

LEGAL NOTICE NO. 6

REPUBLIC OF TRINIDAD AND TOBAGO

FOOD AND DRUGS ACT, CHAP. 30:01

NOTIFICATION

NOTICE OF APPROVAL IN RESPECT OF NEW DRUGS

ISSUED by the Minister of Health 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 of Health 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>
Scheriproct N Cream	Manufactured by: Intendis Manufacturing SpA Via E. Schering	Italy	Freely
Histatussin Pe Liquid	Carlisle Laboratories Limited	Barbados	do.
Octostat (Octreotide Injection 100 mcg/ml, 1 ml Ampoule)	SG Pharma Pvt. Ltd.	India	Third Schedule
Onone (Ondansetron Injection USP 2 mg/ml)	do.	do.	do.
Ondansetron Tablets USP 8 mg	do.	do.	do.
Hydroxycarbamide Capsules B.P. 500 mg	do.	do.	do.
Dextrose Injection USP 50% w/v	Flagship Biotech International	do.	do.
Amphotericin B for Injection USP 50 mg Amphizome (Lyophilized)	do.	do.	do.
Diamin Solution for Infusion 20 mg	Claris Lifesciences Limited	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Kombiglyze XR Film Coated Tablets 5/500 mg	Manufactured by: Bristol-Myers Squibb Company For: AstraZeneca Camcar S.A. Panama	USA	Third Schedule
Kombiglyze XR Film Coated Tablets 2.5/1000 mg	do.	do.	do.
Kombiglyze XR Film Coated Tablets 5/1000 mg	do.	do.	do.
Norgesic (Paracetamol/orphenadrine Tablets 450 mg/35 mg)	Quimica Y Farmacia, S.A. de C.V.	Mexico	do.
Clopidogrel (Bisulfate) 75 mg Coated Tablets	Laboratorios Stein S.A.	Costa Rica	do.
Femaplex 2.5 mg Film-Coated Tablets	Genepharm S.A.	Greece	do.
Clopacin Film Coated Tablets 75 mg	Acino Pharma AG,	Switzerland	do.
Natrol EnerG Chewable Tablets	Natrol Inc.,	USA	Freely
Natrol Red Yeast Rice with Garlic Tablets	do.	do.	do.
Vita-Vim Regular Multivitamins	Jamieson Laboratories Ltd.	Canada	do.
Vita-Vim Women Multivitamins	do.	do.	do.
Vita-Vim Vegetarian Multivitamins	do.	do.	do.
Vita-Vim Kids Iron Free with Extra Calcium and Vitamin C Chewable Tablets	do.	do.	do.
Sutent Hard Gelatin Capsules 50 mg (New Indication)	Pfizer Italia Srl.	Italy	Third Schedule (To Registered Oncologist ONLY)
Sutent Hard Gelatin Capsules 25 mg (New Indication)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Sutent Hard Gelatin Capsules 12.5 mg (New Indication)	Pfizer Italia Srl.	Italy	Third Schedule (To Registered Oncologist ONLY)
Vimovo Modified-Release Tablets 500 mg/20 mg (Change of Artwork Design)	Manufactured by: Patheon Pharmaceuticals Inc. USA Packed by: AstraZeneca AB	Sweden	Third Schedule
Afinitor Tablets 5 mg (Additional Indication)	Manufactured by: Novartis Pharma Stein AG, for Novartis Pharma AG, Switzerland	Switzerland	do.
Afinitor Tablets 10 mg (Additional Indication)	do.	do.	do.
Glivec Film-Coated Tablets 100 mg (Additional Indication)	Manufactured by: Novartis Pharma Stein AG, for Novartis Pharma AG Basel, Switzerland	do.	do.
Glivec Film-Coated Tablets 400 mg (Additional Indication)	do.	do.	do.
Sandostatin Lar Injection 20 mg (Additional Indication)	Manufactured by: Sandoz GmbH Austria and Abbott Biologicals BV Netherlands Packed by: Novartis Pharma Stein AG,	do.	do.
Sandostatin Lar Injection 30 mg (Additional Indication)	do.	do.	do.

Dated this 10th day of January, 2018.

T. DEYALSINGH
Minister of Health