

LEGAL NOTICE No. 165

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
Cilostal® 50mg tablets (Change of Manufacturer)	Altea Farmacéutica S.A. Calle 10 No. 65-28, Bogota D.C. Colombia For: Merck S.A. Bogotá D.C., Colombia	Colombia	Third Schedule (Specialist Use Only)
Cilostal® 100mg tablets (Change of Manufacturer)	Altea Farmacéutica S.A. Calle 10 No. 65-28, Bogota D.C. Colombia For: Merck S.A. Bogotá D.C., Colombia	Colombia	Third Schedule (Specialist Use Only)
Ovidrel® 250µg/0.5 ml Solution for injection in Pre-filled cartridge in injector pen (Additional Presentation-pen; Marketing Authorisation Holder verification as Merck S.A., Guatemala)	Merck Serono S.p.A., Italy For: Merck S.A., Guatemala	Italy	Third Schedule (Specialist Use Only)

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
LASTACRAFT® Alcaftadine Ophthalmic Solution 0.25% Antihistamine Eye Drops (Change of Condition of Sale; Change of Artwork)	Allergan Sales, LLC United States of America For: Allergan, Inc., United States of America	United States of America	Freely
ERBITUX® 5mg/ml Solution for Infusion (Change of Manufacturer; Change of Marketing Authorisation Holder)	Merck Healthcare KGaA. Darmstadt, Germany For: Merck S.A., Guatemala	Germany	Third Schedule (Specialist Use Only)
Carbopa-150 Injection 150mg/15ml - Single Use Vial (Additional Manufacturing Site, Change of Pharmacopoeial Claim – BP to Ph. Eur)	Intas Pharmaceuticals Limited, Plot No. 457-458, Village Matoda, Bavla Road, Tal.: Sanand, Dist. – Ahmedabad, India Intas Pharmaceuticals Limited, Plot No. 5 to 14, Pharmez, Near Village Matoda, Tal. Sanand, Dist. – Ahmedabad, State Gujarat, India	India	Third Schedule (Specialist Use Only)
Carbopa-450 Injection 450mg/45ml - Single Use Vial (Additional Manufacturing Site; Change of Pharmacopoeial Claim – BP to Ph. Eur)	Intas Pharmaceuticals Limited, Plot No. 457-458, Village Matoda, Bavla Road, Tal.: Sanand, Dist. – Ahmedabad, India Intas Pharmaceuticals Limited, Plot No. 5 to 14, Pharmez, Near Village Matoda, Tal. Sanand, Dist. – Ahmedabad, State Gujarat, India	India	Third Schedule (Specialist Use Only)

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Pharmaton® Kiddi Syrup Orange Flavour 100mL, 200mL (Change of Name and Address of Marketing Authorization Holder; Update of Artwork)	Soho Flordis International Switzerland S.A., Switzerland For: Opella Healthcare Panama S.A., Panama	Switzerland	Freely
Allegra® Pediatric 30mg/5mL Suspension (Change of Name and Address of Product Holder; Change of Artwork)	Sanofi Medley Farmacêutica Ltda., Brazil For: Opella Healthcare Panama S.A., Panama	Brazil	Freely
Allegra® 180mg Film-Coated Tablets (Change of Name and Address of Product Holder; Change of Artwork)	Sanofi Medley Farmacêutica Ltda., Brazil For: Opella Healthcare Panama S.A., Panama	Brazil	Freely
Allegra® 120mg Film-Coated Tablets (Change of Name and Address of Product Holder; Change of Artwork)	Sanofi Medley Farmacêutica Ltda., Brazil For: Opella Healthcare Panama S.A., Panama	Brazil	Freely
Allegra® D 60mg/120mg Extended Release Film-Coated Tablets (Change of Name and Address of Product Holder; Change of Artwork)	Sanofi Winthrop Industrie, France Packaged by: Sanofi Medley Farmacêutica Ltda., Brazil For: Opella Healthcare Panama S.A., Panama	Brazil	Freely
Cispa-10 Injection 1mg/mL (Change of Pharmacopoeial Claim-BP to Ph. Eur; Change of Artwork; Additional Manufacturing Site)	Intas Pharmaceuticals Limited, Matoda- 382 210, Dist.: Ahmedabad, India	India	Third Schedule (Specialist Use Only)

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Intas Pharmaceuticals Limited, Plot No:5 to 14, Pharmez, Near Village Matoda, Ta: Sanand, Dist:Ahmedabad, India		
Cispa-50 Injection 1mg/mL (Change of Pharmacopoeial Claim-BP to Ph. Eur; Change of Artwork; Additional Manufacturing Site)	Intas Pharmaceuticals Limited, Matoda- 382 210, Dist.: Ahmedabad, India Intas Pharmaceuticals Limited, Plot No:5 to 14, Pharmez, Near Village Matoda, Ta: Sanand, Dist:Ahmedabad, India	India	Third Schedule (Specialist Use Only)
Zoladex® LA 10.8mg Implant in Prefilled Syringe Applicator (Additional Indication)	Manufactured & Packaged by: AstraZeneca UK Limited, Macclesfield Cheshire SK10 2NA UK For: AstraZeneca UK Limited, UK	United Kingdom	Third Schedule (Specialist Use Only)
Pulmicort 0.25mg/ml Nebulising Suspension (New Indications)	AstraZeneca AB, Södertälje, Sweden	Sweden	Third Schedule
IMFINZI™ 120mg/2.4ml (50mg/ml) Concentrate for solution for infusion (Additional Indication)	Manufacturer & Primary Packaging Site: Catalent Indiana LLC, USA Secondary Packaging Site: AstraZeneca AB, Sweden Södertälje, Sweden For: AstraZeneca UK Ltd, United Kingdom	Sweden	Third Schedule (Specialist Use Only)

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
IMFINZI™ 500mg/10ml (50mg/ml) Concentrate for solution for infusion (Additional Indication)	Manufacturer & Primary Packaging Site: Catalent Indiana LLC, USA Secondary Packaging Site: AstraZeneca AB, Södertälje, Sweden For: AstraZeneca UK Ltd United Kingdom	Sweden	Third Schedule (Specialist Use Only)
Vymada™ 50mg film coated tablets (Additional Indication)	Novartis Singapore Pharmaceutical Manufacturing Private Ltd., Singapore Packaged by: Novartis Farma S.p.A. Torre Annunziata, Italy For: Novartis Overseas Investments AG, Switzerland	Italy	Third Schedule
Vymada™ 100mg film coated tablets (Additional Indication)	Novartis Singapore Pharmaceutical Manufacturing Private Ltd., Singapore Packaged by: Novartis Farma S.p.A. Torre Annunziata, Italy For: Novartis Overseas Investments AG, Switzerland	Italy	Third Schedule
Vymada™ 200mg film coated tablets (Additional Indication)	Novartis Singapore Pharmaceutical Manufacturing Private Ltd., Singapore Packaged by: Novartis Farma S.p.A. Torre Annunziata, Italy	Italy	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	For: Novartis Overseas Investments AG, Switzerland		
Lamisil® 250mg Tablets (Additional Primary & Secondary Packaging Site; Change of Artwork)	Novartis Pharma Produktions GmbH, Wehr, Germany Packaged by: Lek Pharmaceuticals d.d., Slovenia For: Novartis Pharma AG, Basel, Switzerland	Slovenia	Third Schedule
Galvus® 50mg Tablets (Change of Manufacturer; Change of Packager; Change of Artwork)	Manufactured & Packaged by: Siegfried Barbera, S.L., Spain For: Novartis Pharma AG, Basel, Switzerland	Spain	Third Schedule
Galvus® 50mg Tablets (Additional Manufacturer; Additional Packager; Change of Artwork)	Manufactured & Packaged by: Lek Pharmaceuticals d.d., Ljubljana, Slovenia For: Novartis Pharma AG, Basel, Switzerland	Slovenia	Third Schedule
Foradil® 12 mcg Capsules for Oral Inhalation (Change of Manufacturer; Change of Artwork)	Manufactured & Packaged by: Siegfried Barberá SL, Spain For: Novartis Pharma AG Basel, Switzerland	Spain	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
EXFORGE® 5mg/80mg film-coated tablets (Change of Manufacturer; Change of Packager; Change of Artwork)	Manufactured & Packaged by: Siegfried Barbera, S.L., Barberá del Vallès Spain For: Novartis Pharma AG, Basel, Switzerland	Spain	Third Schedule
EXFORGE® 5mg/160mg film-coated tablets (Change of Manufacturer, Change of Packager, Change of Artwork)	Manufactured & Packaged by: Siegfried Barbera, S.L., Barberá del Vallès Spain For: Novartis Pharma AG, Basel, Switzerland	Spain	Third Schedule
EXFORGE® 10mg/160mg film-coated tablets (Change of Manufacturer, Change of Packager, Change of Artwork)	Manufactured & Packaged by: Siegfried Barbera, S.L., Barberá del Vallès Spain For: Novartis Pharma AG, Basel, Switzerland	Spain	Third Schedule
Diovan® 80 mg film-coated tablets (Change of Manufacturer; Change of Packager; Change of Artwork)	Manufactured & Packaged by: Siegfried Barbera, S.L., Barberá del Vallès, Spain For: Novartis Pharma AG, Basel, Switzerland	Spain	Third Schedule
Diovan® 160 mg film-coated tablets (Change of Manufacturer; Change of Packager; Change of Artwork)	Manufactured & Packaged by: Siegfried Barbera, S.L., Barberá del Vallès, Spain For: Novartis Pharma AG, Basel, Switzerland	Spain	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Diovan® 80 mg film-coated tablets (Additional Source; Change of Artwork)	Manufactured & Packaged by: Novartis Farma S.p.A. Torre Annunziata, Italy For: Novartis Pharma AG, Basel, Switzerland	Italy	Third Schedule
Diovan® 160 mg film-coated tablets (Additional Source; Change of Artwork)	Manufactured & Packaged by: Novartis Farma S.p.A. Torre Annunziata, Italy For: Novartis Pharma AG, Basel, Switzerland	Italy	Third Schedule
Diovan® 320 mg film-coated tablets (Change of Manufacturer; Change of Packager; Change of Artwork)	Manufactured & Packaged by: Siegfried Barbera, S.L., Barberà del Vallès, Spain For: Novartis Pharma AG, Basel, Switzerland	Spain	Third Schedule
Diovan® 320 mg film-coated tablets (Additional Source; Change of Artwork)	Manufactured & Packaged by: Novartis Farma S.p.A. Torre Annunziata, Italy For: Novartis Pharma AG, Basel, Switzerland	Italy	Third Schedule
Accentrix® 10mg/ml Solution for injection (Change of Artwork)	Manufactured & Packaged by: Novartis Pharma Stein AG Stein, Switzerland For: Novartis Overseas Investments AG Switzerland	Switzerland	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Dulera® 100 mcg/5 mcg Inhalation Aerosol (Change of Name of Manufacturer; Change of Artwork)	Kindeva Drug Delivery Limited, Loughborough, UK For: Organon LLC, a subsidiary of Organon & Co, Jersey City, NJ, 07302, USA	United Kingdom	Third Schedule
Dulera® 200 mcg/5 mcg Inhalation Aerosol (Change of Name of Manufacturer; Change of Artwork)	Kindeva Drug Delivery Limited, Loughborough, UK For: Organon LLC, a subsidiary of Organon & Co, Jersey City NJ, 07302, USA	United Kingdom	Third Schedule
AERIUS® 5mg Tablet (Change of Marketing Authorization Holder; Change of Artwork)	Schering-Plough Labo N.V. Heist-op-den-Berg, Belgium For: Organon Pharma S.de R.L., Panamá	Belgium	Third Schedule
AERIUS® 0.5mg/mL Syrup (Change of Marketing Authorization Holder; Change of Artwork)	Schering-Plough Labo N.V. Heist-op-den-Berg, Belgium For: Organon Pharma S.de R.L., Panamá	Belgium	Third Schedule
Cancidas® 50mg For Injection (Change of Name of Manufacturer; Change of Name of Packager; Change of Name of Importer; Change of Artwork)	Manufactured & Packaged by: Fareva Mirabel, Clermont-Ferrand, France For: Merck Sharp & Dohme Corp., a subsidiary of MERCK & CO., INC USA	France	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
ancidas® 70mg For Injection (Change of Name of Manufacturer; Change of Name of Packager; Change of Name of Importer; Change of Artwork)	Manufactured & Packaged by: Fareva Mirabel, Clermont-Ferrand, France; For: Merck Sharp & Dohme Corp., a subsidiary of MERCK & CO., INC USA	France	Third Schedule
TYLENOL® Extra Strength 500mg Caplets (Change of Artwork)	McNeil Consumer Healthcare LLC La Piedras, Puerto Rico Distributor: Johnson & Johnson Consumer Inc. McNeil Consumer Healthcare Division, USA	Puerto Rico	Freely
Salve® Antiseptic First Aid Spray 0.45% (Change in Artwork)	Bpi Genethics Limited. No. 5A, CTC Drive, Macoya, Trinidad, West Indies	Trinidad and Tobago	Freely
Genethics Hydrogen Peroxide Solution 6% B.P. (Change in Artwork)	Bpi Genethics Limited, No. 5A CTC Drive, Macoya, Trinidad, West Indies	Trinidad and Tobago	Freely
Kisqali® 200mg film-coated tablets (Change of Primary & Secondary Packaging Site; Change of Country of Origin; New Indication)	Novartis Singapore Pharmaceutical Manufacturing Pte. Ltd., Singapore Packaged by: Novartis Pharma Stein AG, Stein, Switzerland For: Novartis Pharma AG, Basel, Switzerland	Switzerland	Third Schedule (Specialist Use Only)

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Tasigna® 200mg Capsules (Change of Primary & Secondary Packaging Site; Change of Country of Origin; Change of Artwork)	Novartis Pharma Stein AG, Stein, Switzerland Packaged by: Lek Pharmaceuticals d.d., Lendava, Slovenia For: Novartis Pharma AG, Basel, Switzerland	Slovenia	Third Schedule (Specialist Use Only)
Tasigna® 150mg Capsules (Change of Primary & Secondary Packaging Site; Change of Country of Origin; Change of Artwork)	Novartis Pharma Stein AG, Stein, Switzerland Packaged by: Lek Pharmaceuticals d.d., Lendava, Slovenia For: Novartis Pharma AG, Basel, Switzerland	Slovenia	Third Schedule (Specialist Use Only)
Gilvec® 100mg Film-Coated Tablets (Change of Primary & Secondary Packaging Site; Change of Country of Origin; Change of Artwork)	Novartis Pharma Produktions, Wehr, Germany Packaged by: Lek Pharmaceuticals d.d., Lendava, Slovenia For: Novartis Pharma AG, Basel, Switzerland	Slovenia	Third Schedule (Specialist Use Only)
Tremfya® 100 mg/mL Solution for injection in pre-filled syringe (Change in Artwork)	Cilag AG Switzerland	Switzerland	Third Schedule
Tremfya® 100 mg/ml Solution for injection in pre-filled pen (Additional Presentation; Change in Artwork)	Cilag AG Switzerland	Switzerland	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
CoLosar-Denk 50/12.5 film-coated tablets 50mg/12.5mg (Additional Packaging Site)	DENK PHARMA GmbH & Co. KG Göllstr.1, 84529 Tittmoning, Germany Packaged by: Swiss Caps GmbH Grassingerstr. 9 83043 Bad Aibling Germany For: DENK PHARMA GmbH & Co. KG Prinzregentenstr. 79, 81675 München, GERMANY	Germany	Third Schedule
CoLosar-Denk 100/12.5 film-coated tablets 100mg/12.5mg (Additional Packaging Site)	DENK PHARMA GmbH & Co. KG Göllstr.1, 84529 Tittmoning, Germany Packaged by: Swiss Caps GmbH Grassingerstr. 9 83043 Bad Aibling Germany For: DENK PHARMA GmbH & Co. KG Prinzregentenstr. 79, 81675 München, GERMANY	Germany	Third Schedule
Metformin Denk 500 film-coated tablets 500mg (Additional Packaging Site)	DENK PHARMA GmbH & Co. KG Göllstr. 1, 84529 Tittmoning, GERMANY Packaged by: Swiss Caps GmbH Grassingerstr. 9 83043 Bad Aibling GERMANY	Germany	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	For: DENK PHARMA GmbH & Co. KG Prinzregentenstr. 79, 81675 München, GERMANY		
SURVANTA® Intratracheal Suspension 25mg/mL (Change of Artwork)	AbbVie Inc., 1401 Sheridan Road, North Chicago, IL 60064 United States of America	United States of America	Third Schedule (Specialist Use Only)
Vit-B-Denk vitamin B ₁ + vitamin B ₆ film-coated tablets (Additional Packaging Site)	DENK PHARMA GmbH & Co. KG, Göllstr. 1, 84529 Tittmoning, Germany Packaged by: Swiss Caps GmbH Grassingerstr. 9 83043 Bad Aibling Germany For: DENK PHARMA GmbH & Co. KG Prinzregentenstr. 79, 81675 München, GERMANY	Germany	Freely
Avelox® 400 mg film coated tablet (Additional Manufacturer; Additional Packager; Change of Artwork)	Bayer HealthCare Manufacturing S.r.l, Italy For: Bayer AG, Germany	Italy	Third Schedule
Rivotril® 2.5 mg/ml Drops (Change of Product Holder; Change of Artwork)	Productos Roche Químicos e Farmacêuticos, S.A., Rio de Janeiro, Brazil. For: CHEPLAPHARM Arzneimittel GmbH, Greifswald, Germany	Brazil	Controlled

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Rivotril® 0.5 mg tablets (Change of Product Holder; Change of Artwork)	Productos Roche Quimicose Farmacêuticos, S.A., Rio de Janeiro, Brazil. For: CHEPLAPHARM Arzneimittel GmbH, Greifswald, Germany	Brazil	Controlled
Rivotril® 2 mg tablets (Change of Name of Manufacturing Site; Change of Product Licence Holder; Change of Product Design- embossed; Change of Distributor; Change of Artwork)	Recipharm Leganés S.L.U., Spain For: CHEPLAPHARM Arzneimittel GmbH, Greifswald, Germany	Spain	Controlled
Panadol Children 80mg Cherry flavour Chewable Tablets (Change of Artwork; Change of Distributor)	GlaxoSmithKline Panamá S.A., Panama Urbanización Industrial Juan Díaz, Calles A y B, Panamá	Panama	Freely
Panadol Ultra 500 mg/65mg caplets (Change of Secondary Packaging Size; Change of Artwork; Change of Distributor)	GlaxoSmithKline Panamá S.A., Panamá	Panama	Freely
TUMS® Antacid Extra Strength 750mg Assorted Fruit Chewable Tablets (Additional Primary Packaging)	GSK Consumer Healthcare Warren, NJ 07059, USA	United States of America	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Arixtra® 2.5 mg/0.5 mL Subcutaneous Solution for Injection (Change of Artwork)	Aspen Notre Dame de Bondeville, France For: Aspen Labs S.A. de C.V., Mexico	France	Third Schedule (Specialist Use Only)
Alevian duo® 100 mg/300 mg capsules (Primary and Secondary Artwork & Labelling Update)	Gelcaps Exportadora de México S.A. de C.V., Naucalpan de Juárez, Estado de México, Mexico. Packaged by: Takeda México, S.A. de C.V., Naucalpan de Juárez, Estado de México, Mexico. For: Takeda México, S.A. de C.V., Naucalpan de Juárez, Estado de México, Mexico.	Mexico	Third Schedule
Imuran® 50 mg film-coated tablets (Change in Safety Information; Change of Product Design; Monograph and Leaflet Update; Change of Artwork)	Excella GmbH & Co. KG, Feucht, Germany For: Aspen Labs S.A. de C.V., Mexico	Germany	Third Schedule (Specialist Use Only)
Phillips® Milk of Magnesia Original Suspension (Change of Marketing Authorization Holder; Change of Artwork)	Aspen México, S. de R.L. de C.V., México. For: Aspen Caricam S.A., Costa Rica.	Mexico	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Phillips® Milk of Magnesia Mint Suspension (Change of Marketing Authorization Holder; Change of Artwork)	Aspen México, S. de R.L. de C.V., México. For: Aspen Caricam S.A., Costa Rica.	Mexico	Freely
Diprivan 10mg/ml (1%) Emulsion for Injection or Infusion (Change of Packager; Change of Artwork)	Corden Pharma SpA, Viale dell'Industria, 3, 20867 Caponago (MB), Italy. For: Aspen Labs S.A. de C.V., Mexico	Italy	Third Schedule (Specialist Use Only)
Xyntha® 250 IU Powder for Solution for Injection (Change of Diluent Manufacturing Site)	Powder Manufacturer: Wyeth Farma S.A., Madrid, Spain Diluent Manufacturer: Vetter Pharma-Fertigung GmbH & Co. KG, Langenargen, Germany Secondary Packager: Wyeth Farma S.A., Madrid, Spain For: Wyeth Pharmaceuticals Inc., Philadelphia, EEUU	Spain	Third Schedule (Specialist Use Only)
Xyntha® 500 IU Powder for Solution for Injection (Change of Diluent Manufacturing Site)	Powder Manufacturer: Wyeth Farma S.A., Madrid, Spain Diluent Manufacturer: Vetter Pharma-Fertigung GmbH & Co. KG, Langenargen, Germany Secondary Packager: Wyeth Farma S.A., Madrid, Spain	Spain	Third Schedule (Specialist Use Only)

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	For: Wyeth Pharmaceuticals Inc., Philadelphia, EEUU		
Pristiq® 50 mg Extended-Release Tablets (Change in Packaging Material)	Pfizer Ireland Pharmaceuticals, Ireland Packaged by: Pfizer Pharmaceuticals LLC, Vega Baja, Puerto Rico For: PF Prism C.V., c/o Pfizer Netherlands, Capelle aan IJssel, Netherlands	Puerto Rico; United States of America	Third Schedule
Pristiq® 100 mg Extended-Release Tablets (Change in Packaging Material)	Pfizer Ireland Pharmaceuticals, Ireland Packaged by: Pfizer Pharmaceuticals LLC, Vega Baja, Puerto Rico For: PF Prism C.V., c/o Pfizer Netherlands, Capelle aan IJssel, Netherlands	Puerto Rico United States of America	Third Schedule
Prozac™ 20mg Hard Capsules (Change of Product Licence Holder)	Patheon France 40, boulevard de Champaret 38300 BOURGOIN- JALLIEU France For: Asofarma S.A., Guatemala	France	Third Schedule
Cialis™ 10mg film-coated tablets (Change of Product Licence Holder)	Lilly del Caribe Inc., Puerto Rico Industrial Park, 65th Infantry Road, 12.6km Carolina, Puerto Rico 00985	Spain	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Packaged by: Lilly S.A. Avda. Industria 30 28108 Alcobendas Madrid Spain For: Asofarma S.A., Guatemala		
Cialis™ 20mg film-coated tablets (Change of Product Licence Holder)	Lilly del Caribe Inc., Puerto Rico Industrial Park, 65th Infantry Road, 12.6km Carolina, Puerto Rico 00985 Packaged by: Lilly S.A. Avda. Industria 30 28108 Alcobendas Madrid Spain For: Asofarma S.A., Guatemala	Spain	Third Schedule
Cialis™ 5mg film-coated tablets (Change of Product Licence Holder; Change of Artwork)	Lilly del Caribe Inc., Puerto Rico Industrial Park, 65th Infantry Road, 12.6km Carolina, Puerto Rico 00985 Packaged by: Lilly S.A. Avda. Industria 30 28108 Alcobendas Madrid Spain For: Asofarma S.A., Guatemala	Spain	Third Schedule
Humulin® R REGULAR 100 units/ml insulin human injection, USP (rDNA origin) (Change of Product Licence Holder; Change of Distributor)	Eli Lilly and Company Indianapolis, IN 46285, USA For: Asofarma S.A., Guatemala	United States of America	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Humulin® N 100 units/ml NPH human insulin (rDNA origin) isophane suspension (Change of Product Licence Holder; Change of Distributor)	Eli Lilly and Company Indianapolis, IN 46285, USA For: Asofarma S.A., Guatemala	United States of America	Third Schedule
Humalog™ 100 units/ml solution for injection in cartridge (Change of Product Licence Holder; Change of Distributor)	LILLY France S.A.S. F-67640 Fegersheim, France For: Asofarma S.A., Guatemala	France	Third Schedule
Humalog™ Mix 25™ 100 units/ml suspension for injection in cartridge (Change of Product Licence Holder; Change of Distributor)	LILLY France S.A.S. F-67640 Fegersheim, France For: Asofarma S.A., Guatemala	France	Third Schedule
Humalog™ Mix 75/25™ KwikPen™ 100 units per mL injectable suspension (Change of Product Licence Holder; Change of Artwork)	LILLY France, S.A.S. F-67640 Fegersheim, France Packaged by: Eli Lilly and Company Indianapolis, IN 46285, USA For: Asofarma S.A., Guatemala	United States of America	Third Schedule
Humalog™ 100 units per mL insulin lispro injection (Change of Product Licence Holder; Change of Artwork)	Eli Lilly and Company Indianapolis, IN 46285, USA For: Asofarma S.A., Guatemala	United States of America	Third Schedule
Humalog™ KwikPen™ 100 units per mL insulin lispro injection	LILLY France, S.A.S. F-67640 Fegersheim, France	United States of America	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
(Change of Product Licence Holder; Change of Artwork)	Packaged by: Eli Lilly and Company Indianapolis, IN 46285, USA For: Asofarma S.A., Guatemala		
Humulin™ 70/30 100 IU/ml Suspension for Injection in Cartridge insulin human (Change of Product Licence Holder)	Lilly France S.A.S. F-67640 Fegersheim, France For: Asofarma S.A., Guatemala	France	Third Schedule
Humulin™ R REGULAR 100 IU/ml Solution for Injection in Cartridge insulin human (Change of Product Licence Holder)	Lilly France S.A.S. F-67640 Fegersheim, France For: Asofarma S.A., Guatemala	France	Third Schedule
Humulin™ N 100 IU/ml NPH Suspension for Injection in Cartridge insulin human (Change of Product Licence Holder)	Lilly France S.A.S. F-67640 Fegersheim, France For: Asofarma S.A., Guatemala	France	Third Schedule
Humulin® 70/30 100 units per mL 70% human insulin isophane suspension 30% human insulin injection (rDNA origin) (Change of Product Licence Holder; Change of Distributor)	Eli Lilly and Company Indianapolis, IN 46285, USA For: Asofarma S.A., Guatemala	United States of America	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Abasaglar™ KwikPen™ 100 units/mL solution for injection in a pre-filled pen Insulin glARGine (Change of Product Licence Holder)	LILLY France, S.A.S., F-67640 Fegersheim, France For: Asofarma S.A., Guatemala	France	Third Schedule
Forteo™ 20 micrograms/80 microliters, solution for injection in pre-filled pen (Change of Product Licence Holder; Change of Distributor)	LILLY France, S.A.S., F-67640 Fegersheim, France For: Asofarma S.A., Guatemala	France	Third Schedule
ALIMTA™ 500 mg powder for concentrate for solution for infusion (Change of Product Licence Holder)	Eli Lilly and Company Indianapolis, IN 46285, USA Packaged by: LILLY FRANCE S.A.S. F-67640 Fegersheim, France For: Asofarma S.A., Guatemala	France	Third Schedule (Specialist Use Only)
ZYPREXA™ 5 mg coated tablets (Change of Product Licence Holder)	Lilly, S.A. Avda. de la Industria, 30 28108 Alcobendas, Madrid Spain For: Asofarma S.A., Guatemala	Spain	Third Schedule
ZYPREXA™ 10 mg coated tablets (Change of Product Licence Holder)	Lilly, S.A. Avda. de la Industria, 30 28108 Alcobendas, Madrid Spain For: Asofarma S.A., Guatemala	Spain	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Cymbalta™ 30 mg hard gastro-resistant capsules (Change of Product Licence Holder; Change of Artwork)	Lilly del Caribe Inc. Puerto Rico Industrial Park 12.6km 65th Infantry Road Carolina, Puerto Rico PR00985 Packaged by: Lilly S.A. Avda. de la Industria, 30 28108 Alcobendas Madrid Spain For: Asofarma S.A., Guatemala	Spain	Third Schedule
Cymbalta™ 60 mg hard gastro-resistant capsules (Change of Product Licence Holder; Change of Artwork)	Lilly del Caribe Inc. Puerto Rico Industrial Park 12.6km 65th Infantry Road Carolina, Puerto Rico PR00985 Packaged by: Lilly S.A. Avda. de la Industria, 30 28108 Alcobendas Madrid Spain For: Asofarma S.A., Guatemala	Spain	Third Schedule
<u>Veterinary Product</u> RABISIN Suspension for Injection $\geq 2.09 \log_{10} \text{OD}_{50}$ and $\geq 1 \text{ IU}$ (Change of Marketing Authorization Holder; Change in Name of Manufacturer; Change in Artwork)	Boehringer Ingelheim Animal Health France SCS, Rue de l'Aviation 69800 Saint Priest-France	France	(To Veterinarians or by Veterinary Prescription Only)
<u>Veterinary Product</u> Pawfect Pets Antiseptic Spray (Additional Name to Product; Change in Artwork Design)	Bpi Genethics Limited 5A. CTC Drive, Macoya, Trinidad. West Indies	Trinidad and Tobago	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Duphalac® 66.7g/100mL Syrup (Additional Manufacturer)	Abbott Laboratories de México, S.A. de C.V., México	Mexico	Third Schedule
Bradirem 5mg film-coated tablets	Remedica Ltd Aharnon Street, Limassol Industrial Estate, 3056 Limassol, Cyprus	Cyprus	Third Schedule
Bradirem 7.5mg film-coated tablets	Remedica Ltd Aharnon Street, Limassol Industrial Estate, 3056 Limassol, Cyprus	Cyprus	Third Schedule
Biktarvy™ (bictegravir, emtricitabine, and tenofovir alafenamide) tablets 50 mg/ 200 mg/ 25 mg	Gilead Sciences Ireland UC IDA Business & Technology Park Carrigtohill, County Cork, Ireland For: Gilead Sciences Ireland UC Carrigtohill, County Cork, T45 DP77, Ireland	Ireland	Third Schedule (Specialist Use Only)
Dicetel® 100mg Coated Tablets	Mylan Laboratories S.A.S.; France Packaged by: Abbott Laboratories de México S.A. de C.V., México For: Abbott Laboratories de México S.A. de C.V., México	Mexico	Third Schedule
Duspatalin® 200mg Extended Release Capsules	Mylan Laboratories S.A.S.; France Packaged by: Abbott Laboratories de México S.A. de C.V., México	Mexico	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	For: Abbott Laboratories de México S.A. de C.V., México		
Fertilo Forte Denk Oral Powder	C. Hedenkamp GmbH & Co. KG, Germany For: Denk Pharma GmbH & Co. KG, Germany	Germany	Freely
Fungifex 250mg tablets	Remedica Ltd Aharnon Street, Limassol Industrial Estate, 3056 Limassol, Cyprus	Cyprus	Third Schedule
Methotrexate 2.5 mg film-coated tablets	Remedica Ltd Aharnon Street, Limassol Industrial Estate, 3056 Limassol, Cyprus	Cyprus	Third Schedule (Specialist Use Only)
Nutrazul ACTIVE Magnesium + Zinc Effervescent Tablets	C. Hedenkamp GmbH & Co. KG, Schierbusch 1, 33161. Hövelhof, Germany	Germany	Freely
Nutrazul Vitamin C Effervescent Tablets	C. Hedenkamp GmbH & Co. KG, Schierbusch 1, 33161. Hövelhof, Germany	Germany	Freely
VISINE® A.C. ITCHY EYE RELIEF	Janssen Pharmaceutica NV; Turnhoutseweg 30, Beerse, Antwerpen B-2340, Belgium	Belgium	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Distributed by: Johnson & Johnson Consumer Inc., USA		
VISINE® ALLERGY EYE RELIEF MULTI-ACTION	Janssen Pharmaceutica NV; Turnhoutseweg 30, Beerse, Antwerpen B-2340, Belgium Distributed by: Johnson & Johnson Consumer Inc., USA	Belgium	Freely
Edistride™ 10mg film-coated tablets	AstraZeneca Pharmaceuticals LP, USA/EEUU. For: AstraZeneca AB, Sweden	United States of America	Third Schedule
Saphnelo™ (anifrolumab) 300mg/2ml (150mg/ml) concentrate for solution for infusion	AstraZeneca Nijmegen, Netherlands Packaged by: AstraZeneca AB, Sweden For: AstraZeneca AB, Sweden	Sweden	Third Schedule (Specialist Use Only)
MAYZENT™ 0.25 mg film-coated tablets	Novartis Pharma Stein AG, Stein, Switzerland Packaged by: Siegfried Barbera S.L., Spain For: Novartis Pharma AG, Basle, Switzerland	Spain	Third Schedule (Specialist Use Only)
MAYZENT™ 2 mg film-coated tablets	Novartis Pharma Stein AG, Stein, Switzerland Packaged by: Siegfried Barbera, S.L., Spain For: Novartis Pharma AG, Basle, Switzerland	Spain	Third Schedule (Specialist Use Only)

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Sybrava™ 284mg/1.5ml Solution for injection in pre-filled syringe	Sandoz GmbH; Langkampfen, Austria For: Novartis Overseas Investments AG, Switzerland	Austria	Third Schedule (Specialist Use Only)
Nutrazul IMMUNE+ Zinc 10mg + Vit C 150mg + Vit E 27IU Effervescent Tablets	C. Hedenkamp GmbH & Co. KG, Schierbusch 1, 33161. Hövelhof, Germany	Germany	Freely
Salve® Antiseptic Cream	Bpi Genethics Limited 5A CTC Drive, Macoya, Trinidad & Tobago, W.I.	Trinidad and Tobago	Freely
PAINOL 8mg/5ml Mucolytic Syrup	Bpi Genethics Limited 5A CTC Drive, Macoya, Trinidad & Tobago, W.I.	Trinidad and Tobago	Freely
PAINOL jR. 4mg/5ml Mucolytic Syrup	Bpi Genethics Limited 5A CTC Drive, Macoya, Trinidad & Tobago, W.I.	Trinidad and Tobago	Freely
PAINOL jR. Cough + Cold Syrup	Bpi Genethics Limited 5A CTC Drive, Macoya, Trinidad & Tobago, W.I.	Trinidad and Tobago	Freely
No More Mucus 8mg/5mL Syrup	Bpi Genethics Limited 5A CTC Drive, Macoya, Trinidad & Tobago, W.I.	Trinidad and Tobago	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
No More Cough & Cold Kids Syrup	Bpi Genethics Limited 5A CTC Drive, Macoya, Trinidad & Tobago, W.I.	Trinidad and Tobago	Freely
No More Germs Soothing Antiseptic First Aid Cream	Bpi Genethics Limited 5A CTC Drive, Macoya, Trinidad & Tobago, W.I.	Trinidad and Tobago	Freely
No More Mucus 4mg/5mL Kids Syrup	Bpi Genethics Limited 5A CTC Drive, Macoya, Trinidad & Tobago, W.I.	Trinidad and Tobago	Freely
Anastrozole Denk 1 mg film-coated tablets	Haupt Pharma Münster GmbH, Schleebrüggenkamp 15 48159 Münster Germany For: DENK PHARMA GmbH & Co. KG Prinzregentenstr. 79, 81675 München, Germany	Germany	Third Schedule (Specialist Use Only)
Axaban-Denk 2.5 mg film-coated tablets	Combino Pharm (Malta) Ltd HF-60 HAL Far Industrial Estate Hal Far BBG 3000, Malta For: DENK PHARMA GmbH & Co. KG Prinzregentenstr. 79, 81675 München, Germany	Malta	Third Schedule
Axaban-Denk 5 mg film-coated tablets	Combino Pharm (Malta) Ltd HF-60 HAL Far Industrial Estate Hal Far BBG 3000, Malta	Malta	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	For: DENK PHARMA GmbH & Co. KG Prinzregentenstr. 79, 81675 München, Germany		
Ibuprofen Denk 400 film-coated tablets	DENK PHARMA GmbH & Co. KG Göllstr. 1, 84529 Tittmoning, Germany For: DENK PHARMA GmbH & Co. KG Prinzregentenstr. 79, 81675 München, GERMANY	Germany	Third Schedule
Letrozole Denk 2.5 f.c. tablets	Haupt Pharma Münster GmbH, Schleebrüggenkamp 15, 48159 Münster Germany For: DENK PHARMA GmbH & Co. KG Prinzregentenstr. 79 81675 München GERMANY	Germany	Third Schedule (Specialist Use Only)
On.setron-Denk 4 mg ODT orodispersible tablets	DENK PHARMA GmbH & Co. KG Göllstr.1, 84529 Tittmoning, Germany Packaged by: Swiss Caps GmbH, Germany For: DENK PHARMA GmbH & Co. KG Prinzregentenstr. 79, 81675 München, GERMANY	Germany	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
On.setron-Denk 8 mg ODT orodispersible tablets	DENK PHARMA GmbH & Co. KG Göllstr. 1, 84529 Tittmoning, Germany Packaged by: Swiss Caps GmbH, Germany For: DENK PHARMA GmbH & Co. KG Prinzregentenstr. 79, 81675 München, GERMANY	Germany	Third Schedule
OCTREOTIDE 20mg Powder and Solvent for Prolonged-release Suspension for Injection	Pharmathen International S.A., Greece For: Pharmathen S.A., Greece	Greece	Third Schedule
OCTREOTIDE 30mg Powder and Solvent for Prolonged-release Suspension for Injection	Pharmathen International S.A., Greece For: Pharmathen S.A., Greece	Greece	Third Schedule
RoPolivy® 30 mg Powder for concentrate for solution for infusion	F. Hoffmann-La Roche Ltd., Kaiseraugst Switzerland For: F. Hoffmann-La Roche Ltd., Basel, Switzerland	Switzerland	Third Schedule (Specialist Use Only)
Xofluza® 20 mg film-coated tablets	Shionogi & Co., Ltd, Settsu Plant, Japan Packaged by: Sharp Corporation, Pennsylvania United States For: F. Hoffmann-La Roche Ltd., Basel, Switzerland	United States of America	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Xofluza® 40 mg film-coated tablets	Shionogi & Co., Ltd, Settsu Plant, Japan Packaged by: Sharp Corporation, Pennsylvania United States For: F. Hoffmann-La Roche Ltd., Basel, Switzerland	United States of America	Third Schedule
Xofluza® 40 mg film-coated tablets	Shionogi & Co., Ltd, Settsu Plant, Japan Packaged by: F. Hoffmann-La Roche Ltd., Kaiseraugst, Switzerland For: F. Hoffmann-La Roche Ltd., Basel, Switzerland	Switzerland	Third Schedule
Actemra® 162 mg Solution for subcutaneous injection (162 mg/0.9 ml) in a pre-filled syringe	Vetter Pharma-Fertigung GmbH & Co. KG, Ravensburg, Germany For: F. Hoffmann-La Roche Ltd, Basel, Switzerland	Germany	Third Schedule (Specialist Use Only)
Androcur® 100 mg Tablets	Bayer Weimar GmbH und Co. KG, Weimar, Germany For: Bayer AG, Germany	Germany	Third Schedule
Androcur® 50 mg Tablets	Bayer Weimar GmbH und Co. KG, Weimar, Germany For: Bayer AG, Germany	Germany	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
PROGYNOVA® 1 mg tablets	Bayer Weimar GmbH und Co. KG, Germany For: Bayer AG, Germany	Germany	Third Schedule
PROGYNOVA® 2 mg tablets	Bayer Weimar GmbH und Co. KG, Germany For: Bayer AG, Germany	Germany	Third Schedule
Firialta® 10 mg Film-coated tablets	Bayer AG, Leverkusen Germany.	Germany	Third Schedule (Specialist Use Only)
Firialta® 20 mg Film-coated tablets	Bayer AG, Leverkusen Germany	Germany	Third Schedule (Specialist Use Only)
Redoxitos® Plus Chewable gummies	Trolli GmbH, Germany Packaged by: Amapharm GmbH, Germany For: Bayer S.A., Guatemala.	Germany	Freely
Cibinqo™ 200 mg Film-coated tablets	Pfizer Manufacturing Deutschland GmbH, Freiburg, Germany For: Pfizer Europe MA EEIG, Belgium	Germany	Third Schedule (Specialist Use Only)
Cibinqo™ 100 mg Film-coated Tablets	Pfizer Manufacturing Deutschland GmbH, Freiburg, Germany For: Pfizer Europe MA EEIG, Belgium	Germany	Third Schedule (Specialist Use Only)

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Cibinqo™ 50 mg Film-coated Tablets	Pfizer Manufacturing Deutschland GmbH, Freiburg, Germany For: Pfizer Europe MA EEIG, Belgium	Germany	Third Schedule (Specialist Use Only)
Alive!® Men's Gummy 100 mg	Nature's Way Brand, LLC	United States of America	Freely
Alive!® Kids Multivitamin Gummy 100 mg	Nature's Way Brand, LLC	United States of America	Freely
Broksil Syrup 6 mg/mL	Farmalabor - Productos Farmaceuticos, S.A.	Portugal	Freely
Ezimiva Coated Tablets 2.5 mg	Towa Pharmaceutical Europe, S.L.	Spain	Third Schedule
Ezimiva Coated Tablets 5.0 mg	Towa Pharmaceutical Europe, S.L.	Spain	Third Schedule
Osteo Joint Ease Caplets	Factors Group of Nutritional Companies Inc.	Canada	Freely
Valmac A 10 mg/160 mg Tablets (Amlodipine 10 mg and Valsartan 160 mg)	Macleods Pharmaceuticals Ltd.	India	Third Schedule
Diutol Tablets 4 mg (Tolterodine Tartrate Extended Release Tablet)	Macleods Pharmaceuticals Ltd.	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Tamsumac Capsules 0.4 mg (Tamsulosin Hydrochloride Capsules USP 0.4 mg)	Macleods Pharmaceuticals Ltd.	India	Third Schedule
Mo-Floren Ophthalmic Solution 5 mg/mL (Moxifloxacin Ophthalmic Solution 5 mg/mL)	Indoco Remedies Ltd.	India	Third Schedule
Metchek 850 (Metformin Tablets BP 850 mg)	Indoco Remedies Ltd.	India	Third Schedule
ALBUREL (Human Solution BP, 20% Solution for Infusion 50 mL)	Reliance Life Sciences Pvt Ltd.	India	Specialist Use Only
CARBOL (Carboplatin Concentrate for Solution for Infusion 450 mg/45 mL)	Venus Remedies Limited	India	Specialist Use Only
CYTOMIB (Bortezomib 3.5 mg Powder for Solution for Injection)	Venus Remedies Limited	India	Specialist Use Only
DOXOL (Docetaxel Concentrate for Solution for Infusion 80 mg/4 mL)	Venus Remedies Limited	India	Specialist Use Only
GLEMONT - L (Montelukast Sodium 10 mg and Levocetirizine Dihydrochloride 5 mg Tablets)	Glenmark Pharmaceuticals Ltd.	India	Third Schedule
Combiwave SF 250 (Salmeterol and Fluticasone Propionate Pressurized Inhalation 25+250 mcg/actuation)	Glenmark Pharmaceuticals Ltd.	India	Third Schedule
Combiwave SF 125 (Salmeterol and Fluticasone Propionate Pressurized Inhalation 25+125 mcg/actuation)	Glenmark Pharmaceuticals Ltd.	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
GLENCET (Levocetirizine Dihydrochloride Tablets 5 mg)	Glenmark Pharmaceuticals Ltd.	India	Third Schedule
RESCUWAVE Salbutamol Pressurized Inhalation BP (100 mcg/actuation)	Glenmark Pharmaceuticals Ltd.	India	Third Schedule
Tacroz Forte Ointment 0.1% W/W (Tacrolimus Ointment)	Glenmark Pharmaceuticals Ltd.	India	Third Schedule
Jamieson Probiotic 30 Billion Capsules	Jamieson Laboratories Ltd	Canada	Freely
Valsartan and Hydrochlorothiazide Tablets USP 160 mg/12.5 mg	Hetero Labs Limited	India	Third Schedule
Valsartan and Hydrochlorothiazide Tablets USP 160 mg/25 mg	Hetero Labs Limited	India	Third Schedule
Valsartan and Hydrochlorothiazide Tablets USP 80 mg/12.5 mg	Hetero Labs Limited	India	Third Schedule
Ezetimibe and Simvastatin Tablets 10 mg/20 mg	Hetero Labs Limited	India	Third Schedule
Etoricoxib Tablets 120 mg	Hetero Labs Limited	India	Third Schedule
Etoricoxib Tablets 90 mg	Hetero Labs Limited	India	Third Schedule
Fingolimod Capsules 0.5 mg	Hetero Labs Limited	India	Third Schedule
Temozolomide Capsules 180 mg	Hetero Labs Limited	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Temozolomide Capsules 20 mg	Hetero Labs Limited	India	Third Schedule
Irbesartan and Hydrochlorothiazide Tablets 150 mg/12.5 mg	Hetero Labs Limited	India	Third Schedule
Telmisartan Tablets 40 mg	Hetero Labs Limited	India	Third Schedule
Valsartan Tablets 80 mg	Hetero Labs Limited	India	Third Schedule
Valsartan Tablets 160 mg	Hetero Labs Limited	India	Third Schedule
Trifluoperazine Hydrochloride Tablets 5 mg	SGPharma Pvt. Ltd.	India	Third Schedule
Deferasirox Tablets 125 mg	SGPharma Pvt. Ltd.	India	Third Schedule
Deferasirox Tablets 250 mg	SGPharma Pvt. Ltd.	India	Third Schedule
Deferasirox Tablets 500 mg	SGPharma Pvt. Ltd.	India	Third Schedule
Acetazolamide Tablets USP 250 mg	SGPharma Pvt. Ltd.	India	Third Schedule
Benzotropine Mesylate Tablets USP 2 mg	SGPharma Pvt. Ltd.	India	Third Schedule
Gabapentin Capsules USP 300 mg	SGPharma Pvt. Ltd.	India	Third Schedule
Carbimazole Tablets B.P. 5 mg	SGPharma Pvt. Ltd.	India	Third Schedule
Microdacyn 60 Oropharynx Antiseptic Oropharynx Solution (Additional Manufacturing Site and Update of Artwork)	Aerobal S.A. de C.V.	Mexico	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Aleve Extra Strength Tablets 220 mg (Change of Primary Packaging, Update of Artwork, Update of Specifications)	Bayer Bitterfeld GmbH	Guatemala	Freely
Beriate Powder and Solvent for Solution for Injection or Infusion 250 IU (Update of Secondary Label to Include Venipuncture Kit with Instructions for Use, PIL)	CSL Behring GmbH	Germany	Third Schedule
Beriate Powder and Solvent for Solution for Injection or Infusion 500 IU (Update of Secondary Label to Include Venipuncture Kit with Instructions for Use, PIL)	CSL Behring GmbH	Germany	Third Schedule
Beriate Powder and Solvent for Solution for Injection or Infusion 1000 IU (Update of Secondary Label to Include Venipuncture Kit with Instructions for Use, PIL)	CSL Behring GmbH	Germany	Third Schedule

Dated this 31st day of May, 2023.

T. DEYALSINGH
Minister of Health