

LEGAL NOTICE NO. 27

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>
RhoGAM Ultra-Filtered PLUS Injection 300µg Dose (1500IU)-Pre-Filled Syringe Thimerosal-Free (Change of Manufacturer)	Kedrion Biopharma Inc.	USA	Third Schedule
Children's Cetamol Liquid 160mg/5ml (Change of Distributor)	Federated Pharmaceutical	Jamaica	Freely
DPH Elixir 12.5mg/5ml (Change of Distributor)	do.	do.	do.
DPH Expectorant 14.08mg/5ml (Change of Distributor)	do.	do.	do.
Cetamol Extra Strength Caplets 500mg (Change of Distributor)	do.	do.	do.
Ezetrol Tablets 10mg (Change of Name of Manufacturing Site)	MSD International GMBH (Puerto Rico Branch) LLC., Puerto Rico Packaged by: Schering-Plough S.A. de C.V.	Mexico	Third Schedule
Minirin Nasal Spray Solution 0.1mg/ml (Change of Net Volume)	FERRING GmbH Holder: FERRING AG Switzerland	Germany	do.
Zovirax Cream (Change of Name of Manufacturer)	GlaxoSmithKline Brasil Limitada	Brazil	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Ribomustin 100mg Powder for Concentrate for Solution for Infusion (Change of Name and Address of Manufacturer)	Oncotec Pharma Produktion GmbH	Germany	Third Schedule
Ribomustin 25mg Powder for Concentrate for Solution for Infusion (Change of Name and Address of Manufacturer)	do.	do.	do.
Genethics Allergy Syrup (Change of Name and Address of Manufacturer)	Bpi Genethics Limited	Trinidad and Tobago	Freely
Genethics Hydrogen Peroxide Solution 6% B.P. (Change of Name and Address of Manufacturer)	do.	do.	do.
Genethics Cough Expectorant (Change of Name and Address of Manufacturer)	do.	do.	do.
Painol Jr Raspberry Flavoured Syrup (Aspirin Free, Alcohol Free, Ibuprofen Free) (Change of Name and Address of Manufacturer)	do.	do.	do.
Genethics VP Rub (Change of Name and Address of Manufacturer)	do.	do.	do.
Hytrin Tablets 2mg (Change of Name of Manufacturer and Change of Artwork Design)	Aesica Queenborough Ltd.	UK	Third Schedule
Hytrin Tablets 5mg (Change of Name of Manufacturer and Change of Artwork Design)	do.	do.	do.
Glaucoprost Sterile Ophthalmic Solution 0.004% (Change of Artwork Design)	Poen Laboratories SACIFI	Argentina	do.
Flexbumin 25% Albumin (Human) USP 25% Solution (Change of Name of Manufacturer)	Baxalta US Inc.	USA	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Gammagard S/D Immune Globulin Intravenous (Human) Solvent/Detergent Treated 2.5G (5%) (Change of Name of Manufacturer and Change of Product Name)	Baxalta US Inc.	USA	Third Schedule
Gammagard S/D Immune Globulin Intravenous (Human) Solvent/Detergent Treated 5G (5%) (Change of Name of Manufacturer and Change of Product Name)	do.	do.	do.
Gammagard S/D Immune Globulin Intravenous (Human) Solvent/Detergent Treated 10G (5%) (Change of Name of Manufacturer and Change of Product Name)	do.	do.	do.
Hemofil M Antihemophilic Factor (Human) Method M, Monoclonal Purified FVIII Powder For Reconstitution and Sterile Water For Injection, USP (Change of Name and Address of Manufacturer and Change of Artwork Design)	do.	do.	do.
Intalfa Solution for Subcutaneous Injection 3MIU/1ml PFS (Change of Name of Manufacturer)	Intas Pharmaceuticals Ltd.	India	do.
Intalfa Solution for Subcutaneous Injection 5MIU/1ml PFS (Change of Name of Manufacturer)	do.	do.	do.
Erykine 2,000 IU/1.0ml PFS Injection 2,000 IU (Change of Name of Manufacturer)	do.	do.	do.
Erykine 4,000 IU/1.0ml PFS Injection 4,000 IU (Change of Name of Manufacturer)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Erykine 10,000 IU/1.0ml PFS Injection 10,000 IU (Change of Name of Manufacturer)	Intas Pharmaceuticals Ltd.	India	Third Schedule
Neukine PFS 1.0ml/300mcg s.c./i.v. Infusion-Pre-filled Syringe (Change of Name of Manufacturer)	do.	do.	do.
Casodex Film-Coated Tablets 50mg (Change of Packager and Change of Country of Origin)	Corden Pharma GmbH, Germany Packaged by: AstraZeneca UK Limited	UK	do.
Casodex Film-Coated Tablets 150mg (Change of Packager and Change of Country of Origin)	do.	do.	do.
Arimidex Tablets 1mg (Change of Packager and Change of Country of Origin)	AstraZeneca Pharmaceuticals LP, USA Packaged by: AstraZeneca UK Limited	do.	do.
Voltaren Emulgel Gel 1.16% (Change of Marketing Authorisation Holder, Change of Distributor and Change of Artwork Design)	Novartis Consumer Health S.A. for: GlaxoSmithKline Costa Rica S.A., Costa Rica	Switzerland	do.
Otrivin Nasal Drops Solution 0.05%-Children (Change of Marketing Authorisation Holder and Change of Artwork Design)	do.	do.	do.
Otrivin Nasal Drops Solution 0.1%-Adults (Change of Marketing Authorisation Holder and Change of Artwork Design)	do.	do.	do.
Otrivin Nasal Spray Nebuliser 0.1%-Adults (Change of Marketing Authorisation Holder and Change of Artwork Design)	do.	do.	do.
Otrivin Metered Dose Nasal Spray 0.1%-Adults (Change of Marketing Authorisation Holder and Change of Artwork Design)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Andrews Sparkling Salts- Original (Sachets) (Change of Primary and Secondary Artwork Design)	GlaxoSmithKline Costa Rica S.A.	Costa Rica	do.
Andrews Sparkling Salts- Lemon (Sachets) (Change of Primary and Secondary Artwork Design)	do.	do.	do.
Norgesic Tablets 450mg/35mg (Change of Artwork Design and Change of Address of Marketing Authorisation Holder)	Quimica y Farmacia S.A. de C.V. for: More Pharma Corporation, S. de R.L. de C.V., Mexico	Mexico	Third Schedule
Vicks VapoRub Ointment (Change of Artwork Design, Change of Name of Manufacturer, Change of Marketing Authorisation Holder and Change of Distributor)	Procter & Gamble Manufactura Mexico S. de R.L. de C.V. for: Procter & Gamble International Operations S.A., Panama	do.	Freely
Pharmaton Capsules (Change of Artwork Design)	Ginsana S.A.	Switzerland	do.
Seroquel Film-Coated Tablets 25mg (Additional Indication)	AstraZeneca UK Limited	UK	Third Schedule
Seroquel Film-Coated Tablets 100mg (Additional Indication)	do.	do.	do.
Seroquel Film-Coated Tablets 200mg (Additional Indication)	do.	do.	do.
Seroquel Film-Coated Tablets 300mg (Additional Indication)	do.	do.	do.
Seroquel XR Extended- Release Tablets 50mg (Additional Indication)	do.	do.	do.
Seroquel XR Extended- Release Tablets 200mg (Additional Indication)	do.	do.	do.

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Seroquel XR Extended-Release Tablets 300mg (Additional Indication)	AstraZeneca UK Limited	UK	Third Schedule
Seroquel XR Extended-Release Tablets 400mg (Additional Indication)	do.	do.	do.
X-Piles Ointment	L'amar Natural Products Pvt. Ltd.	India	Freely
BC 56 Cream	do.	do.	Freely
Tamsol 0.4mg Prolonged-Release Capsules	Gedeon Richter Romania S.A.	Romania	Third Schedule
Natrixam Modified Release Tablets 1.5mg/5mg	Les Laboratories Servier Industries	France	do.
Natrixam Modified Release Tablets 1.5mg/10mg	do.	do.	do.
Seroflo 125 Inhaler CFC Free Salmeterol/Fluticasone Propionate pressurised Inhalation 25/125mcg	Cipla Ltd.	India	do.
Seroflo 250 Inhaler CFC Free Salmeterol/Fluticasone Propionate pressurised Inhalation 25/250mcg	do.	India	do.
Kapetral 150mg Film-Coated Tablets 150mg	Remedica Ltd.	Cyprus	do.
Kapetral 500mg Film-Coated Tablets 500mg	do.	do.	do.
Risperidone-Remedica 2mg Film-Coated Tablets 2mg	do.	do.	do.
Devodil 200 Tablets 200mg	do.	do.	do.
Devodil Tablets 50mg	do.	do.	do.
Iricip-100 (Irinotecan Hydrochloride Injection 100mg/5ml)	Cipla Ltd.	India	do.
Oncogem-200 (Gemcitabine for Injection USP 200mg)	do.	do.	do.
Oncogem-1000 (Gemcitabine for Injection USP 1000mg)	do.	do.	do.

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Ipravent Inhaler CFC Free (Ipratropium pressurised Inhalation BP 20mcg/dose)	Cipla Ltd.	India	Third Schedule
Flohale-125 Inhaler CFC Free Fluticasone Propionate Inhaler 125mcg/dose	do.	do.	do.
Flohale-250 Inhaler CFC Free Fluticasone Propionate Inhaler 250mcg/dose	do.	do.	do.
Beclate-250 HFA Inhaler CFC Free Beclometasone Pressurized Inhalation BP 250mcg/dose	do.	do.	do.
Aucic 0.5% Ophthalmic Solution	Poen Laboratories S.A.C.I.F.I.	Argentina	Freely
Aucic 1% Ophthalmic Solution	do.	do.	do.
Gatif Forte Ophthalmic Solution	do.	do.	Third Schedule
Natax Ophthalmic Solution 0.09%	do.	do.	do.
Celzar 1000 Gemcitabine, Lyophilized Injection 1000mg	Celon Laboratories Limited	India	do.
Ldnil 5 Tablets 5mg	MSN Laboratories Private Ltd.	do.	do.
Ramcor-5 Capsules	Ipca Laboratories Ltd.	do.	do.
Zerodol-CR Film-Coated Controlled Release Tablets 200mg	do.	do.	do.
Paraconica™ 1000mg IV Solution for Infusion	SM Farmaceutici SRL for: Acino Pharma AG, Switzerland	Italy	do.
Nolicin 400mg Film-Coated Tablets	KRKA	Slovenia	do.
Vasilip 10mg Film-Coated Tablets	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Vasilip 20mg Film-Coated Tablets	KRKA	Slovenia	Third Schedule
Vasilip 40mg Film-Coated Tablets	do.	do.	do.
Rumalaya Gel	The Himalaya Drug Company	India	Freely
Clarina Anti-Acne Face Wash Gel	do.	do.	do.
Clarina Anti-Acne Face Mask	do.	do.	do.
Echinacea with Garlic & Ginger Capsules 100mg	Jamieson Laboratories Ltd.	Canada	do.
Slimdown® Green Tea with Apple Cider Vinegar Complex Caplets 113mg	do.	do.	do.
Slimdown® CLA-95 Capsules 950mg	do.	do.	do.
Amisped Pediatric Chewable Tablet 4mg	Sanofi-Aventis de Colombia S.A.	Colombia	Third Schedule
Amisped Pediatric Chewable Tablet 5mg	Sanofi-Aventis de Colombia S.A.	Colombia	do.
Amisped Pediatric Chewable Tablet 10mg	do.	do.	do.
Atazanavir Capsules 300mg	Mylan Laboratories Limited	India	do.
Nexquin 500 Tablets 500mg	MSN Laboratories Pvt. Ltd. for: Mylan Pharmaceuticals Pvt. Ltd., India	do.	do.
Lanzul 30mg Capsules	KRKA	Slovenia	do.
Nolpaza 20mg Gastro Resistant Tablets	do.	do.	do.
Nolpaza 40mg Gastro Resistant Tablets	do.	do.	do.
Dicynone 250mg Ampoules	Sanofi Winthrop Industrie for: OM Pharma S.A., Switzerland	France	do.
Dicynone 500mg Capsules	OM Pharma S.A. for: OM Pharma S.A., Switzerland	Portugal	do.

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Uro-Vaxom Capsules	OM Pharma S.A.	Switzerland	Third Schedule
Valsaden 160mg/12.5mg Film Coated Tablets	KRKA	Slovenia	do.
Valsaden 80mg/12.5mg Film Coated Tablets	do.	do.	do.
Valsaden 160mg/25mg Film Coated Tablets	do.	do.	do.
Doxiproct Ointment	OM Pharma S.A. for: OM Pharma S.A., Switzerland	Portugal	do.
Doxiproct Plus Ointment	do.	do.	do.
Betaxolol Eye Drops, Solution BP 0.5%	Ciron Drugs & Pharmaceuticals Pvt. Ltd.	India	do.
Arimidex Film Coated Tablets 1mg (Additional Source, Primary and Secondary Packager, Labelling and Batch Release)	AstraZeneca Pharmaceuticals LP, USA Packed by: AstraZeneca do Brasil Ltda. for: AstraZeneca UK Limited, United Kingdom	Brazil	do.
Efavirenz Film-Coated Tablets 600mg (Change of Name of Manufacturer and Change of Batch Size)	Mylan Laboratories Limited	India	do.
Tenofovir Disoproxil Fumarate/Lamivudine Film-Coated Tablets 300mg/300mg (Change of Name of Manufacturer and Change of Film Coating Composition)	do.	do.	do.
Lamivudine/Nevirapine/ Zidovudine Film-Coated Tablets 150mg/200mg/ 300mg (Change of Name of Manufacturer and Change of Tablet Size)	do.	do.	do.

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Lamivudine/Zidovudine Film-Coated Tablets 150mg/300mg (Change of Name of Manufacturer, Change of Condition of Use and Change of Batch Size)	Mylan Laboratories Limited	India	Third Schedule
Nevirapine Tablets 200mg (Change of Name of Manufacturer, Change of Batch Size and Change of Shelf Life)	do.	do.	do.
Emtricitabine/Tenofovir Disoproxil Fumarate Film-Coated Tablets 200mg/300mg (Change of Name of Manufacturer and Change of Shelf Life)	do.	do.	do.
Ciprinol 500mg Film-Coated Tablets	KRKA	Slovenia	do.
Haloperidol Injection BP 5mg/ml	Flagship Biotech International	India	do.
Bupican™ Heavy (Bupivacaine Hydrochloride in Dextrose Injection USP)	Clarix Injectables Limited	do.	do.
Clozarem 100mg Tablets	Remedica Ltd.	Cyprus	do.
Lanoxin Paediatric Elixir 50mcg/ml (Change of Artwork Design to reflect Change of Marketing Authorisation Holder and Change of Legal Entity and Manufacturer Name)	GlaxoSmithKline Mexico S.A. de C.V., for: Aspen Labs S.A. de C.V., Mexico	Mexico	do.
Enterogermina Oral Suspension 2 billion/5ml (Change of Name of Manufacturer)	Sanofi S.p.A.	Italy	do.
Simponi Solution for Injection in Pre-filled Pen 50mg/0.5ml	Baxter Pharmaceutical Solutions, USA Packaged by: Cilag AG	Switzerland	do.

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Tivicay Film-Coated Tablets 50mg	Glaxo Operations UK Limited, United Kingdom Packaged by: Glaxo Wellcome S.A.	Spain	Third Schedule
Tafinlar Hard Capsule 50mg	do.	do.	do.
Tafinlar Hard Capsule 75mg	do.	do.	do.
Lamictal Dispersible Chewable Tablets 2mg	GlaxoSmithKline Pharmaceuticals S.A., Poland Packaged by: GlaxoSmithKline Mexico, S.A. De C.V.	Mexico	do.
Lamictal Dispersible Chewable Tablets 5mg	do.	do.	do.
Synagis Solution for Injection 100mg/ml	Boehringer Ingelheim Pharma GmbH & Co. KG Secondary Packaging: AbbVie S.r.L., Italy for: AbbVie Limited, UK	Germany	do.
Heberprot-P® 75 Lyophilized Powder for Solution/Intralesional and Perilesional Injection	Center for Genetic Engineering and Biotechnology For: Heber Biotec S.A., Cuba	Cuba	do.

Dated this 30th day of January, 2019.

T. DEYALSINGH
Minister of Health