Maximum Strength Gel	do.	do.	do.
Rub A535 Extra Strength Cream	do.	do.	do.
Trajenta 5 mg Tablets	Boehringer Ingelheim Roxane Inc.	USA	Third Schedule

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Bisolvon Dry Cough Syrup 2.0 mg/ml	Manufacturer: Boehringer Ingelheim do Brazil Quimica e Farmacêutica Ltda., Distributor: Boehringer Ingelheim (Canada) Ltd. Canada	Brazil	Third Schedule
Asprega ProPac Probiotic Formula Delayed Release Capsule 20 Billion CFU	Manufactured by: Millenium Natural Health Products Inc. for: Scimera Bioscience, USA	USA	Freely
Xyntha Powder and Solvent for Solution for Injection 250 IU	Powder Manufactured by: Wyeth Pharma S.A. Spain, Diluent Manufactured by: Vetter Pharma Fertigung GmbH, Germany, Secondary Packager: Wyeth Pharma S.A., Licence Holder: Wyeth Pharmaceuticals Inc., USA	Spain	Third Schedule
Xyntha Powder and Solvent for Solution for Injection 500 IU	do.	do.	do.
Asprega Complete Probiotic Delayed Release Capsule 20 Billion CFU	Manufactured by: Millenium Natural Health Products Inc. for: Scimera Bioscience, USA	USA	Freely
Prexator Complete Heart Formulation Capsules	do.	do.	do.
SciMune Immune Support Pac Physician Formulated Capsules	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Vyzetra Essential Multivitamin/Multimineral Plus Antioxidants Vegetarian Capsules	Manufactured by: Millenium Natural Health Products Inc. for: Scimera Bioscience, USA	USA	Freely
Vyzetra Ultra Multivitamin/ Multimineral Plus Antioxidants Capsules	do.	do.	do.
SciKrill Natural Antartic Krill Oil Capsules	do.	do.	do.
Ubiquinol CoEnzyme Q-10 Kaneka QH Softgels	do.	do.	do.
Lyxumia 10 mcg Solution for Injection	Sanofi-Aventis Deutschland GmbH	Germany	Third Schedule
Lyxumia 20 mcg Solution for Injection	do.	do.	do.
Lyxumia 10 mcg & 20 mcg Solution for Injection	do.	do.	do.
Exelon Patch 15 Transdermal Patch13.3 mg/24 h	LTS Lohmann Therapie-Systeme AG, for Novartis Pharma AG, Switzerland	do.	do.
Anastrozole Denk 1 Film- Coated Tablets 1 mg	Distributor: DENK PHARMA GmbH & Co. KG Germany Manufacturer: Haupt Pharma München GmbH	do.	do.
Grani-Denk 1 mg/ml Ampoules	Distributor: DENK PHARMA GmbH & Co. KG Germany Manufacturer: Hameln Pharmaceuticals GmbH	do.	do.
Zoledro-Denk 4 mg/5 ml Concentrate for Solution for Infusion	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
CoLosar-Denk 100/12.5 mg Film-Coated Tablets	Distributor: DENK PHARMA GmbH & Co. KG Prinzregentenstr. 79, Germany Manufacturer: DENK PHARMA GmbH & Co. KG Göllstr	Germany	Third Schedule
Losar-Denk 25 Film-Coated Tablets	do.	do.	do.
Tramadol Denk 50 Effervescent Tablets 50 mg	Losan Pharma GmbH	do.	do.
Panto-Denk 20 Gastro- Resistant Tablets 20 mg	Distributor: DENK PHARMA GmbH & Co. KG Prinzregentenstr. Germany Manufacturer: Advance Pharma GmbH	do.	do.
Panto-Denk 40 Gastro- Resistant Tablets 40 mg	do.	do.	do.
Clopi-Denk 75 Film-Coated Tablets 75 mg	Distributor: DENK PHARMA GmbH & Co. KG Prinzregentenstr. Germany Manufacturer: Artesan Pharma GmbH & Co. KG	do.	do.
Vikonon Tablets	Manufactured for: Savoy Laboratories (International) Ltd., UK Manufactured by: Surepharm Services Ltd.	UK	Freely
Synagis Powder and Solvent for Solution for Injection 50 mg	Packaged by: AbbVie S.r.L. for AbbVie Ltd. United Kingdom	Italy	Third Schedule
Synagis Powder and Solvent for Solution for Injection 100 mg	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Norvir 100 mg Film-Coated Tablets	AbbVie Deutschland GmbH & Co. KG	Germany	Third Schedule
Advil [®] Liqui-Gels Liquid Filled Capsules 200 mg	Catalent Pharma Solutions, LLC USA, Packaged by: Fareva Richmond Inc. For: Pfizer Inc., USA	USA	Freely
Advil [®] Tablets 200 mg Coated Tablets	Wyeth Pharmaceuticals Company for Pfizer Inc. New Jersey	Puerto Rico	do.
Phosphonorm Capsules 300 mg	MEDICE Arzneimittel Pütter GmbH & Co. KG	Germany	Third Schedule
Nefrocarnit 1 g/3.3 ml Oral Solution	do.	do.	do.
Nefrocarnit 1 g/5 ml Solution for Injection	do.	do.	do.
Imovax Polio Suspension for Injection in multidose—Poliomyelitis Vaccine (inactivated)	Sanofi Pasteur	France	do.
Oral Bivalent Types 1 and 3 Poliomyelitis Vaccine, oral Suspension in Multidose Container	do.	do.	do.
Medikinet [®] 5 mg Tablets	MEDICE Arzneimittel Pütter GmbH & Co. KG	Germany	do.
Medikinet [®] 10 mg Tablets	do.	do.	do.
Medikinet [®] 20 mg Tablets	do.	do.	do.
Medikinet [®] Retard 5 mg Prolonged Release Capsules	do.	do.	do.
Medikinet [®] Retard 10 mg Prolonged Release Capsules	do.	do.	do.
Medikinet [®] Retard 20 mg Prolonged Release Capsules	do.	do.	do.
Medikinet [®] Retard 30 mg Prolonged Release Capsules	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Medikinet® Retard 40 mg Prolonged Release Capsules	MEDICE Arzneimittel Pütter GmbH & Co. KG	Germany	Third Schedule
Zarzio Solution for Injection or Infusion Pre Filled Syringe 49 MU/0.5 ml	IDT Biologika GmbH	do.	do.
Protopam Chloride Liophilized Powder for Injection 1 g	Baxter Pharmaceutical Solutions LLC	USA	do.
Orajel Toothache Maximum Strength Liquid (Benzocaine 20%)	Church & Dwight Co. Inc.	do.	Freely
Rub A535 Sport Ultra Heat Cream	Church & Dwight Canada Corp.	Canada	do.
Profile AWC Hydrogel Dressing 15 g	Advanced Medical Solutions Ltd.	United Kingdom	do.
Profile AWC Alginate Dressing 5x5 cm/10x10 cm /10x20 cm Rope	do.	do.	do.
Profile AWC Hydrocolloid Dressing 5x7.5 cm/ 10x10 cm/15x15 cm Sacral	do.	do.	do.
Profile AWC Foam Dressing Adhesive 10x10 cm /12.5x12.5 cm/15x15 cm/ 20x20 cm Non-Adhesive 5x5 cm/7.5 cmx7.5 cm/ 10x10 cm/10x20 cm/ 20x20 cm Heel	do.	do.	do.
Medyn Forte Capsules	MEDICE Arzneimittel Pütter GmbH & Co. KG	Germany	Freely
GNC Super Magnesium 400 mg Capsules	General Nutrition Corporation	USA	do.
Total Lean CLA 2000 mg Softgel Capsules	do.	do.	do.
Apo-Irbesartan Tablets 75 mg	Apotex Inc.	Canada	Third Schedule
Apo-Lamivudine-Zidovudine Tablets 150/30 mg	do.	do.	do.
Apo-Esomeprazole Magnesium Delayed-release Tablets 20 mg	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Apo-Esomeprazole Magnesium Delayed-release Tablets 40 mg	Apotex Inc.	Canada	Third Schedule
Apo-Donepezil Tablets 5 mg	do.	do.	do.
Apo-Simvastatin Tablets 40 mg	do.	do.	do.
Apo-Divalproex Enteric Coated Tablets 250 mg	do.	do.	do.
Apo-Divalproex Enteric Coated Tablets 500 mg	do.	do.	do.
Apo-Imatinib Tablets 400 mg	do.	do.	do.
Apo-Imatinib Tablets 100 mg	do.	do.	do.
Apo-Fluticasone Aqueous Nasal Spray 50 mcg/ Metered Dose	do.	do.	do.
Apo-Mometasone Aqueous Nasal Spray 50 mcg/Spray	do.	do.	do.
Apo-Letrozole Tablets 2.5 mg	do.	do.	do.
Men's Power Multi Caplets	Jamieson Laboratories Ltd.	do.	Freely
Vita-Vim Kids with Iron Chewable Tablets	do.	do.	do.
Arthrimin Glucosamine Chondroitin with MSM & Hyaluronic Acid (Orange Effervescent Drink Crystals)	do.	do.	do.
Probiotics Sticks Powdered Crystals 3 Billion Active Cells	Jamieson Laboratories Ltd.	Canada	do.
Zyrtec Film-Coated Tablets 10 mg (Change of Packaging Site and Source)	Manufacturer: UCB Farchim SA Switzerland Packager: Aesica Pharmaceuticals S.r.l Via Praglia 15	Italy	Third Schedule
Pectylin-C Expectorant Syrup 5 ml (Change of Importer)	IPCA Laboratories Ltd.	India	Freely

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Advantan Cream 0.1% (Change of Name of Manufacturing and Packaging Site and Change of Name of Marketing Authorization Holder)	Manufactured by: Bayer Healthcare Manufacturing S.R.L., For: Bayer Pharma AG Germany	Italy	Third Schedule
Panadol Joint Prolonged Release Tablets 665 mg (Change of Artwork Design)	Manufacturer: GlaxoSmithKline (Dungarvan) Ltd. Ireland Packaging Site GlaxoSmithKline Panama S.A.	Panama	Freely
Advantan Ointment 0.1% (Change of Name of Manufacturing and Packaging Site and Change of Name of Marketing Authorization Holder)	Manufactured by: Bayer Healthcare Manufacturing S.R.L. for: Bayer Pharma AG Germany	Italy	Third Schedule
Travogen Cream Dermatological 1% (Change of Name of Manufacturing and Packaging Site and Change of Name of Marketing Authorization Holder)	do.	do.	do.
Gyno Travogen Cream 1% (Change of Name of Manufacturing and Packaging Site and Change of Name of Marketing Authorization Holder)	do.	do.	do.
Galvus Tablets 50 mg (Additional Source)	Manufactured by Novartis Farmacéutica, S.A. for Novartis Pharma AG Switzerland	Spain	Third Schedule
Lamictal Dispersible Chewable Tablets 25 mg (Additional Manufacturing Site)	GlaxoSmithKline Pharmaceuticals SA, Poland Packaging Site GlaxoSmithKline Mexico, S.A. De C.V.	Mexico	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Lamictal Dispersible Chewable Tablets 50 mg (Additional Manufacturing Site)	GlaxoSmithKline Pharmaceuticals SA, Poland Packaging Site GlaxoSmithKline Mexico, S.A. De C.V.	Mexico	Third Schedule
Lamictal Dispersible Chewable Tablets 100 mg (Additional Manufacturing Site)	do.	do.	do.
Novolin 70/30 Suspension for Injection 100 IU/ml, 10 ml Vial (Additional Manufacturing Site)	Novo Nordisk Production SAS	France	do.
Novolin N Suspension for Injection 100 IU/ml (Additional Manufacturing Site)	do.	do.	do.
Novolin R Solution for Injection 100 IU/ml, 10 ml Vial (Additional Manufacturing Site)	do.	do.	do.
Emend Capsules 125 mg/ 80 mg (Change of Manufacturing and Packaging Site)	Alkermes Pharma Ireland Ltd. Ireland Monksland, Athlone Co. Ireland, Packager: MSD, Campinas	Brazil	do.
Glucophage XR Tablets 500 mg (Change of Manufacturing and Packaging Site)	Merck S.A.	do.	do.
Glucophage XR Tablets 750 mg (Change of Manufacturing and Packaging Site)	do.	do.	do.
Glucophage XR Tablets 1000 mg (Change of Manufacturing and Packaging Site)	do.	do.	do.
LiquiBand Optima Topical Skin Adhesive 0.5 g (Change of Name of Manufacturer)	Advanced Medical Solutions (Plymouth) Limited	United Kingdom	Freely (Pharmacy ONLY)

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Natele Easy Gel Soft Capsules (Change of Manufacturing Site, Change in the Quantity of excipients in the Formula and Change in the Primary Packaging Material)	Manufactured by: Berlimed, S.A. for Bayer Pharma AG, Germany	Spain	Freely
Advil® Ibuprofen Tablets 200 mg (Change of Name of Distributor and Change of Name of Manufacturer)	Wyeth Pharmaceuticals Company for: Pfizer, USA	Puerto Rico	do.
Advil Cold Sinus Caplets (Change of Name of Distributor and Change of Name of Manufacturer)	Wyeth Pharmaceuticals Company, Puerto Rico, Packaged by: Fareva Richmond Inc. for: Pfizer USA	USA	do.
Vaxigrip Pediatric, Suspension for Injection in Prefilled Syringe Influenza Vaccine (split virion, inactivated) (Change in Label and in Packaging)	Sanofi Pasteur S.A.	France	Third Schedule
Vaxigrip Suspension for Injection in Prefilled Syringe, Influenza Vaccine (split virion, inactivated) (Change in Label and in Packaging)	do.	do.	do.
PNEUMO 23, Solution for Injection in Prefilled Syringe Pneumococcal Polysaccharide Vaccine (Change in Label and in Packaging)	do.	do.	do.
Meningococcal Polysaccharide A+C Vaccine-Powder and Solvent for Suspension for Injection in Prefilled Syringe (Change in Label and in Packaging)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Avaxim 160 U Suspension for Injection in a prefilled syringe Hepatitis A Vaccine (inactivated, adsorbed) (Change in Label and in Packaging)	Sanofi Pasteur S.A.	France	Third Schedule
Trimovax Merieux Powder and Solvent for Solution for Injection, Attenuated live virus vaccine against measles, mumps and rubella (Change in Label and in Packaging)	do.	do.	do.
Stamaril Powder and solvent for Suspension for Injection in Prefilled Syringe Yellow Vaccine (Live) (Change in label and in Packaging)	do.	do.	do.
ACT-HIB 10 mcg/0.5 ml, Powder and Solvent for Solution for Injection in Prefilled Syringe Haemophilus Influenzae type b Conjugate Vaccine (Change in Label and in Packaging)	do.	do.	do.
Verorab Powder and Solvent for Suspension for Injection Rabies, Vaccine for human use, prepared in cell cultures (inactivated) (Change in Label and in Packaging)	do.	do.	do.
TETAVAX Suspension for Injection in Multidose Presentation Adsorbed Tetanus Vaccine (Change in Label and in Packaging)	do.	do.	do.
PENTAXIM, Powder and Suspension for Injection in Prefilled Syringe Diphtheria, Tetanus, Pertussis, (acellular component) Poliomyelitis (inactivated) Vaccine and Haemophilus type b Conjugate Vaccine, Adsorbed (Change in Label and in Packaging)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Typhim Vi Solution for Injection in a Prefilled Syringe Polysaccharide Typhoid Vaccine (Change in Label, Change in Packaging, Change in Specification of Water, Change in Reference of Antifoam, Change in Autolytic Yeast Extract and Rationalization of in-process controls)	Sanofi Pasteur S.A.	France	Third Schedule
Orofer Capsules (Change of Importer)	M/S Emcure Pharmaceutical Ltd.	India	Freely
Requip Tablets 0.25 mg (Change of Source)	Glaxo Wellcome S.A.	Spain	Third Schedule
Requip Tablets 1 mg (Change of Source)	do.	do.	do.
Requip Tablets 2 mg (Change of Source)	do.	do.	do.
Requip Tablets 5 mg (Change of Source)	do.	do.	do.
Asacol Gastro-Resistant Tablets 400 mg (Change in Excipient)	Haupt Pharma Wülfing GmbH for Tillotts Pharma AG Switzerland	Germany	do.
Immunate Powder for Solution for Injection 500 I.E./IU FVIII/375 I.E. IU VWF (Change of Trade name)	Baxter AG	Austria	Third Schedule
Asthalin Inhaler (CFC Free) Salbutamol Pressurised Inhalation BP 100 mcg/spray (Change of CFC Content)	Cipla Ltd.	India	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
<i>Veterinary Products</i>			
Lhiflunex Injectable Solution 50 mg	Laboratorio Hispanoamericano SA de CV	El Salvador	Veterinary Prescription Only
Albendazol LH 10% Oral Suspension	do.	do.	Freely
Hierro Injectable-LH Solution	do.	do.	Veterinary Prescription Only
Dexametasone LH-10 Injectable Suspension	do.	do.	do.
Exeldor 1% Injectable Solution	do.	do.	do.
Troton Oral Paste Ivermectin 18.7 mg	do.	do.	Freely
Lhivermectin Avicola Oral Solution Ivermectin 1 g	do.	do.	do.
Lhifloxacina 20% Oral Solution	do.	do.	Veterinary Prescription Only
Chickenvit-Pius Oral Solution	do.	do.	do.
MULTIVIT CH-Oral Solution	KELA N.V.	Belgium	Freely
Vitamin B Complex Injectable Solution	do.	do.	Veterinary Prescription Only
Ivermectin 10 Injectable Solution	ANUPCO Ltd.	UK	do.
Hunter 4 Oral Powder	do.	do.	do.
Albendazole 1500 mg/Bolus	KELA N.V.	Belgium	Freely
Albendazole 250 mg/Bolus	do.	do.	do.
Trisulkel 240 Injectable Solution	do.	do.	do.
Phenylbutakel Injectable Solution 20%	do.	do.	Veterinary Prescription Only

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Dexakel 02 Injectable Solution for Veterinary Use	KELA N.V.	Belgium	Veterinary Prescription Only
Oxytokel 10 IU Injectable Solution	do.	do.	do.
Combistress Injectable Solution 2%	do.	do.	do.
Adedrikel 300 Injectable Solution	do.	do.	do.
Cotrim 480W Oral Powder	ANUPCO Ltd.	UK	do.
RwR Stanzol Suspension Injection 50 mg/mL	RwR Veterinary Products Pty Ltd.	Australia	do.
Exodus Paste	Bimeda MTC Animal Health Inc.	Canada	Freely
Dexamethasone Injection 2 mg Liquid for Injection	Kepto B.V.	The Netherlands	Veterinary Prescription Only
Oxytocin Injection 10 IU Liquid for Injection	do.	do.	do.
Kepromec Drench 0.8 mg	do.	do.	Freely

Dated this 23rd day of September, 2015

T. DEYALSINGH
Minister of Health