

LEGAL NOTICE NO. 444

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
Gasnot Gel Liquid	Accretion Pharmaceuticals 29, Xcelon Industrial Park-1, Behind Intas Pharmaceuticals, Vasna-Chacharwadi, Tal. Sanand, Dist. Ahmedabad, Gujarat-382213, India	India	Freely
Advancis Omega-3 Super EPA Capsules 1000 mg	Farmodietica S.A. Estrada de Sao Marcos Elospark II, Armazem 1, 2735-521 Cacem, Portugal	Portugal	do.
Advancis Passival Sleep Tablets	do.	do.	do.
Advancis Essential Vitamins Tablets	do.	do.	do.
Virig Advance Oral Suspension 12.5 mg/0.5 ml	Edefarm, S.L. Poligono Industrial Enchilagar del Rullo 117, Villamarchante 46191	do.	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Valencia, Spain		
Advancis Omega-3 Super DHA Capsules 844 mg	Labialfarma Laboratorio de Produtos, Farmaceuticos e, Nutraceuticos, S.A. Felgueira Sobral Mortagua, 3450 Portugal	Portugal	Freely
Advancis Omega Mousse 10 ml	do.	do.	do.
Advancis Magnesium Woman Tablets 1350 mg & Capsules 673.3 mg	do.	do.	do.
Losacar 50 (Losartan Potassium Tablets USP 50 mg)	Zydus Lifesciences Limited Kundaim Industrial Estate, Plot No. 203-213 Kundaim Goa 403 115, India	India	Third Schedule
Trap (Tramadol Hydrochloride & Paracetamol Tablets 37.5 mg/325 mg)	do.	do.	do.
Noklot (Clopidogrel Tablets USP 75 mg)	do.	do.	do.
Zyvalprex 250 (Divalproex Sodium Delayed Release Tablets USP 250 mg)	Zydus Lifesciences Limited Survey No. 417, 419 & 420 Sarkhej-Bavla National Highway No. 8 A, Village-Moraiya, Taluka-Sanand, Dist- Ahmedabad-382 210, Gujarat State, India	do.	do.
Zyvalprex 500 (Divalproex Sodium Delayed Release Tablets USP 500 mg)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Temorel 140 (Temozolomide 140 mg Capsules)	Reliance Life Sciences Pvt. Ltd. Dhirubhai Ambani Life Sciences Centre (DALC) Plant 3, 5, 6, 9 and 10 Plot No. R-282, Thane-Belapur Road, Rabale, Thane 400701, Maharashtra State, India	India	Third Schedule
Adalirel (Adalimumab Injection 40 mg/0.8 ml)	Reliance Life Sciences Pvt. Ltd. Dhirubhai Ambani Life Sciences Centre, Plant 2 & 7 Plot No. R-282, TTC Area of MIDC, Thane-Belapur Road, Rabale, Navi Mumbai Thane 400701, Maharashtra State, India	do.	do.
Derihaler Inhaler (Salbutamol Pressurised Inhalation BP 100 mcg) 200 Metered Doses	Zydus Lifesciences Limited Survey No. 417, 419 & 420 Sarkhej - Bavla National Highway No. 8 A, Village - Moraiya, Taluka - Sanand, Dist. - Ahmedabad 382 210, Gujarat State	do.	do.
Nepexto Solution for Injection in Pre-Filled Pen 50 mg/ml	Lupin Limited No. 1156-1160 Taluka Mulshi, Gat, Ghotawade, 412115, India	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Nepexto Solution for Injection in Pre-Filled Syringe 25 mg/0.5 ml	Lupin Limited No. 1156-1160 Taluka Mulshi, Gat, Ghotawade, 412115, India	India	Third Schedule
Nepexto Solution for Injection in Pre-Filled Syringe 50 mg/ml	do.	do.	do.
Trastmab 440 Lyophilised Powder for Concentrate for Solution for Infusion 440 mg/vial (20 ml)	Intas Pharmaceuticals Ltd. Plot No. - 423/P/A, Sarkhej Bavla Highway, Village - Moraiya, Tal- Sanand, Dist.- Ahmedabad - 382 213, Gujarat State, India	do.	do.
Yuflyma Solution for Injection in a Pre-Filled Pen 40 mg/0.4 ml (Change of Marketing Authorization Holder; Change of Manufacturer; Change of Primary Artworks; Change of Secondary Artworks; Update of Leaflet)	Celltrion Pharm, Inc. 82, 2sandan-ro, Ochang-eup, Cheongwon-gu, Cheongju-si, Chungcheongbuk-do, 28117 Republic of Korea Marketing Authorization Holder: Celltrion, Inc. 23, Academy-ro, Yeonsu-gu, Incheon, 22014 Republic of Korea	Republic of Korea	Third Schedule
Avaxim 80 U Pediatric Hepatitis A Vaccine (inactivated, adsorbed) Suspension for Injection in Pre-Filled Syringe (Change of Manufacturer Name; Change of Artwork)	Sanofi Pasteur Parc industriel d'Incarville 27100 Vale de Reuil, France and Sanofi Pasteur 1541, Avenue Marcel Mérieux 69280 Marcy L'Etoile France	France	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Eproliv® Met XR (Sitagliptin + Metformin Hydrochloride) Prolonged-Release Tablets 50 mg/1000 mg	Sandoz Private Limited Plot No. 8-A / 2 & 8-B, TTC Industrial Area, Kalwe Block, Village Dighe, Navi Mumbai, Thane 400708 Maharashtra State, India	India	Third Schedule
Eproliv® Met XR (Sitagliptin + Metformin Hydrochloride) Prolonged-Release Tablets 100 mg/1000 mg	do.	do.	do.
ProVisc Ophthalmic Viscosurgical Device (Change in the Manufacturer's Legal Entity Name and Address; Update to Artwork to reflect such change)	Legal Entity/Manufacturer: Novartis Manufacturing N.V. Rijksweg 14, 2870 Puurs-Sint-Amans Belgium Distributed by: Alcon Laboratories Inc. 6201 South Freeway, Fort Worth, TX USA, 76134	United States of America	Third Schedule
Viscoat Ophthalmic Viscosurgical Device (Change in the Manufacturer's Legal Entity Name and Address; Update to Artwork to reflect such change)	do.	do.	do.
Enterogermina® Oral Suspension 2 billion/5 ml (Change of Artwork - Color, Design, Elimination of Texts in Arabic and from Asian and Eastern Countries)	Opella Healthcare Italy SRL Viale Europa, 11-21040 Origgio (VA), Italy	Italy	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Feiba (Factor Eight Inhibitor bypassing Activity) Powder and Solvent for Solution for Infusion 50 U/mL (Change of Reference Authority; Change of Packaging Material and Label)	Takeda Manufacturing Austria AG Lange Allee 24, 1221 Wien, Austria	Austria	Third Schedule
Allegra 120 mg Film Coated Tablets (Change in the Name and Address of the Manufacturing Site; Update to Artwork; Update to Patient Information Leaflet)	Opella Healthcare Brazil Ltda. Rua Conde Domingos Papaiz, 175, Suzano São Paulo, Brasil	Brazil	do.
Allegra 180 mg Film Coated Tablets (Change in the Name and Address of the Manufacturing Site; Update to Artwork; Update to Patient Information Leaflet)	Opella Healthcare Brazil Ltda. Rua Conde Domingos Papaiz, 175, Suzano São Paulo, Brasil	do.	do.
Tafinlar Hard Capsules 75 mg (Change in Legal Entity Name of the Manufacturing Site; Change in Legal Entity Name of the Primary and Secondary Packaging site; Update of Artworks to reflect Changes)	Novartis Pharmaceutical Manufacturing LLC Verovskova Ulica 57, Ljubljana, 1000, Slovenia	Slovenia	do.
Allegra D 60 mg/120 mg Extended Release Film Coated Tablets (Change in name and address of Packaging Site)	Opella Healthcare International SAS 56, Route de Choisy-60200, Compiègne - France Packaged by:	Brazil	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Opella Healthcare Brazil Ltda., Rua Conde Domingos Papaiz, 175, Suzano São Paulo, Brazil		
DisCoVisc Ophthalmic Viscosurgical Device (Additional Manufacturer; Change in the Manufacturer's Legal Entity Name and Address; Update in Artworks to reflect the Change)	Legal Entity/Manufacturer: Novartis Manufacturing N.V. Rijksweg 14, 2870 Puurs-Sint-Amans Belgium Additional Manufacturer: Lifecore Biomedical, LLC 3515 Lyman Boulevard, Chaska, MN 55318, United States of America	United States of America	Third Schedule
DuoVisc™ Viscoelastic System (Additional Manufacturer; Change in the Manufacturer's Legal Entity Name and Address; Update in Leaflet Artwork)	Legal Entity/Manufacturer: Novartis Manufacturing N.V. Rijksweg 14, 2870 Puurs-Sint-Amans Belgium Additional Manufacturer: Lifecore Biomedical, LLC 3515 Lyman Boulevard, Chaska, MN 55318, United States of America	do.	do.
Desloratadine oral solution 0.5 mg/mL Oral Solution	Emcure Pharmaceuticals LTD Plot no. P1 and P2, I.T.B.T Park Phase-II, M.I.D.C. Hinjawadi Pune 411057, Maharashtra State, India	India	do.
Azaglin M 10/1000 (Dapagliflozin 10 mg and Metformin	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Hydrochloride 1000 mg Extended Release Tablets)			
Megval Injection 50 mg	Emcure Pharmaceuticals LTD Plot no. P1 and P2, I.T.B.T Park Phase-II, M.I.D.C. Hinjawadi Pune 411057, Maharashtra State, India	India	Third Schedule
Sitagliptin Tablets BP 100 mg	do.	do.	do.
Milrinone 1 mg/ml Solution for Injection or Infusion	do.	do.	do.
Solivo 20 - Leflunomide Tablets 20 mg	do.	do.	do.
Rosuvastatin Calcium Tablets 20 mg	Unichem Laboratories Limited Village Bhatauli Kalan, Baddi, Dist. Solan (H.P) - 173 205, India	do.	do.
Cistother 50 Concentration for Solution for Infusion 50 mg/50 mL	TherDose Pharma Private Limited Plot No. 118,119 & 120, Sy. No. 342, Road No. 6, ALEAP Industrial Estate, Opp: JNTU Lane, Pragathi Nagar, Gajularamaram (V), Quthbullapur (M), Medchal- Malkajgiri District- 500090, Hyderabad, Telangana State, India	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Cistother 10 Concentration for Solution for Infusion 10 mg/10 mL	TherDose Pharma Private Limited Plot No. 118,119 & 120, Sy. No. 342, Road No. 6, ALEAP Industrial Estate, Opp: JNTU Lane, Pragathi Nagar, Gajularamaram (V), Quthbullapur (M), Medchal- Malkajgiri District- 500090, Hyderabad, Telangana State, India	India	Third Schedule
Axaver 5 mg (Apixaban Tablets 5 mg)	Gliese Pharmaceuticals Private Limited Survey No. 23/3 P & 24, Opp. Jeans Factory, Daduram vistar, Village - Bagdol, Tal: Kathlal, Dist. Kheda - 387630. Gujarat, India	India	Third Schedule
Axaver 2.5 mg (Apixaban Tablets 2.5 mg)	do.	do.	do.
Hawthorn Berry Fluid Extract	Nature's Answer Inc. 85 commerce Drive Hauppauge, NY 11788,	The United States of America	Freely
Oil of Oregano Soft Gels	do.	do.	do.
Zinc Plus Capsules	do.	do.	do.
Liquid Vitamin B-Complex	do.	do.	do.
Melatonin Capsules 5 mg	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Viagra Film Coated Tablets 50 mg (Update of Finished Product Specifications - Imprint on Tablets from Pfizer to VIAGRA; Update of Distributor's Name from Smith Robertson & Co. Ltd to Aventa Trinidad & Tobago Limited)	Pfizer S.A. de C.V. Km. 63 Carretera México Toluca, Zona Industrial, C.P. 50140, Toluca, Mexico	Mexico	Third Schedule
Viagra Film Coated Tablets 100 mg (Update of Finished Product Specifications - Imprint on Tablets from Pfizer to VIAGRA; Update of Distributor's Name from Smith Robertson & Co. Ltd to Aventa Trinidad & Tobago Limited)	do.	do.	do.
Zoloft Tablets 50 mg (Update of Finished Product Specifications - Imprint on Tablets from Pfizer to VLE; Update of Distributor's Name from Smith Robertson & Co. Ltd to Aventa Trinidad & Tobago Limited)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Zoloft Tablets 100 mg (Update of Finished Product Specifications - Imprint on Tablets from Pfizer to VLE; Update of Distributor's Name from Smith Robertson & Co. Ltd to Aventa Trinidad & Tobago Limited)	Pfizer S.A. de C.V. Km. 63 Carretera México Toluca, Zona Industrial, C.P. 50140, Toluca, Mexico	Mexico	Third Schedule
Neurontin Capsules 300 mg (Specifications Update: Imprint change on Capsule from PD to VLE; Primary Package Update: Logo Change from Pfizer to Viatris; Addition of Security Microtext: VIATRISVIATRISVIATRIS; Deletion of the text Made in India)	Viatris Pharmaceuticals LLC Road 689 Km 1.9, Vega Baja, Puerto Rico 00693 For: Viatris Specialty LLC 3711 Collins Ferry Road, Morgantown, WV 26505, United States of America	United States of America	do.
Dilantin Extended Release Capsules 100 mg (Specifications Update; Distributor Name Update)	do.	do.	do.
Relpax Tablets 40 mg (Specifications Update; Distributor Name Update)	Pfizer, S.A. de C.V. Km. 63 Carretera México Toluca, Zona Industrial, C.P. 50140, Toluca, Mexico	Mexico	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	For: Upjohn Export BV Sucursal Costa Rica, Costa Rica		
Vabysmo Solution for Injection (Intravitreal Use) 6 mg/0.05 ml (New Indication; Update of Package Insert/Leaflet; Distributor Name Update)	F. Hoffmann-La Roche AG Wurmisweg 4303, Kaiseraugst, Switzerland	Switzerland	Third Schedule
Viagra Film Coated Tablets 50 mg (Addition of Manufacturing and Packaging Site - FAREVA Amboise; Update of License Holder for Manufacturing Site - Upjohn EESV Netherlands; Update of Distributor's Name from Smith Robertson & Co. Ltd to Aventa Trinidad & Tobago Limited)	Fareva Amboise Zone Industrielle, 29 Route des Industries, 37530 Po��e-sur-Cisse, France	France	do.
Viagra Film Coated Tablets 100 mg (Addition of Manufacturing and Packaging Site - FAREVA Amboise; Update of License Holder for Manufacturing Site - Upjohn EESV Netherlands; Update of Distributor's Name from Smith Robertson & Co. Ltd to Aventa Trinidad & Tobago Limited)	do.	do.	do.
Prostin VR Concentrate for Solution for Infusion 500 mcg/ml	Pfizer Manufacturing Belgium NV	Belgium	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
(Update of Address of Manufacturing Site; Artwork Updates; Distributor Name Update)	Rijksweg 12 2870 Puurs-Sint-Amants, Belgium For: Pfizer S.A. Boulevard de la Plaine 17, 1050 Bruxelles, Belgium		
Valdureim IM/IV Powder for Solution for Injection 40 mg/2 ml (Update of Address of Manufacturing Site; Artwork Updates; Distributor Name Update)	Powder Manufactured by: Pharmacia & Upjohn Company LLC 7000 Portage Road, Kalamazoo, MI 49001, United States of America Solvent Manufactured by: Pfizer Manufacturing Belgium NV 12 Rijksweg, Puurs-Sint-Amants, 2870 Belgium License Holder & Secondary Packager: Pfizer S.A. de C.V., Mexico KM 63 Carretera Mexico Toluca, Zona Industrial, C.P. 50140, Toluca, Mexico	Mexico	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Xyntha Powder and Solvent for Solution for Injection 250 IU (Alternative Drug Substance Manufacturing Site)	Powder Manufactured by: Wyeth Farma S.A. Autovia del norte A-1 23 Desvio Algete Km 1 San Sebastian de los Reyes 28700, Spain Diluent Manufactured by: Vetter Pharma Fertigung GmbH & Co. KG Eisenbahnstrasse 2-4 Langenargen 88085, Germany Secondary Packager: Wyeth Farma S.A. Autovia del norte A-1 23 Desvio Algete Km 1 San Sebastian de los Reyes 28700, Spain	Spain	Third Schedule
Xyntha Powder and Solvent for Solution for Injection 500 IU (Alternative Drug Substance Manufacturing Site)	do.	do.	do.
FASLODEX™ (Fulvestrant) Solution for Injection in a Pre-Filled Syringe 250 mg/5 mL (Change of Address of the Marketing Authorization Holder; Update of Secondary Artwork to Reflect; Change of Marketing Authorization Holder; Update of the Prescribing Information and Patient Leaflet; Change of Name of Distributor)	Vetter Pharma-Fertigung GmbH & Co. KG Schuetzenstrasse 87 and 99-101, Ravensburg, D-88212, Germany Packaged by: AstraZeneca UK Limited Silk Road Business Park, Macclesfield, Cheshire SK10 2NA, United Kingdom	United Kingdom	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Sinemet Plus® 25 mg/100 mg Tablets (Change of Distributor Name from Smith Robertson & Co. Ltd to Aventa Trinidad & Tobago Limited)	Savio Industrial S.R.L. Via Emilia, 21-27100 Pavia (PV), Italy For: Organon Pharma S. de R.L. Panama Distributor: Aventa Trinidad & Tobago Limited	Italy	Third Schedule
Gardasil 9 Human Papillomavirus 9-valent Vaccine, Recombinant Suspension for Intramuscular Injection 0.5 ml Syringe (Addition of Secondary Packager; Update to the Name of the Manufacturer; Artwork Update to reflect changes of Name of Manufacturer and Additional Packager)	Merck Sharp & Dohme LLC. 770 Sumneytown Pike, West Point, Pennsylvania 19486, United States of America Secondary Packager Site: Merck Sharp & Dohme LLC. 4633 Merck Road, Wilson North Carolina (NC) 27893, United States of America For: Merck Sharp & Dohme LLC. 126 E. Lincoln Avenue P.O. Box 2000, Rahway, NJ 07065, United States of America	United States of America	do.
Lynparza™ Film Coated Tablets 100 mg (Change of Distributor Name from Smith Robertson & Co. Ltd to Aventa Trinidad & Tobago Limited; New Indication)	AbbVie Limited, Carretera 2 KM 58.0, Cruce Davila, Barceloneta, PR 00617, Puerto Rico Packager Name and Address: AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, SK10 2NA, United Kingdom For:	Puerto Rico	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	AstraZeneca AB SE-152 85 Södertälje, Sweden		
Lynparza TM Film Coated Tablets 150 mg (Change of Distributor Name from Smith Robertson & Co. Ltd to Aventa Trinidad & Tobago Limited; New Indication)	do.	Puerto Rico	Third Schedule
Xolair Solution for Injection in Pre- Filled Syringe 150 mg/1 ml (Addition of Manufacturing and Primary Packaging Site; Update of Container Closure System; Addition of New Needle Safety Device; Specification Update)	Novartis Pharma Stein AG Schaffhauserstrasse, 4332 Stein, Switzerland	Switzerland	do.
Xolair Solution for Injection in Pre- Filled Pen 150 mg/1 ml (Additional Presentation)	do.	do.	do.
Xolair Solution for Injection in Pre- Filled Syringe 75 mg/0.5 mL (Addition of Manufacturing and Primary Packaging Site; Update of Container Closure System; Addition of New Needle Safety Device; Specifications Update)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Xolair Solution for Injection in Pre-Filled Pen 75 mg/0.5 mL (Additional Presentation)	Novartis Pharma Stein AG Schaffhauserstrasse, 4332 Stein, Switzerland	Switzerland	Third Schedule
Symbicort Rapihaler® Pressurised Inhalation Suspension 80/2.25 µg (Change to the Material Used for the Can Coating and the Rubber Material; Additional Alternative Process for Purging Can; Update of Primary and Secondary Artwork; Update of the Name of the Distributor)	AstraZeneca Dunkerque Production 224 avenue de la Dordogne 59640 Dunkerque - France	France	do.
Lantus Injectable 100 IU/mL Vial (Update to Logo - Reflected on Secondary and Primary Packaging; Change of Distributor Name from Agostini Pharmaceuticals Limited to Aventa Trinidad & Tobago Limited)	Sanofi-Aventis Deutschland GmbH Brüningstraße 50, Industriepark Höchst, D-65926 Frankfurt am Main, Germany	Germany	do.
Lantus SoloStar 100 IU/mL Injectable Solution 100 IU/mL Vial (Update to Logo - Reflected on Secondary and Primary Packaging; Change of Distributor Name from Agostini Pharmaceuticals Limited to Aventa Trinidad & Tobago Limited)	do.	do.	do.
Apidra SoloStar 100 Units/ml Solution for Injection in a Pre-filled Pen (Update to Logo - Reflected on Secondary and Primary Packaging; Change of Distributor Name from	Sanofi-Aventis Deutschland GmbH Brüningstraße 50, Industriepark Höchst, D-65926 Frankfurt am Main,	Germany	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Agostini Pharmaceuticals Limited to Aventa Trinidad & Tobago Limited)	Germany		
Apidra Injectable Solution 100 IU/mL Vials (Update to Logo - Reflected on Secondary and Primary Packaging; Change of Distributor Name from Agostini Pharmaceuticals Limited to Aventa Trinidad & Tobago Limited)	Sanofi-Aventis Deutschland GmbH Brüningstraße 50, Industriepark Höchst, D-65926 Frankfurt am Main, Germany	Germany	Third Schedule
Amaryl M Film Coated Tablets 4 mg/1000 mg (Update of Logo - Reflected on Secondary and Primary Packaging; Change of Distributor Name from Smith Robertson & Co. Ltd to Aventa Trinidad & Tobago Limited)	Laboratorios Silanes, S.A. de C.V. North Axis 3 SQ Prol. 6 North No. 200 KM 52.8, Parque Industrial Toluca 2000, C.P. 50200, Toluca, Mexico	Mexico	do.
Amaryl M Film Coated Tablets 2 mg/1000 mg (Update of Logo - Reflected on Secondary and Primary Packaging; Change of Distributor Name from Smith Robertson & Co. Ltd to Aventa Trinidad & Tobago Limited)	do.	do.	do.
Diamicron MR tablets 60 mg (Change in Primary Packaging)	Les Laboratoires Servier Industrie 905 route de Saran, 45520 Gidy-France	France	do.
Gliclazide MR 60 mg tablets (Change of Logo; Update of Secondary Packaging; Update of Leaflet)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Alphagan P (Brimonodine Tartrate Ophthalmic Solution) 0.1% Drops (Change in Marketing Authorization Holder; Change in Primary Artworks; Change in Secondary Artworks)	Allergan Sales, LLC, 8301 Mars Drive, Waco, TX 76712, United States of America Marketing Authorization Holder: AbbVie Inc., 1 N. Waukegan Rd, North Chicago, IL 60064 United States of America	United States of America	Third Schedule
Refresh Liquigel Lubricant Eyedrops 1% (Change in Marketing Authorization Holder; Change in Primary Artworks; Change in Secondary Artworks)	do.	do.	Freely
Refresh Optive Lubricant Eyedrops 0.5% (Change in Marketing Authorization Holder; Change in Primary Artworks; Change in Secondary Artworks)	do.	do.	do.
Triveram 10 mg/5 mg/5 mg Film-Coated Tablets (Additional Primary and Secondary Packager; Additional Batch Release Site)	Les Laboratoires Servier Industrie 905 route de Saran, 45520 Gidy-France Additional Primary & Secondary Packager: ANPHARM Przedsiębiorstwo Farmaceutyczne S.A ul. Annopol 6 B, 03-236 Warszawa, Poland Additional Batch Release Site: ANPHARM Przedsiębiorstwo	Poland	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Farmaceutyczne S.A ul. Annopol 6 B, 03-236 Warszawa, Poland		
Triveram 20 mg/10 mg/10 mg Film-Coated Tablets (Additional Primary and Secondary Packager; Additional Batch Release Site)	Les Laboratoires Servier Industrie 905 route de Saran, 45520 Gidy-France Additional Primary & Secondary Packager: ANPHARM Przedsiębiorstwo Farmaceutyczne S.A ul. Annopol 6 B, 03-236 Warszawa, Poland Additional Batch Release Site: ANPHARM Przedsiębiorstwo Farmaceutyczne S.A ul. Annopol 6 B, 03-236 Warszawa, Poland	Poland	Third Schedule
Triveram 20 mg/5 mg/5 mg Film- Coated Tablets (Additional Primary and Secondary Packager; Additional Batch Release Site)	do.	do.	do.
Triveram 20 mg/10 mg/5 mg Film- Coated Tablets (Additional Primary and Secondary Packager; Additional Batch Release Site)	do.	do.	do.
Esprit Vita Vitamin D3 1000 IU + K2 100 mcg Tablets	Pharma Natural 14500 N.W. 60th Avenue, Building 7F Miami Lakes, Florida 33014,	United States of America	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	USA For: Esprit Vita 8336 N.W. 68th Street Miami, Florida 33166, USA		
Esprit Vita Ashwagandha 500 mg + Shilajit 500 mg Veggie Capsules	Pharma Natural 14500 N.W. 60th Avenue, Building 7F Miami Lakes, Florida 33014, USA For: Esprit Vita 8336 N.W. 68th Street Miami, Florida 33166, USA	United States of America	Freely
Esprit Vita Creatine Powder 225 g	do.	do.	do.
Neurobion Advance Film Coated Tablets	P&G Health Austria GmbH & Co. OG Höblgasse 20 9800 Spittal an der Drau For: Procter Gamble Interaméricas de Guatemala LTDA., Guatemala	Austria	do.
Vital Pro Energizer Soft Capsules	Ha Noi CPC1 Pharmaceuticals Joint Stock Company Ha Binh Phuong Industrial Zone, Van Binh Commune, Thuong Tin District, Hanoi, Vietnam	Vietnam	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Orzax Black Seed Oil Softgel Capsules 1000 mg	Nuvita Ilac ve Kimya Sanayi Ticaret Anonim Sirketi Akcaburgaz Mahallesi 153 Sokak, No:27 / A Esenyurt / Istanbul / Turkiye	Turkey	Freely
Orzax Collagen Peptides Powder	do.	do.	do.
Orzax Cycle Comfort Tablets	do.	do.	do.
Orzax Elderberry Sambucus with Vitamin C & Zinc Vegetable Capsules	do.	do.	do.
Orzax Fish Oil Lemon Flavor Softgel Capsules	do.	do.	do.
Orzax Glucosamine Chondroitin MSM Complex Tablets	do.	do.	do.
Orzax Magnesium Triple Complex Tablets	do.	do.	do.
Orzax Milk Thistle Plus Vegetable Capsules	do.	do.	do.
Orzax Oregano Oil Drops	do.	do.	do.
Orzax Premium Ginseng Vegetable Capsules	do.	do.	do.
Orzax Saw Palmetto Vegetable Capsules 2000 mg	do.	do.	do.
Orzax Selenium Vegetable Capsules 200 mcg	Nuvita Ilac ve Kimya Sanayi Ticaret Anonim Sirketi Akcaburgaz Mahallesi 153	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Sokak, No:27 / A Esenyurt / Istanbul / Turkiye		
Livealthgra-100 (Sildenafil Tablets USP 100 mg)	Livealth Biopharma PVT. LTD Mfgd AT:- Survey NO.- 889/1, B/H Chadasana- Jhulasan Road, AT & Post- Jhulasan, Tal- Kadi, Dist.- Mehsana-382 705 Gujarat State, India	India	Third Schedule
Ciprohealth-D (Ciprofloxacin & Dexamethasone Eye/Ear Drops)	do.	do.	do.
Wellteen Her Tablets	Vitabiotics Limited 1 Apsley Way London, NW2 7HF, United Kingdom	United Kingdom	Freely
Wellbaby Multivitamin Liquid	do.	do.	do.
Ultra Ginkgo & Ginseng Tablets	do.	do.	do.
Pregnacare Conception Tablets	do.	do.	do.
Newton-Everett® Garcinia Ultra Blend Vegetarian Capsules	Nutritional Manufacturing Services LLC 3205 North Delaware, Chandler, AZ, 85225, United States of America For: Newton-Everett Nutraceuticals 2625 S. 16th Street, Phoenix, AZ 85034, United States of America	United States of America	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Newton-Everett® Berberine Vegetarian Capsules 500 mg	Nutritional Manufacturing Services LLC 3205 North Delaware, Chandler, AZ, 85225, United States of America For: Newton-Everett Nutraceuticals 2625 S. 16th Street, Phoenix, AZ 85034, United States of America	United States of America	Freely
Genesisvit Natural Magnesium Glycinate 240 mg Premium Line	Alfa Vitamins Laboratories Inc. 4701 NW 77 Ave., Miami FL 33166	do.	do.
Apo-Ipravent Inhalation Solution 250 mcg/mL (Change of Marketing Authorization Holder; Label Update; Change of Name)	AA Pharma Inc. 1165 Creditsone Road, Unit #1 Vaughan Ontario Canada, L4K 4N7	Canada	Third Schedule
Apo-Rivaroxaban Tablets 10 mg	Apotex Inc. 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9	do.	do.
Apo-Rivaroxaban Tablets 15 mg	do.	do.	do.
Apo-Rivaroxaban Tablets 20 mg	do.	do.	do.
Celemin 10-Plus Amino Acids Injection with Electrolytes 10% (Update of Address of Finished Product Manufacturer - Inclusion of Finished Good Warehouse Address into the Existing Facility Address)	Otsuka Pharmaceutical India Private Limited Survey No. 188, 194, 195 Paiki 1 & 2, 199 / 1, 200 / 1, 201 / 1, 199 to 201 & 208 to 210,	India	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Village - Vasana - Chacharwadi, Tal - Sanand, Dist.-Ahmedabad - 382 213, India		
Ciproquin 0.2% (Ciprofloxacin Injection USP 0.2% w/v) (Update of Address of Finished Product Manufacturer - Inclusion of Finished Good Warehouse Address into the Existing Facility Address)	Otsuka Pharmaceutical India Private Limited Survey No. 188, 194, 195 Paiki 1 & 2, 199 / 1, 200 / 1, 201 / 1, 199 to 201 & 208 to 210, Village - Vasana - Chacharwadi, Tal - Sanand, Dist.-Ahmedabad - 382 213, India	India	Third Schedule
RL Compound Sodium Lactate Intravenous Infusion (Update of Address of Finished Product Manufacturer - Inclusion of Finished Good Warehouse Address into the Existing Facility Address)	do.	do.	do.
5D Glucose Intravenous Infusion BP (50 g/l) (Update of Address of Finished Product Manufacturer - Inclusion of Finished Good Warehouse Address into the Existing Facility Address)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Celepid 10% Intravenous Fat Emulsion (Intravenous fat emulsion 10% w/v) (Update of Address of Finished Product Manufacturer - Inclusion of Finished Good Warehouse Address into the Existing Facility Address)	Otsuka Pharmaceutical India Private Limited Survey No. 188, 194, 195 Paiki 1 & 2, 199 / 1, 200 / 1, 201 / 1, 199 to 201 & 208 to 210, Village - Vasana - Chacharwadi, Tal - Sanand, Dist.-Ahmedabad - 382 213, India	India	Third Schedule
Celepid 20% Intravenous Fat Emulsion (Intravenous fat emulsion 20% w/v) (Update of Address of Finished Product Manufacturer - Inclusion of Finished Good Warehouse Address into the Existing Facility Address)	do.	do.	do.
Tenaflox Metronidazole Injection USP 0.5% w/v (Update of Address of Finished Product Manufacturer - Inclusion of Finished Good Warehouse Address into the Existing Facility Address)	do.	do.	do.
NS Sodium Chloride Intravenous Infusion BP (0.9% w/v) (Update of Address of Finished Product Manufacturer - Inclusion of Finished Good Warehouse Address into the Existing Facility Address)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
SuperAmp Sterilised Water for Injections BP (Update of Address of Finished Product Manufacturer - Inclusion of Finished Good Warehouse Address into the Existing Facility Address)	Otsuka Pharmaceutical India Private Limited Survey No. 188, 194, 195 Paiki 1 & 2, 199 / 1, 200 / 1, 201 / 1, 199 to 201 & 208 to 210, Village - Vasana - Chacharwadi, Tal - Sanand, Dist.-Ahmedabad - 382 213, India	India	Third Schedule
Oplev Levofloxacin Infusion I.V. 5 mg/ml (Update of Address of Finished Product Manufacturer - Inclusion of Finished Good Warehouse Address into the Existing Facility Address)	do.	do.	do.
Leniol Paracetamol Infusion 1% w/v (Update of Address of Finished Product Manufacturer - Inclusion of Finished Good Warehouse Address into the Existing Facility Address)	do.	do.	do.
20M Mannitol Intravenous Infusion BP 20% w/v (Update of Address of Finished Product Manufacturer - Inclusion of Finished Good Warehouse Address into the Existing Facility Address)	do.	do.	do.
DNS Sodium Chloride and Glucose Intravenous Infusion BP (0.9% w/v & 5% w/v)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
(Update of Address of Finished Product Manufacturer - Inclusion of Finished Good Warehouse Address into the Existing Facility Address)			
SYSZOL Fluconazole Infusion BP (2 mg/ml) (Update of Address of Finished Product Manufacturer - Inclusion of Finished Good Warehouse Address into the Existing Facility Address)	Otsuka Pharmaceutical India Private Limited Survey No. 188, 194, 195 Paiki 1 & 2, 199 / 1, 200 / 1, 201 / 1, 199 to 201 & 208 to 210, Village - Vasana - Chacharwadi, Tal - Sanand, Dist.-Ahmedabad - 382 213, India	India	Third Schedule
10D (Glucose Intravenous Infusion BP 100 g/L) (Update of Address of Finished Product Manufacturer - Inclusion of Finished Good Warehouse Address into the Existing Facility Address)	do.	do.	do.
Moxfor (Moxifloxacin IV Infusion 1.6 mg/ml) (Update of Address of Finished Product Manufacturer - Inclusion of Finished Good Warehouse Address into the Existing Facility Address)	do.	do.	do.
ErlotiRel 150 (Erlotinib 150 mg Tablets)	Reliance Life Sciences Pvt. Ltd Dhirubhai Ambani Life	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Sciences Center (DALC) R-282, TTC Area of MIDC, Thane Belapur Road, Rabale, Navi Mumbai- 400701, Maharashtra, India		
Sunitinib Malate Capsules 50 mg	MSN Laboratories Private Limited Formulation Division UNIT-H, SY NO 1227 & 1319 to 1324 Nandigama Village, Nandigama, Mandal, Ranga Reddy District, Telangana State, India	India	Third Schedule

Dated this 28th day of November, 2025.

L. BODOE
Minister of Health