LEGAL NOTICE NO. 17

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
Noradrenaline (Norepinephrine) Solution for Infusion 1 mg/ml	Laboratoire Aguettant, 1 Rue Alexander Fleming, Lyon, 69007, France	France	Third Schedule
Adrenaline Aguettant Solution for Intravenous, Intramuscular or Subcutaneous Injection 1 mg/mL	Laboratoire Aguettant, 1 Rue Alexander Fleming, Lyon, 69007, France	France	Third Schedule
Midazolam 5 mg/mL Solution for Injection/Infusion 50 mg/10 mL	HBM Pharma s.r.o., Sklabinská 30, Martin, 036 01, Slovakia	Slovakia	Third Schedule
Cisatracurium 2 mg/mL Solution for Injection/Infusion 10 mg/5 ml	HBM Pharma s.r.o., Sklabinská 30, Martin, 036 01, Slovakia	Slovakia	Third Schedule
Adrenaline (Epinephrine Injection 1 in 1000) for Intramuscular or Subcutaneous Injection 1 mg/mL	HBM Pharma s.r.o., Sklabinská 30, Martin, 036 01, Slovakia	Slovakia	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Naloxone Solution for Injection/Infusion 400 mcg/ml	Siegfried Hameln GmbH, Langes Feld 13, Afferde, Hameln, Lower Saxony, 31789, Germany	Germany	Third Schedule
Adcetris® 50 mg Powder for Concentrate for Solution for Infusion	BSP Pharmaceuticals S.p.S., Via Appia Km 65, 561, (loc. Latina scalo)-04013 Latina (LT), Italy For: Takeda Austria Gmbh, Austria	Austria	Third Schedule
Ovestin Cream 1 mg/1 g	Aspen Bad Oldesloe GmbH Industriestraße 32-36 23843 Bad Oldesloe, Germany For: Aspen Labs S.A. de C.V., Mexico	Germany	Third Schedule
Imipramine Tablets 25 mg	Surepharm Services Limited Unit 2H, Bretby Business Park, Ashby Road East, Bretby, Burton-on-Trent, DE15 0YZ, United Kingdom Name of Packer/Batch Release Site: Crescent Pharma Limited Key House, Sarum Hill, Basingstoke, RG21 8SR, United Kingdom	United Kingdom	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Anusol Ointment	Laboratoires M. Richard Rue Du Progres Zone Industrielle Des Reys de Saulce, Saulce Sur Rhone, F-26270, France Marketing Authorisation Holder: Church & Dwight UK Limited Premier House, Shearway Business Park, Pent Road, Folkstone, Kent, CT19 4RJ, United Kingdom	United Kingdom	Third Schedule
Replens Long Lasting Vaginal Moisturizer	Church & Dwight Co. Inc., 500 Charles Ewing Blvd, Ewing NJ, 08628 United States of America	United States of America	Freely
Allopurinol Tablets 100 mg	Yiling Pharmaceutical Limited No. 36 Zhujiang Road, Shijiazhuang, Hebei, CN 050035, The People's Republic of China Name and Address of Packager/Batch Release Site: Crescent Pharma Limited Key House, Sarum Hill, Basingstoke, RG21 8SR, United Kingdom	United Kingdom	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Oxytocin Concentrate for Solution for Infusion 10 IU/mL	HBM Pharma s.r.o. Sklabinská 30, Martin 036 80, Slovak Republic Distributor: Hameln pharma ltd, Nexus, Gloucester Business Park Gloucester, GL3 4AG, United Kingdom	Slovak Republic	Third Schedule
Potassium Chloride ProAmp® Concentrate for Solution for Infusion 0.15 g/mL	Laboratoire Aguettant, 1 Rue Alexander Fleming, Lyon, 69007, France	France	Third Schedule
Cisatracurium Besylate Solution for Injection/Infusion 2 mg/mL (10 mg/5 mL)	Somerset Therapeutics Limited 54/1, Boodihal Village, Nelamangala Taluk, Bengaluru, Karnataka 562123, India Distributor: Somerset Therapeutics, LLC, Hollywood, Florida 33024 United States of America	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Genfurosemide (Furosemide) Tablets USP 40 mg (Update to correct the Name of Manufacturer as previously registered from Genetics Pharmaceuticals Ltd. to Cipro Pharmaceuticals. Update to correct the address of the Manufacturer as previously registered from Lot #14 O'Meara Road, Arima, Republic of Trinidad and Tobago, West Indies to Shed No. 74 A&B, IDA, Phase- II Mallapur, Hyderabad- 500076, India; Update in Artwork to reflect the above as well as to include the Name and Address of the Distributor - Bpi Genetics Limited, 5A CTC Drive, Macoya, Tunapuna, Trinidad and Tobago; Change in Country of Origin from Trinidad and Tobago to India)	Cipro Pharmaceuticals Shed no. 74A&B, Phase II, Industrial Area, Mallapur, Hyderabad, Mallapur Village, Upper Mandal, Medchal- Malkajgiri District, Pincode 500076, Telangana State India For: Bpi Genetics Limited 5A CTC Drive, Macoya, Tunapuna, Trinidad	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
GEN-FAXINE XR Extended Release Capsules 37.5 mg (Update to correct the Name of Manufacturer as previously registered from Genetics Pharmaceuticals Ltd. to Cipro Pharmaceuticals. Update to correct the address of the Manufacturer as previously registered from Lot #14 O'Meara Road, Arima, Republic of Trinidad and Tobago, West Indies to Shed No. 74 A&B, IDA, Phase- II Mallapur, Hyderabad- 500076, India; Update in Artwork to reflect the above as well as to include the Name and Address of the Distributor - Bpi Genetics Limited, 5A CTC Drive, Macoya, Tunapuna, Trinidad and Tobago; Change in Country of Origin from Trinidad and Tobago to India)	Cipro Pharmaceuticals Shed no. 74A&B, Phase II, Industrial Area, Mallapur, Hyderabad, Mallapur Village, Upper Mandal, Medchal- Malkajgiri District, Pincode 500076, Telangana State India For: Bpi Genetics Limited 5A CTC Drive, Macoya, Tunapuna, Trinidad	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Gen- Peridone Tablets 2 mg (Update to correct the Name of Manufacturer as previously registered from Genetics Pharmaceuticals Ltd. to Cipro Pharmaceuticals. Update to correct the address of the Manufacturer as previously registered from Lot #14 O'Meara Road, Arima, Republic of Trinidad and Tobago, West Indies to Shed No. 74 A&B, IDA, Phase- II Mallapur, Hyderabad- 500076, India; Update in Artwork to reflect the above as well as to include the Name and Address of the Distributor - Bpi Genetics Limited, 5A CTC Drive, Macoya, Tunapuna, Trinidad and Tobago; Change in Country of Origin from Trinidad and Tobago to India)	Cipro Pharmaceuticals Shed no. 74A&B, Phase II, Industrial Area, Mallapur, Hyderabad, Mallapur Village, Upper Mandal, Medchal- Malkajgiri District, Pincode 500076, Telangana State India For: Bpi Genetics Limited 5A CTC Drive, Macoya, Tunapuna, Trinidad	India	Third Schedule
Methodex Cough Mixture - Oral Solution (Change in Artwork Design; Roll on Pilfer Proof (ROPP) Changed to Child Resistant Closure (CRC); Change in Distributor from Alfred Telfer & Company Limited to Smith Robertson & Company Limited)	Bell, Sons & Co. (Druggists) Ltd. Gifford House, Slaidburn Crescent, Southport, PR9 9AL, United Kingdom	United Kingdom	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Takfa 0.5 (Tacrolimus Capsules USP 0.5 mg)	Intas Pharmaceuticals Limited Plot No. 457 & 458, Village Matoda, Bavla Road, and Plot No. 191/218P, Village Chacharwadi, Tal-Sanand, Vill-Matoda & Chacharwadi - 382 210, Dist. - Ahmedabad, Gujarat State, India	India	Third Schedule
Takfa 1 (Tacrolimus Capsules USP 1 mg)	Intas Pharmaceuticals Limited Plot No. 457 & 458, Village Matoda, Bavla Road, and Plot No. 191/218P, Village Chacharwadi, Tal-Sanand, Vill-Matoda & Chacharwadi - 382 210, Dist. - Ahmedabad, Gujarat State, India	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Takfa 5 (Tacrolimus Capsules USP 5 mg)	Intas Pharmaceuticals Limited Plot No. 457 & 458, Village Matoda, Bavla Road, and Plot No. 191/218P, Village Chacharwadi, Tal-Sanand, Vill-Matoda & Chacharwadi - 382 210, Dist. - Ahmedabad, Gujarat State, India	India	Third Schedule
Antibothropic Antilachetic Pentavalent Serum Solution for Injection	Instituto de Butantan 1500 Vital Brazil Butantan Sao Paulo Brazil	Brazil	Specialist Use Only
Antielapidic Bivalent Serum Solution for Injection	Instituto de Butantan 1500 Vital Brazil Butantan Sao Paulo Brazil	Brazil	Specialist Use Only
Rivaroxaban Film Coated Tablets 2.5 mg	Hetero Labs Limited Unit-V, Sy. No. 439,440,441 & 458, TSIIC Formulation SEZ, Polepalle Village, Jadcherla Mandal, Mahabubnagar District, Pincode 509301, Telangana State, India	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Celginase 10,000 IU Lyophilized Powder for Injection	Celon Laboratories Pvt. Ltd, India Plot no-2, ALEAP Industrial area Estate, Gajularamaram, Medchal District- 500090, Telangana State, India	India	Third Schedule
Cafnea Oral Solution 25 mg/5 mL	Phebra Pty Ltd. Australian Government-Dept. of Health and Aged Care 17-19 Orion Road, Lane Cove West NSW 2066 Australia	Australia	Third Schedule
Cafnea Injection 40 mg/2 mL	Phebra Pty Ltd. Australian Government-Dept. of Health and Aged Care 17-19 Orion Road, Lane Cove West NSW 2066 Australia	Australia	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Benztrop Tablets 2mg	Phebra Pty Ltd. Australian Government- Dept. of Health and Aged Care 17-19 Orion Road, Lane Cove West NSW 2066 Australia Distributed in New Zealand by: AFT Pharmaceuticals Ltd. P.O.Box 33-203 Auckland	Australia	Third Schedule
Aramine Solution for Injection 10 mg/mL	Phebra Pty Ltd. Australian Government- Dept. of Health and Aged Care 17-19 Orion Road, Lane Cove West NSW 2066 Australia Distributed in New Zealand by: AFT Pharmaceuticals Ltd. P.O.Box 33-203 Auckland	Australia	Third Schedule
Lexotanil 3mg Tablets	Delpharm Milano S.r.l., Via Carnevale, 1 20054, Segrate MI, Italy Secondary Packager: Delpharm Milano S.r.l., Via Carnevale, 1 20054, Segrate MI, Italy	Italy	Controlled

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Lexotanil 3mg Tablets	Delpharm Milano S.r.l., Via Carnevale, 1 20054, Segrate MI, Italy Secondary Packager: Aescia Pharameuticals GmbH Mittelstraβe 15 40789 Monheim am Rhein, Germany	Germany	Controlled
Domperidone Tablets 10mg	Zhejiang Jingxin Pharmaceutical Company Limited 800 Xinchang East Road, Yulin Subdistrict, Xinchang County, Zhejiang, RC-312500, The People's Republic of China Packer/Batch Release Site: Crescent pharma Limited Key House, Sarum Hill, Basingstoke, RG21 8SR, United Kingdom	United Kingdom	Third Schedule
Sunitinib Malate Tablets 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

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Zitram P Tablets (Paracetamol 325 mg & Tramadol Hydrochloride 37.5 mg)	Ipca Laboratories Limited Plot No. 255/1, Village-Athal, Silvassa 396230 Union Territory of Dadra & Nagar Haveli and Daman & Diu, India	India	Third Schedule
Ibandronate Sodium Tablets 150 mg	Macleods Pharmaceuticals Ltd. Block N-2, Village Theda, PO Lodhimajra, Tehsil Baddi, Dist. Solan, Himachal Pradesh-174101, India	India	Third Schedule
Lamivudine Tablets 150 mg	Macleods Pharmaceuticals Limited Atlanta Arcade, Marol Church Road, Andheri (East), Mumbai-400 059, India	India	Third Schedule
Isoniazid 100 mg Tablets	Oxalis Labs., Block N-2, Village Theda, Post Office Lodhimajra, Tehsil Baddi, Distt. Solan, Himachal Pradesh-174101, India	India	Third Schedule
Isoniazid 300 mg Tablets	Oxalis Labs., Block N-2, Village Theda, Post Office Lodhimajra, Tehsil Baddi, Distt. Solan, Himachal Pradesh-174101, India	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Rivaroxaban Tablets 10 mg	Macleods Pharmaceuticals Ltd. Block N-2, Village Theda, Post Office Lodhimajra, Tehsil Baddi, Distt. Solan, Himachal Pradesh-174101, India	India	Third Schedule
Rivaroxaban Tablets 15 mg	Macleods Pharmaceuticals Ltd. Block N-2, Village Theda, Post Office Lodhimajra, Tehsil Baddi, Distt. Solan, Himachal Pradesh-174101, India	India	Third Schedule
Rivaroxaban Tablets 20 mg	Macleods Pharmaceuticals Ltd. Block N-2, Village Theda, Post Office Lodhimajra, Tehsil Baddi, Distt. Solan, Himachal Pradesh-174101, India	India	Third Schedule
PTU-50 (Propylthiouracil Tablets 50 mg)	Macleods Pharmaceuticals Ltd. Block N-2, Village Theda, Post Office Lodhimajra, Tehsil Baddi, Distt. Solan, Himachal Pradesh-174101, India	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Ramgic Injectable Solution 50 mg/ml	MSN Laboratories Private Limited Formulation Division, Plot No. 42, ANRICH, Industrial Estate, Bollaram, Sangareddy District, Telangana, India	India	Third Schedule
Quetiapine Fumarate Extended Release Tablets 300 mg	Macleods Pharmaceuticals Limited Plot No. 25-27, Survey No. 366, Premier Industrial Estate, Kachigam, Daman - 396210 (U.T.) India	India	Third Schedule
Vegzelma® (Bevacizumab) Concentrate for Solution for Infusion 100 mg/4 mL	CELLTRION, Inc. (Plant 2) 20 Academy-ro 51 beon-gil, Yeonsu-gu, Incheon, 22014, Republic of Korea	Republic of Korea	Third Schedule
Vegzelma® (Bevacizumab) Concentrate for Solution for Infusion 400 mg/16 mL	CELLTRION, Inc. (Plant 2) 20 Academy-ro 51 beon-gil, Yeonsu-gu, Incheon, 22014, Republic of Korea	Republic of Korea	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Tecentriq Solution for Injection 1875 mg/15 ml	Roche Diagnostics GmbH Sandhofer Straβe 116, 68305 Mannheim Germany Secondary Packager: F. Hoffmann-La Roche Ltd., Wurmisweg, 4303 Kaiseraugst, Switzerland	Switzerland	Third Schedule
Etimib-Denk Tablets 10 mg	Artesan Pharma GmbH & Co. KG Wendlandstr. 1 29439 Lüchow Germany	Germany	Third Schedule
Librela Solution for Injection 30 mg/mL	Zoetis Belgium SA Rue Laid Burniat 1, 1348 Louvain-La-Neuve, Belgium	Belgium	Third Schedule (Veterinary Use Only)
Librela Solution for Injection 20 mg/mL	Zoetis Belgium SA Rue Laid Burniat 1, 1348 Louvain-La-Neuve, Belgium	Belgium	Third Schedule (Veterinary Use Only)
Librela Solution for Injection 15 mg/mL	Zoetis Belgium SA Rue Laid Burniat 1, 1348 Louvain-La-Neuve, Belgium	Belgium	Third Schedule (Veterinary Use Only)
Librela Solution for Injection 10 mg/mL	Zoetis Belgium SA Rue Laid Burniat 1, 1348 Louvain-La-Neuve, Belgium	Belgium	Third Schedule (Veterinary Use Only)

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Librela Solution for Injection 5 mg/mL	Zoetis Belgium SA Rue Laid Burniat 1, 1348 Louvain-La-Neuve, Belgium	Belgium	Third Schedule (Veterinary Use Only)
Newton-Everett Think-Rite Advanced	Nutritional Manufacturing Services LLC 3295 N. Nevada Street, 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
Nature's Truth Potassium Citrate Capsules 275 mg	Piping Rock Health Products LLC. /Nature's Truth, LLC 3900 Veterans Memorial Highway, Bohemia, NY 11716 United States of America	United States of America	Freely
Nature's Truth Triple Omega 3-6-9 Fish, Flax, Borage Soft Gels 3600 mg	Piping Rock Health Products LLC. /Nature's Truth, LLC 3900 Veterans Memorial Highway, Bohemia, NY 11716 United States of America	United States of America	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Nature's Truth Triple Glucosamine Sulfate 2KCL 3,000 mg	Piping Rock Health Products LLC. /Nature's Truth, LLC 3900 Veterans Memorial Highway, Bohemia, NY 11716 United States of America	United States of America	Freely
Jarrow Formulas Energy Optimizer Veggie Capsules	Jarrow Industries, LLC 12246 Hawkins Street, Santa Fe Springs, CA, 90670, United States of America For: Jarrow Formulas, Inc. Sherman Oaks, CA 91403, United States of America	United States of America	Freely
Nature's Way Sambucus Elderberry Immune Syrup for Kids	Schwabe North America, Inc., 825 Challenger Drive, Green Bay, WI, 54311, United States of America	United States of America	Freely
Taglin 50 mg Tablets	Nobel Ilac San. Ve Tic. A.S., Sancaklar Mah. Eski Akçakoca Cad. No: 299 81100 Düzce/Türkiye	Turkey	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
ErlotiRel 150 (Erlotirel 150 mg) Tablets	Reliance Life Sciences Pvt. Ltd. Dhirubhai Ambani Life Sciences Center (DALC) R-282, TTC Area of MIDC, Thane Belapur Road, Rabale, Navi Mumbai-400701, Maharashtra, India	India	Third Schedule
Newton-Everett L-Arginine 500 mg Capsules	Nutritional Manufacturing Services LLC 3295 N. Nevada Street, 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
Newton-Everett L-Carnitine 500 mg Capsules	Nutritional Manufacturing Services LLC 3295 N. Nevada Street, 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
Systane Hydration PF Lubricant Eye Drops	Alcon Research LLC, 6201 South Freeway, Fort Worth, TX 76134, United States of America	United States of America	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Broksil Syrup, 6 mg/mL (Change of Manufacturer from Farmalabor- Productos Farmaceuticos, S.A. to Medinfar Manufacturing, S.A.)	Medinfar Manufacturing S.A, Parque Industrial Armando Martins Tavares Rua Outeiro da Armada, 5, Condeixa-a-Nova 3150-194 Sebal, Portugal For: Willams and Halls, Reykjavikurvegur 62, IS-220 Hafnarfjordur, Iceland	Portugal	Freely
Safebul 8 mg Tablets (Change of Manufacturer's Name; Change of Bulk Manufacturer; Change in Primary and Secondary Packager; Update to Label)	Novartis Pharmaceutical Manufacturing LLC Verovskova Ulica 57, 1000 Ljubljana Slovenia	Slovenia	Third Schedule
Safebul 16 mg Tablets (Change of Manufacturer's Name; Change of Bulk Manufacturer; Change in Primary and Secondary Packager; Update to Label)	Novartis Pharmaceutical Manufacturing LLC Verovskova Ulica 57, 1000 Ljubljana Slovenia	Slovenia	Third Schedule
Safebul 32 mg Tablets (Change of Manufacturer's Name; Change of Bulk Manufacturer; Change in Primary and Secondary Packager; Update to Label)	Novartis Pharmaceutical Manufacturing LLC Verovskova Ulica 57, 1000 Ljubljana Slovenia	Slovenia	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Amlodipine Tablet 5 mg (Change of Manufacturer from Meditab Specialties Pvt. Ltd to S Kant Healthcare Limited)	S Kant Healthcare Limited, Plot No. 1802-1805, G.I.D.C. Phase II, Vapi 396 195. Gujarat, India	India	Third Schedule
Amlodipine Tablet 10 mg (Change of Manufacturer from Meditab Specialties Pvt. Ltd to S Kant Healthcare Limited)	S Kant Healthcare Limited, Plot No. 1802-1805, G.I.D.C. Phase II, Vapi 396 195. Gujarat, India	India	Third Schedule
Procto-Glyvenol Suppositories 400 mg/40 mg (Change of the Legal Entity Name of the Holder; Change in the Monograph and Insert/Leaflet; Change of Information on Primary and Secondary Labelling; Haleon Logo Inclusion on Primary and Secondary Artworks)	Delpharm Huningue S.A.S. 26 Rue De La Chapelle, Huningue, 68330, France For: Haleon Costa Rica, S.A., Costa Rica	France	Third Schedule
Procto-Glyvenol Cream (Change of the Legal Entity Name of the Holder; Change of Legal Entity Name of Manufacturer; Change in Monograph and Insert/Leaflet; Change of Information on Primary and Secondary Labelling; Haleon Logo Inclusion on Primary and Secondary Artworks)	Haleon CH SARL Route de l'Etraz 2, 1260 Nyon, Switzerland For: Haleon Costa Rica, S.A., Costa Rica	Switzerland	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Voltaren Emulgel 1.16% Gel (Change of the Legal Entity Name of the Holder; Change of Legal Entity Name of Manufacturer; Change in the Monograph and Insert/Leaflet; Change of Information on Primary and Secondary Labelling; Haleon Logo Inclusion on Primary and Secondary Artworks)	Haleon CH SARL Route de l'Etraz 2, 1260 Nyon, Switzerland For: Haleon Costa Rica, S.A., Costa Rica	Switzerland	Third Schedule
Nizoral Gel Shampoo 2% (Change in Manufacturer)	Industria Farmacéutica Andrómaco, S.A. de C.V EJE 3 Norte No.202, Parque Industrial Toluca 2000, C.P. 50233, Toluca Mexico, Mexico	Mexico	Third Schedule
Arasid-100 Cytarabine Injection BP 100 mg/ml, 1 ml vials (Change in the Name of the API Supplier from Pro Bio Sint to Archimica S.P.A.; Addition in new API Manufacturing Site of the same API Supplier - Viale Milano, Italy)	Intas Pharmaceuticals Ltd. Plot No. 457-458, Village Matoda, Bavla Road, Tal Sanand Dist Ahamedabad, India	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Arasid-500 Cytarabine Injection BP 100 mg/ml, 5 ml vials (Change in the Name of the API Supplier from Pro Bio Sint to Archimica S.P.A.; Addition in new API Manufacturing Site of the same API Supplier - Viale Milano, Italy)	Intas Pharmaceuticals Ltd. Plot No. 457-458, Village Matoda, Bavla Road, Tal Sanand Dist Ahamedabad, India	India	Third Schedule
Arasid-1000 Cytarabine Injection BP 100 mg/ml, 10 ml vials (Change in the Name of the API Supplier from Pro Bio Sint to Archimica S.P.A.; Addition in new API Manufacturing Site of the same API Supplier - Viale Milano, Italy)	Intas Pharmaceuticals Ltd. Plot No. 457-458, Village Matoda, Bavla Road, Tal Sanand Dist Ahamedabad, India	India	Third Schedule
Metoclopramide Solution for Injection 10 mg/2 ml	B. Braun Melsungen AG, Mistelweg 2, Berlin, D-12357, Germany	Germany	Third Schedule
Adrenaline Solution for Injection 1 mg/ml	B. Braun Melsungen AG, Mistelweg 2, Berlin, D-12357, Germany	Germany	Third Schedule
Haloperidol Solution for Injection 5 mg/ml	B. Braun Melsungen AG, Mistelweg 2, Berlin, D-12357, Germany	Germany	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Enhertu Powder for Concentrate for Solution for Infusion 100 mg	Baxter Oncology GmbH, Kantstrasse 2, 33790 Halle/Westfalen, Germany	Germany	Third Schedule
Norvasc Tablets 5 mg (Change of Manufacturer's Legal Entity Name; Artwork update to reflect change to entity's name and added safety microtext: VIATRIS VIATRIS VIATRIS VIATRIS; Change to specification 3.2P.5.1- rebranding (engravement) of tablets; Change to manufacturing process control to reflect change to the step for tablet engravement)	Viatris Pharmaceuticals LLC KM 1.9, Road 689 Vega Baja, Puerto Rico 00693 United States of America Packager: Pfizer Manufacturing Deutschland GmbH Betriebsstätte Freiburg Mooswaldallee 1 79090 Freiburg, Germany	Germany	Third Schedule
Norvasc Tablets 10 mg (Change of Manufacturer's Legal Entity Name; Artwork update to reflect change to entity's name and added safety microtext: VIATRIS VIATRIS VIATRIS VIATRIS; Change to specification 3.2P.5.1- rebranding (engravement) of tablets; Change to manufacturing process control to reflect change to the step for tablet engravement)	Viatris Pharmaceuticals LLC KM 1.9, Road 689 Vega Baja, Puerto Rico 00693 United States of America Pfizer Manufacturing Deutschland GmbH Betriebsstätte Freiburg Mooswaldallee 1 79090 Freiburg, Germany	Germany	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Ciproxina® Solution for Infusion 200 mg/100 ml (Update of Primary and Secondary Artwork Design Colour and Font Size for the 200 ml bottle)	Fresenius Kabi Italia S.r.l., Italy Via Camagre, 41/43-37063 Isola Della Scala (VR), Italy For: Bayer AG Kaiser-Wilhelm-Allee, 51368 Leverkusen, Germany	Italy	Third Schedule
Celebrex Hard Capsules 200 mg (Change of Manufacturer's Legal Entity Name; Artwork update to reflect change to entity's name and added safety microtext: VIATRIS VIATRIS VIATRIS VIATRIS)	Viatris Pharmaceuticals LLC KM 1.9, Road 689 Vega Baja, Puerto Rico 00693 United States of America Packager: Pfizer Manufacturing Deutschland GmbH Betriebsstätte Freiburg, Mooswaldallee 1 79090 Freiburg Federal Republic of Germany	Germany	Third Schedule
Warfarin 1 mg Tablets	Crescent Pharma Ltd. Units 3&4, Quidhampton Business Units, Polhampton Lane, Overton, Hants RG25 3ED, United Kingdom	United Kingdom	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Warfarin 5 mg Tablets	Crescent Pharma Ltd. Units 3&4, Quidhampton Business Units, Polhampton Lane, Overton, Hants RG25 3ED, United Kingdom	United Kingdom	Third Schedule
Naproxen 500 mg Tablets	Crescent Pharma Ltd. Units 3&4, Quidhampton Business Units, Polhampton Lane, Overton, Hants RG25 3ED, United Kingdom	United Kingdom	Third Schedule
Metoclopramide 10 mg Tablets	Crescent Pharma Ltd. Units 3&4, Quidhampton Business Units, Polhampton Lane, Overton, Hants RG25 3ED, United Kingdom	United Kingdom	Third Schedule

Dated this 15th day of January, 2025.

T. DEYALSINGH
Minister of Health

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