

LEGAL NOTICE NO. 122

REPUBLIC OF TRINIDAD AND TOBAGO

THE FOOD AND DRUGS ACT, CHAP. 30:01

NOTIFICATION

APPROVAL IN RESPECT OF NEW DRUGS

ISSUED by the Minister of Health on the advice of the Drug Advisory Committee in accordance with paragraph 7, Division 3 of the Second Schedule of the Food and Drugs Act.

The Minister signifies his approval of the following new drugs:

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Ad-Muc Ointment	Merz + Co.	Germany	Freely
Miconazole Nitrate Teuto Lotion 20 mg/mL	Laboratorio Teuto Brasileiro Ltda.	Brazil	Third Schedule
Miconazole Nitrate Teuto Vaginal Cream 20 mg/g + Applicator	do.	do.	do.
Ketoconazole Teuto Tablets 200 mg	do.	do.	do.
Ketoconazole Teuto Dermatological Cream 20 mg/g	do.	do.	do.
Fluconazole Teuto Capsules 150 mg	do.	do.	do.
Ranitidine Teuto Coated Tablets 300 mg	do.	do.	do.
Myfortic Gastro-Resistant Tablets 180 mg	Novartis Pharma AG	Switzerland	do.
Myfortic Gastro-Resistant Tablets 360 mg	do.	do.	do.
Sandimmun Neoral Soft Gelatin Capsules 50 mg	Manufactured by R.P. Scherer GmbH for Novartis Pharma AG Switzerland	Germany	do.
Advil Cold & Sinus Coated Tablets (Non-Drowsy)—	Whitehall-Robins Health Care	USA	Freely
Visine Tears Lubricant Eye Drops	Consumer Health Care Group Pfizer Inc.	do.	do.
Dukoral Oral Suspension and Effervescent Granules —Combined Pack	SBL Vaccin AB	Sweden	Third Schedule

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Valixa Film-Coated Tablets 450 mg	Made under licence from F. Hoffman- La Roche Ltd. Switzerland by Patheon Inc.	Canada	Third Schedule
Cardioprotect Chewing Tablets	Janssen Cilag, S.A. de C.V.	Mexico	do.
Haliborange Halibonbons Children's Chewable Vitamin C Tablets —Orange Flavour	Seven Seas Health Care Ltd.	England	Freely
Multibionta 50 + Probiotic Multivitamin Tablets	do.	do.	do.
Seven Seas Boost Effervescent Tablets	do.	do.	do.
Schiff Children's Chewable Vitamins with Minerals Tablets	Schiff Products	USA	do.
Spiriva Powder Inhalation Hard Capsules 18 mcg	Manufactured by Boehringer Ingelheim KG for Boehringer Ingelheim International GmbH	Germany	Third Schedule
Spiriva Powder Inhalation Hard Capsules 18 mcg and HandiHaler Device —Combopack	do.	do.	do.
Buckley's Jack & Jill Cough, Cold & Flu Junior Strength Chewable Tablets —Grape Flavoured	W.K. Buckley Limited	Canada	Freely
Ciplox-D Eye Drops	Cipla Ltd.	India	Third Schedule
Paracip Syrup 125 mg/5 ml	do.	do.	Freely
BurnHeal Cream	do.	do.	Third Schedule
Lanzol-30 Capsules	do.	do.	do.
Etrux Anti-dandruff Hair Gel	Laboratorios Celsius S.A.	Uruguay	do.
Etrux Lotion	do.	do.	do.
Reflugel Oral Suspension	do.	do.	Freely
Nimulid Transgel	Panacea Biotec Ltd.	India	do.
Nimulid Nugel	do.	do.	do.
Nimulid-MD Dispersible Tablets	do.	do.	Third Schedule
Dultavax Injectable Suspension in Prefilled Syringe	Aventis Pasteur SA	France	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Seretide Evohaler 25/50	Glaxo Wellcome Operations	UK	Third Schedule
Seretide Evohaler 25/125	do.	do.	do.
Seretide Evohaler 25/250	do.	do.	do.
Calpol Six Years Plus Suspension—Orange Flavour	do.	do.	Freely
LAS-Paracetamol Effervescent Tablets 500 mg	Manufactured by Cipla Ltd. for LasMed A division of Lasco Distributors Ltd. Jamaica	India	Freely
LAS-Betaxolol Eye Drops 0.25%	do.	do.	Third Schedule
Tritace Prevent Capsules 10 mg	Packed by Aventis Pharma, S.A.	Guatemala	do.
Ativan Injection 2 mg/mL	Wyeth Laboratories Inc. A Wyeth-Ayerst Company	USA	Controlled Drug
Cuprofen Tablets 200 mg	Manufactured by Cupal Ltd. Distributed by Seton Healthcare Group plc England	UK	Freely
Cuprofen Maximum Strength Tablets 400 mg	do.	do.	Third Schedule
Presiten 20 Tablets	Magnachem Laboratory International S.A.	Dominican Republic	do.
Hemarexin Drinkable Ampoules (Change of Name of Manufacturer)	Sabex 2002 Inc.	Canada	Freely
Hemarexin Liquid (Change of Name of Manufacturer)	do.	do.	do.
Dormicum Ampoules 5 mg/5 ml for I.V.-I.M. Injection and Rectal Application in Children (Additional Source)	Made under licence from F. Hoffmann-La Roche Ltd. Switzerland by Roche Fontenay-sous-Bois	France	Controlled Drug
Dormicum Ampoules 15 mg/3 ml for I.V.-I.M. Injection (Additional Source)	do.	do.	do.
Valium Ampoules 10 mg for I.M., if necessary I.V. Injection (Additional Source)	do.	do.	do.
Konakion MM Paediatric Ampoules 2 mg for Oral Use or I.M./I.V. Injection (Additional Source)	do.	do.	Third Schedule

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Nizoral Gel Shampoo (Change of Name of Manufacturer)	Janssen Cilag, S.A. de C.V.	Mexico	Third Schedule
Infanrix Hexa Powder and Suspension for Injection (Change of Name of Manufacturer)	GlaxoSmithKline Biologicals s.a.	Belgium	do.
Baralgin "M" Tablets (Change of Name of Manufacturer)	Aventis Pharma, S.A.	Guatemala	do.
Methotrexate Sodium Tablets 2.5 mg (Additional Source)	Cyanamid GMBH (Lederle Pharmaceuticals)	Germany	do.
Tofranil 10 Coated Tablets 10 mg (Additional Source)	Manufactured by Novartis Urunleri A.S. for Novartis Pharma AG, Switzerland	Turkey	do.
Casodex Tablets 150 mg (Additional Indication and Change of Name of Manufacturer)	Manufactured for AstraZeneca UK Limited by AstraZeneca GmbH Germany	UK	do.
Simchol-10 Film-Coated Tablets	Aristo Pharmaceuticals Ltd.	India	do.
Simchol-20 Film-Coated Tablets	do.	do.	do.
Honitus Syrup	Dabur India Ltd. (Pharmaceutical Division)	do.	Freely
Colo VapoRex Rub-Strong	Syncom Formulations (India) Ltd.	do.	do.
Black Walnut Hulls Capsules 500 mg	Nature's Way Products Inc.	USA	do.
Cranberry Fruit Capsules 500 mg	do.	do.	do.
Bilberry Extract Capsules	do.	do.	do.
Pudin Hara Pearls	Dabur India Ltd.	India	do.
Iron 100 Inj.	Kepro B.V.	Holland	To Veterinarians or by Veterinary Prescription only
Ciplox Eye Ointment	Cipla Ltd.	India	do.

Dated this 11th day of June, 2003.

C. IMBERT
Minister of Health