

LEGAL NOTICE NO. 1

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:

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Hemarexin Solution (Change in Name of Licence Holder)	Sandoz, Canada Inc.	Canada	Freely
Androcur Tablets 50 mg (Change of Name of Marketing Authorisation Holder)	Manufactured by: Delpharm Lille S.A.S. France Packaged by: Schering do Brasil for Bayer Pharma AG Germany	Brazil	Third Schedule
Androcur Tablets 100 mg (Change of Name of Marketing Authorisation Holder)	do.	do.	do.
Cliane Coated Tablets (Change of Name of Marketing Authorisation Holder)	Manufactured by: Schering do Brasil, Quimica e Farmaceutica Ltda. for Bayer Pharma AG Germany	do.	do.
Femiane Sugar Coated Tablets (Change of Name of Marketing Authorisation Holder)	do.	do.	do.
Gynera Film-Coated Tablets (Change of Name of Marketing Authorisation Holder)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Yaz Film-Coated Tablets 3 mg/0.02 mg (Change of Name of Marketing Authorisation Holder)	Manufactured by: Schering do Brasil, Quimica e Farmaceutica Ltda. for Bayer Pharma AG Germany	Brazil	Third Schedule
Ventavis Solution for Inhalation 10 mcg/ml (Change of Name of Marketing Authorisation Holder)	Manufactured by: BerliMed S.A., for Bayer Pharma AG Germany	Spain	do.
Ultravist Solution for Injection and Infusion 300 mg/1 ml (Change of Name of Manufacturing Site, Packaging Site and Marketing Authorisation Holder)	Bayer Pharma AG,	Germany	do.
Ultravist Solution for Injection and Infusion 370 mg/1 ml (Change of Name of Manufacturing Site, Packaging Site and Marketing Authorisation Holder)	do.	do.	do.
Ciproxina XR Film-Coated Tablets 500 mg (Change of Name of Marketing Authorisation Holder and Manufacturing Site)	Manufactured by: Bayer Pharma AG, Germany Packaged by: Bayer, S.A. for Bayer Pharma AG, Germany	El Salvador	do.
Ciproxina XR Film-Coated Tablets 1000 mg (Change of Name of Marketing Authorisation Holder and Manufacturing Site)	do.	do.	do.
Proviron Tablets 25 mg (Change of Name of Marketing Authorisation Holder)	Manufactured by: Schering do Brasil, Quimica e Farmaceutica Ltda., for Bayer Pharma AG, Germany	Brazil	do.
Yasmin Film-Coated Tablets (Change of Name of Marketing Authorisation Holder)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Progynova Tablets 1 mg (Change of Name of Marketing Authorisation Holder)	Manufactured by: Delpharm Lille S.A.S. France Packaged by: Schering do Brasil Quimica e Farmaceutica Ltda. for Bayer Pharma AG, Germany	Brazil	Third Schedule
Progynova Tablets 2 mg (Change of Name of Marketing Authorisation Holder)	do.	do.	do.
Nebido 1000 mg/4 ml Solution for Injection (Change of Name of Marketing Authorisation Holder, Manufacturing and Packaging Site)	Manufactured by: Bayer Pharma AG	Germany	do.
Xarelto Film-Coated Tablets (Change of Name of Marketing Authorisation Holder, Manufacturing and Packaging Site)	Manufactured by: Bayer Pharma AG, Leverkusen, for Bayer Pharma AG Germany	do.	do.
Levitra Orodispersible Tablets 10 mg (Change of Name of Marketing Authorisation Holder, Manufacturing and Packaging Site)	do.	do.	do.
Levitra Tablets 5 mg (Change of Name of Marketing Authorisation Holder, Manufacturing and Packaging Site)	do.	do.	do.
Scheriproct Suppositories (Change of Name of Marketing Authorisation Holder)	Manufactured by: Bayer de Mexico, S.A. de C.V. for Bayer Pharma AG Germany	Mexico	do.
Glucobay 50 Tablets 50 mg (Change of Name of Marketing Authorisation Holder)	Manufactured by: Bayer, S.A. for Bayer Pharma AG Germany	El Salvador	do.
Glucobay 100 Tablets 100 mg (Change of Name of Marketing Authorisation Holder)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Gyno-Travogen Ovule 600 mg (Change of Name of Marketing Authorisation Holder)	Manufactured by: Bayer de Mexico, S.A. de C.V. for Bayer Pharma AG, Germany	Mexico	Third Schedule
Primoteston Depot Injectable (Change of Name of Marketing Authorisation Holder, Manufacturing and Packaging Site)	Bayer Pharma AG	Germany	do.
Noristerat Injectable Solution 200 mg/ml (Change of Name of Marketing Authorisation Holder, Manufacturing and Packaging Site)	Manufactured and Packaged by: Bayer Pharma AG, for Bayer Pharma AG, Germany	do.	do.
Betaferon Powder and Solvent for Solution for Injection 0.25 mg (Change of Name of Marketing Authorisation Holder, Manufacturing and Packaging Site)	Powder Manufactured by: Boehringer Ingelheim Pharma GmbH and Co. KG Germany Solvent Manufactured by: Bayer Pharma AG, Germany Solvent and Powder Packaged by: Bayer Pharma AG, for Bayer Pharma AG, Germany	do.	do.
Advantan Milk 0.1% (Change of Name of Manufacturing and Packaging Site)	Manufactured by: Bayer HealthCare Manufacturing S.r.l., for: Bayer Pharma AG, Germany	Italy	do.
Qlaira Film-Coated Tablets (Change of Name of Marketing Authorisation Holder, Manufacturing and Packaging Site)	Manufactured and Packaged by: Bayer Weimar GmbH und Co. KG, for Bayer Pharma AG, Germany	Germany	do.
Ciproxina Film-Coated Tablets (Change of Name of Marketing Authorisation Holder)	Manufactured by: Bayer, S.A. For Bayer Pharma AG, Germany	El Salvador	do.
Nimotop Film-Coated Tablets (Change of Name of Marketing Authorisation Holder)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Magnevist Solution for Injection Vial 14.07 g (Change of Name of Marketing Authorisation Holder, Manufacturing and Packaging Site)	Manufactured by: Bayer Pharma AG, for Bayer Pharma AG Germany	Germany	Third Schedule
Mirena Intrauterine System 20µg/24h (Change of Name of Marketing Authorisation Holder and Update of Packaging Material)	Manufactured by: Bayer OY for: Bayer Pharma AG Germany	Finland	do
Adalat Oros Tablets 30 mg (Additional Secondary Packaging Site)	Manufacturer and Primary Packager: Bayer Pharma AG Germany Secondary Packager: Bayer S.A.	Guatemala	do.
Adalat Oros Tablets 60 mg (Additional Secondary Packaging Site)	do.	do.	do.
Avelox Film-Coated Tablets 400 mg (Additional Packaging Site)	do.	do.	do.
Redoxon Vitamin C 1000 mg Effervescent Tablets– Orange Flavor (Change in the Primary and Secondary Package Labelling)	Made by: Bayer S.A. Under license from Bayer Consumer Care AG, Guatemala	do.	Freely
Lexotan Tablets 6 mg (Change of Artwork Design)	Made by: Productos Roche Quimicos e Farmaceutica S.A.	Brasil	Controlled Drug
Rivotril Tablets 0.5 mg (Change of Artwork Design)	do.	do.	do.
Alimta Powder for Concentrate for Solution for Infusion 500 mg (Additional Manufacturing Site)	Manufactured by: Eli Lilly & Company USA Packaging by: Lilly France	France	Third Schedule
Cymbalta Hard Gastro-Resistant Capsules 30 mg (Additional Source)	Manufactured by: Lilly del Caribe Inc. Puerto Rico Packaged by: Lilly S.A.	Spain	do.
Cymbalta Hard Gastro-Resistant Capsules 60 mg (Additional Source)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Alocid Capsules 20 mg (Change of Artwork Design)	Made by: Carlisle Laboratories Ltd.	Barbados	Freely
Pantogar Capsules (Change in Name of Manufacturer and Change of Artwork Design)	Acino Pharma AG	Switzerland	Third Schedule
Poen-Caina Ophthalmic Solution 0.5% (Change of Distributor)	Poen Laboratories SACIFI	Argentina	do.
Dropstar Ophthalmic Solution 0.4% (Change of Distributor)	do.	do.	Freely
Brimopress Ophthalmic Solution 0.2% (Change of Distributor)	do.	do.	Third Schedule
Glaucoprost Sterile Ophthalmic Solution 0.004% (Change of Distributor)	do.	do.	do.
Poenkerat Ophthalmic Solution 0.5% (Change of Distributor)	do.	do.	do.
Louten Ophthalmic Solution 0.005% (Change of Distributor)	do.	do.	do.
Poentimol Ophthalmic Solution 0.25% (Change of Distributor)	do.	do.	do.
Poentimol Ophthalmic Solution 0.5% (Change of Distributor)	do.	do.	do.
Quidex Ophthalmic Suspension 0.3%/0.1% (Change of Distributor)	do.	do.	do.
Glaucotensil D Ophthalmic Solution 2% (Change of Distributor)	do.	do.	do.
EPAQ™ Gel 0.75% (Change of Name of Product, Change of Marketing Authorisation Holder and Change of Artwork Design)	Manufactured by: DPT Laboratories, Ltd. for: More Pharma Corporacion S.de.R.L. de C.V. Mexico	USA	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
QVAR 100 Aerosol (Change of Marketing Authorisation Holder and Change of Artwork Design)	Made in United Kingdom by: 3M Health Care Limited for: More Pharma Corporacion S.de.R.L. de C.V. Mexico	UK	Third Schedule
Minitran Transdermal Delivery System (Patch) 0.2 mg/HR - 18 mg (Change of Marketing Authorisation Holder and Change of Artwork Design and Change of Source)	Made in USA by: 3M Drug Delivery Systems Packed by: More Pharma Corporacion S.de.R.L. de C.V. Mexico for: More Pharma Corporacion S.de.R.L. de C.V. Mexico	USA	do.
Minitran Transdermal Delivery System (Patch) 0.4 mg/HR - 36 mg (Change of Marketing Authorisation Holder and Change of Artwork Design and Change of Source)	do.	do.	do.
Hiprex 1 g Tablets (Change of Marketing Authorisation Holder and Change of Artwork Design)	Made in UK by: 3M Health Care Limited for: More Pharma Corporacion S.de.R.L. de C.V. Mexico	UK	do.
Tambocor 100 mg Tablets (Change of Marketing Authorisation Holder and Change of Artwork Design)	do.	do.	do.
Aldara Cream 5% (Change of Marketing Authorisation Holder and Change of Artwork Design)	do.	do.	do.
One Alpha [®] Capsules 1 mcg (Change of Artwork Design)	LEO Pharmaceutical Products Ltd. A/S	Denmark	do.
Daivobet Gel (Additional Manufacturing Site)	LEO Laboratories Ltd. (LEO Pharma)	Ireland	do.
Rivotril Drops 2.5 mg/ml (Change of Artwork Design)	Made by: Productos Roche Quimicos e Farmaceuticos S.A.	Brasil	Controlled Drug

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Provera Tablets 5 mg (Additional Source and Change of Packaging)	Pfizer Italia S.r.l.	Italy	Third Schedule
Provera Tablets 10 mg (Additional Source and Change of Packaging)	do.	do.	do.
Lipitor Tablets 40 mg (Additional Source)	Manufacturer: Pfizer Pharmaceuticals LLC, United States Packager: Pfizer Manufacturing Deutschland, GmbH	Germany	do.
Lipitor Tablets 80 mg (Additional Source)	do.	do.	do.
Xalkori [®] Capsules 200 mg (Change in Secondary Packager and Change in Marketing Authorisation Holder)	Manufacturer & Packager: Pfizer Manufacturing Deutschland, GmbH License Holder: Pfizer Ltd., UK	do.	Third Schedule (Consultant Only)
Xalkori [®] Capsules 250 mg (Change in Secondary Packager and Change in Marketing Authorisation Holder)	do.	do.	do.
Salazopyrin [®] EN-Tabs Enteric Coated Tablets 500 mg (Change of Name of Manufacturer, Change of Artwork Design and Change of Name of Licence Holder)	Manufactured, Packaged & Released by: Kemwell AB, for Pfizer AB, Sweden	Sweden	Third Schedule
Vfend Powder for Solution for Infusion 200 mg (Additional Source)	Manufacturer: Pharmacia & Upjohn Co., USA Packager: Pfizer PGM	France	do.
Vfend Film Coated Tablets 200 mg (Additional Manufacturer)	Manufacturer: Pfizer Italia S.r.l. Italy Packager: Pfizer Manufacturing Deutschland, GmbH	Germany	do.
Dilantin Extended Oral Capsules (Change of Art- work Design and Change of Licence Holder)	Manufactured by: Pfizer Pharmaceuticals LLC., License Holder: Parke-Davis, USA	USA	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Celebrex Capsules 200 mg (Change of Name of Manufacturer and Change of Name of Packaging Site)	Manufacturer: Neopharma Inc., USA Packager: Pfizer Manufacturing Deutschland GmbH	Germany	Third Schedule
Celebrex Capsules 200 mg (Additional Source)	Manufacturer: Pfizer Pharmaceuticals LLC., Puerto Rico Packager: Pfizer Manufacturing Deutschland GmbH	do.	do.
Olfen™ Gel (Change of Artwork Design and Change in License Holder)	Merckle GmbH	Germany	do.
Olfen-75 IM Ampoules 75 mg (Change of License Holder, Change of Artwork Design and Additional Source)	Merckle, Blaubeuren- Weiler	do.	do.
Olfen Dispersible, Dispersible Tablets 50 mg (Change of Name of Manufacturer and Change of Artwork Design)	do.	do.	do.
Zenusin-20 SR Cardotabs (Change of Name of Manufacturer and Change of Artwork Design)	Acino Pharma AG	Switzerland	do.
Simepar Capsules (Change of Name of Manufacturer and Change of Artwork Design)	Acino	do.	do.
Olfen-75 SR Depotabs 75 mg (Change of Name of Manufacturer and Change of Artwork Design)	do.	do.	do.
Neurorubine-forte Lactabs (Change of Name of Manufacturer and Change of Artwork Design)	do.	do.	Freely
Olfen-50 Lactabs 50 mg (Change of Name of Manufacturer Change of Art- work Design)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Bactiflox-500 Lactabs 500 mg (Change of Name of Manufacturer Change of Art- work Design and Additional Source)	Sofarimex	Portugal	Third Schedule
Gasec-20 Gastrocaps 20 mg (Change of Name of Manufacturer Change of Art- work Design and Additional Source)	do.	do.	do.
Artequin-300/750 Film-Coated Tablets (Change of Name of Manufacturer Change of Art- work Design)	Acino	Switzerland	do.
Uvamin Retard Capsules 100 mg (Change of Name of Manufacturer Change of Art- work Design)	do.	do.	do.
Olfen 100 SR Depocaps 100 mg (Change of Name of Manufacturer Change of Art- work Design)	do.	do.	do.
Lofral-5 Tablets 5 mg Change of Artwork Design and Change of Name of License Holder	Atlantic Pharma	Portugal	do.
Lofral-10 Tablets 10 mg Change of Artwork Design and Change of Name of License Holder	do.	do.	do.
Decatylen Lozenges (Change of Name of Manufacturer Change of Artwork Design)	Acino	Switzerland	Freely
Propess 10 mg Vaginal Delivery System (Change of Name of Manufacturer)	Ferring Controlled Therapeutics Ltd.	UK	Third Schedule
DDAVP Melt/Oral Disintegrating Tablets 120 mcg (Additional Source)	Catalent UK Swindon Zydis Limited Switzerland Packager: Ferring International Center	Switzerland	do.
Duratocin Solution for Injection 100 mcg/ml (Change of Marketing Authorisation Holder, Change of Manufacturing Site and Change of Artwork Design)	Ferring GmbH Germany Packager: Ferring 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>
Prostatonin Capsules (Change of Marketing Authorisation Holder, Change of Name of Manufacturing Site and Change of Artwork Design)	Ginsana SA Via Mulini	Switzerland	Third Schedule
Aggrenox 200 mg/25 mg Controlled Release Capsules (Change of Label and Change in Appearance of Capsule) (imprint)	Boehringer Ingelheim Pharma GmbH & Co. KG	Germany	do.
Tri-Luma Cream (Additional Source and Change in Storage Conditions)	G Production Inc.,	Canada	do.
Pradaxa 75 mg Capsules (Change of Name of Product and Change of Artwork Design)	Boehringer Ingelheim (Canada) Ltd.	do.	do.
Pradaxa 110 mg Capsules (Change of Name of Product New Indication and Change of Artwork Design)	do.	do.	do.
Pradaxa 150 mg Capsules (Change of Name of Product New Indication and Change of Artwork Design)	do.	do.	do.
Dulcolax Tablets 5 mg—100's (Change in Packaging)	do.	do.	Freely
Dulcolax Tablets 5 mg—30's (Change of Artwork Design)	do.	do.	do.
Volini Tablets 50 mg (Change of Name of Product)	Ranbaxy Laboratories Limited	India	Third Schedule
Januvia Film-Coated Tablets 25 mg (Change of Manufacturing Site and Packaging Site)	Merck Sharp & Dohme Ltd. United Kingdom Packaged by: Merck Sharp & Dohme Farmaceutica Ltd.	Brazil	do.
Januvia Film-Coated Tablets 50 mg (Change of Manufacturing Site and Packaging Site)	do.	do.	do.
Januvia Film-Coated Tablets 100 mg (Change of Manufacturing Site and Packaging Site)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Isentress Tablets 400 mg (Change of Manufacturing Site and Packaging Site)	MSD International GmbH, Singapore Packaging Site: MSD Haarlem	The Netherlands	Third Schedule
Stocrin Tablets 600 mg (Change of Manufacturing Site and Packaging Site)	Zhejiang Huahai Pharmaceutical Co. Ltd., China Packaging Site: MSD Haarlem	do.	do.
Concerta Prolonged-Release Tablets 18 mg (Additional Manufacturing Site and Change of Name of Product)	Janssen-Cilag Manufacturing LLC HC, Puerto Rico Packaged by: Anderson Brecon Incorporated	USA	Controlled Drug
Concerta Prolonged-Release Tablets 27 mg (Additional Manufacturing Site and Change of Name of Product)	do.	do.	do.
Concerta Prolonged-Release Tablets 36 mg (Additional Manufacturing Site and Change of Name of Product)	do.	do.	do.
Concerta Prolonged-Release Tablets 54 mg (Additional Manufacturing Site and Change of Name of Product)	do.	do.	do.
Singulair 4 mg Chewable Tablets (Change of Packaging Site)	Merck Sharp & Dohme Limited, England Packaging Site: Merck Sharp & Dohme Farmaceutica Limited, Campinas	Brazil	Third Schedule
Singulair Tablets 5 mg (Change of Packaging Site)	do.	do.	do.
Singulair Tablets 10 mg (Change of Packaging Site)	do.	do.	do.
Fosamax Plus Tablets 70 mg/2800IU (Change of Packaging Site)	Frost Iberica, S.A. Via Complutense Spain Packaging Site: MSD Campinas	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Vaseretic Tablets 20/12.5 mg (Change of Manufacturing and Packaging Site)	Merck Sharp & Dohme Farmaceutica Ltd. Brazil Packaging Site: MSD Campinas	Brazil	Third Schedule
Cozaar Tablets 100 mg (Change of Packaging Site)	Merck Sharp & Dohme Limited England Packaging Site: MSD Campinas	do.	do.
Zocor Tablets 20 mg (Change of Packaging Site)	do.	do.	do.
Zocor Tablets 80 mg (Change of Packaging Site)	do.	do.	do.
Singulair Oral Granules 4 mg (Additional Manufacturing Site and Change of Packaging Site)	DSM Pharmaceuticals Inc., USA Packaging Site: Merck Sharp & Dohme Corp.	USA	do.
Hyzaar Tablets 50/12.5 mg (Change of Manufacturing and Packaging Site)	Merck Sharp & Dohme Farmaceutica Ltd. Brazil Packaging Site: MSD Campinas Brazil	Brazil	do.
Proscar Film-Coated Tablets 5 mg (Change of Manufacturing Site)	MSD International GmbH, Puerto Rico Packaged by: Merck Sharp & Dohme Limited	England	do.
Allegra D 60 mg/120 mg Extended Release Film- Coated Tablets (Additional Manufacturing Site and Change of Name of Product)	Sanofi Winthrop Industries France Packager: Sanofi-Aventis Farmaceutica Ltda.	Brazil	do.
Enterogermina Oral Suspen- sion 2 billion/5 mL (Additional Manufacturing Site and Change of Artwork Design)	Sanofi-Aventis S.p.A.	Italy	Freely
Fluarix Suspension for Injection (Change in Formulation and Strain Update)	GlaxoSmithKline Biologicals	Germany	Third Schedule

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Seretide Diskus 100/50 mcg (Additional Manufacturing Site)	GlaxoSmithKline, LLC	USA	Third Schedule
Seretide Diskus 250/50 mcg (Additional Manufacturing Site)	do.	do.	do.
Seretide Diskus 500/50 mcg (Additional Manufacturing Site)	do.	do.	do.
Benztropine Mesylate Injection USP , 1 mg/ml, 2 ml Ampoule, (Change of Name of Drug)	SG Pharma Pvt. Ltd.	India	do.
Byetta Solution for Injection 5 mcg Prefilled Pen (Change of Product Licence Holder)	Manufactured for: Baxter Pharmaceutical Solutions LLC USA Packed by: Lilly Pharma Fertigung und Distribution GmbH & Co. KG Assembly by: Eli Lilly and Company USA Holder: AstraZeneca S.A. Panama	Germany	do.
Byetta Solution for Injection Prefilled Pen 10 mcg (Change of Product Licence Holder)	do.	do.	do.
Cascodex Film-Coated Tablets 50 mg (Additional Packager)	Manufactured by: Corden Pharma GmbH Germany Packed by: AstraZeneca do Brazil Ltd. for: AstraZeneca UK Limited, United Kingdom	Brazil	do.
Nolvadex-D Film-Coated Tablets 20 mg (Additional Source)	Manufactured by: AstraZeneca UK Limited, United Kingdom Packed by: AstraZeneca do Brasil, Ltda. for: AstraZeneca UK Limited, United Kingdom	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Betaloc ZOK Prolonged-Release Tablets (Additional Source)	Manufactured by: AstraZeneca AB Sweden Packed by: AstraZeneca S.A. De C.V. for: AstraZeneca AB Mexico	Mexico	Third Schedule
Nexium™ Gastro-Resistant Granules for Oral Suspension 10 mg (Additional Source)	Manufactured by: AstraZeneca AB, Sweden Packed and Distributed by: AstraZeneca S.A. De C.V. for: AstraZeneca AB, Sweden	do.	do.
Exelon 1.5 mg Capsules (Blister Presentation Extension)	Novartis Farmacéutica S.A. for: Novartis Pharma AG, Switzerland	Spain	do.
Exelon 3 mg Capsules (Blister Presentation Extension)	do.	do.	do.
Exelon 4.5 mg Capsules (Blister Presentation Extension)	do.	do.	do.
Exelon 6 mg Capsules (Blister Presentation Extension)	do.	do.	do.
Glivec Film-Coated Tablets 100 mg (Additional Source)	Novartis Produktions GmbH for: Novartis Pharma AG Switzerland	Germany	Third Schedule
Certican Tablets 0.25 mg (Additional Indication)	Novartis Pharma Stein AG, for: Novartis Pharma AG, Switzerland	Switzerland	do.
Certican Tablets 0.5 mg (Additional Indication)	do.	do.	do.
Certican Tablets 0.75 mg (Additional Indication)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Sandostatin Lar Injection 20 mg (Change in Composition & Volume of Vehicle Solution, Change in Administrative Accessories and Change) in Packaging	Manufactured by: Sandoz GmbH Austria and Abbott Biologicals B.V. Netherlands Packaged by: Novartis Pharma Stein AG, for: Novartis Pharma Stein AG, Switzerland	Switzerland	Third Schedule
Sandostatin Lar Injection 30 mg, (Change in Composition & Volume of Vehicle Solution, Change in Administrative Accessories and Change in Packaging)	do.	do.	do.
Leponex 25 mg Tablets (Additional Source)	Novartis Ürünleri for: Novartis Pharma AG Switzerland	Turkey	do.
Leponex 100 mg Tablets (Additional Source)	do.	do.	do.
Exforge HCT Film-Coated Tablets 5 mg/160 mg/25 mg (Transfer of Manufacturing Site)	Novartis Farmaceutica S.A. for: Novartis Pharma AG Switzerland	Spain	do.
Exforge HCT Film-Coated Tablets 5 mg/160 mg/12.5 mg (Transfer of Manufacturing Site)	do.	do.	do.
Exforge HCT Film-Coated Tablets 10 mg/160 mg/25 mg (Transfer of Manufacturing Site)	do.	do.	do.
Exforge HCT Film-Coated Tablets 10 mg/160 mg/12.5 mg (Transfer of Manufacturing Site)	do.	do.	do.
Exforge HCT Film-Coated Tablets 10 mg/320 mg/12.5 mg (Transfer of Manufacturing Site)	do.	do.	do.
Lamisil Cream 1% (Change of Primary Packaging and Change of Primary and Secondary Artwork Design)	Manufactured by: Novartis Consumer Health S.A.	Switzerland	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Lamisil Dermgel 1% (Change of Artwork Design of Primary & Secondary Packaging)	Manufactured by: Novartis Consumer Health S.A.	Switzerland	Third Schedule
Lamisil Spray 1% (Change of Name of Manufacturer and Change of Primary and Secondary Artwork Design)	Manufactured by: Delpharm Huningue S.A.S. for: Novartis Consumer Health S.A. Switzerland	France	do.
Voltaren [®] Retard Coated Tablets 100 mg (Change of Artwork Design and Change of Name of Manufacturer)	Novartis Pharma AG Stein, for: Novartis Pharma AG Basel, Switzerland	Switzerland	do.
Voltaren [®] Solution For Injection 75 mg/3 mL (Change of Name of Manufacturer and Change of Artwork Design)	do.	do.	do.
Voltaren [®] Suppositories 50 mg (Change of Name of Manufacturer and Change of Artwork Design)	Delpharm Huningue S.A.S. for: Novartis Pharma AG Basel, Switzerland	France	do.
Tegretol Syrup 2% (Change of Name of Manufacturer)	do.	do.	do.
Exelon 2 mg/ml Oral Solution (Change of Name of Manufacturing Site)	do.	do.	do.
Trileptal Oral Suspension 60 mg/ml (Change of Name of Manufacturer)	do.	do.	do.
Cataflam 1.5% Drops (Change of Name of Manufacturer)	do.	do.	do.
Jevtana Concentrate and Solvent for Solution for Infusion 60 mg/1.5 ml (Additional Source)	Sanofi-Aventis Deutschland GmbH for: Sanofi-Aventis Groups France	Germany	do.
Ambien Tablets 10 mg (Additional Source, Additional Packager and Change of Condition of Sale)	Manufactured by: Sanofi-Winthrop Industries France Packaged by: Sanofi-Aventis U.S. LLC	USA	Controlled Drug

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Ambien CR Extended-Release Tablets 6.25 mg (Additional Source and Change of Condition of Sale)	Manufactured by: Sanofi-Winthrop Industries France Packaged by: Sanofi-Aventis U.S. LLC	USA	Controlled Drug
Ambien CR Extended-Release Tablets 12.5 mg (Additional Source and Change of Condition of Sale)	do.	do.	do.
Taxotere Concentrate Injectable for Solution for I.V. Infusion 20 mg/1 ml (Transfer of Manufacturing Site)	Sanofi-Aventis Deutschland GmbH	Germany	Third Schedule
Taxotere Concentrate Injectable for Solution For I.V. Infusion 80 mg/4 ml (Transfer of Manufacturing Site)	do.	do.	do.
Eloxatin Concentrate Solution for Infusion 5 mg/ml 50 mg (Transfer of Manufacturing Site)	do.	do.	do.
Eloxatin Concentrate Solution for Infusion 5 mg/ml 100 mg (Transfer of Manufacturing Site)	do.	do.	do.
Candid V Gel 2% (Change of Artwork Design)	Glenmark Pharma Ltd.	India	do.
Candid Cream 1% (Change of Artwork Design)	do.	do.	do.
Candid Dusting Powder 1% (Change of Artwork Design)	do.	do.	Freely
Candid Mouth Paint 1% (Change of Artwork Design)	do.	do.	Third Schedule
Candid B Cream 1%/0.025% (Change of Artwork Design)	do.	do.	-do
Candid V3 Tablets 200 mg (Change of Artwork Design)	do.	do.	do.
Candid V6 Tablets 100 mg (Change of Artwork Design)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Children's Dimetapp® Cold & Cough Liquid (Change of Manufacturing / Packaging Site, Change of Distributor, Change of Product Registered name and Change of Artwork Design)	Fareva Richmond, Inc., for Pfizer Inc., USA	USA	Freely
Robitussin® Peak Cold Multi-Symptom Cold (Change of Artwork Design)	do.	do.	do.
Robitussin® Peak Cold Sugar-Free Cough & Chest Congestion DM (Change of Artwork Design)	do.	do.	do.
Robitussin® Peak Cold Cough & Chest Congestion DM (Change of Artwork Design, Change in Formulation and Change in Shelf Life)	do.	do.	do.
LEXAPRO® Film-Coated Tablets 10 mg (Change in Marketing Authorization Holder and Update of Packaging Insert)	H. Lundbeck A/S	Denmark	Third Schedule
Storilat 200 Tablets (Change of Artwork Design and Update of Packaging Insert)	Remedica Ltd.	Cyprus	do.
Credanil 25/100 Tablets (Change of Artwork Design and Update of Packaging Insert)	do.	do.	do.
Simva-Denk 20 (Leaflet Update)	Denk Pharma GmbH & Co. KG	Germany	do.
Simva-Denk 40 (Leaflet Update)	do.	do.	do.
Norvir 100 mg Capsules (Change in Marketing Authorization Holder, Change of Name of Manufacturer and Change in Branding)	Catalent Pharma Solutions, LLC, USA Packager: AbbVie Inc.,	USA	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Kaletra Oral Solution 80 mg/20 mg (Change in Marketing Authorization Holder, Change of Name of Manufacturer and Change in Branding)	AbbVie Inc.,	USA	Third Schedule
Kaletra 200 mg/50 mg Tablets (Change in Marketing Authorization Holder, Change of Name of Manufacturer and Change in Branding)	do.	do.	do.
Advil Liqui Gels [®] (Change of Name of Manufacturer, Change of Name of Packaging Site, Change of Name of Distributor and Change of Shelf Life)	Manufactured for: Pfizer Inc., USA Manufactured by: Catalent Pharma Solutions, LLC, USA Packaged by: Fareva Richmond, Inc.,	do.	Freely
Survanta Intratracheal Suspension 25 mg/mL (Change of Name of Manufacturer, Change in Marketing Authorization Holder and Change in Branding)	AbbVie Inc.,	do.	Third Schedule To Neonatologists, Paediatricians or Registrars in a Neonatal Unit ONLY (From Agent ONLY)
Ultane Liquid Inhalation Anesthetic Liquid 100% (Change of Name of Manufacturer, Change in Marketing Authorization Holder and Change in Branding)	do.	do.	do.
Zemplar 1 mcg Capsules (Change of Name of Manufacturer, Change in Marketing Authorization Holder and Change in Branding)	Manufactured by: Catalent Pharma Solutions, LLC, USA Packaged by: AbbVie Inc., for: AbbVie Inc., USA	do.	do.
Zemplar 2 mcg Capsules (Change of Name of Manufacturer, Change in Marketing Authorization Holder and Change in Branding)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Vaxigrip, Suspension for Injection in Prefilled Syringe Influenza Vaccine (Adult) (Update of New Strain Composition)	Sanofi Pasteur S.A.	France	Third Schedule
Vaxigrip, Suspension for Injection in Prefilled Syringe Influenza Vaccine (Pediatric) (Update of New Strain Composition)	do.	do.	do.
Depakote ER 500 mg Tablets (Change of Manufacturing and Packaging Site, and Change in Branding)	Abbvie Ltd. Puerto Rico Packaged by: Abbvie Inc.	USA	do.
Depakote ER 250 mg Tablets (Change of Manufacturing and Packaging Site, and Change in Branding)	do.	do.	do.
Emnorm-500 Tablets (Change of Importer)	Ipca Laboratories Ltd.	India	do.
Biofreeze Pain Relieving Gel (Change of Importer)	Manufacturer: Span Packaging Services, LLC for Performance Health, LLC USA	USA	Freely
Biofreeze Pain Relieving Roll On (Change of Importer)	do.	do.	do.
Pantonex DR-20 Delayed Release Tablets	Ipca Laboratories Ltd.	India	Third Schedule
Pantonex DR-40 Delayed Release Tablets	do.	do.	do.
Cebion Vitamin C Chewable Tablets Tropical Flavour (Change of Name of Manufacturer)	Altea Farmaceutica S.A.	Colombia	Freely
Cebion Vitamin C Chewable Tablets Orange Flavour (Change of Name of Manufacturer)	do.	do.	do.
Cebion Vitamin C Chewable Tablets Strawberry Flavour (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>
Cebion Vitamin C Chewable Tablets Tangerine Flavour (Change of Name of Manufacturer)	Altea Farmaceutica S.A.	Colombia	Freely
Cebion Vitamin C Chewable Tablets Multi Flavours 100 mg (Change of Name of Manufacturer)	do.	do.	do.
Cebion Vitamin C Drops Strawberry Flavour 100 mg/ml (Change of Name of Manufacturer)	do.	do.	do.
Cebion Zinc Vitamin C Effervescent Tablets Orange Flavour (Change of Name of Manufacturer)	do.	do.	do.
Cebion Calcio Vitamin C + Calcium Effervescent Tablets—Orange Flavour 1000 mg/600 mg (Change of Name of Manufacturer)	do.	do.	do.
Cebion 2000 mg Vitamin C Effervescent Tablets—Orange Flavour 2 g (Change of Name of Manufacturer)	do.	do.	do.
Cebion Effervescent Tablets Tropical Flavour 1 g (Change of Name of Manufacturer)	do.	do.	do.
Cebion Effervescent Tablets Orange Flavour 1 g (Change of Name of Manufacturer)	do.	do.	do.
Ziac Film Coated Tablets 2.5 mg/6.25 mg (Change of Name of Manufacturer)	do.	do.	Third Schedule

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Ziac Film Coated Tablets 5 mg/6.25 mg (Change of Name of Manufacturer)	Altea Farmaceutica S.A.	Colombia	Third Schedule
Ziac Film Coated Tablets 10 mg/6.25 mg (Change of Name of Manufacturer)	do.	do.	do.

Dated this 22nd day of December, 2014.

F. KHAN
Minister of Health