

LEGAL NOTICE No. 263

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
Imacord 100, (Imatinib Mesylate) Tablets 100 mg	Intas Pharmaceuticals Limited, Plot No.: 5 to 14, Pharmez, Near Village Matoda, Tal. Sanand, Dist. Ahmedabad, State Gujarat, India	India	Third Schedule (Specialist Use Only)
Imacord 400, (Imatinib Mesylate) Tablets 400mg	Intas Pharmaceuticals Limited, Plot No.: 5 to 14, Pharmez, Near Village Matoda, Tal. Sanand, Dist. Ahmedabad, State Gujarat, India	India	Third Schedule (Specialist Use Only)
Eligard® 22.5 mg for Injectable Suspension	Manufacturer: Tolmar, Inc., 1201 Cornerstone Drive, Windsor CO 80550, USA For: Tolmar Therapeutics, Inc., 701 Centre Avenue Fort Collins, CO 80526, USA	United States of America	Third Schedule (Specialist Use Only)
Eligard® 45 mg for Injectable Suspension	Manufacturer: Tolmar, Inc., 1201 Cornerstone Drive, Windsor CO 80550, USA For: Tolmar Therapeutics, Inc., 701 Centre Avenue Fort Collins, CO 80526, USA	United States of America	Third Schedule (Specialist Use Only)
Vabysmo® 6 mg/0.05 mL Solution for Injection	F. Hoffmann-La Roche Ltd., Kaiseraugst, Switzerland	Switzerland	Third Schedule (Specialist Use Only)

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	For: F. Hoffmann-La Roche Ltd., Basel, Switzerland		
Tivicay 5 mg dispersible tablets	Glaxo Operations UK Ltd. Ware, United Kingdom Packaged by: Glaxo Wellcome, S.A., Aranda de Duero, Spain	Spain	Third Schedule
Shingrix Powder and Suspension for Suspension for Injection 50 µg	Formulation: GlaxoSmithKline Biologicals S.A., Wavre, Belgium Filling and Lyophilisation: GlaxoSmithKline Biologicals, Saint-Amand-les-Eaux, France Packaged by: GlaxoSmithKline Vaccines S.r.l., Bellaria-Rosia, Sovicille, Italy For: GlaxoSmithKline Biologicals S.A., Wavre, Belgium	Italy	Third Schedule
Leponex® 25 mg Tablets	Madaus GmbH, Lütticher Strasse 5, 53842 Troisdorf, Germany For: Mylan Pharma GmbH Switzerland	Germany	Third Schedule
Visine® Red Eye Hydrating Comfort Drops	Distributed by: Johnson & Johnson Consumer Inc., Skillman NJ 08558	Belgium	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
EMISTOP™ I.V. (Ondansetron Injection USP 2 mg/mL)	Baxter Pharmaceuticals India Private Limited Ahmedabad, Gujarat- 382 213, India	India	Third Schedule (Specialist Use Only)
Rothrom® 20 mg Film-coated tablets	Oman Pharmaceutical Products Co. LLC, Oman Plot No. 101, Raysut Industrial Estate, P.O. Box 2240, Salalah, 211, Oman For: Sandoz GmbH, Kundl- Austria	Oman	Third Schedule
IRBITAS-150 (Irbesartan Tablets) Film coated tablets 150 mg	Intas Pharmaceuticals Ltd., Plot No. 457 & 458, Village Matoda, Bavla Road, Tal. Sanand - 382210 Dist. Ahmedabad Gujarat State, Ahmedabad India	India	Third Schedule
IRBITAS-300 (Irbesartan Tablets) Film coated tablets 300 mg	Intas Pharmaceuticals Ltd., Plot No. 457 & 458, Village Matoda, Bavla Road, Tal. Sanand - 382210 Dist. Ahmedabad Gujarat State, Ahmedabad India	India	Third Schedule
Furotas 10 mg/ml, 25 ml Solution for Injection or Infusion	Intas Pharmaceuticals Ltd., Plot No. 457 & 458, Village Matoda, Bavla Road, Tal. Sanand - 382210 Dist. Ahmedabad Gujarat State, Ahmedabad India	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Furotas 10 mg/ml, 5 ml Solution for Injection or Infusion	Intas Pharmaceuticals Ltd., Plot No. 457 & 458, Village Matoda, Bavla Road, Tal. Sanand - 382210 Dist. Ahmedabad Gujarat State, Ahmedabad India	India	Third Schedule
Furotas 10 mg/ml, 4 ml Solution for Injection or Infusion	Intas Pharmaceuticals Ltd., Plot No. 457 & 458, Village Matoda, Bavla Road, Tal. Sanand - 382210 Dist. Ahmedabad Gujarat State, Ahmedabad India	India	Third Schedule
Furotas 10 mg/ml, 2 ml Solution for Injection or Infusion	Intas Pharmaceuticals Ltd., Plot No. 457 & 458, Village Matoda, Bavla Road, Tal. Sanand - 382210 Dist. Ahmedabad Gujarat State, Ahmedabad India	India	Third Schedule
AMADAZ Midazolam Injection BP 1 mg/ml - 5 ml	Intas Pharmaceuticals Ltd., Plot No. 457 & 458, Village Matoda, Bavla Road, Tal. Sanand - 382210 Dist. Ahmedabad Gujarat State, Ahmedabad India	India	Controlled
AMADAZ Midazolam Injection BP 5 mg/ml, 1 ml	Intas Pharmaceuticals Ltd., Plot No. 457 & 458, Village Matoda, Bavla Road, Tal. Sanand -	India	Controlled

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	382210 Dist. Ahmedabad Gujarat State, Ahmedabad India		
AMADAZ Midazolam Injection BP 5 mg/ml - 3 ml	Intas Pharmaceuticals Ltd., Plot No. 457 & 458, Village Matoda, Bavla Road, Tal. Sanand - 382210 Dist. Ahmedabad Gujarat State, Ahmedabad India	India	Controlled
AMADAZ Midazolam Injection BP 5 mg/ml - 10 ml	Intas Pharmaceuticals Ltd., Plot No. 457 & 458, Village Matoda, Bavla Road, Tal. Sanand - 382210 Dist. Ahmedabad Gujarat State, Ahmedabad India	India	Controlled
Cistrax (Cisatracurium Besylate Injection USP 2 mg/ml, 5 ml)	Intas Pharmaceuticals Ltd., Plot No. 457 & 458, Village Matoda, Bavla Road, Tal. Sanand - 382210 Dist. Ahmedabad Gujarat State, Ahmedabad India	India	Third Schedule (Specialist Use Only)
Rothrom® 10 mg film- coated tablets	Oman Pharmaceutical Products Co. LLC, Oman Plot No. 101, Raysut Industrial Estate, P.O. Box 2240, Salalah, 211, Oman For: Sandoz GmbH, Kundl- Austria	Oman	Third Schedule
Rothrom® 15 mg film- coated tablets	Oman Pharmaceutical Products Co. LLC, Oman Plot No. 101, Raysut	Oman	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Industrial Estate, P.O. Box 2240, Salalah, 211, Oman For: Sandoz GmbH, Kundl- Austria		
Amva Denk 5/80 mg film-coated tablets	Manufactured & Packaged by: Balkanpharma Dupnitsa AD 3 Samokovsko Shosse Street, Dupnitsa, 2600, Bulgaria For: DENK PHARMA GmbH & Co. KG Prinzregentenstr. 79, 81675 München, Germany	Bulgaria	Third Schedule
Amva Denk 5/160 mg film-coated tablets	Manufactured & Packaged by: Balkanpharma Dupnitsa AD 3 Samokovsko Shosse Street, Dupnitsa, 2600, Bulgaria For: DENK PHARMA GmbH & Co. KG Prinzregentenstr. 79, 81675 München, Germany	Bulgaria	Third Schedule
Amva Denk 10/160 mg film-coated tablets	Manufactured & Packaged by: Balkanpharma Dupnitsa AD 3 Samokovsko Shosse Street, Dupnitsa, 2600, Bulgaria	Bulgaria	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	For: DENK PHARMA GmbH & Co. KG Prinzregentenstr. 79, 81675 München, Germany		
calcium active Denk Effervescent Tablet	SUNLIFE® Produktions- und Vertriebsgesellschaft mbH C. Hedenkamp GmbH & Co. KC Schierbusch 1 33161 Hövelhof Germany For: DENK PHARMA GmbH & Co. KG Prinzregentenstr. 79 81675 München, Germany	Germany	Freely
Cipro-Denk 750 film-coated tablets 750 mg	Manufactured & Packaged by: allphamed PHARBIL Arzneimittel GmbH Hildebrandstr. 10-12, 37081 Göttingen, Germany For: DENK PHARMA GmbH & Co. KG Prinzregentenstr. 79 81675 München, Germany	Germany	Third Schedule
D3 active Denk Tablet	Artesan Pharma GmbH &Co.KG Wendlandstraße 1 29439 Lücknow Germany Distributor: DENK PHARMA GmbH & Co. KG	Germany	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Prinzregentenstr. 79 81675 München, Germany		
Deslora-Denk 5 mg f.c.tablets	DENK PHARMA GmbH & Co. KG Göllstr. 1, 84529 Tittmoning, Germany For: DENK PHARMA GmbH & Co. KG Prinzregentenstr. 79 81675 München, Germany	Germany	Third Schedule
Denk-Air Junior 4 mg chewable tablets	DENK PHARMA GmbH & Co. KG Göllstr. 1, 84529 Tittmoning, Germany Primary and Secondary Packager: Swiss Caps GmbH, Germany For: DENK PHARMA GmbH & Co. KG Prinzregentenstr. 79 81675 München, Germany	Germany	Third Schedule
Denk-Air Junior 5 mg chewable tablets	DENK PHARMA GmbH & Co. KG Göllstr. 1, 84529 Tittmoning, Germany Primary and Secondary Packager: Swiss Caps GmbH, Germany	Germany	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	For: DENK PHARMA GmbH & Co. KG Prinzregentenstr. 79 81675 München, Germany		
Denk-Air 10 mg f.c.tablets	DENK PHARMA GmbH & Co. KG Göllstr. 1, 84529 Tittmoning, Germany Primary and Secondary Packager: Swiss Caps GmbH, Germany For: DENK PHARMA GmbH & Co. KG Prinzregentenstr. 79 81675 München, Germany	Germany	Third Schedule
Depakene® Oral Solution 250 mg/5 ml	Abbott Laboratories de México S.A. de C.V. Calz. De Tlapan No. 3092, Col. Ex Hacienda Coapa, C.P. 04980, Coyoacán, Ciudad de México, México	Mexico	Third Schedule
Ibuprofen Denk 600 Film- coated Tablets 600 mg	DENK PHARMA GmbH & Co. KG Göllstr. 1, 84529 Tittmoning, Germany Primary and Secondary Packager: Swiss Caps GmbH, Germany	Germany	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	For: DENK PHARMA GmbH & Co. KG Prinzregentenstr. 79 81675 München, Germany		
Kivala 600 mg/300 mg film-coated tablets	Remedica Ltd Aharnon Str. Limassol Industrial Estate 3056, Limassol, Cyprus	Cyprus	Third Schedule
Levoflox-Denk 5 mg/ml Solution for Infusion	Solpharm Pharmazeutische Erzeugnisse GmbH Industriestr. 3, 34212 Melsungen, Germany For: DENK PHARMA GmbH & Co. KG Prinzregentenstr. 79 81675 München, Germany	Germany	Third Schedule
Rezavir 600 mg film-coated tablets	Remedica Ltd Aharnon Str. Limassol Industrial Estate 3056, Limassol, Cyprus	Cyprus	Third Schedule
magnes-denk 150 Hard Capsules, 150 mg	Bulk Manufacture and Packaging: Protina Pharmazeutische Gesellschaft mbH Release of Finished Product: Octopan Pharma GmbH Adalperostr. 37 85737 Ismaning Germany	Germany	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	For: DENK PHARMA GmbH & Co. KG Prinzregentenstr. 79 81675 München, Germany		
Vilda Denk 50 mg Tablets	Combino Pharm (Malta) Ltd. HF60, Hal Far Industrial Estate BBG3000, Malta Batch Release: DENK PHARMA GmbH & Co. KG Göllstr. 1 84529 Tittmoning Germany For: DENK PHARMA GmbH & Co. KG Prinzregentenstr. 79 81675 München, Germany	Germany	Third Schedule
Voricono-Denk 200 mg film-coated tablets	Actavis Ltd. BLB 016 Bulebel Industrial Estate ZTN 3000 Zejtun Malta For: DENK PHARMA GmbH & Co. KG Prinzregentenstr. 79 81675 München, Germany	Malta	Third Schedule
Amlo-Denk 5 Tablets 5mg	DENK PHARMA GmbH & Co. KG Göllstr. 1 84529 Tittmoning Germany	Germany	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Distributor: DENK PHARMA GmbH & Co. KG Prinzregentenstr. 79 81675 München, Germany		
Amlo-Denk 10 Tablets 10mg	DENK PHARMA GmbH & Co. KG Göllstr. 1 84529 Tittmoning Germany Distributor: DENK PHARMA GmbH & Co. KG Prinzregentenstr. 79 81675 München, Germany	Germany	Third Schedule
Esomeprazole 40 mg Film-coated tablets	AstraZeneca AB, Sweden Primary & Secondary Packaging Site: AstraZeneca S.A. de C.V., Mexico Marketing Authorisation Holder: Astra Zaeneca S.A. de C.V. Mexico	Mexico	Third Schedule
Panadol Day Non-Drowsy Film Coated Tablets (Update of the Registered Commercial Presentation; Update in the Artwork Information and Design)	GlaxoSmithKline Dungarvan Ltd., Ireland Packed by: GlaxoSmithKline Panamá S.A., Panamá For: GlaxoSmithKline Consumer Healthcare (Ireland) Limited, Ireland	Panama	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
PANTECTA® I.V. 40 mg Lyophilized powder for injectable solution (Change of Marketing Authorization Holder; Amended Manufacturing Site Address; Updated Artwork Design)	Manufacturer and Primary Packager: Takeda GmbH Robert-Bosch-Str.8, 78224, Singen, Germany Secondary Packager: Takeda México, S.A. de C.V., México For: Asofarma S.A., Guatemala	Mexico	Third Schedule
Dormicum® 15 mg film-coated tablets (Correction of Description of Form of Tablet)	Productos Roche Químicos e Farmacêuticos S.A., Rio de Janeiro, Brasil For: Laboratorios Siegfried, S.A. Panamá	Brazil	Controlled
Dormicum® 50 mg/10 ml Ampoules I.V., I.M. and Rectal Solution for Injection (Update to the Manufacturer Address; Artwork Update)	Roemmers S.A.I.C.F.- Buenos Aires, Argentina For: Laboratorios Siegfried, S.A. Panamá	Argentina	Controlled
Dormicum® 15 mg film-coated tablets (Update to the Manufacturer Address; Artwork Update)	Roemmers S.A.I.C.F.- Buenos Aires, Argentina For: Laboratorios Siegfried, S.A. Panamá	Argentina	Controlled
Dormicum® 5 mg/5 ml Ampoules I.V., I.M. and Rectal Solution for Injection (Update to the Manufacturer Address; Artwork Update)	Roemmers S.A.I.C.F.- Buenos Aires, Argentina For: Laboratorios Siegfried, S.A. Panamá	Argentina	Controlled
Dormicum® 15 mg/3 ml Ampoules I.V., I.M. and Rectal Solution for Injection	Roemmers S.A.I.C.F.- Buenos Aires, Argentina	Argentina	Controlled

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
(Update to the Manufacturer Address; Artwork Update)	For: Laboratorios Siegfried, S.A. Panamá		
PANTECTA® 40 mg Gastroresistant tablets (Change of Marketing Authorization Holder; Updated Artwork Design)	Takeda GmbH Lehnitzstrasse 70-98 16515 Oranienburg Germany Packaged by: Takeda México, S.A. de C.V., México For: Asofarma S.A., Guatemala	Mexico	Third Schedule
PANTECTA® P20 20 mg Gastroresistant tablets (Change of Marketing Authorization Holder; Updated Artwork Design)	Takeda GmbH Lehnitzstrasse 70-98 16515 Oranienburg Germany Packaged by: Takeda México, S.A. de C.V., México For: Asofarma S.A., Guatemala	Mexico	Third Schedule
ALEVIAN DUO® 100 mg/ 300 mg Capsules (Change of Marketing Authorization Holder; Updated Artwork Design)	Gelcaps Exportadora de México S.A. de C.V., Naucalpan de Juárez, Estado de México, México Packaged by: Takeda México, S.A. de C.V., Mexico For: Asofarma S.A., Guatemala	Mexico	Third Schedule
RIOPAN® Gel 80 mg/ 10mg/1 mL	Takeda México, S.A. de C.V., México	Mexico	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
(Change of Marketing Authorization Holder; Updated Artwork Design)	For: Asofarma S.A., Guatemala		
Trulicity™ 0.75 mg Solution for Injection in Pre-Filled Pen (Change of Product Licence Holder; Artwork Update)	Eli Lilly and Company Indianapolis, IN 46285, USA For: Asofarma S.A. Guatemala	United States of America	Third Schedule
Trulicity™ 1.5 mg Solution for Injection in Pre-Filled Pen (Change of Product Licence Holder; Artwork Update)	Eli Lilly and Company Indianapolis, IN 46285, USA For: Asofarma S.A. Guatemala	United States of America	Third Schedule
Phillips® Milk of Magnesia Mint Suspension (Additional Manufacturing Site; Artwork Update)	Química y Farmacia S.A. de C.V., México For: Aspen Caricam S.A., Costa Rica	Mexico	Freely
Phillips® Milk of Magnesia Suspension (Additional Manufacturing Site; Artwork Update)	Química y Farmacia S.A. de C.V., México For: Aspen Caricam S.A., Costa Rica	Mexico	Freely
Privigen® 10 g Solution for Infusion (10%) (Additional Secondary Packaging Site)	CSL BEHRING AG Wankdorfstrasse 10, CH-3000 Berne 22, Switzerland Secondary Packaging Site: B93, at Bollingenstrasse 93, 3006 Bern, Switzerland	Switzerland	Third Schedule (Specialist Use Only)
Privigen® 5 g Solution for Infusion (10%) (Additional Secondary Packaging Site)	CSL BEHRING AG Wankdorfstrasse 10, CH-3000 Berne 22, Switzerland	Switzerland	Third Schedule (Specialist Use Only)

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Secondary Packaging Site: B93, at Bollingenstrasse 93, 3006 Bern, Switzerland		
Privigen® 2.5 g Solution for Infusion (10%) (Additional Secondary Packaging Site)	CSL BEHRING AG Wankdorfstrasse 10, CH-3000 Berne 22, Switzerland Secondary Packaging Site: B93, at Bollingenstrasse 93, 3006 Bern, Switzerland	Switzerland	Third Schedule (Specialist Use Only)
Alburex® 20 Human albumin 20% Solution for intravenous infusion (Additional Secondary Packaging Site)	CSL Behring AG Wankdorfstrasse 10, CH-3014 Bern 22, Switzerland Secondary Packaging Site: B93, at Bollingenstrasse 93, 3006 Bern, Switzerland	Switzerland	Third Schedule
BENJAMINS CHILDREN'S Relief® FEVER & PAIN Grape Elixir (Change in Name of Product; Change in Artwork design)	P.A. Benjamin Mfg. Co. Ltd. 97 East Street, Kingston, Jamaica	Jamaica	Freely
BENJAMINS CHILDREN'S Relief® FEVER & PAIN Cherry Elixir (Change in Name of Product; Change in Artwork design)	P.A. Benjamin Mfg. Co. Ltd. 97 East Street, Kingston, Jamaica	Jamaica	Freely
Forxiga™ 5 mg film-coated tablets (New Indication)	AstraZeneca Pharmaceuticals LP, Mt. Vernon, Indiana, USA	United States of America	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	For: AstraZeneca CAMCAR S.A., Panamá		
Forxiga™ 10 mg film-coated tablets (New Indication)	AstraZeneca Pharmaceuticals LP, Mt. Vernon, Indiana, USA For: AstraZeneca CAMCAR S.A., Panamá	United States of America	Third Schedule
Arava® 20 mg film-coated tablets (Change of Name of Manufacturer and Legal Entity; Update of the Address of Manufacturer; Change in Artwork)	OPELLA HEALTHCARE INTERNATIONAL SAS Compiègne, France	France	Third Schedule
APROVASC® 300 mg/ 10 mg film-coated tablets (Update of the Primary and Secondary Packaging Dimensions)	sanofi-aventis de México S.A. de C.V. Acueducto del Alto Lerma No.2, Zona Industrial de Ocoyoacac, Mexico	Mexico	Third Schedule
APROVASC® 300 mg/5 mg film-coated tablets (Update of the Primary and Secondary Packaging Dimensions)	sanofi-aventis de México S.A. de C.V. Acueducto del Alto Lerma No.2, Zona Industrial de Ocoyoacac, Mexico	Mexico	Third Schedule
APROVASC® 150 mg/5 mg film-coated tablets (Update of the Primary and Secondary Packaging Dimensions)	sanofi-aventis de México S.A. de C.V. Acueducto del Alto Lerma No.2, Zona Industrial de Ocoyoacac, Mexico	Mexico	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Bridion® 100 mg/mL Solution for Injection (Change in the Marketing Authorization Holder; Change in Artwork)	PATHEON MANUFACTURING SERVICES LLC, United States of America Packaged by: N. V. ORGANON, The Netherlands For: Merck Sharp & Dohme B.V., The Netherlands	The Netherlands	Third Schedule
Cozaar® 100 mg Tablets (Change in the Name of the Manufacturing Site; Change in the Name of the Packaging Site; Change in the Name of the Marketing Authorization Holder; Change of Distributor; Artwork Update)	ORGANON PHARMA (UK) LIMITED Shotton Lane, Cramlington, Northumberland NE23 3 JU, United Kingdom Packaged by: ORGANON FARMACEUTICA LTDA. Rua 13 de Maio, 1161 - Sousas, Campinas, S.P. Brazil For: ORGANON PHARMA S. De R.L., PANAMA	Brazil	Third Schedule
EXFORGE® 10 mg/ 160 mg film-coated tablets (Additional Manufacturing Site; Artwork Update)	Novartis Farma S.p.A., Via Provinciale Schito 131, 80058 Torre Annunziata (NA), Italy For: Novartis Pharma AG, Basel, Switzerland	Italy	Third Schedule
EXFORGE® 5 mg/80 mg film-coated tablets	Novartis Farma S.p.A., Via Provinciale Schito 131, 80058 Torre Annunziata (NA), Italy	Italy	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
(Additional Manufacturing Site; Artwork Update)	For: Novartis Pharma AG, Basel, Switzerland		
EXFORGE HCT® 10 mg/320 mg/25 mg film-coated tablets (Change in Name of Manufacturing, Primary & Secondary Site; Artwork Update)	SIEGFRIED BARBERA, S.L., Ronda de Santa Maria, 158 08210 BARBERÀ DEL VALLÉS (Barcelona) Spain For: Novartis Pharma AG, Basel, Switzerland	Spain	Third Schedule
EXFORGE HCT® 10 mg/160 mg/25 mg film-coated tablets (Change in Name of Manufacturing, Primary & Secondary Site; Artwork Update)	SIEGFRIED BARBERA, S.L., Ronda de Santa Maria, 158 08210 BARBERÀ DEL VALLÉS (Barcelona) Spain For: Novartis Pharma AG, Basel, Switzerland	Spain	Third Schedule
EXFORGE HCT® 10 mg/160 mg/12.5 mg film-coated tablets (Change in Name of Manufacturing, Primary & Secondary Site; Artwork Update)	SIEGFRIED BARBERA, S.L., Ronda de Santa Maria, 158 08210 BARBERÀ DEL VALLÉS (Barcelona) Spain For: Novartis Pharma AG, Basel, Switzerland	Spain	Third Schedule
EXFORGE HCT® 5 mg/160 mg/25 mg film-coated tablets (Change in Name of Manufacturing, Primary & Secondary Site; Artwork Update)	SIEGFRIED BARBERA, S.L., Ronda de Santa Maria, 158 08210 BARBERÀ DEL VALLÉS (Barcelona) Spain	Spain	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	For: Novartis Pharma AG, Basel, Switzerland		
EXFORGE HCT® 5 mg/160 mg/12.5 mg film-coated tablets (Change in Name of Manufacturing, Primary & Secondary Site; Artwork Update)	SIEGFRIED BARBERA, S.L., Ronda de Santa Maria, 158 08210 BARBERÀ DEL VALLÈS (Barcelona) Spain For: Novartis Pharma AG, Basel, Switzerland	Spain	Third Schedule
EXFORGE® 5 mg/160 mg film-coated tablets (Additional Manufacturing Site; Artwork Update)	Novartis Farma S.p.A., Via Provinciale Schito 131, 80058 Torre Annunziata (NA), Italy For: Novartis Pharma AG, Basel, Switzerland	Italy	Third Schedule
Hyzaar® 50/12.5 mg Tablets (Change in the Manufacturing Site; Artwork Update)	ORGANON FARMACEUTICA LTDA., Brazil	Brazil	Third Schedule
Cataflam® 1.5% Oral Suspension-Drops (Update of Secondary Artwork Design)	Delpharm Huningue S.A.S, France For: Novartis Pharma AG, Basel, Switzerland	France	Third Schedule
Cetrotide® 0.25 mg Powder and Solvent for Solution for Injection (Change of Manufacturer of API; Change of Manufacturer of Water; Change of Packager; Change of Marketing)	Vial of Powder: FAREVA PAU 2 50 Chemin de Mazerolles, 64320 Idron, France Solvent: Abbott Biologicals B.V., Netherlands	Uruguay	Third Schedule (Specialist Use Only)

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Authorization Holder; Change in Artwork)	Packaged by: Ares Trading Uruguay S.A., Uruguay For: Merck S.A. 12 Av. 0-33 Zona 2 de Mixco, Guatemala		
Crinone® 8%/Vaginal Gel (Change in Name of Manufacturer; Change in Marketing Authorization Holder; Change in Artwork)	Dendron Brands Limited 94 Rickmansworth Road, Watford Hertfordshire, WD18 7JJ, United Kingdom For: Merck S A. 12 Av. 0-33 Zone 2 de Mixco, Guatemala	United Kingdom	Third Schedule (Specialist Use Only)
Concor® AM 5 mg/5 mg Tablets (Change of Marketing Authorization Holder; Change in Artwork)	Egis Pharmaceuticals PLC. 1165 Budapest, Bökényföldi út 118-120, Hungary For: Merck S.A. 12 Av. 0-33 Zona 2 de Mixco, Guatemala	Hungary	Third Schedule
Concor® AM 5 mg/10 mg Tablets (Change of Marketing Authorization Holder; Change in Artwork)	Egis Pharmaceuticals PLC. 1165 Budapest, Bökényföldi út 118-120, Hungary For: Merck S.A. 12 Av. 0-33 Zona 2 de Mixco, Guatemala	Hungary	Third Schedule
Allegra® D 60 mg/120 mg extended-release film-coated tablets	Opella Healthcare International SAS, 56, Route de Choisy 60200 Compiègne, France	Brazil	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
(Change in the Name and Address of the Manufacturer; Artwork Update)	Packaged by: Sanofi Medley Farmaceutica Ltda, Brazil		
Dulcolax® 5 mg Gastro-resistant coated Tablet (Change in Marketing Authorization Holder; Artwork Update)	Delpharm Reims, 10, Rue Colonel Charbonneaux, 51100 Reims, France For: Opella Healthcare Panamá S.A., Panama	France	Freely
Buscopan® 20 mg/mL Ampoules Solution for Intramuscular, Subcutaneous, or Intravenous Injection (Change in the Name of the Manufacturer; Change in Marketing Authorization Holder, Change in Artwork)	Sanofi İlaç Sanayi ve Ticaret, Anonim Şirketi, Turkey For: Opella HealthCare Panamá S.A., Panama	Turkey	Third Schedule
Enterogermina® 2 billion/ 5 mL Oral Suspension (Change in Name and Address of Marketing Authorization Holder; Artwork Update)	Sanofi S.r.l., Viale Europa 11 21040 Origgio (Va)- Italy For: Opella Healthcare Panama, S.A.	Italy	Freely
IMMUNINE 600 IU Powder and Solvent for Solution for Injection or Infusion (Change in the Name of the Marketing Authorization Holder; Change in the Name of Manufacturing Site; Artwork Update)	Takeda Manufacturing Austria AG, 1221 Vienna, Austria	Austria	Third Schedule (Specialist Use Only)

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Acyclovir Denk 200 tablets 200 mg (Text Update)	DENK PHARMA GmbH & Co. KG Göllstr. 1 84529 Tittmoning, Germany Distributor: DENK PHARMA GmbH & Co. KG Prinzregentenstr. 79 81675 München, Germany	Germany	Third Schedule
Levo-Denk 500 film coated tablets 500 mg (New Packaging Site; New Artwork)	Rottendorf Pharma GmbH Ostenfelder Str. 51-61 59320 Ennigerloh Germany Primary and Secondary Packaging: Rottendorf Pharma GmbH Am Fleigendahl 3 59320 Ennigerloh Germany For: DENK PHARMA GmbH & Co. KG Prinzregentenstr. 79 81675 München, Germany	Germany	Third Schedule

Dated this 25th day of August, 2023.

T. DEYALSINGH
Minister of Health