

LEGAL NOTICE NO. 43

REPUBLIC OF TRINIDAD AND TOBAGO

FOOD AND DRUGS ACT, CHAP. 30:01

NOTIFICATION

ISSUED BY THE MINISTER ON THE RECOMMENDATION OF AND AFTER
CONSULTATION WITH THE DRUG ADVISORY COMMITTEE IN
ACCORDANCE WITH PARAGRAPH 7, DIVISION 3 OF THE SECOND
SCHEDULE OF THE FOOD AND DRUGS REGULATIONS, CHAP. 30:1

APPROVAL IN RESPECT OF NEW DRUGS

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>
Taxuba Injection 20 mg	Manufactured by: Laboratorios IMA S.A.I.C. Argentina Packaged by: Glenmark Generics S.A.	Argentina	Third Schedule
Taxuba Injection 80 mg	do.	do.	do.
Sandoz Desloratadine Film-Coated Tablets 5 mg	Manufactured by: Sandoz Private Limited for Sandoz GmbH Austria	India	do.
Sandoz Escitalopram Film-Coated Tablets 20 mg	do.	do.	do.
GNC Glucosamine/Chondroitin Capsules 250 mg/200 mg	Distributed by: General Nutrition Corporation, USA (Product of USA)	USA	Freely
Tramapar Film-Coated Tablets	Indoco Remedies Ltd.	India	Third Schedule
Aanmol Tablets BP 500 mg	Manufactured by: Centurion Laboratories Division of Centurion Remedies PVT Ltd., India Marketed by: Aanjaney Lifecare Limited, India	do.	Freely

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Zerodol P Film-Coated Tablets	Ipca laboratories Ltd.	India	Third Schedule
Iressa Tablets 250 mg	AstraZeneca UK Limited	United Kingdom	do.
Flucan-150 Hard Gelatin Capsules	Lincoln Pharmaceuticals Ltd.	India	do.
Flucan-200 Hard Gelatin Capsules	do.	do.	do.
Vomez-20 Delayed-Release Capsules USP	Vision Pharmaceuticals	do.	do.
Diolin Tablets BP 5 mg	Lincoln Pharmaceuticals Ltd.	India	do.
Anol-50 Tablets	do.	do.	do.
Majerol Tablets BP	do.	do.	do.
Omlink-20 Hard Gelatin Capsules	do.	do.	do.
Diabend MR 30 Tablets	Bal Pharma Limited	do.	do.
NovoMix 30 Flexpen Suspension for Injection in a pre-filled pen 100U/ml (Change of Formulation)	Novo Nordisk A/S	Denmark	do.
NovoMix 30 Penfill Suspension for Injection in Cartridge 100U/ml (Change of Formulation)	do.	do.	do.
Raciper 20 Gastro-Resistant Tablets 20 mg	Ranbaxy Laboratories Limited	India	do.
Raciper 40 Gastro-Resistant Tablets 40 mg	do.	do.	do.
DuoPlavin Film-Coated Tablets 75 mg/100 mg	Sanofi Winthrop Industrie	France	do.
Glucophage 500 XR Extended-Release Tablets 500 mg	Manufactured by: Merck Santé s.a.s. France for Merck, S.A. Guatemala Packaged by: Farmaquila, S.A.	Guatemala	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Glucovance Film-Coated Tablets 1000 mg/5 mg	Manufactured by: Merck Santé s.a.s. France for Merck, S.A. Guatemala Packaged by: Farmaquila, S.A.	Guatemala	Third Schedule
Bypro Film-Coated Tablets USP 50 mg	Fresenius Kabi Oncology Ltd.	India	do.
Zolocan Capsules 150 mg	Meyer Healthcare Pvt. Ltd.	do.	do.
Apo-Pantoprazole Enteric-Coated Tablets 20 mg	Apotex Inc.	Canada	do.
Apo-Pantoprazole Enteric-Coated Tablets 40 mg	do.	do.	do.
Apo-Amlodipine Tablets 5 mg	do.	do.	do.
Apo-Amlodipine Tablets 10 mg	do.	do.	do.
Metformin Denk 1000 Film-Coated Tablets	DENK PHARMA GmbH & Co. KG	Germany	do.
Tarceva Film-Coated Tablets 100 mg (Additional Source, Change of Artwork Design and New Indication)	Made for: F. Hoffmann-La Roche Ltd., Switzerland by Roche S.p.A.	Italy	do.
Tarceva Film-Coated Tablets 150 mg (Additional Source, Change of Artwork Design and New Indication)	do.	do.	do.
Tavanic Film-Coated Tablets 500 mg (Additional Source)	sanofi-aventis de México S.A. de C.V.	do.	do.
Avamys Nasal Spray Suspension 27.5 mcg/dose–120 doses (Additional Source, Change of Name of Product and Change of Artwork Design)	Glaxo Wellcome S.A.	Spain	do.
Repisprin-81 Tablets USP 81 mg	Manufactured by: Aurochem Laboratories (I) Pvt. Ltd. Marketed by: Trinpharm Co. Ltd., Trinidad and Tobago	India	Freely

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Diabend MR 60 Modified Release Tablets	BAL PHARMA Ltd.	India	Third Schedule
Celparin 5000 Injection USP 5000 IU/5 mL	Celon Laboratories Ltd.	do.	do.
GNC Triple Strength Fish Oil Softgels	Distributed by: General Nutrition Corporation, USA (Product of USA)	USA	Freely
GNC alpha-Lipoic Acid 600 Caplets 600 mg	do.	do.	do.
Cyctocel 200 Powder for Solution for Injection USP 200 mg-Vials	Celon Laboratories Ltd.	India	Third Schedule
GNC CoQ-10 Softgel Capsules 50 mg	Distributed by: General Nutrition Corporation, USA (Product of USA)	USA	Freely
GNC CoQ-10 Softgel Capsules 100 mg	do.	do.	do.
GNC CoQ-10 Softgel Capsules 200 mg	do.	do.	do.
GNC CoQ-10 Softgel Capsules 400 mg	do.	do.	do.
GNC Calcium Complete Tablets	do.	do.	do.
GNC Glucosamine Sulfate 1000 Tablets	do.	do.	do.
GNC Glucosamine Sulfate 550 Capsules	do.	do.	do.
GNC Natural E 400 Softgel Capsules 400IU	do.	do.	do.
GNC Natural E 1000 Softgel Capsules 1000IU	do.	do.	do.
GNC Herbal Plus Milk Thistle Capsules 200 mg-Vegetarian	do.	do.	Freely (Pharmacy ONLY)
Zoledronic Acid Lyophilized Powder for Injection 4 mg/vial	Gland Pharma Ltd.	India	Third Schedule

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Celplat 10 Injection BP 10 mg/10 mL	Celon Laboratories Ltd.	India	Third Schedule
Celplat 50 Injection BP 50 mg/50 mL	do.	do.	do.
Invega Extended-Release Tablets 6 mg (Additional Source)	Manufactured by: Janssen Cilag Manufacturing LLC Puerto Rico Packaged and Released by: Janssen-Cilag S.p.A., Via C. Janssen	Italy	do.

Dated this 8th day of February, 2013.

F. KHAN
Minister of Health