

LEGAL NOTICE No. 162

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
Triumeq 50mg/600mg/300mg Film-Coated Tablets (Additional Manufacturing Site)	GlaxoSmithKline Pharmaceuticals S.A.	Poland	Third Schedule
Zentel 4% Oral Suspension (Change of Artwork; Additional Manufacturing Site)	Aspen Bad Oldesloe GmbH For: GlaxoSmithKline GmbH & Co. KG Germany	Germany	Freely
Tremfya 100mg/ml Solution for Injection in Pre-filled Syringe (Additional Indication)	Cilag AG	Switzerland	Third Schedule
Avonex 30µg/0.5ml Solution for Injection (Change of Name of Packager; Change of Address of Packager; Change of Artwork)	Vetter Pharma-Fertigung GmbH & Co. Kg, Germany Packaged by: Fujifilm Diosynth Biotechnologies Denmark ApS	Denmark	do.
Dolo-Denk Gel (Change of Name of Manufacturer; Change of Artwork)	C.P.M. ContractPharma GmbH Germany For: Denk Pharma GmbH & Co. KG Germany	Germany	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Losar-Denk 25 Film-Coated Tablets 25mg (Change in Packaging)	Denk Pharma GmbH & Co. KG, Germany For: Denk Pharma GmbH & Co. KG Germany	Germany	Third Schedule
Losar-Denk 100 Film-Coated 100mg Tablets (Change in Packaging)	do.	do.	do.
Roaccutane 10mg Capsules (Additional Packaging Site; Change in Artwork; Change in Distributor)	Catalent Germany Eberbach GmbH, Germany For: F. Hoffmann-La Roche Ltd., Switzerland	do.	do.
Roaccutane 20mg Capsules (Additional Packaging Site; Change in Artwork; Change in Distributor)	do.	do.	do.
Herceptin 440mg Powder for Concentration for Solution for Infusion (Additional Packaging Site; Change in Artwork; Change in Distributor)	Genentech Inc., USA For: F. Hoffmann-La Roche Ltd. Switzerland	USA	do.
RoPolivy® 140mg Powder for Concentrate for Solution for Infusion (Change in Artwork)	BSP Pharmaceuticals S.p.A. Italy Packaged by: F. Hoffmann-La Roche Ltd. For: F. Hoffmann-La Roche Ltd. Switzerland	Switzerland	do.
Dormicum 15mg/3ml Ampoules I.V., I.M. and Rectal Solution for Injection (Change in Marketing Authorisation Holder; Change in Artwork)	F. Hoffmann-La Roche S.A., France For: Laboratorios Siegfried S.A. Panama	France	Controlled

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Dormicum 50mg/10ml Ampoules I.V., I.M. and Rectal Solution for Injection (Change in Marketing Authorisation Holder)	F. Hoffmann-La Roche S.A., France For: Laboratorios Siegfried S.A. Panama	France	Controlled
Dormicum 15mg Tablets (Change of Marketing Authorisation Holder; Change in Artwork; Change in Distributor)	Productos Roche Quimicos e Farmaceuticos S.A., Brazil For: Laboratorios Siegfried S.A. Panama	Brazil	do.
Bactrim Forte 800/160mg Tablets (Change of Marketing Authorisation Holder; Change in Artwork; Change in Distributor)	Productos Roche Quimicos e Farmaceuticos S.A., Brazil For: Laboratorios Siegfried S.A. Panama	Brazil	Third Schedule
Bactrim Forte 200/40mg Suspension (Change of Marketing Authorisation Holder; Change in Artwork)	do.	do.	do.
Lamisil Dermgel 1% Gel (Change of Name of Manufacturer; Change in Artwork)	GSK Consumer Healthcare SARL, Switzerland For: GlaxoSmithKline Costa Rica S.A. Costa Rica	Switzerland	do.
Lamisil 1% Cream (Change of Name of Manufacturer; Change in Artwork)	do.	do.	do.
Voltaren Emulgel 1.16% Gel (Change of Name of Manufacturing Site; Change of Artwork)	GSK Consumer Healthcare SARL, Switzerland For: GlaxoSmithKline Costa Rica S.A. Costa Rica	Switzerland	do.
Procto-Glyvenol Cream (Change of Name of Manufacturing Site; Change of Artwork)	GSK Consumer Healthcare SARL For: GlaxoSmithKline Costa Rica S.A. Costa Rica	Switzerland	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Otrivin Metered Dose Nasal Spray 0.1% (Change of Name of Manufacturing Site; Change of Artwork)	GSK Consumer Health SARL, Switzerland For: GlaxoSmithKline Costa Rica S.A. Costa Rica	Switzerland	Freely
Otrivin Nasal Spray Nebuliser Solution 0.1% (Change of Name of Manufacturing Site; Change of Artwork)	do.	do.	do.
Otrivin Nasal Drops Solution 0.1% (Change of Name of Manufacturing Site; Change of Artwork)	GSK Consumer Healthcare S.A.R.L. For: GlaxoSmithKline Costa Rica S.A. Costa Rica	Switzerland	do.
Otrivin Children Nasal Drops Solution 0.05% (Change of Name of Manufacturing Site; Change of Artwork)	do.	do.	do.
Amaryl 2mg Tablets (Change of Name of Manufacturer; Change of Name of Product Holder; Change of Artwork)	Sanofi-Medley Farmaceutica Ltda., Brazil	Brazil	Third Schedule
Amaryl 4mg Tablets (Change of Name of Manufacturer; Change of Name of Product Holder; Change of Artwork)	do.	do.	do.
Daonil 5mg Tablets (Change of Name of Manufacturer; Change of Name of Product Holder; Change of Artwork)	do.	do.	do.
Calcort 6mg Tablets (Change of Name of Packing Site; Change of Name of Product Holder; Change of Artwork)	Sanofi S.p.A., Italy Packaged by: Sanofi Medley Farmaceutica Ltda., Brazil	do.	do.
Calcort 30mg Tablets (Change of Name of Packing Site; Change of Name of Product Holder; Change of Artwork)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Lasix 40mg Tablets (Change of Name of Manufacturer; Change of Name of Product Holder; Change of Artwork)	Sanofi Medley Farmaceutica Ltda., Brazil	Brazil	Third Schedule
Lasix 20mg/2ml Injectable Solution (Change of Name of Manufacturer; Change of Name of Product Holder; Change of Artwork)	do.	do.	do.
Biprofenid 150mg Prolonged Release Tablets (Change of Name of Manufacturing Site; Change of Name of Product Holder; Change of Artwork)	do.	do.	do.
Aprovel 150mg Film-Coated Tablets (Change of Name of Marketing Authorisation Holder; Change of Distributor)	Sanofi-Winthrop Industrie, France For: Sanofi-Aventis Groupe, France	France	do.
Aprovel 300mg Film-Coated Tablets (Change of Name of Marketing Authorisation Holder; Change of Distributor)	do.	do.	do.
CoAprovel 150mg/12.5mg Film-Coated Tablets (Change of Name of Marketing Authorisation Holder; Change of Distributor)	do.	do.	do.
CoAprovel 300mg/12.5mg Film-Coated Tablets (Change of Name of Marketing Authorisation Holder; Change of Distributor)	do.	do.	do.
CoAprovel 300mg/25mg Film-Coated Tablets (Change of Name of Marketing Authorisation Holder; Change of Distributor)	do.	do.	do.
Toujeo® SoloStar® 300 units/ml Solution for Injection in Pre-filled Pen (Additional Indication; Change in Artwork)	Sanofi-Aventis Deutschland GmbH, Germany For: Sanofi-Aventis Deutschland GmbH Germany	Germany	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Plavix 75mg Film-Coated Tablets (Change of Name of Product Holder; Additional Indication; Change in Artwork)	Sanofi Winthrop Industrie For: Sanofi-Aventis Groupe France	France	Third Schedule
Galvus Met 50mg/500mg Film-Coated Tablets (Additional Packaging Site)	Novartis Pharma Produktions GmbH Germany Packaged by: Novartis Urunleri, A.S., Turkey For: Novartis Pharma AG Switzerland	Turkey	do.
Galvus Met 50mg/850mg Film-Coated Tablets (Additional Packaging Site)	do.	do.	do.
Galvus Met 50mg/1000mg Film- Coated Tablets (Additional Packaging Site)	do.	do.	do.
Accentrix 10mg/ml Solution for Injection (New Indication)	Novartis Pharma Stein AG, Switzerland For: Novartis Overseas Investment AG Switzerland	Switzerland	Third Schedule (Specialist Use Only)
Elocom® 0.1% Ointment (Change of Product Name; Change of Artwork; Change of Importer)	Schering-Plough Labo N.V., Belgium	Belgium	Third Schedule
Elocom® 0.1% Cream (Change in Marketing Authorisation Holder; Change in Artwork)	Schering-Plough Labo N.V., Belgium For: Organon Pharma S.de R.L., Panama	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Bridion 100mg/ml Solution for Injection (Change in Marketing Authorisation Holder; Additional Manufacturer)	Patheon Manufacturing Services LLC United States of America Packaged by: N.V. Organon, The Netherlands For: Merck Sharp & Dohme (UK) Limited, United Kingdom	The Netherlands	Third Schedule
Esmeron® 10mg/ml Solution for Injection (Change in Marketing Authorisation Holder; Change in Name of Manufacturer)	Siegfried Hameln GmbH, Germany Packaged by: N.V. Organon, The Netherlands For: Merck Sharp & Dohme B.V. The Netherlands	do.	do.
Nexium Gastro-Resistant Sachet 10mg Granules for Oral Suspension (Change in Marketing Authorisation Holder; Change in Packaging)	AstraZeneca AB Sweden Packaged by: AstraZeneca S.A. de C.V. Mexico For: AstraZeneca UK Limited United Kingdom	Mexico	do.
Riopan 80mg/10mg/1ml Gel (Change of Packaging)	Takeda México, S.A. de C.V., Mexico For: Aspen Panama S.A. Panama	do.	do.
Imuran 50mg Film-Coated Tablets (Additional Manufacturing Site)	Aspen Port Elizabeth (PTY) Ltd, South Africa For: Aspen Labs S.A. de C.V., Mexico	South Africa	do.
Acetylcysteine 200mg/ml Injection (Additional Packaging Site)	Demo SA Pharmaceutical Industry For: Aurum Pharmaceutical Ltd. United Kingdom	Greece	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
NeoMercazole 5mg Tablets (Change of Primary Packaging)	Cenexi SAS, France For: Amdipharm Limited, Ireland	France	Third Schedule
Clarityne 10mg Tablets (Change of Manufacturer; Change of Packager)	Bayer Bitterfeld GmbH, Germany Packaged by: Bayer de México S.A. de C.V., Mexico For: Bayer S.A. Guatemala	Mexico	Freely
Nebido 1000mg/4ml Solution for Injection (Additional Presentation 6ml/vial)	Bayer AG Germany	Germany	Third Schedule
Sutent 12.5mg Hard Gelatin Capsules (New Indication)	Pfizer Italia S.r.l, Ascoli Piceno, Italy For: Pfizer Europe MA EEIG, Belgium	Italy	do.
Sutent 50mg Hard Gelatin Capsules (New Indication)	do.	do.	do.
Sutent 25mg Hard Gelatin Capsules (New Indication)	do.	do.	do.
Ecalta 100mg/vial Powder for Solution for Injection (New Indication)	Pharmacia & Upjohn Company LLC, USA For: Vicuron Holdings LLC USA	USA	Third Schedule (Specialist Use Only)
Xeljanz 5mg Film-Coated Tablets (Change in Licence Holder; Change in Packaging Site; New Indication)	Pfizer Manufacturing Deutschland GmbH, Germany For: Pfizer Europe MA EEIG Belgium	Germany	Third Schedule (Specialist Use Only)



TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Aldactone 100mg Tablets (Change of Name of Manufacturer; Change of Name of Packager; Change in Artwork)	Piramal Healthcare UK Limited, United Kingdom For: Pfizer Limited United Kingdom	UK	Third Schedule
Ibrance 75mg Capsules (Change of Licence Holder; Change of Packaging Site; Change in Artwork)	Pfizer Manufacturing Deutschland GmbH Germany For: Pfizer Europe MA EEIG Belgium	Germany	do.
Aleve® Liqui-Gels® Liquid Filled Capsules 200mg (Change of Packaging Site; Change in Artwork)	Catalent Argentina S.A.I.C., Argentina Packaged by: Bayer S.A., Guatemala For: Bayer S.A., Guatemala	Guatemala	Freely
Prograf® XL 1mg Prolonged-Release Hard Capsules (Change of Marketing Authorisation Holder; Change in Artwork; Change in Name; Change in Distributor)	Astellas Ireland Co., Ltd., Ireland For: Asofarma S.A.	Ireland	Third Schedule
Prograf® XL 5mg Prolonged-Release Hard Capsules (Change of Marketing Authorisation Holder; Change in Artwork; Change in Name; Change in Distributor)	do.	do.	do.
Doloforte Denk Film-Coated Tablets (Change of Packaging)	Denk Pharma GmbH & Co. KG	Germany	do.
Isoptin® 80mg Coated Tablets (Change of Manufacturer)	Abbott Laboratories de México S.A. de C.V.	Mexico	do.
Isoptin® 120mg Retard/Extended- Release Coated Tablets (Change of Manufacturer)	do.	do.	do.
Isoptin® SR 240mg Extended-Release Coated Tablets (Change of Manufacturer)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Immunine-600IU Powder in vial for Solution for Injection/Infusion (Change in Marketing Authorisation Holder; Change in Artwork)	Baxter AG, Austria	Austria	Third Schedule
Zestoretic 20/12.5mg Tablets (Additional Manufacturing Site)	AstraZeneca Pharmaceutical Company Limited China Packaged by: AstraZeneca S.A. de C.V., Mexico For: AstraZeneca UK Limited United Kingdom	Mexico	do.
Enbrel 50mg Solution for Injection in Pre-filled Pen (Change in Packaging Site; Change in Artwork)	Pfizer Manufacturing Belgium NV, Belgium For: Pfizer Europe MA EEIG Belgium	Belgium	do.
Xanax 0.5mg Tablets (Change of Licence Holder; Change of Artwork; Change of Distributor)	Sanico N.V., Belgium Packaged by: Pfizer Italia S.r.l., Italy For: Upjohn S.R.L./BV, Belgium	Italy	Controlled
Dilantin 100mg Extended Oral Capsules (Change of Licence Holder; Change of Artwork; Change of Distributor)	Pfizer Pharmaceuticals LLC, Puerto Rico For: Upjohn US 1 LLC, USA	Puerto Rico	Third Schedule
Dilantin-125® Oral Suspension USP (Change of Licence Holder; Change of Artwork; Change of Distributor)	Pharmacia & Upjohn Company LLC, USA For: Upjohn US 1 LLC USA	USA	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Detrusitol SR 4mg Prolonged Release Capsules (Change of Licence Holder; Change of Artwork)	Catalent Pharma Solutions LLC USA Packaged by: Pfizer Italy S.r.l, Italy For: Upjohn US 2 LLC, USA	Italy	Third Schedule
Detrusitol SR 2mg Prolonged Release Capsules (Change of Licence Holder; Change of Artwork)	do.	do.	do.
Lyrica 25mg Capsules (Change of Licence Holder; Change of Artwork)	Pfizer Manufacturing Deutschland GmbH Germany For: Upjohn EESV, Netherlands	Germany	do.
Lyrica 75mg Capsules (Change of Licence Holder; Change of Artwork)	do.	do.	do.
Lyrica 150mg Capsules (Change of Licence Holder; Change of Artwork)	Pfizer Manufacturing Deutschland GmbH Germany For: Upjohn EESV Netherlands	do.	do.
Lyrica 300mg Capsules (Change of Licence Holder; Change of Artwork)	do.	do.	do.
Lipitor 10mg Tablets (Change of Licence Holder; Change of Artwork)	Pfizer Pharmaceuticals LLC Puerto Rico Packaged by: Pfizer Manufacturing Deutschland GmbH Germany For: Pfizer OFG Germany GmbH Germany	do.	do.
Lipitor 20mg Tablets (Change of Licence Holder; Change of Artwork)	do.	do.	do.

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Lipitor 40mg Tablets (Change of Licence Holder; Change of Artwork)	Pfizer Pharmaceuticals LLC Puerto Rico Packaged by: Pfizer Manufacturing Deutschland GmbH Germany For: Pfizer OFG Germany GmbH Germany	Germany	Third Schedule
Lipitor 80mg Tablets (Change of Licence Holder; Change of Artwork)	do.	do.	do.
Neurontin 100mg Capsules (Change of Licence Holder; Change of Distributor)	Pfizer Pharmaceuticals LLC, Puerto Rico For: Upjohn US 1 LLC USA	Puerto Rico	do.
Neurontin 300mg Capsules (Change of Licence Holder; Change of Distributor)	do.	do.	do.
Norvasc 5mg Tablets (Change of Licence Holder; Change of Distributor)	Pfizer Pharmaceuticals LLC Puerto Rico Packaged by: Pfizer Manufacturing Deutschland GmbH, Germany For: Pfizer OFG Germany GmbH Germany	Germany	do.
Norvasc 10mg Tablets (Change of Licence Holder; Change of Distributor)	do.	do.	do.
Xalacom 50mcg/ml + 5mg/ml Eye Drop Solution (Change of Licence Holder; Change of Distributor)	Pfizer Manufacturing Belgium NV For: Upjohn S.R.L./BV Belgium	Belgium	do.
Xalatan 0.005% Eye Drops (Change of Licence Holder; Change of Distributor)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Stelara 45mg/0.5ml Solution for Injection Pre-filled Syringe (New Indication)	Cilag AG	Switzerland	Third Schedule (Specialist Use Only)
Lonsurf 15mg/6.14mg Film-Coated Tablets (New Indication)	Taiho Pharmaceutical Co. Ltd. Japan Packaged by: Les Laboratoires Servier For: Les Laboratoires Servier France	France	do.
Lonsurf 20mg/8.19mg Film-Coated Tablets (New Indication)	do.	do.	do.
Invokana 100mg Film-Coated Tablets (Change of Manufacturer)	Janssen-Cilag S.p.A., Italy	Italy	Third Schedule
Invokana 300mg Film-Coated Tablets (Change of Manufacturer)	do.	do.	do.
Vokanamet 50mg/850mg Film-Coated Tablets (Change of Manufacturer)	do.	do.	do.
Vokanamet 50mg/1000mg Film-Coated Tablets (Change of Manufacturer)	do.	do.	do.
Vokanamet 150mg/850mg Film-Coated Tablets (Change of Manufacturer)	do.	do.	do.
Vokanamet 150mg/1000mg Film-Coated Tablets (Change of Manufacturer)	do.	do.	do.
Haliborange High Strength Vitamin C 1000mg - Blackcurrant Flavour Effervescent Tablets (Change of Marketing Authorisation Holder; Change of Manufacturer; Change of Artwork; Change of Product Licence Holder)	Kruger GmbH & Co. KG Germany For: PharmaCare (Europe) Ltd. United Kingdom	Germany	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Haliborange High Strength Vitamin C 1000mg - Ruby Orange Flavour Effervescent Tablets (Change of Marketing Authorisation Holder; Change of Manufacturer; Change of Artwork; Change of Product Licence Holder)	Kruger GmbH & Co. KG Germany For: PharmaCare (Europe) Ltd. United Kingdom	Germany	Freely
Haliborange High Strength Vitamin C 1000mg - Citrus Flavour Effervescent Tablets (Change of Marketing Authorisation Holder; Change of Manufacturer; Change of Artwork; Change of Product Licence Holder)	do.	do.	do.
Avelox 400mg Solution for Infusion (Additional Manufacturing Site; Additional Packaging Site; Change of Artwork)	Fresenius Kabi Italia S.r.l., Italy For: Bayer AG, Germany	Italy	Third Schedule
Avelox 400mg Film Coated Tablets (Additional Manufacturing Site; Additional Packaging Site; Change of Artwork)	Bayer HealthCare Manufacturing S.r.l., Italy Packaged by: Bayer S.A., Guatemala For: Bayer AG, Germany	Guatemala	do.
Ciproxina 500mg Film Coated Tablets (Additional Manufacturing Site; Additional Packaging Site)	Bayer HealthCare Manufacturing S.r.l., Italy For: Bayer AG, Germany	Italy	do.
Ciproxina 0.2g Solution for Infusion (Additional Manufacturing Site; Additional Packaging Site; Additional Presentation - 200ml)	Fresenius Kabi Italia S.r.l., Italy For: Bayer AG, Germany	Italy	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Betaferon 250mcg/ml Powder and Solvent for Solution for Injection (Change of Packaging Material; Change of Artwork)	Powder: Boehringer Ingelheim Pharma GmbH & Co. KG, Germany Solvent: Bayer AG, Germany Packaged by: Bayer AG Germany For: Bayer AG Germany	Germany	Third Schedule
Nimbex 2mg/ml (5mg in 2.5ml) Solution for Injection or Infusion (Additional Manufacturing Site)	Aspen SVP, Port Elizabeth, Republic of South Africa For: Aspen Labs S.A. de C.V., Mexico	South Africa	do.
Nimbex 2mg/ml (10mg in 5ml) Solution for Injection or Infusion (Additional Manufacturing Site)	do.	do.	do.
Panadol Sinus Tablets (Additional Presentation - 48 Tablets; Change of Artwork)	GlaxoSmithKline Panama S.A., Panama	Panama	Freely
Panadol Multisymptom Tablets (Additional Presentation - 48 Tablets; Change of Artwork)	do.	do.	do.
Epaq 0.75% Gel (Additional Manufacturer; Change of Artwork)	Grimann, S.A. de C.V. México	Mexico	Third Schedule
Epaq 0.75% Gel (Change of Marketing Authorisation Holder; Change of Artwork)	DPT Laboratories, Ltd., USA For: Grimann, S.A. de C.V. Mexico	USA	do.
Tambocor 100mg Tablets (Change of Marketing Authorisation Holder; Change of Artwork)	3M Health Care Limited, United Kingdom For: Grimann, S.A. de C.V. México	UK	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Microdacyn 60 Oropharynx Antiseptic Oropharynx Solution (Change of Marketing Authorisation Holder, Change of Artwork)	Oculus Technologies of México, S.A. de C.V., México For: Aerobal, S.A. de C.V. México	Mexico	Freely
Aldara 5% Cream (Change of Marketing Authorisation Holder, Change of Artwork)	3M Health Care Limited, United Kingdom For: Grimann, S.A. de C.V. México	UK	Third Schedule
Aldara 3.75% Cream (Change of Marketing Authorisation Holder, Change of Artwork)	do.	do.	do.
Hiprex 1g Tablets (Change of Marketing Authorisation Holder, Change of Artwork)	3M Health Care Limited, United Kingdom For: Grimann, S.A. de C.V. México	do.	do.
Zestril 10mg Tablets (Additional Manufacturing Site)	AstraZeneca Pharmaceutical Co. Ltd., China Packaged by: AstraZeneca, S.A. de C.V., México For: AstraZeneca UK Limited United Kingdom	Mexico	do.
Zestril 20mg Tablets (Additional Manufacturing Site)	do.	do.	do.
Tenormin 50mg Film Coated Tablets (Additional Manufacturing Site)	AstraZeneca Pharmaceutical Co. Ltd., China Packaged by: AstraZeneca, S.A. de C.V., México For: AstraZeneca, S.A. de C.V. México	do.	do.



TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Tenormin 100mg Film Coated Tablets (Additional Manufacturing Site)	AstraZeneca Pharmaceutical Co. Ltd., China Packaged by: AstraZeneca, S.A. de C.V., México For: AstraZeneca, S.A. de C.V. México	Mexico	Third Schedule
Nexium 40mg Powder for Solution for Injection/Infusion (Change of Marketing Authorisation Holder; Change of Packaging)	AstraZeneca AB Sweden For: AstraZeneca UK Limited United Kingdom	Sweden	do.
Lynparza 100mg Film Coated Tablets (New Indication)	Abbvie Limited KM, United States Packaged by: AstraZeneca UK Limited For: AstraZeneca AB Sweden	UK	Third Schedule (Specialist Use Only)
Lynparza 150mg Film Coated Tablets (New Indication)	do.	do.	do.
Pulmicort 0.5mg/ml Nebulising Suspension (Additional Indications)	AstraZeneca AB Sweden	Sweden	Third Schedule
Atacand 32mg Tablets (Change of Marketing Authorisation Holder)	AstraZeneca AB Sweden Packaged by: AstraZeneca, S.A. de C.V., México For: AstraZeneca AG Switzerland	Mexico	do.
Atacand Plus 32/12.5mg Tablets (Change of Marketing Authorisation Holder)	do.	do.	do.
Tylenol Cold Max Day Caplets (Change of Name of Product; Change of Artwork)	Johnson & Johnson Consumer Inc. USA	USA	Freely

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Tylenol Extra Strength 500mg Rapid Release Gelcaps (Change of Artwork)	Johnson & Johnson Consumer Inc. USA	USA	Freely
Sandimmun Neoral 25mg Capsules (Change of Packaging Site)	Catalent Germany Eberbach GmbH, Germany Packaged by: Lek Pharmaceuticals d.d. Slovenia For: Novartis Pharma AG Basle, Switzerland	Slovenia	Third Schedule
Sandimmun Neoral 100mg Capsules (Change of Packaging Site)	do.	do.	do.
Vymada 50mg (24mg/26mg) Film Coated Tablets (Additional Manufacturing Site; Change of Product Holder)	Novartis Farma S.p.A, Italy For: Novartis Overseas Investments AG Switzerland	Italy	do.
Vymada 100mg (49mg/51mg) Film Coated Tablets (Additional Manufacturing Site; Change of Product Holder)	do.	do.	do.
Vymada 200mg (97mg/103mg) Film Coated Tablets (Additional Manufacturing Site; Change of Product Holder)	do.	do.	do.
Myfortic Gastro-Resistant 180mg Tablets (Additional Packager)	Novartis Pharma Produktions GmbH, Wehr Germany Packaged by: Lek Pharmaceuticals Slovenia For: Novartis Pharma AG Basle, Switzerland	Slovenia	do.
Myfortic Gastro-Resistant 360mg Tablets (Additional Packager)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Singulair 4mg Chewable Tablets (Change of Marketing Authorisation Holder; Change of Name of Manufacturer; Change of Name of Packager; Change of Distributor; Change of Artwork)	Organon Pharma (UK) Ltd., United Kingdom Packaged by: Organon Farmaceutica Ltda. Brazil For: Organon Pharma S. de R.L., Panama	Brazil	Third Schedule
Singulair 5mg Chewable Tablets (Change of Marketing Authorisation Holder; Change of Name of Manufacturer; Change of Name of Packager; Change of Distributor; Change of Artwork)	do.	do.	do.
Singulair 10mg Chewable Tablets (Change of Marketing Authorisation Holder; Change of Name of Manufacturer; Change of Name of Packager; Change of Distributor; Change of Artwork)	do.	do.	do.
Januvia 25mg Film Coated Tablets (Change of Address of Marketing Authorisation Holder; Change of Name of Manufacturer; Change of Name of Packager; Change of Distributor; Change of Artwork)	Organon Pharma (UK) Limited., United Kingdom Packaged by: Organon Farmaceutica Ltda. Brazil For: Merck Sharpe & Dohme Farmaceutica Ltda., Brazil	do.	do.
Januvia 50mg Film Coated Tablets (Change of Address of Marketing Authorisation Holder; Change of Name of Manufacturer; Change of Name of Packager; Change of Distributor; Change of Artwork)	do.	do.	do.
Januvia 100mg Film Coated Tablets (Change of Address of Marketing Authorisation Holder; Change of Name of Manufacturer; Change of Name of Packager; Change of Distributor; Change of Artwork)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Singulair 4mg Oral Granules (Change of Marketing Authorisation Holder; Change of Distributor)	Patheon Manufacturing Services LLC, USA For: Organon Pharma S. de R.L. Panama	USA	Third Schedule
Janumet 50/500mg Tablets (Change of Address of Marketing Authorisation Holder; Change of Packager; Change of Distributor)	Patheon Puerto Rico, Inc., Puerto Rico Packaged by: Organon Farmaceutica Ltda Brazil For: Merck Sharp & Dohme Farmaceutica Ltda., Brazil	Brazil	do.
Janumet 50/1000mg Tablets (Change of Address of Marketing Authorisation Holder; Change of Packager; Change of Distributor)	do.	do.	do.
Vytorin 10mg/20mg Tablets (Change of Name of Marketing Authorisation Holder; Change of Name of Packager; Change of Distributor; Change of Artwork; Change of Name of Manufacturer)	MSD International GmbH (Singapore Branch) Packaged by: Organon Farmaceutica Ltda, Brazil For: Organon Farmaceutica Ltda., Brazil	do.	do.
Vytorin 10mg/40mg Tablets (Change of Address of Marketing Authorisation Holder; Change of Name of Packager; Change of Distributor; Change of Artwork; Change of Name of Manufacturer)	do.	do.	do.
Vasotec 10mg Tablets (Change of Name of Marketing Authorisation Holder; Change of Name of Packager; Change of Distributor; Change of Artwork; Change of Name of Manufacturer)	Organon Farmaceutica Ltda., Brazil For: Organon Farmaceutica Ltda., Brazil	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Vasotec 20mg Tablets (Change of Name of Marketing Authorisation Holder; Change of Name of Packager; Change of Distributor; Change of Artwork; Change of Name of Manufacturer)	Organon Farmaceutica Ltda., Brazil For: Organon Farmaceutica Ltda., Brazil	Brazil	Third Schedule
Hyzaar 100/25mg Tablets (Change of Name of Marketing Authorisation Holder; Change of Name of Packager; Change of Distributor; Change of Artwork; Change of Name of Manufacturer)	Organon Pharma (UK) Ltd., United Kingdom Packaged by: Organon Farmaceutica Ltda., Brazil For: Organon Farmaceutica Ltda., Brazil	do.	do.
Hyzaar 50/12.5mg Tablets (Change of Name of Marketing Authorisation Holder; Change of Name of Packager; Change of Name of Manufacturer; Change of Artwork)	do.	do.	do.
Cozaar 50mg Tablets (Change of Name of Marketing Authorisation Holder; Change of Name of Packager; Change of Distributor; Change of Artwork; Change of Name of Manufacturer)	Organon Farmaceutica Ltda Brazil	do.	do.
Arcoxia 60mg Film Coated Tablets (Change of Name of Marketing Authorisation Holder; Change of Name of Manufacturer; Change of Distributor; Change of Artwork)	Rovi Pharma Industrial Services, S.A., Spain Packaged by: Merck Sharp & Dohme B.V., The Netherlands For: Organon Pharma S. de R.L., Panamá	The Netherlands	do.
Arcoxia 90mg Film Coated Tablets (Change of Name of Marketing Authorisation Holder; Change of Name of Manufacturer; Change of Distributor; Change of Artwork)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Arcoxia 120mg Film Coated Tablets (Change of Name of Marketing Authorisation Holder; Change of Name of Manufacturer; Change of Distributor; Change of Artwork)	Rovi Pharma Industrial Services, S.A., Spain Packaged by: Merck Sharp & Dohme B.V., The Netherlands For: Organon Pharma S. de R.L., Panamá	The Netherlands	Third Schedule
Emend 125mg/80mg Capsules (Change of Name of Packager; Change of Distributor)	Alkermes Pharma Ireland Ltd., Ireland Packaged by: Organon Farmaceutica Ltda., Brazil For: Merck Sharp & Dohme Farmaceutica Ltda., Brazil	Brazil	do.
Proscar 5mg Film Coated Tablets (Change of Marketing Authorisation Holder; Change of Name of Packager; Change of Distributor; Change of Artwork)	AIAC International Pharma LLC., United States of America Packaged by: Organon Pharma (UK) Limited United Kingdom For: Organon Pharma S. de R.L., Panama	UK	do.
Sinemet® 275 Tablets 25mg/250mg (Change of Marketing Authorisation Holder; Change of Distributor; Change of Artwork)	Savio Industrial S.R.L., Italy For: Organon Pharma S. de R.L. Panama	Italy	do.
Sinemet® Plus 25mg/100mg Tablets (Change of Marketing Authorisation Holder; Change of Distributor; Change of Artwork)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Faslodex 250mg/5ml Solution for Injection in a pre-filled syringe (Additional Indications)	Vetter Pharma-Fertigung GmbH & Co. KG, Germany Packaged by: AstraZeneca UK Limited United Kingdom For: AstraZeneca UK Limited United Kingdom	UK	Third Schedule
Microdacyn 60 Sterilizing and Strong Oxidising Antiseptic Solution (Change of Marketing Authorisation Holder; Change of Artwork)	Oculus Technologies of México, México For: Aerobal, S.A. de C.V. México	Mexico	Freely
Microdacyn 60 Sterilizing and Strong Oxidising Antiseptic Solution (Additional Manufacturer)	Aerobal, S.A. de C.V. México	do.	do.
Panadol Extra Strength 500mg Tablets (Change of Artwork; New Presentation)	GlaxoSmithKline Panama, S.A., Panama	Panama	do.
Panadol Woman Tablets (Change of Artwork)	do.	do.	do.
Qlaira Film-Coated Tablets (Change of Artwork)	Bayer Weimar GmbH und Co. KG, Germany For: Bayer AG, Germany	Germany	Third Schedule
Bactrim 200/40mg Suspension (Change of Manufacturer; Change of Marketing Authorisation Holder; Change of Distributor; Change of Artwork)	Roemmers, S.A.I.C.F.- Argentina For: Laboratorios Siegfried, S.A.- Panamá	Argentina	do.
Bactrim Forte 800/160mg Tablets (Change of Manufacturer; Change of Marketing Authorisation Holder; Change of Distributor; Change of Artwork)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Dormicum 15mg/3ml Ampoules I.V., I.M. and Rectal Solution for Injection (Change of Manufacturer; Change of Marketing Authorisation Holder, Change of Distributor, Change of Artwork)	Roemmers S.A.I.C., Argentina For: Laboratorios Siegfried, S.A- Panamá	Argentina	Controlled
Dormicum 50mg/10ml Ampoules I.V., I.M. and Rectal Solution for Injection (Change of Manufacturer; Change of Marketing Authorisation Holder, Change of Artwork)	do.	do.	do.
Revcos 200mg Capsules (Change of Name of Product; Additional Indications)	Lek Pharmaceuticals d.d., Slovenia For: Sandoz GmbH, Kundl-Austria	Slovenia	Third Schedule
Zarzio 30MU/0.5ml Solution for Injection or Infusion in Pre-filled Syringe (Change of Artwork)	Sandoz GmbH, Langkampfen- Austria For: Sandoz GmbH, Kundl-Austria	Austria	do.
Tagrisso 40mg Film Coated Tablets (Additional Indication)	AstraZeneca AB, Sweden	Sweden	Third Schedule (Specialist Use Only)
Tagrisso 80mg Film Coated Tablets (Additional Indication)	do.	do.	do.
Dormicum 5mg/5ml Ampoules I.V., I.M. and Rectal Solution for Injection (Change of Manufacturer; Change of Marketing Authorisation Holder, Change of Artwork)	Roemmers S.A.I.C., Argentina For: Laboratorios Siegfried, S.A- Panamá	Argentina	Controlled
Dormicum 15mg Film Coated Tablets (Change of Manufacturer; Change of Marketing Authorisation Holder, Change of Distributor, Change of Artwork)	do.	do.	do.
Wisdom Active Whitening Alcohol Free Mouthwash Activated Charcoal	Wisdom Toothbrushes Ltd.	Bulgaria	Freely
Wisdom Active Whitening Alcohol Free Mouthwash Instant Bright	do.	do.	do.



TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Wisdom Daily Gum Health Alcohol Free Mouthwash	Wisdom Toothbrushes Ltd.	England	Freely
Wisdom Fresh Effect Total Care Deep Clean Mouthwash	do.	do.	do.
Octagam 5% Solution for Infusion 50 mg/mL	Octapharma Pharmazeutika Produktionsges m.b.H.	Austria	Third Schedule
Octanate 250 IU Powder and Solvent for Solution for Injection 50 IU/mL	Octapharma AB	Sweden	do.
Nuwiq Powder and Solvent for Solution for Injection 250 IU/vial	do.	do.	do.
Albunorm 25% Solution for Infusion 250 g/L	Octapharma Pharmazeutika Produktionsges m.b.H.	Austria	do.
Albunorm 5% Solution for Infusion 50 g/L	do.	do.	do.
Rivaxored 10 Tablets 10 mg	Dr. Reddy's Laboratories Limited	India	do.
Rivaxored 15 Tablets 15 mg	do.	do.	do.
Rivaxored 20 Tablets 20 mg	do.	do.	do.
Valganciclovir Tablets 450 mg	do.	do.	do.
Sevelamer Carbonate Tablets 800 mg	do.	do.	do.
Azacididine for Injection IV 100 mg/vial	do.	do.	do.
Budesonide Nasal Spray 100 mcg/dose 200 doses	Jewim Pharmaceutical (Shandong) Co., Ltd.	China	do.
Sodium Phosphate Rectal Solution 133 mL/bottle	do.	do.	do.
Dropstar PF Sterile Ophthalmic Solution 0.4 %	Poen Laboratories S.A.C.I.F.I.	Argentina	do.
Traler PF Sterile Ophthalmic Solution 1.5 %	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Dutabit Soft Capsules 0.5 mg	Aurobindo Pharma Limited	India	Third Schedule
IRB 150 Tablets 150 mg	do.	do.	do.
IRB-H Tablets 300/25 mg	do.	do.	do.
Replac 40 Film Coated Tablets 40 mg	do.	do.	do.
Paclither 100 Paclitaxel Injection USP 100 mg	TherDose Pharma Private Ltd.	do.	Specialist Use Only
Oxalither 100 Oxaliplatin Injection USP 100 mg	do.	do.	do.
Doceted 80 Docetaxel Injection USP 80 mg	do.	do.	do.
Bortether 3.5 Bortezomib for Injection 3.5 mg	do.	do.	do.
Olopatadine Hydrochloride Ophthalmic Solution USP 0.2%	Indiana Ophthalmics Marketed By: Juvencia Lifesciences	do.	Third Schedule
Timolol Maleate Ophthalmic Solution USP 0.5%	do.	do.	do.
Tropicamide Ophthalmic Solution USP 1%	do.	do.	do.
Erelzi 50 mg/mL Solution for Injection in Pre-filled Syringe 50 mg	Sandoz GmbH Schafftenau	Austria	do.
Erelzi 50 mg/mL Solution for Injection in Pre-filled Syringe 25 mg	do.	do.	do.
Erelzi 50 mg/mL Solution for Injection in Pre-filled Pen 50 mg	do.	do.	do.
PREZCOBIX Film Coated Tablets 800 mg/150 mg	Janssen Ortho, LLC Packager: Janssen Cilag S.p.A., Italy For: Ethnor del Istmo, S.A., Panama	Italy	Specialist Use Only

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Vitacox Film Coated Tablets 90 mg	Cadila Pharmaceuticals Limited	India	Third Schedule
Vitacox Film Coated Tablets 120 mg	do.	do.	do.
Adakveo Concentrate for Solution for Infusion 10 mg/mL	Novartis Pharma Stein AG	Switzerland	do.
NanoGreens 10 Vegetable & Fruit Super Foods (Natural Strawberry Flavor) Powder	Health Specialties Manufacturing Inc.	USA	Freely
NanoGreens 10 Vegetable & Fruit Super Foods (Natural Green Apple Flavor) Powder	do.	do.	do.
NanoGreens 10+ Probiotic Vegetable & Fruit Superfood (Natural Green Apple Flavor) Powder	do.	do.	do.
NanoGreens 10+ Probiotic Vegetable & Fruit Superfood (Natural Strawberry Flavor) Powder	do.	do.	do.
Acetazolamide Tablets 250 mg	Remedica Ltd.	Cyprus	Third Schedule
Colgate Total Gum Health Clean Mint Antigingivitis Antiplaque Mouthwash Liquid 0.75 mg per mL	Colgate-Palmolive Company	USA	Freely
Herzuma Trastuzumab Powder for Concentrate for Solution for Infusion 150 mg	Celltrion Inc.	Republic of Korea	Third Schedule
Remsima Infliximab Powder for Concentrate for Solution for Infusion 100 mg	do.	do.	do.
Neo Baby Gripe Mixture Oral Liquid 50 mg Sodium Bicarbonate per 5 mL	Laleham Health and Beauty Ltd.	UK	Freely
Advancis® Energy Vitamins Tablets 1500 mg	Labialfarma – Laboratório de Produtos Farmacêuticos e Nutracêuticos, S.A.	Portugal	do.
Advancis® Flexijoints Ultra Tablets + Capsules	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Advancis® Smart Neuro 10 ml vial	Labialfarma – Laboratório de Produtos Farmacêuticos e Nutracêuticos, S.A.	Portugal	Freely
Advancis® Smart Plus Capsules 1529.1 mg	do.	do.	do.
Advancis® Vitamin C + Echinacea Effervescent Tablets 315 g	do.	do.	do.
Cisplatin Injection 50 mg/50 mL	Naprod Life Sciences PVT. Ltd.	India	Specialist Use Only
ABINGEM-200 Gemcitabine for Injection USP 200 mg Lyophilised	do.	do.	do.
Imatinib Mesylate Tablets 400 mg	do.	do.	do.
Naprodox-50 Doxorubicin Hydrochloride for Injection BP 50 mg/vial	do.	do.	do.
NAPROPLAT Carboplatin Injection BP 150 mg/15 mL	do.	do.	do.
Omeprazole for Injection 40 mg/vial	do.	do.	Third Schedule
Zildox-50 Oxaliplatin for Injection USP 50 mg/vial	do.	do.	do.
Zildox-100 Oxaliplatin for Injection USP 100 mg/vial	do.	do.	do.
Aciclovir Sodium for Intravenous Infusion BP 250 mg/mL	do.	do.	do.
Taceedo 80 Docetaxel Injection USP Concentrated 80 mg/2 mL	do.	do.	Specialist Use Only
TORSIRIN 100 Irinotecan Hydrochloride Injection USP 100 mg/5 mL	do.	do.	do.
MO-FLOREN (Moxifloxacin) Ophthalmic Solution 5.45 mg/mL	Indoco Remedies Ltd.	do.	Third Schedule
Pregabalin 300 mg Capsules	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Zolichek-T Eye Drops Solution 2% Dorzolamide Hydrochloride & 0.5% Timolol Maleate	Indoco Remedies Ltd.	India	Third Schedule
Prolonged Release Diclofenac Capsules 100 mg	Emil Pharmaceutical Industries PVT. Ltd.	do.	do.
Fluoxetine Capsules 20 mg	do.	do.	do.
Interflox-100 Solution for Injection 100 mg/mL	Interchemie Werken "De Adelaar" B.V. & Interchemie Werken De Adelaar Eesti AS	The Netherlands	Veterinary Prescription Only
Simparica Chewables 10 mg	Zoetis Inc.	USA	Veterinary Use Only
Simparica Chewables 20 mg	do.	do.	do.
Simparica Chewables 40 mg	do.	do.	do.
Simparica Chewables 80 mg	do.	do.	do.
Simparica TRIO Chewable Tablets 6 mg/0.12 mg/ 25 mg	Corden Pharma GmbH	Germany	do.
Simparica TRIO Chewable Tablets 48 mg/0.96 mg/ 200 mg	do.	do.	do.
Vanguard CV Vaccine for Subcutaneous or Intramuscular Injection	Zoetis Inc.	USA	do.
Vanguard Plus 5 L4 / Vaccine for Subcutaneous or Intramuscular Injection	do.	do.	do.
Granisetron Kabi Solution for Injection 3 mg/3 mL	Fresenius Kabi Pharma Portugal Ltd.	India	Third Schedule
Labetalol Hydrochloride Injection USP 5 mg/mL	Gland Pharma Limited	do.	do.
Esomeprazole Sodium Powder for Solution for Injection 40 mg/vial Lyophilized	do.	do.	do.
TemoRel Capsules 100 mg	Reliance Life Sciences PVT Ltd.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
ReliTrexed Powder for Concentrate for Solution for Infusion 500 mg	Reliance Life Sciences PVT Ltd.	India	Third Schedule
BortiRel Powder for Solution for Injection 3.5 mg	do.	do.	do.
Abacavir Tablets USP 300 mg	Hetero Labs Limited	do.	Specialist Use Only
Efavirenz, Lamivudine and Tenofovir Disoproxil Fumarate Tablets 600 mg/300 mg/300 mg	do.	do.	do.
Erloven Erlotinib Tablets 100 mg	do.	do.	do.
Erloven Erlotinib Tablets 150 mg	do.	do.	do.
LAVUDIN Lamivudine Tablets 150 mg	do.	do.	do.
Beclametasone Dipropionate Pressurised Inhalation 50 mcg/dose 200 metered doses	do.	do.	Third Schedule
DABITRIN 75 Dabigatran Etexilate Capsules 75 mg	do.	do.	do.
Entricitabine and Tenofovir Disoproxil Fumarate Tablets 200 mg/300 mg	do.	do.	do.
Mycophenolate Mofetil Capsules 250 mg	do.	do.	do.
Mycophenolate Mofetil Tablets 500 mg	do.	do.	do.
Salmeterol and Fluticasone Propionate Inhalation 25 mcg/125 mcg	do.	do.	do.
Salmeterol and Fluticasone Propionate Inhalation 25 mcg/250 mcg	do.	do.	do.
Tenofovir Disoproxil Fumarate Tablets 300 mg	do.	do.	do.
PROFOL Propofol Injectable Emulsion USP 200 mg/20 mL	Aspiro Pharma Limited	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Ritonavir Tablets 100 mg	Hetero Labs Limited	India	Specialist Use Only
Butylscopolamin PANPHARMA Solution for Injection 20 mg/mL (Change of Name of Product and Change of Artwork, Change of Importer/Distributor)	PANPHARMA GmbH	Germany	Third Schedule
Zincovit-B Syrup	Apex Laboratories PVT LTD	India	Freely
Elutit Granules 400 g	Agraria Pharma GmbH	Germany	Third Schedule
Bortezomib Powder for Injection 3.5 mg	Pharmascience Inc., Quebec, Canada Marketing Authorisation Holder: Laboratorios Stein S.A	Canada	do.
Tranexamic Acid Film Coated Tablets 500 mg	Mepro Pharmaceuticals Private Limited Marketing Authorisation Holder: Waymade PLC Sovereign House, United Kingdom	UK	do.
Yuflyma Solution for Injection in a Pre-filled Pen 40 mg/0.4 mL	Catalent Belgium S.A., Belgium Labeler and Packager: Celltrion Pharm, Inc., Republic of Korea Marketing Authorisation Holder: Celltrion Healthcare Co., Ltd., Republic of Korea	Republic of Korea	Specialist Use Only
Apo-Carvedilol Tablets 6.25 mg	Apotex Inc.	Canada	Third Schedule

<b>TRADE NAME AND FORM</b>	<b>MANUFACTURER</b>	<b>COUNTRY OF ORIGIN</b>	<b>CONDITION OF SALE</b>
Apo-Granisetron Tablets 1 mg	Apotex Inc.	Canada	Third Schedule
Apo-Risperidone Tablets 1 mg	do.	do.	do.
Apo-Linezolid Tablets 600 mg	do.	do.	do.

Dated this 2nd day of August, 2022.

T. DEYALSINGH  
*Minister of Health*