

LEGAL NOTICE No. 235

## 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
Kick Tape Cat Tablets (Praziquantel and Pyrantel Pamoate Tablets)	Veko Care Pvt. Ltd. Plot No. E - 48 & 49, MIDC Ranjangaon, District - Pune Maharashtra, India	India	Freely (Veterinary Use Only)
DVL Poultry Supplement Liquid	International Health Care Limited D.No. 40-9-60, GFD, Kohinoor Apartments, Kalanagar, Opp: Trust Hospital, Near Benz Circle, Vijayawada-520 010, A.P-520010., India	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
PVE Canine Supplement Liquid	International Health Care Limited D.No. 40-9-60, GFD, Kohinoor Apartments, Kalanagar, Opp: Trust Hospital, Near Benz Circle, Vijayawada-520 010, A.P-520010., India	India	Freely (Veterinary Use Only)
COTRIM FS (Trimethoprim and Sulphamethoxazole Veterinary Oral Powder)	do.	do.	Third Schedule (Veterinary Use Only)
Alfatam-D (Dutasteride and Tamsulosin Hydrochloride Capsules 0.5 mg/0.4 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.	Third Schedule
Amlodac 10 (Amlodipine Besilate Tablets 10 mg)	Zydus Lifesciences Limited Kundaim Industrial Estate, Plot no. 203-213, Kundaim, GOA-403 115, India	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Actilyse 50 mg Powder and Solvent for Solution for Injection and Infusion (Change in Drug Substance Manufacturing Process; Change in Packaging; Change of Artwork Design)	Boehringer Ingelheim Pharma GmbH & Co. KG Birkendorfer Strasse 65, 88397 Biberach/Riss, Germany	Germany	Third Schedule
Neurobion N Film Coated Tablets	INDEUREC S.A. Av Principal S/N Autopista Duran Boliche, Ecuador	Ecuador	Freely
Sunitinib Hard Capsules 50 mg	Remedica Ltd Aharnon Street, Limassol Industrial Estate, 3056 Limassol, Cyprus	Cyprus	Third Schedule
Sorefenib Tablets USP 200 mg	Dr. Reddy's Laboratories Limited Formulation Unit-VII, Plot Nos. P1 to P9, Phase III, VSEZ, Duvvada, Visakhapatnam District 530046, Andhra Pradesh, India	India	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Zometa Concentrate for Solution for Infusion 4 mg/5 ml (Addition of an Additional Secondary Packaging Site; Change of Country of Origin; Change of Secondary Packaging Site)	Frensenius Kabi Austria GmbH Hafnerstrasse 36 A-8055 Graz, Austria Secondary Packager: Lek Pharmaceuticals d.d. Ljubljana, Slovenia	Slovenia	Third Schedule
Mekinist 2 mg Film-Coated Tablets (Change in the Name and Address of the Primary and Secondary Packaging Site; Change in Secondary Artwork)	Novartis Pharma Stein AG, Switzerland Schaffhauserstrasse 4332, Stein, Switzerland Packaged by: Novartis Pharmaceutical Manufacturing LLC Verovskova ulica 57, 1000 Ljubljana, Slovenia	do.	do.
Enapril-10 (Enalapril Maleate Tablets USP 10 mg) (Additional Manufacturing Site; Change of Primary and Secondary Packaging; Update of Patient Information Leaflet)	Intas Pharmaceuticals Limited Camp Road, Selaqui-248197 Dehradun, Uttarakhand, India	India	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Revcos 200 mg Capsules (Change in the Name of the Bulk Manufacturing Site; Change of the Primary and Secondary Packaging Site; Change of Marketing Authorization Holder; Change of Secondary Artwork; Update of Patient Information Leaflet)	Novartis Pharmaceutical Manufacturing LLC, Slovenia Verovskova ulica 57, 1000 Ljubljana, Slovenia Packaged by: Lek Pharmaceutical d.d. Lendava, Slovenia	Slovenia	Third Schedule
Enoxaparin Sodium Injection USP 40 mg/0.4 ml	Divine Laboratories Pvt Ltd Block No. 471, Dabhasa, Tal-Padra, Dist-Vadodara 391440, India Marketed by: Flagship Biotech International Pvt. Ltd. Navi Mumbai, India	India	do.
Enoxaparin Sodium Injection USP 60 mg/0.6 ml	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Picoprep Powder for Oral Solution (Additional Indication; Update of Summary Product Characteristics; Update of Leaflet; Update of Primary and Secondary Artworks)	Ferring Pharmaceuticals (China) Co., Ltd. No. 6, Hui Ling Lu (Ferring Road), National Health Technology Park, 528437, Zhongshan City, Guangdong Province, China Marketing Authorization Holder: Ferring GmbH Wittland 11, 24109, Kiel, Germany	China	Third Schedule
Gonapeptyl Daily Solution for Injection 0.1 mg/mL (Update of Summary Product Characteristics; Update of Leaflet; Update of Primary and Secondary Artworks)	Ferring GmbH Wittland 11, 24109 Kiel, Germany Secondary Packager: Ferring-Léčiva, a.s. Areál spol ECP, a.s., Ke Skále 455, Vestec u Prahy, 25242, Czech Republic For: Ferring GmbH Wittland 11, 24109 Kiel, Germany	Czech Republic	do.
Duratocin Solution for Injection 100 µg/mL (Update of Address of Secondary Packager; Update of Artwork; Update in Monograph and Leaflet)	Ferring GmbH Wittland 11, 24109 Kiel, Germany Secondary Packager: Ferring-Léčiva, a.s., Ke Skále 455, 252 50 Vestec, Czech Republic	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Fastosil Lozenges Orange Flavour (Change of Brand Name; Change of Manufacturer; Change of Artwork Design)	Plethico Laboratories Pvt. Ltd. B-9/2, MIDC Road, Ratnagiri, Mirjole-415639, District: Ratnagiri, Maharashtra, India	India	Freely
Fastosil Lozenges Honey & Lemon Flavour (Change of Brand Name; Change of Manufacturer; Change of Artwork Design)	do.	do.	do.
Skyrizi (Risankizumab Injection) 150 mg/mL Sterile Solution for Subcutaneous Injection in Single-Use Pen (Change of Primary and Secondary Artworks; Change of Leaflet)	AbbVie Biotechnology Ltd. Road NO 2 KM 59.2, Barceloneta, Puerto Rico, 00617, United States of America Secondary Packager: AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen Am Rhein, Germany For: AbbVie Deutschland GmbH & Co. KG Ludwigshafen, Germany	Germany	Third Schedule
Fungifex Tablets 250mg (Update of Patient Information Leaflet; Update of Primary and Secondary Packaging)	Remedica Ltd Ahamon Street, Limassol Industrial Estate 3056 Limassol, Cyprus	Cyprus	do.



TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Acetazolamide Tablets 250 mg (Update of Patient Information Leaflet; Update of Primary and Secondary Packaging; Addition of an Additional Pack Size)	Remedica Ltd Aharnon Street, Limassol Industrial Estate 3056 Limassol, Cyprus	Cyprus	Third Schedule
Remevia Film-Coated Tablets 25 mg	Remedica Ltd Aharnon Street, Limassol Industrial Estate Estate 3056 Limassol, Cyprus	do.	do.
Remevia Film-Coated Tablets 50 mg	do.	do.	do.
Remevia Film-Coated Tablets 100 mg	do.	do.	do.
RituxiRel® Rituximab Solution for Injection 100 mg	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	India	Third Schedule



TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
RituxiRel® Rituximab Solution for Injection 500 mg	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	India	Third Schedule
HealthAid® Vitamin B Complex Supreme Capsules	Eurocaps Limited Units A, B, C & D. Crown Business Park, Dukestown, Tredegar, Np22 4 EF, United Kingdom	United Kingdom	Freely
Omeprazole Delayed Release Capsules USP 20 mg	Centurion Healthcare Pvt. Ltd 601, Atlantis Heights, Sarabhai Compound, Vadi Wadi, Vadodara-390 007, Gujarat, India	India	Third Schedule
Hydrocortisone Sodium Succinate for Injection USP 100 mg	Swiss Parenterals Ltd 808, 809, 810, Kerala Industrial Estate, GIDC, Nr. Bavla, Dist. Ahmedabad-382, 220, Gujarat, India	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Clopacin Film-Coated Tablets 75 mg (Change of Primary Packaging; Change of Packaging Site; Increase in Shelf Life; Change of Artwork Design)	Acino Pharma AG Birsweg 2, 4253 Liesberg, Switzerland	Switzerland	Third Schedule
Alpha Lipoic Acid 300 mg Capsules (Update of Label)	NATROL LLC Chatsworth, CA 91311, United States of America	United States of America	Freely
Melatonin 10 mg Time Release Tablets (Update of Label)	do.	do.	do.
PROBIOGEN Daily Spore Probiotic Capsules (Change of Name of Product; Change of Artwork Design)	Nutritional Manufacturing Services North Delaware, Chandler, Arizona, 85225, United States of America For: PROBIOGEN North Scottsdale Road, Scottsdale, Arizona, 85224, United States of America	United States of America	Freely
PROBIOGEN Mood Balance Spore Probiotic Capsules (Change of Name of Product; Change of Artwork Design)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Jamieson <sup>TM</sup> Ashwagandha Capsules 6000 mg	Jamieson Laboratories Ltd 4025 Rhodes Drive, Windsor, Ontario N8W 5B5, Canada	Canada	Freely
Jamieson <sup>TM</sup> Advanced Multi with Glucose Control Caplets	do.	do.	do.
Jamieson <sup>TM</sup> Melatonin Gummies	Sirio Healthcare (Anhui) Co., Ltd No. 1980 Hongqinanlu Maanashan, Anhui/ 243071 China For: Jamieson Laboratories Ltd	China	Freely
Apo-Letrozole 2.5 mg Tablets (Additional Manufacturing Site)	Genvion Corporation 500 Camiel Sys Street Winnipeg, Manitoba Canada, R2J 4K2 For: Apotex Inc., Canada	Canada	Third Schedule
Pedia D-Vite Drops	Bayshore Pharmaceuticals, LLC 1202 Tech Blvd Ste 107 Tampa FL 33619, United States of America	United States of America	Freely
Pedia Iron Drops	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Pedia Tri-Vite Drops	Bayshore Pharmaceuticals, LLC 1202 Tech Blvd Ste 107 Tampa FL 33619, United States of America	United States of America	Freely
Raltegravir Tablets 400 mg	Hetero Labs Limited Unit III 22 110 IDA Jeedimetla Village Quthbullapur Mandal Medchal Malkajgiri District Pincode 500055 Telangana State, India	India	Third Schedule
Fosaprepitant Dimeglumine Injection 150 mg/vial	Aspiro Pharma Limited Sy.No. 321, Biotech Park, Phase-III, Karkapatla Village, Markook Mandal, Siddipet District, Pincode 502281, Telangana State, India	do.	do.
Sacubitril and Valsartan Tablets 97 mg/103 mg	Hetero Labs Limited Unit III 22 110 IDA Jeedimetla Village Quthbullapur Mandal Medchal Malkajgiri District Pincode 500055 Telangana State, India	India	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Sacubitril and Valsartan Tablets 24 mg/26 mg	Hetero Labs Limited Unit III 22 110 IDA Jeedimetla Village Quthbullapur Mandal Medchal Malkajgiri District Pincode 500055 Telangana State, India	India	Third Schedule
Sacubitril and Valsartan Tablets 49 mg/51 mg	do.	do.	do.
Apixaban 2.5 mg Film- Coated Tablets	Hetero Labs Limited Unit-V, Sy. No. 439, 440, 441 & 458, TSIC Formulation SEZ, Polepally Village, Jadcheria Mandal, Mahabubnagar District, Pincode 509301, Telangana State, India	India	Third Schedule
Apixaban 5 mg Film- Coated Tablets	do.	do.	do.
Bisoprolol Fumarate 5 mg Film-Coated Tablets	do.	do.	do.
Bisoprolol Fumarate 10 mg Film-Coated Tablets	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Bisoprolol Fumarate 2.5 mg Film-Coated Tablets	Hetero Labs Limited Unit-V, Sy. No. 439, 440, 441 & 458, TSIIC Formulation SEZ, Polepally Village, Jadcheria Mandal, Mahabubnagar District, Pincode 509301, Telangana State, India	India	Third Schedule
MMF CORD 500 mg (Mycophenolate Mofetil Tablets USP 500 mg)	Concord Biotech Limited 297-298/2P, Valthera, Ta.: Dholka, Dist.: Ahmedabad - 382225, Gujarat, India Marketing Authorization Holder: Caritas Healthcare Pvt. Ltd. Ahmedabad, Gujarat, India	do.	do.
PLASCORD 0.5 mg (Tacrolimus Capsules USP 0.5 mg)	do.	do.	do.
PLASCORD 1 mg (Tacrolimus Capsules USP 1 mg)	do.	do.	do.
PLASCORD 5 mg (Tacrolimus Capsules USP 5 mg)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
IMMUNITY VITAMIN C + ZINC POWDER Sachet (Super Immune Support System*)	Natural Vitamins Laboratory Corp. 4400 NW 133rd St., Opa Locka, FL 330054, United States of America	United States of America	Freely
Nature's Way Ginkgold Eyes Vegan Tablets	Schwabe North America, Inc. 825 Challenger Drive Green Bay, WI, 54311, United States of America	do.	do.
Nature's Way Acidophilus Probiotic Softgels 1 Billion (Change of Artwork Design)	Nature's Way 825 Challenger Drive Green Bay, Wisconsin 54311, United States of America	United States of America	Freely
Nature's Way Activated Charcoal Capsules 560 mg (Change of Artwork Design)	do.	do.	do.
Nature's Way Ashwagandha Gummy 125 mg (Change of Artwork Design)	do.	do.	do.
Nature's Way Bilberry Premium Extract Capsules (Change of Artwork Design)	do.	do.	do.



TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Nature's Way Black Cohosh Root Capsules 540 mg (Change of Artwork Design)	Nature's Way 825 Challenger Drive Green Bay, Wisconsin 54311, United States of America	United States of America	Freely
Nature's Way Black Walnut Hulls Capsules 900 mg (Change of Artwork Design)	do.	do.	do.
Nature's Way Blood Sugar Manager Capsules (Change of Artwork Design)	do.	do.	do.
Nature's Way Cranberry Fruit Capsules 930 mg (Change of Artwork Design)	do.	do.	do.
Nature's Way Dong Quai Root Capsules 1130 mg (Change of Artwork Design)	do.	do.	do.
Nature's Way Echinacea Goldenseal Capsules 900 mg (Change of Artwork Design)	do.	do.	do.
Nature's Way Echinacea Purpurea Herb Capsules 1200 mg (Change of Artwork Design)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Nature's Way Evening Primrose Softgels 1300 mg (Change of Artwork Design)	Nature's Way 825 Challenger Drive Green Bay, Wisconsin 54311, United States of America	United States of America	Freely
Nature's Way Ginkgo Premium Extract Capsules (Change of Artwork Design)	do.	do.	do.
Nature's Way Ginkgold® Tablets 120 mg (Change of Artwork Design)	do.	do.	do.
Nature's Way Gotu Kola Herb Capsules 950 mg (Change of Artwork Design)	do.	do.	do.
Nature's Way Alive! Gummy Multivitamin for Kids (Change of Artwork Design)	do.	do.	do.
Nature's Way Krill Oil Softgels (Change of Artwork Design)	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Nature's Way Primadophilus® Probiotic Capsules 5 Billion CFU (Change of Artwork Design)	Nature's Way 825 Challenger Drive Green Bay, Wisconsin 54311, United States of America	United States of America	Freely
Nature's Way Senna Leaves Capsules 1350 mg (Change of Artwork Design)	do.	do.	do.
Nature's Way Turmeric Premium Extract Tablets 500 mg (Change of Artwork Design)	do.	do.	do.
Nature's Way Valerian Root Capsules 1590 mg (Change of Artwork Design)	do.	do.	do.
Nature's Way Zinc Lozenges (Zinc, Vitamin C and Echinacea) (Change of Artwork Design)	do.	do.	do.
Natele Stage 3 Gel Capsules	Berlimed S.A C/Francisco Alonso no.7 Poligono Industrial Santa Rosa Alcala de Henares, 28806 Madrid, Spain	Spain	Freely

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Lipitor Coated Tablets 80 mg (Change in Legal Entity Name of the Manufacturer; Update of Secondary Artwork to Reflect Name Change)	Viartis Pharmaceuticals LLC Km.1.9, Road 689 Vega Baja, PR 00693 Puerto Rico/ United States of America Packaged by: Pfizer Manufacturing Deutschland GmbH Mooswaldallee 1 79090 Freiburg, Germany	Germany	Third Schedule
Lipitor Coated Tablets 40 mg (Change in License Holder; Change of Legal Entity Name of the Manufacturer; Update of Secondary Artwork to Reflect Name Change of License Holder and Manufacturer; Addition of the Security Microtext)	do.	do.	do.
Lipitor Coated Tablets 20 mg (Change in License Holder; Change of Legal Entity Name of the Manufacturer; Update of Secondary Artwork to Reflect Name Change of License Holder and Manufacturer; Addition of the Security Microtext)	Viartis Pharmaceuticals LLC Km.1.9, Road 689 Vega Baja, PR 00693 Puerto Rico/ United States of America Packaged by: Pfizer Manufacturing Deutschland GmbH Mooswaldallee 1 79090 Freiburg, Germany	Germany	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Lipitor Coated Tablets 10 mg (Change in Legal Entity Name of the Manufacturer; Update of Secondary Artwork to Reflect Name Change of Manufacturer)	Viartis Pharmaceuticals LLC Km.1.9, Road 689 Vega Baja, PR 00693 Puerto Rico/ United States of America Packaged by: Pfizer Manufacturing Deutschland GmbH Mooswaldallee 1 79090 Freiburg, Germany	Germany	Third Schedule
Humalog Mix 25 Kwikpen Suspension for Injection (Change of Packaging Site; Change of Primary and Secondary Packaging; Amendment of Product Name)	LILLY FRANCE, S.A.S. F-67640 Fegersheim, France	France	do.
Humalog Kwikpen Solution for Injection in a Pre-Filled Pen 100 IU (Change of Packaging Site; Change of Primary and Secondary Packaging)	do.	do.	do.
DEPO-MEDROL® Sterile Aqueous Suspension 40 mg/ml (Change in the Address of the Manufacturer and Packager; Update of Primary and Secondary Artwork)	Pfizer Manufacturing Belgium NV Rijksweg 12, 2870 Puurs-Sint-Amands, Belgium	Belgium	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Clear Eyes Redness Relief Drops	Aspen SA Sterile Operations PTY Ltd 8B Gibaud Road, Korsten, Gqeberha, Eastern Cape 6020, South Africa	South Africa	Freely
Clear Eyes Maximum Itchy Eye Relief Drops	Pillar5 Pharma, Inc 365 Madawaska Blvd, Amprior, Ontario K7S0C9, Canada	Canada	do.
Bactrim® Forte (Sulfamethoxazole + Trimethoprim) Tablets 800 mg/160 mg (Update of Summary of Product Characteristics, Patient Information Leaflet, Primary and Secondary Artwork)	Roemmers S.A.I.C.F José E. Rodó, 6424, Ciudad Autónoma de Buenos Aires, República Argentina	Argentina	Third Schedule
Bactrim® (Sulfamethoxazole + Trimethoprim) Injectable Solution 400 mg/80 mg (Update of Summary of Product Characteristics, Patient Information Leaflet, Primary and Secondary Artwork)	Roemmers S.A.I.C.F Álvaro Barros 1113 Localidad Luis Guillón, Partido de Esteban Echeverría, Provincia de Buenos Aires, República Argentina	do.	do.



TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
<p>Advil Ibuprofen Tablets 200 mg (Pouches) (Change of the Legal Entity Name of the Holder; Change of the Legal Entity Name of the Manufacturer; Change of Information on Labelling to Reflect Changes on Primary and Secondary Packaging)</p>	<p>PF Consumer Healthcare B.V. (Puerto Rico Operations) LLC State Road No.3 (Km.141.3), Guayama, Puerto Rico (PR) 00784, United States of America For: Haleon US Holdings LLC 184 Liberty Corner Road, Suite 200, Warren, NJ 07059, United States of America</p>	<p>United States of America</p>	<p>Freely</p>
<p>Advil Ibuprofen Tablets 200 mg (Bottles) (Change of the Legal Entity Name of the Holder; Change of the Legal Entity Name of the Manufacturer; Change of the Information on Labelling to Reflect Changes on Primary and Secondary Packaging; Haleon Logo Inclusion)</p>	<p>do.</p>	<p>do.</p>	<p>do.</p>



TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
<p>Advil LIQUI-GELS® Liquid Filled Capsules 200 mg (Bottles) (Change of Legal Entity Name of the License Holder; Change in Primary and Secondary Artworks)</p>	<p>Catalent Pharma Solutions, LLC 2725 Scherer Drive, Saint Petersburg, FL 33716, United States of America Packaged by: Reed-Lane Inc 359 Newark Prompton Turnpike Wayne, NJ 07470, United States of America For: Haleon US Holdings LLC Warren NJ 07470, United States of America</p>	<p>United States of America</p>	<p>Freely</p>
<p>Advil LIQUI-GELS® Liquid Filled Capsules 200 mg (Pouches) (Change of Legal Entity Name of the License Holder; Change in Primary and Secondary Artworks)</p>	<p>Catalent Pharma Solutions, LLC 2725 Scherer Drive, Saint Petersburg, FL 33716, United States of America Packaged by: Reed-Lane Inc 359 Newark Prompton Turnpike Wayne, NJ 07470, United States of America For: Haleon US Holdings LLC Warren NJ 07470, United States of America</p>	<p>do.</p>	<p>do.</p>

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Advil LIQUI-GELS® Liquid Filled Capsules 200 mg (Bottles) (Change of Legal Entity Name of the License Holder; Change in Primary and Secondary Artworks)	Catalent Pharma Solutions, LLC 2725 Scherer Drive, Saint Petersburg, FL 33716, United States of America Packaged by: Fareva Richmond, Inc. 2248 Darbytown Road, Henrico, VA 23231, United States of America For: Haleon US Holdings LLC Warren NJ 07470, United States of America	United States of America	Freely
Advil LIQUI-GELS® Liquid Filled Capsules 200mg (Pouches) (Change of Legal Entity Name of the License Holder; Change in Primary and Secondary Artworks)	Catalent Pharma Solutions, LLC 2725 Scherer Drive, Saint Petersburg, FL 33716, United States of America Packaged by: Fareva Richmond, Inc. 2248 Darbytown Road, Henrico, VA 23231, United States of America For: Haleon US Holdings LLC Warren NJ 07470, United States of America	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Synvisc Injectable Intra Articular Synovial Fluid Supplement (Hylan G-F-200) (Change of Marketing Authorization Holder Address; Update of Patient Information Leaflet; Primary and Secondary Packaging; Update of Logo)	Genzyme Corporation 1125 Pleasant View Terrace Ridgefield, NJ 07657, United States of America	United States of America	Third Schedule
Rilutek Film Coated Tablets 50 mg (Change of Marketing Authorization Holder; Update of Secondary Artwork)	Opella Healthcare International SAS 56, Route de Choisy au Bac 60200 Compiègne, France	France	Third Schedule (Specialist Use Only)
Nexium Powder for Solution for Injection/Infusion 40 mg (Additional Manufacturer and Packager; Update of Primary and Secondary Packaging and Patient Information Leaflet)	AstraZeneca Pharmaceutical Co. Ltd #2 Huangshan Road, Wuxi, Jiangsu, 214028, China	China	Third Schedule

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Imfinzi Injection for Intravenous Use 120 mg/2.4 ml (Additional Indication - Small Cell Lung Cancer and Endometrial Cancer)	Catalent Indiana LLC. 1300 South Patterson Drive, Bloomington Indiana, 47403, United States of America Secondary Packager: AstraZeneca AB Forskargatan 18, Sodertalje, 15136, Sweden	Sweden	Third Schedule
Imfinzi Injection for Intravenous Use 500 mg/10 ml (Additional Indication - Small Cell Lung Cancer and Endometrial Cancer)	do.	do.	do.
Epilim Syrup 200 mg/5 ml Oral Solution (Change of Marketing Authorization Holder, Primary and Secondary Artworks, Labelling and Design; Logo Update)	Unither Liquid Manufacturing Zone Industrielle D En Sigal, Entree1, 3 Allee De La Neste, Bp 70319, Colomiers, 31770, France	France	do.
Truqap Film Coated Tablets 160 mg	AstraZeneca AB Gartunavagen 152 57 Sodertalje, Sweden	Sweden	do.
Truqap Film Coated Tablets 200 mg	do.	do.	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Cordarone Solution for Injection 150 mg/3 ml Ampoule (Change of Marketing Authorization Holder; Additional Manufacturing Site; Artwork Update)	Sanofi SRL via Valcanello, 4-03012 Anagni (FR), Italy	Italy	Third Schedule
Toujeo Solostar Solution for Injection in Pre-Filled Pen 300 U/ml (Update of Patient Information Leaflet, Primary and Secondary Packaging; Update of Logo)	Sanofi-Aventis Deutschland GmbH Industriepark Höchst Bruningstrabe 50, D 65926 Frankfurt am Main, Germany	Germany	do.
Trileptal Film Coated Tablets 300 mg (Addition of Primary and Secondary Packaging Site; Change of Marketing Authorization Holder; Update of Artworks to Reflect Changes)	Novartis Farma S.P.A Provinciale Schiti 131, 80058 Torre Annunziata, Italy	Italy	do.
Sidapvia Film Coated Tablets 10 mg/100 mg	SK Chemicals Co. Ltd 149 Sandan-ro Heungdeok-gu Cheongju-si, Chungcheongbuk-do 28445, Republic of Korea	Republic of Korea	do.

TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Amaryl M Film Coated Tablets 2 mg/500 mg (Change of Name of Manufacturer; Update of Patient Information Leaflet, Primary and Secondary Artworks and Logo)	Handok Inc 78 Daepungsandan-ro, Daeso-myeon, Eumseonggun, Chungcheongbuk-do, Republic of Korea	Republic of Korea	Third Schedule
Botox (Botulinum Toxin Type A) Powder for Solution for Injection Purified Neurotoxin Complex 100 Units (Additional Manufacturer of Drug Substance; Change of Marketing Authorization Holder; Update of Artwork)	Allergan Pharmaceuticals Ireland Unlimited Company Castlebar Road, Westport, F28 AW83, Ireland	Ireland	do.
Darzalex Concentrate for Solution for Infusion 100 mg/5 ml (Additional Manufacturer of Drug Substance)	Cilag AG Hochstrasse 201, 8200 Schaffhausen, Switzerland	Switzerland	do.



TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
<p>Advil LIQUI-GELS® Liquid Filled Capsules 200 mg (Change of Legal Entity Name of the License Holder; Change of Legal Entity Name of the Packager; Change in Primary and Secondary Artworks)</p>	<p>Catalent Pharma Solutions, LLC 2725 Scherer Drive, Saint Petersburg, FL 33716, United States of America Packaged by: PF Consumer Healthcare B.V. (Puerto Rico Operations) LLC State Rd No. 3 (Km. 141.3) Guayama, PR 00784, United States of America For: Haleon US Holdings LLC Warren NJ 07470, United States of America</p>	<p>United States of America</p>	<p>Freely</p>
<p>EspritVita Immune Booster Capsules</p>	<p>Pharma Natural Inc. 14500 NW 60th Ave Miami Lakes, FL 33014, United States of America Manufactured For: Esprit Vita 8336 NW 68th Street Miami FL 33166, United States of America</p>	<p>do.</p>	<p>do.</p>



TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
Anastrozole Film Coated Tablets 1 mg	Steril- Gene Life Sciences Private Limited. Block A and Block D, No 45, Mangalam Main Road, Villianur Commune, Puducherry, IN- 60511, India For: Crescent Pharma Ltd. Key House, Sarum Hill, Basingstoke, RG21 8SR, United Kingdom	United Kingdom	Third Schedule

Dated this 1st day of July, 2025.

L. BODOE  
*Minister of Health*