

LEGAL NOTICE NO. 336

## 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 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>
Tracrium Solution for Injection and Infusion 10mg/ml (25mg/2.5ml) (Change of Marketing Authorisation Holder, Change of Artwork, Additional Presentation, Change of Importer and Change of Label)	Manufactured by: GlaxoSmithKline Manufacturing S.p.A., Pharma, Italy For: Aspen Labs S.A. de C.V., Mexico	Italy	Third Schedule
Ozurdex Intravitreal Implant in Applicator 0.7mg	Allergan Pharmaceuticals Ireland	Ireland	Third Schedule (For Specialists Use Only)
Cosyrel Film-Coated Tablets 5mg/5mg	Les Laboratoires Servier Industrie	France	Third Schedule
Cosyrel Film-Coated Tablets 5mg/10mg	do.	do.	do.
Cosyrel Film-Coated Tablets 10mg/5mg	do.	do.	do.
Cosyrel Film-Coated Tablets 10mg/10mg	do.	do.	do.
Trostigmin (Pyridostigmine Tablets BP) 60mg	Troikaa Pharmaceuticals Limited	India	Third Schedule
Isotroy 250 (Isoflurane USP Inhalation Liquid 250mL)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Lamivudine Oral Solution USP 10mg/mL	Macleods Pharmaceuticals Limited	India	Third Schedule
Zidovudine Oral Solution USP 50mg/5mL	do.	do.	do.
Hyrimoz Solution for Injection 40mg/0.8mL	Sandoz GmbH Langkampfen- Austria for Sandoz GmbH, Kundl-Austria	Austria	Third Schedule
Rixathon Concentrate for Solution for Infusion 100mg/10mL	Lek Pharmaceuticals d.d., Slovenia For: Sandoz GmbH, Austria	Slovenia	Third Schedule (For Specialist Use Only)
Rixathon Concentrate for Solution for Infusion 500mg/50mL	do.	do.	do.
Truxima Rituximab 500mg/50mL Concentrate for Solution for Infusion	Celltrion Inc. MAH: Celltrion Healthcare Co. Ltd., Republic of Korea	Republic of Korea	Third Schedule
Topraz Tablets 40mg	Aurobindo Pharma Limited	India	Third Schedule
Myotram-P Tablets 37.5/325mg	do.	do.	do.
Lynparza Film Coated Tablets 100mg	Manufactured by: Abbvie Limited KM, Puerto Rico, United States Packaged by: AstraZeneca UK Limited Marketing Authorisation Holder: AstraZeneca AB, SE-151 85 Södertälje, Sweden	United Kingdom	Third Schedule
Lynparza Film Coated Tablets 150mg	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Latanoprost Ophthalmic Solution 0.005%	Indiana Ophthalmics	India	Third Schedule
Prednisolone Acetate Ophthalmic Suspension USP 1%	Indiana Ophthalmics	India	Third Schedule
Redoxon Double Action Effervescent Tablets	Bayer S.A. Guatemala	Guatemala	Freely
Truxima Rituximab 100mg/10mL Concentrate for Solution for Infusion	Celltrion Inc. MAH: Celltrion Healthcare Co. Ltd., Republic of Korea	Republic of Korea	Third Schedule

Dated this 29th day of September, 2020.

T. DEYALSINGH  
*Minister of Health*