

LEGAL NOTICE No. 289

## 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:

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Abevmy® 100 Concentrate for Solution for Intravenous (I.V.) Infusion 100mg/4mL	Biocon Biologics Limited Block No. B1, B2, Q13 of Q1 and W20, Unit S18, 1st Floor, Block B4, Special Economic Zone, Plot No. 2, 3, 4 & 5, Phase IV, Bommasandra-Jigani Link Road, Bommasandra Post, Bengaluru - 560 099, India For: Mylan Pharmaceuticals Ltd., India	India	Third Schedule
Abevmy® 400 Concentrate for Solution for Intravenous (I.V.) Infusion 400mg/16mL	Biocon Biologics Limited Block No. B1, B2, Q13 of Q1 and W20, Unit S18, 1st Floor, Block B4, Special Economic Zone, Plot No. 2, 3, 4 & 5, Phase IV,	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Bommasandra-Jigani Link Road, Bommasandra Post, Bengaluru - 560 099, India For: Mylan Pharmaceuticals Ltd., India		
Erlotinib Remedica 150 mg Film-Coated Tablets	Remedica Ltd Aharnon Str., Limassol Industrial Estate, 3056 Limassol, Cyprus	Cyprus	Third Schedule
Exedra 25 film-coated tablets 25 mg	Remedica Ltd Aharnon Str., Limassol Industrial Estate, 3056 Limassol, Cyprus	Cyprus	Third Schedule
Imarem 100 mg film-coated tablets	Remedica Ltd Aharnon Street Limassol Industrial Estate 3056, Limassol, Cyprus	Cyprus	Third Schedule
Imarem 400 mg film-coated tablets	Remedica Ltd Aharnon Street Limassol Industrial Estate 3056, Limassol, Cyprus	Cyprus	Third Schedule
Scapho® 300 mg/ 2 mL Solution for Injection in a Single-Use UnoReady® Pre-Filled Pen	Novartis Pharma Stein AG, Stein, Switzerland For: Novartis Overseas Investments AG, Basel, Switzerland	Switzerland	Third Schedule



TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Verzenio™ 50 mg film-coated tablets (Change of Product Licence Holder)	Lilly del Caribe, Inc. 12.6 KM 65 <sup>th</sup> Infantry Road (PR01) Carolina, Puerto Rico (PR) 00985, USA Packaged by: Lilly, S.A. Avda. de la Industria, 30, 28108 Alcobendas, Madrid Spain	Spain	Third Schedule
Verzenio™ 100 mg film-coated tablets (Change of Product Licence Holder)	Lilly del Caribe, Inc. 12.6 KM 65 <sup>th</sup> Infantry Road (PR01) Carolina, Puerto Rico (PR) 00985, USA Packaged by: Lilly, S.A. Avda. de la Industria, 30, 28108 Alcobendas, Madrid Spain	Spain	Third Schedule
Verzenio™ 150 mg film-coated tablets (Change of Product Licence Holder)	Lilly del Caribe, Inc. 12.6 KM 65 <sup>th</sup> Infantry Road (PR01) Carolina, Puerto Rico (PR) 00985, USA Packaged by: Lilly, S.A. Avda. de la Industria, 30, 28108 Alcobendas, Madrid Spain	Spain	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Lynparza™ 100 mg Film Coated Tablets (Additional Indications)	Abbvie Limited KM 58.0 Cruce Davilia Barceloneta Puerto Rico, United States Packaged by: AstraZeneca UK Limited, Silk Road Business Park Macclesfield SK 10 2NA United Kingdom For: AstraZeneca AB, SE-152 85 Södertälje, Sweden	United Kingdom	Third Schedule
Lynparza™ 150 mg Film Coated Tablets (Additional Indications)	Abbvie Limited KM 58.0 Cruce Davilia Barceloneta Puerto Rico, United States Packaged by: AstraZeneca UK Limited, Silk Road Business Park Macclesfield SK 10 2NA United Kingdom For: AstraZeneca AB, SE-152 85 Södertälje, Sweden	United Kingdom	Third Schedule
RILUTEK® 50 mg Film-Coated Tablets (Change of Name of Manufacturer and Legal Entity; Update of the Address of Manufacturer; Change in Name of the Marketing Authorization Holder; Update of Artwork)	OPELLA HEALTHCARE INTERNATIONAL SAS Compiègne, France	France	Third Schedule (Specialist Use Only)

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Scapho® 150 mg Powder for Solution for Injection (New Indication; Modification of Dose Flexibility)	Novartis Pharma Stein AG, Stein, Switzerland For: Novartis Overseas Investments AG, Switzerland	Switzerland	Third Schedule
Skyrizi (Risankizumab injection) 150 mg/ mL Sterile Solution for Subcutaneous Injection in Single-Use PEN (New Indication)	Manufacturer & Primary Packager: AbbVie Biotechnology LTD PR, USA Secondary Packager: AbbVie Deutschland GmbH & Co. KG Ludwigshafen, Germany For: AbbVie Deutschland GmbH & Co. KG Ludwigshafen, Germany	Germany	Third Schedule
Rumalaya® forte Tablets (Change of Name of Manufacturer; Artwork Update)	Himalaya Wellness Company, Makali, Bengaluru 562 162, India	India	Freely
Rumalaya® Gel (Change of Name of Manufacturer; Artwork Update)	Himalaya Wellness Company, Makali, Bengaluru 562 162, India	India	Freely
Rumalaya® Cream (Change of Name of Manufacturer; Artwork Update)	Himalaya Wellness Company, Makali, Bengaluru 562 162, India	India	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Himplasia <sup>TM</sup> Tablets (Change of Name of Manufacturer; Artwork Update)	Himalaya Wellness Company, Makali, Bengaluru 562 162, India	India	Freely
Liv.52 <sup>®</sup> Tablets (Change of Name of Manufacturer; Artwork Update)	Himalaya Wellness Company, Makali, Bengaluru 562 162, India	India	Freely
Liv.52 <sup>®</sup> DS Tablets (Change of Name of Manufacturer; Artwork Update)	Himalaya Wellness Company, Makali, Bengaluru 562 162, India	India	Freely
Liv.52 <sup>®</sup> Syrup (Change of Name of Manufacturer; Artwork Update)	Himalaya Wellness Company, Makali, Bengaluru 562 162, India	India	Freely
Bonnisan <sup>®</sup> Liquid (Change of Name of Manufacturer; Artwork Update)	Himalaya Wellness Company, Makali, Bengaluru 562 162, India	India	Freely
Bonnisan <sup>®</sup> Drops (Change of Name of Manufacturer; Artwork Update)	Himalaya Wellness Company, Makali, Bengaluru 562 162, India	India	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Pilex <sup>®</sup> Tablets (Change of Name of Manufacturer; Artwork Update)	Himalaya Wellness Company, Makali, Bengaluru 562 162, India	India	Freely
Pilex <sup>®</sup> Ointment (Change of Name of Manufacturer; Artwork Update)	Himalaya Wellness Company, Makali, Bengaluru 562 162, India	India	Freely
Cystone <sup>®</sup> Tablets (Change of Name of Manufacturer; Artwork Update)	Himalaya Wellness Company, Makali, Bengaluru 562 162, India	India	Freely
Cystone <sup>®</sup> Tablets (Double Strength) (Change of Name of Manufacturer; Artwork Update)	Himalaya Wellness Company, Makali, Bengaluru 562 162, India	India	Freely
Septilin <sup>®</sup> Tablets (Change of Name of Manufacturer; Artwork Update)	Himalaya Wellness Company, Makali, Bengaluru 562 162, India	India	Freely
Septilin <sup>®</sup> Syrup (Change of Name of Manufacturer; Artwork Update)	Himalaya Wellness Company, Makali, Bengaluru 562 162, India	India	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Koflet® Lozenge (Change of Name of Manufacturer; Artwork Update)	Himalaya Wellness Company, Makali, Bengaluru 562 162, India	India	Freely
Koflet® Cough Syrup (Change of Name of Manufacturer; Artwork Update)	Himalaya Wellness Company, Makali, Bengaluru 562 162, India	India	Freely
Diakof™ Cough Linctus (Change of Name of Manufacturer; Artwork Update)	Himalaya Wellness Company, Makali, Bengaluru 562 162, India	India	Freely
Evecare™ Capsules (Change of Name of Manufacturer; Artwork Update)	Himalaya Wellness Company, Makali, Bengaluru 562 162, India	India	Freely
Himcocid™ Suspension (Change of Name of Manufacturer; Artwork Update)	Himalaya Wellness Company, Makali, Bengaluru 562 162, India	India	Freely
Geriforte® Tablets (Change of Name of Manufacturer; Artwork Update)	Himalaya Wellness Company, Makali, Bengaluru 562 162, India	India	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Geriforte® Syrup (Change of Name of Manufacturer; Artwork Update)	Himalaya Wellness Company, Makali, Bengaluru 562 162, India	India	Freely
V-Gel™ Vaginal Gel (Change of Name of Manufacturer; Artwork Update)	Himalaya Wellness Company, Makali, Bengaluru 562 162, India	India	Freely
Mentat® Tablets (Change of Name of Manufacturer; Artwork Update)	Himalaya Wellness Company, Makali, Bengaluru 562 162, India	India	Freely
Mentat® Syrup (Change of Name of Manufacturer; Artwork Update)	Himalaya Wellness Company, Makali, Bengaluru 562 162, India	India	Freely
Abana® Tablets (Change of Name of Manufacturer; Artwork Update)	Himalaya Wellness Company, Makali, Bengaluru 562 162, India	India	Third Schedule
Diabecon® Tablets (Change of Name of Manufacturer; Artwork Update)	Himalaya Wellness Company, Makali, Bengaluru 562 162, India	India	Third Schedule
Gasex® Tablets (Change of Name of Manufacturer; Artwork Update)	Himalaya Wellness Company, Makali, Bengaluru 562 162, India	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Speman® Tablets (Change of Name of Manufacturer; Artwork Update)	Himalaya Wellness Company, Makali, Bengaluru 562 162, India	India	Freely
Menosan™ Tablets (Change of Name of Manufacturer; Artwork Update)	Himalaya Wellness Company, Makali, Bengaluru 562 162, India	India	Freely
Glivec® 100mg Film-Coated Tablets (Change of Primary & Secondary Packaging Site; Change of Country of Origin; Change of Artwork)	Novartis Pharma Produktions, Wehr, Germany Packaged by: Lek Pharmaceuticals d.d., Lendava, Slovenia For: Novartis Pharma AG, Basel, Switzerland	Slovenia	Third Schedule (Specialist Use Only)

Dated this 11th day of September, 2023.

T. DEYALSINGH  
*Minister of Health*