



Government of the Republic of Trinidad and Tobago

Ministry of Health

CHEMISTRY FOOD AND DRUGS DIVISION

#92 Frederick Street, Port of Spain

List of Drugs Registered in Accordance with the provisions of the Food and Drugs Act and Regulations
Chapter 30:01

Year 2019

DAN	TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
95890619T	Mabthera Solution for Subcutaneous Injection 1400mg/11.7ml (Change of Marketing Authorisation Holder and Change of Label)	Manufactured by: F. Hoffmann-La Roche Ltd., Kaiseraugst, Switzerland For: F. Hoffmann-La Roche Ltd., Basel, Switzerland	Switzerland	Third Schedule
95900619T	Kadcyla Powder for Concentrate for Solution for Infusion 100mg (Additional Manufacturing Site and Change of Label)	Manufactured by: F. Hoffmann-La Roche Ltd., Kaiseraugst, Switzerland For: F. Hoffmann-La Roche Ltd., Basel, Switzerland	Switzerland	Third Schedule
95910619T	Kadcyla Powder for Concentrate for Solution for Infusion 160mg (Additional Manufacturing Site and Change of Label)	Manufactured by: F. Hoffmann-La Roche Ltd., Kaiseraugst, Switzerland For: F. Hoffmann-La Roche Ltd., Basel, Switzerland	Switzerland	Third Schedule
95920619T	Herceptin Solution for Injection 600mg/5ml (Change of Marketing Authorisation Holder and Change of Label)	Manufactured by: F. Hoffmann-La Roche Ltd., Kaiseraugst, Switzerland For: F. Hoffmann-La Roche Ltd., Basel, Switzerland	Switzerland	Third Schedule
95930619T	Perjeta Concentrate for Solution for Infusion 420mg/14ml (Additional Indication)	Manufactured by: Roche Diagnostics GmbH, Mannheim, Germany For: F. Hoffmann-La Roche Ltd., Basel, Switzerland	Germany	Third Schedule
95940619T	Zelboraf Film-Coated Tablets 240mg (Change of Name and Address of Manufacturer and Change of Label)	Manufactured by: Delpharm Milano S.r.l., Segrate, Milan, Italy For: F. Hoffmann-La Roche Ltd., Basel, Switzerland	Italy	Third Schedule



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DAN	TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
95950619T	Adalat Oros Tablets 30mg (Change of Marketing Authorisation Holder and Change of Name of Manufacturer)	Manufacturer and Primary Packager: Bayer AG, Germany Secondary Packager: Bayer S.A., Guatemala	Guatemala	Third Schedule
95960619T	Adalat Oros Tablets 60mg (Change of Marketing Authorisation Holder and Change of Name of Manufacturer)	Manufacturer and Primary Packager: Bayer AG, Germany Secondary Packager: Bayer S.A., Guatemala	Guatemala	Third Schedule
95970619T	Avelox Film-Coated Tablets 400mg (Change of Marketing Authorisation Holder and Change of Name of Manufacturer)	Manufacturer and Primary Packager: Bayer AG, Germany Secondary Packager: Bayer S.A., Guatemala For: Bayer AG, Germany	Guatemala	Third Schedule
95980619T	Ciproxina Solution for Infusion 0.2g (Change of Name of Marketing Authorisation Holder, Change of Name of Manufacturing and Packaging Site and Change of Label)	Manufactured by: Bayer AG, Germany	Germany	Third Schedule
95990619T	Ciproxina Solution for Infusion 0.4g (Change of Name of Marketing Authorisation Holder, Change of Name of Manufacturing and Packaging Site and Change of Label)	Manufactured by: Bayer AG, Germany	Germany	Third Schedule
96000619T	Levitra Film Coated Tablets 5mg (Change of Name of Marketing Authorisation Holder, Change of Name of Manufacturing and Packaging Site and Change of Label)	Manufactured by: Bayer AG, Germany	Germany	Third Schedule
96010619T	Levitra Film Coated Tablets 10mg (Change of Name of Marketing Authorisation Holder, Change of Name of Manufacturing and	Manufactured by: Bayer AG, Germany	Germany	Third Schedule



DAN	TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Packaging Site and Change of Label)			
96020619T	Levitra Film Coated Tablets 20mg (Change of Name of Marketing Authorisation Holder and Change of Name of Manufacturing and Packaging Site)	Manufactured by: Bayer AG, Germany	Germany	Third Schedule
96030619T	Nebido Solution for Injection 1000mg/4ml (Change of Name of Marketing Authorisation Holder, Change of Name of Manufacturing and Packaging Site and Change of Label)	Manufactured by: Bayer AG, Germany	Germany	Third Schedule
96040619T	Primoteston Depot Injectable Solution 250mg (Change of Name of Marketing Authorisation Holder, Change of Name of Manufacturing and Packaging Site and Change of Label)	Manufactured by: Bayer AG, Germany	Germany	Third Schedule
96050619T	Proviron Tablets 25mg (Change of Name of Marketing Authorisation Holder and Change of Label)	Manufactured by: Schering do Brasil, Quimica e Farmaceutica Ltda. Brazil For: Bayer AG, Germany	Brazil	Third Schedule
96060619T	Jaydess® Intrauterine Delivery System (Change of Name of Marketing Authorisation Holder and Change of Label)	Manufactured by: Bayer Oy, Turku, Finland For: Bayer AG, Germany	Finland	Third Schedule
96070619	Natele Easy Gel Soft Capsules (Change of Name of Marketing Authorisation Holder and Change of Label)	Manufactured by: Berlimed, S.A., Spain For: Bayer AG, Germany	Spain	Freely
96080619T	Gadovist Solution for Injection 1.0mmol/ml (Change of Name of Marketing Authorisation Holder, Manufacturer and Packager, Additional	Manufactured by: Bayer AG, Germany	Germany	Third Schedule



DAN	TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Indication and Change of Label)			
96090619T	Stivarga Film-Coated Tablets 40mg (New Indication)	Manufactured by: Bayer AG, Germany	Germany	Third Schedule
96100619	Clarityne Tablets 10mg (Change of Name of Product and Change of Label)	Manufactured by: Schering-Plough Lab N.V., Belgium For: Bayer S.A., Guatemala	Belgium	Freely
96110619T	Tarceva Film-Coated Tablets 100mg (Additional Indication, Change of Name and Address of Manufacturer, Additional Primary and Secondary Packager and Change of Label)	Manufactured by: Delpharm Milano S.r.l., Italy Packed by: F. Hoffmann-La Roche Ltd., Kaiseraugst, Switzerland For: F. Hoffmann-La Roche Ltd. Basel, Switzerland	Italy	Third Schedule
96120619T	Tarceva Film-Coated Tablets 150mg (Additional Indication, Change of Name and Address of Manufacturer, Additional Primary and Secondary Packager and Change of Label)	Manufactured by: Delpharm Milano S.r.l., Italy Packed by: F. Hoffmann-La Roche Ltd., Kaiseraugst, Switzerland For: F. Hoffmann-La Roche Ltd. Basel, Switzerland	Italy	Third Schedule
96130619T	Cellcept® Capsules 250mg (Change of Name and Address of Manufacturer , Additional Secondary Packaging Site and Change of Label)	Manufactured by: Delpharm Milano S.r.l., Milan, Italy Packed by: F. Hoffmann-La Roche Ltd, Kaiseraugst, Switzerland For: F. Hoffmann-La Roche Ltd Basel, Switzerland	Italy	Third Schedule
96140619T	Cellcept® Film-Coated Tablets 500mg (Additional Manufacturing Site and Change of Label)	Made for: F. Hoffmann-La Roche Ltd., Basel, Switzerland By: Recipharm Leganes, Spain Packed by: F. Hoffmann-La Roche Ltd., Kaiseraugst, Switzerland	Switzerland	Third Schedule
96160619T	Xeloda Film-Coated Tablets 500mg (Additional Manufacturing Site and Packager and Change of Label)	Manufacturing Site: Shanghai Roche Pharmaceuticals Ltd., Shanghai, China Packed by: F. Hoffmann-La Roche Ltd., Kaiseraugst, Switzerland Made for: F. Hoffmann-La Roche Ltd., Basel, Switzerland	Switzerland	Third Schedule
96170619T	Xeloda Film-Coated Tablets 500mg (Additional	Manufacturing Site: Excella GmbH & Co. KG, Feucht,	Switzerland	Third Schedule



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DAN	TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Manufacturing Site and Packager and Change of Label)	Germany Packed by: F. Hoffmann La Roche Ltd., Kaiseraugst, Switzerland Made for: F. Hoffmann-La Roche Ltd., Basel, Switzerland		
96180619T	Xenical Capsules 120mg (Change of Marketing Authorisation Holder, Change of Name and Address of Manufacturing Site and Change of Label)	Made for: CHEPLAPHARM Arzneimittel GmbH, Germany By: Delpharm Milano S.r.l., Segrate, Italy	Italy	Third Schedule
96190619T	Coreg Tablets 6.25mg (Change of Marketing Authorisation Holder, Change of Manufacturing Site and Change of Label)	Made for: CHEPLAPHARM Arzneimittel GmbH, Germany By: Delpharm Milano S.r.l., Segrate, Italy	Italy	Third Schedule
96200619T	Coreg Tablets 12.5mg (Change of Marketing Authorisation Holder, Change of Manufacturing Site and Change of Label))	Made for: CHEPLAPHARM Arzneimittel GmbH, Germany By: Delpharm Milano S.r.l., Segrate, Italy	Italy	Third Schedule
96210619T	Coreg Tablets 25mg (Change of Marketing Authorisation Holder, Change of Manufacturing Site, Change of Packaging and Change of Label)	Made for: CHEPLAPHARM Arzneimittel GmbH, Germany By: Delpharm Milano S.r.l., Segrate, Italy	Italy	Third Schedule
96220619T	Dermovate Cream 0.05% w/w (Change of Name of Manufacturer and Change of Label)	GlaxoSmithKline Brasil LTDA, Rio de Janeiro, Brazil	Brazil	Third Schedule
96230619T	Dermovate Ointment 0.05% w/w (Change of Name of Manufacturer and Label)	GlaxoSmithKline Brasil LTDA, Rio de Janeiro, Brazil	Brazil	Third Schedule
96240619T	Trizivir Film-Coated Tablets 300mg/150mg/300mg (Additional Manufacturing Site and Change of Label)	GlaxoSmithKline Pharmaceuticals S.A., Poznan, Poland	Poland	Third Schedule
96250619T	Kivexa Film-Coated Tablets 600mg/300mg (Additional Manufacturing Site and Change of Label)	Made by: GlaxoSmithKline Pharmaceuticals S.A., Poznan, Poland Packed by: Glaxo Wellcome S.A., Aranda de Duero, Spain	Spain	Third Schedule



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96260619T	3TC Film Coated Tablets 150mg (Additional Manufacturing Site and Change of Label)	GlaxoSmithKline Pharmaceuticals S.A., Poznan, Poland	Poland	Third Schedule
96270619	Retrovir Oral Syrup 50mg/5ml (Change of Manufacturing Site and Change of Label)	GlaxoSmithKline Inc., Mississauga	Canada	Third Schedule
96280619T	Duratocin Solution for Injection 100mcg/ml (Additional Secondary Packager and Change of Label)	Manufactured by: Ferring GmbH, Germany Secondary Packager: Ferring-Leciva a.s., Czech Republic	Czech Republic	Third Schedule
96290619T	Tractocile Solution for Injection 7.5mg/ml (6.75mg/0.9ml) (Addition of Secondary Packaging Site, Change of Artwork and Change of Label)	Manufactured by: Ferring GmbH, Germany Secondary Packager: Ferring-Leciva a.s., Czech Republic	Czech Republic	Third Schedule
96300619T	Tractocile Concentrate for Solution for Infusion 7.5mg/ml (37.5mg/5ml) (Addition of Secondary Packaging Site, Change of Artwork and Change of Label)	Manufactured by: Ferring GmbH, Germany Secondary Packager: Ferring-Leciva a.s., Czech Republic	Czech Republic	Third Schedule
96310619T	Firmagon Powder and Solvent for Solution for Injection 120mg (Additional Manufacturing and Packaging Site, Change of Artwork and Change of Label)	Manufactured by: Ferring GmbH, Germany Secondary Packager: Ferring-Leciva a.s., Czech Republic	Czech Republic	Third Schedule
96320619T	Firmagon Powder and Solvent for Solution for Injection 80mg (Additional Manufacturing and Packaging Site, Change of Artwork and Change of Label)	Manufactured by: Ferring GmbH, Germany Secondary Packager: Ferring-Leciva a.s., Czech Republic	Czech Republic	Third Schedule
96330619T	Pentasa Slow Release Tablets 500mg (Change of Packaging, Artwork and Label)	Ferring International Center S.A., Switzerland	Switzerland	Third Schedule
96340619T	Pentasa Prolonged Release Granules Sachets 2g (Change of Packaging)	Ferring International Center S.A., Switzerland For Holder: Ferring AG, Switzerland	Switzerland	Third Schedule



DAN	TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Change of Artwork and Change of Label)			
96350619T	Picoprep Powder for Oral Solution/Sachet 10mg, 3.5g, 12g (Change of Packaging and Change of Artwork)	Ferring Pharmaceuticals (China) Co. Ltd., China For Holder: Ferring GmbH, Germany	China	Third Schedule
96360619T	Glypressin Powder and Solvent for Solution for Injection 1mg/5ml (Addition of Secondary Packaging Site and Change of Label)	Ferring GmbH, Germany Secondary Packager: Ferring-Léčiva a.s., Czech Republic	Czech Republic	Third Schedule
96370619T	Menopur Powder and Solvent for Solution for Injection 75 IU (Additional Secondary Packaging Site and Change of Label)	Ferring GmbH, Germany Secondary Packager: Ferring-Léčiva a.s., Czech Republic	Czech Republic	Third Schedule
96380619T	Gonapeptyl Depot Powder and Solvent for Suspension for Injection Pre-Filled Syringe 3.75mg/ml (Additional Secondary Packaging Site and Change of Label)	Ferring GmbH, Germany Secondary Packager: Ferring-Léčiva a.s., Czech Republic	Czech Republic	Third Schedule
96390619	Differin Gel 0.1% (Change of Condition of Sale, Change of Name of Manufacturer, Change of Name of Packaging and Change of Label)	Manufactured by: G.Production Inc. Distributed by: Galderma Laboratories L.P., U.S.A.	Canada	Freely
96400619T	Azopt 1% (Brinzolamide Ophthalmic Suspension) 5ml, 10ml (Change of Marketing Authorization Holder and Change of Label)	Manufactured by: Alcon Laboratories Inc. For: Novartis Pharma AG, Basel Switzerland	USA	Third Schedule
96410619T	Azarga Eye Drops Suspension (Change of Marketing Authorization Holder and Change of Label)	S.A. Alcon-Couvreur N.V., Belgium For: Novartis Pharma AG, Basel, Switzerland	Belgium	Third Schedule
96420619T	Betoptic S Ophthalmic Suspension 0.25% (Change of Marketing Authorization Holder and Change of Label)	Alcon Laboratories Inc. For: Novartis Pharma AG, Basel, Switzerland	USA	Third Schedule



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96430619T	DuoTrav Sterile Ophthalmic Solution 40mcg/ml + 5mg/ml (Change of Name of Product, Marketing Authorization Holder and Label)	Manufactured by: S.A. Alcon-Couvreur N.V., Belgium For: Novartis Pharma AG, Basel, Switzerland	Belgium	Third Schedule
96440619T	Nevanac Ophthalmic Suspension, 0.1% (Change of Marketing Authorization Holder, Packaging and Label)	Alcon Laboratories Inc. For: Novartis Pharma AG, Basel, Switzerland	USA	Third Schedule
96450619T	Patanol Ophthalmic Solution, 0.1% (Change of Marketing Authorization Holder and Change of Label)	Alcon Laboratories Inc. For: Novartis Pharma AG, Basel, Switzerland	USA	Third Schedule
96460619T	Pataday Ophthalmic Solution 0.2% (Change of Marketing Authorization Holder, Change of Packaging and Change of Label)	Alcon Laboratories Inc. For: Novartis Pharma AG, Basel, Switzerland	USA	Third Schedule
96470619T	Vigadexa Sterile Ophthalmic Solution 0.5%/0.1% 2.5ml, 5ml (Change of Packaging and Change of Label)	Novartis Biocienias S.A. Sao Paulo – SP	Brazil	Third Schedule
96480619T	Vigamox Ophthalmic Solution 0.5% (Change of Marketing Authorization Holder and Change of Label)	Alcon Laboratories Inc. For: Novartis Pharma AG, Basel, Switzerland	USA	Third Schedule
96490619	Systane Icaps Tablets - (Change of Name of Product and Change of Shelf Life)	Alcon Laboratories Inc.	USA	Freely
96500619T	Buscopan Solution for Injection 20mg/ml (Change of Marketing Authorization Holder and Distributor and Change of Label)	Boehringer Ingelhiem Espana For: Sanofi-Aventis de Panama	Spain	Third Schedule
96510619T	Dulcolax Tablets 5mg – (Carton) (Change of Marketing Authorization Holder, Change of	Boehringer Ingelheim Promeco S.A. de C.V. For: Sanofi-Aventis de Panama	Mexico	Freely



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	Packaging and Change of Label)			
96520619	Dulcolax Tablets 5mg – (Bottle) (Change of Distributor and Marketing Authorization Holder and Change of Label)	Boehringer Ingelheim Promeco S.A. de C.V. For: Sanofi-Aventis de Panama	Mexico	Freely
96530619	Pharmaton Kiddi Syrup - Orange Flavour 100ml, 200ml (Change of Marketing Authorization Holder and Distributor and Change of Label)	Ginsana SA	Switzerland	Freely
96540619	Painol Allergy Syrup (Additional Name of Product and Change of Artwork)	Bpi Genethics Limited	Trinidad and Tobago	Freely
96550619	Painol Jr Pain and Fever Raspberry Flavoured Syrup (Change of Artwork and Additional Name of Product)	Bpi Genethics Limited	Trinidad and Tobago	Freely
96560619	Painol Jr Nausea Relief Syrup (Change in Dosage, Additional Name of Product and Change of Artwork)	Bpi Genethics Limited	Trinidad and Tobago	Freely
96570619	Painol Cough Expectorant Syrup (Additional Name of Product and Change of Artwork)	Bpi Genethics Limited	Trinidad and Tobago	Freely
96580619	Genethics Paracetamol Syrup B.P. (Change in Name of Product, Change in Name and Address of Manufacturer)	Bpi Genethics Limited	Trinidad and Tobago	Freely
96590619	Genethics Diphenhydramine Elixir (Change in Name and Address of Manufacturer)	Bpi Genethics Limited	Trinidad and Tobago	Freely
96600619	Genethics Sports Balm Ultra with Capsicum-Stick Applicator (Change of Artwork)	Bpi Genethics Limited	Trinidad and Tobago	Freely
96610619T	Clavix-75 Film Coated Tablets (Additional Manufacturing Site, Change	Intas Pharmaceuticals Ltd.	India	Third Schedule



DAN	TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	of Name, Change of Packaging and Change of Label)			
96620619T	Zarzio Solution for Injection or Infusion in Pre-Filled Syringe 30MU/0.5ml (Change of Name and Address of Manufacturer and Country of Origin)	Sandoz GmbH	Austria	Third Schedule
96630619T	Bromocriptine Tablets 2.5mg (Change of Distributor and Change of Label)	Manufactured by: Apotex Inc. Distributed by: AA Pharma Inc.	Canada	Third Schedule
96640619T	Imipramine Tablets 10mg (Change of Distributor and Change of Label)	Manufactured by: Apotex Inc. Distributed by: AA Pharma Inc.	Canada	Third Schedule
96650619T	Imipramine Tablets 25mg (Change of Distributor and Change of Label)	Manufactured by: Apotex Inc. Distributed by: AA Pharma Inc.	Canada	Third Schedule
96660619T	Sulfatrim Tablets 800-160mg (Change of Distributor and Change of Label)	Manufactured by: Apotex Inc. Distributed by: AA Pharma Inc.	Canada	Third Schedule
96670619T	Sulfatrim Tablets 400-80mg (Change of Distributor and Change of Label)	Manufactured by: Apotex Inc. Distributed by: AA Pharma Inc.	Canada	Third Schedule
96680619T	Mefloquine Tablets 250mg (Change of Distributor and Change of Label)	Manufactured by: Apotex Inc. Distributed by: AA Pharma Inc.	Canada	Third Schedule
96690619T	ISDN Tablets 30mg (Change of Distributor and Change of Label)	Manufactured by: Apotex Inc. Distributed by: AA Pharma Inc.	Canada	Third Schedule
96700619T	Norflox Tablets 400mg (Change of Distributor and Change of Label)	Manufactured by: Apotex Inc. Distributed by: AA Pharma Inc.	Canada	Third Schedule
96710619	Folic Acid Tablets 5mg (Change of Distributor and Change of Label)	Manufactured by: Apotex Inc. Distributed by: AA Pharma Inc.	Canada	Freely
96720619T	Flurbiprofen Tablets 100mg (Change of Distributor and Change of Label)	Manufactured by: Apotex Inc. Distributed by: AA Pharma Inc.	Canada	Third Schedule
96730619T	Flurbiprofen Tablets 50mg (Change of Distributor and Change of Label)	Manufactured by: Apotex Inc. Distributed by: AA Pharma Inc.	Canada	Third Schedule



DAN	TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
96740619T	Nitrofurantoin Tablets 100mg (Change of Distributor and Change of Label)	Manufactured by: Apotex Inc. Distributed by: AA Pharma Inc.	Canada	Third Schedule
96750619T	Metronidazole Tablets 250mg (Change of Distributor and Change of Label)	Manufactured by: Apotex Inc. Distributed by: AA Pharma Inc.	Canada	Third Schedule
96760619T	Methyldopa Tablets 250mg (Change of Distributor and Change of Label)	Manufactured by: Apotex Inc. Distributed by: AA Pharma Inc.	Canada	Third Schedule
96770619T	VFEND Powder for Solution for Infusion 200mg (Change of Product License Holder, Change of Name of Manufacturer and Primary Packager, Change of Artwork and Change of Label)	Manufacturer: Pharmacia & Upjohn Company LLC, USA Secondary Packager: Fareva Amboise, France License Holder: Pfizer Europe MA EEIG, Belgium	France	Third Schedule
96780619T	Ecalta Powder for Solution for Injection 100mg/vial (Change of Name of Manufacturer and Change of Label)	Manufacturer and Packager: Pharmacia & Upjohn Company LLC, USA License Holder: Vicuron Holdings LLC	USA	Third Schedule
96790619T	Xalkori ® Capsules 200mg (Change of Product License Holder, Change of Artwork, New Indication and Change of Label)	Manufacturer and Packager: Pfizer Manufacturing Deutschland GmbH, Germany License Holder: Pfizer Europe MA EEIG, Belgium	Germany	Third Schedule
96800619T	Xalkori ® Capsules 250mg (Change of Product License Holder, Artwork, New Indication and Label)	Manufacturer and Packager: Pfizer Manufacturing Deutschland GmbH, Germany License Holder: Pfizer Europe MA EEIG, Belgium	Germany	Third Schedule
96810619T	Inlyta Film-Coated Tablets 1mg (Change of Product License Holder, Change of Artwork and Change of Label)	Manufacturer and Packager: Pfizer Manufacturing Deutschland GmbH, Germany License Holder: Pfizer Europe MA EEIG, Belgium	Germany	Third Schedule
96820619T	Inlyta Film-Coated Tablets 5mg (Change of Product License Holder, Change of Artwork and Change of Label)	Manufacturer and Packager: Pfizer Manufacturing Deutschland GmbH, Germany License Holder: Pfizer Europe MA EEIG, Belgium	Germany	Third Schedule
96830619T	Lyrica Capsules 25mg (Change of Product License Holder, Change of	Manufacturer and Packager: Pfizer Manufacturing Deutschland GmbH, Germany	Germany	Third Schedule



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	Artwork, Change of Packaging and Change of Label)	License Holder: Pfizer Europe MA EEIG, Belgium		
96840619T	Lyrica Capsules 75mg (Change of Product License Holder, Change of Artwork and Change of Label)	Manufacturer and Packager: Pfizer Manufacturing Deutschland GmbH, Germany License Holder: Pfizer Europe MA EEIG, Belgium	Germany	Third Schedule
96850619T	Lyrica Capsules 150mg (Change of Product License Holder, Change of Artwork and Change of Label)	Manufacturer and Packager: Pfizer Manufacturing Deutschland GmbH, Germany License Holder: Pfizer Europe MA EEIG, Belgium	Germany	Third Schedule
96860619T	Lyrica Capsules 300mg (Change of Product License Holder, Change of Artwork and Change of Label)	Manufacturer and Packager: Pfizer Manufacturing Deutschland GmbH, Germany License Holder: Pfizer Europe MA EEIG, Belgium	Germany	Third Schedule
96870619T	Sutent Hard Gelatin Capsules 12.5mg (Change of Product License Holder, Change of Artwork and Change of Label)	Manufacturer: Pfizer Italia Srl., Ascoli Piceno, Italy License Holder: Pfizer Europe MA EEIG, Belgium	Italy	Third Schedule
96880619T	Sutent Hard Gelatin Capsules 25mg (Change of Product License Holder, Change of Artwork and Change of Label)	Manufacturer: Pfizer Italia Srl., Ascoli Piceno, Italy License Holder: Pfizer Europe MA EEIG, Belgium	Italy	Third Schedule
96890619T	Sutent Hard Gelatin Capsules 50mg (Change of Product License Holder, Change of Artwork and Change of Label)	Manufacturer: Pfizer Italia Srl., Ascoli Piceno, Italy License Holder: Pfizer Europe MA EEIG, Belgium	Italy	Third Schedule
96900619T	Viagra ODT® Orodispersible Tablets 50mg (Change of Product License Holder, Artwork and Label)	Manufactured by: Fareva Amboise License Holder: Pfizer Europe MA EEIG, Belgium	France	Third Schedule
96910619T	Prevenar 13® Pneumococcal 13-Valent Conjugate Vaccine (Diphtheria CRM197 Protein) (Change of Secondary Packager, Product License Holder and Label)	Manufacturer and Primary Pkger: Pfizer Ireland Pharmaceuticals, Ireland Secondary Packager: Pfizer Manufacturing Belgium NV, Belgium License Holder: Pfizer Europe MA EEIG, Belgium	Belgium	Third Schedule



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96920619T	Celebrex Capsules 200mg (Change of Name of Product License Holder, Change of Packaging and Change of Label)	Manufacturer: Pfizer Pharmaceuticals LLC, Puerto Rico Packager: R-Pharm Germany GmbH, Germany License Holder: Pfizer Pharma PFE GmbH, Germany	Germany	Third Schedule
96930619T	Sayana Suspension for Injection 104mg/0.65ml (Change of Packaging, Change of Artwork and Change of Label)	Manufacturer & Packager: Pfizer Manufacturing Belgium NV, Belgium Product License Holder: Pfizer S.A. Belgium	Belgium	Third Schedule
96940619T	Depo-Provera Sterile Aqueous Suspension for Intramuscular Use 150mg (Change of Name of Manufacturer, Change of Artwork, Change of Packaging and Change of Label)	Manufacturer & Packager: Pfizer Manufacturing Belgium NV, Belgium Product License Holder: Pfizer S.A. Belgium	Belgium	Third Schedule
96950619T	Xeljanz Film-Coated Tablets 5mg (Change of Product License Holder, Change of Artwork, New Indication, Change of Packaging and Change of Label)	Manufacturer and Primary Packager: Pfizer Manufacturing Deutschland GmbH Germany Secondary Packager: Pfizer Pharmaceuticals LLC, Puerto Rico Licence Holder: PF PRISM C.V. Netherlands	USA	Third Schedule
96960619	Ferrol Children's Elixir - Strawberry Flavoured Liquid, Alcohol Free 120ml (Change of Packaging and Label)	Manufactured by: New GPC Inc. Distributed by: A1 Farm, E.B.D. Guyana	Guyana	Freely
96970619	Ferrol Expectorant - Cherry Flavoured Flavoured Liquid 120ml (Change of Packaging and Label)	Manufactured by: New GPC Inc. Distributed by: A1 Farm, E.B.D. Guyana	Guyana	Freely
96980619	Ferrol DM - Orange Flavoured Liquid – Alcohol Free - Sugar Free 120ml (Change of Packaging and Label)	Manufactured by: New GPC Inc. Distributed by: A1 Farm, E.B.D. Guyana	Guyana	Freely
96990619T	Elocom® Cream 0.1% (Change in Product Name, Change in Formulation, Change of Artwork and Change of Importer)	Manufactured & Packaged by: Schering-Plough Labo N.V.	Belgium	Third Schedule



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97000619T	Lasix Injectable Solution 20mg/2ml (Additional Manufacturing Site)	Manufactured by: Sanofi-Aventis Farmaceutic Ltd., Suzano	Brazil	Third Schedule
97010619T	Epilim Chrono 500 Controlled Release Tablets (Additional Manufacturing Site)	Manufactured by: Sanofi-Aventis S.A., Spain Marketing Authorisation Holder: Sanofi UK	Spain	Third Schedule
97020619T	Forxiga Film Coated Tablets 5mg (Change of Name of Manufacturer and Change of Packaging Site)	Manufactured & Packaged by: AstraZeneca Pharmaceuticals LP, USA For: AstraZeneca CAMCAR S.A. Panama	USA	Third Schedule
97030619T	Forxiga Film Coated Tablets 10mg (Change of Name of Manufacturer and Change of Packaging Site)	Manufactured & Packaged by: AstraZeneca Pharmaceuticals LP, USA For: AstraZeneca CAMCAR S.A. Panama	USA	Third Schedule
97040619T	Seroquel Film-Coated Tablets 100mg (Change of Manufacturer and Change of Packaging Site)	Manufactured by: AstraZeneca Pharmaceuticals LP, USA Packaged by: AstraZeneca S.A. de C.V., Mexico For: AstraZeneca UK Limited, UK	Mexico	Third Schedule
97050619T	Seroquel XR Extended - Release Tablets 50mg (New Manufacturing Site)	Manufactured by: AstraZeneca Pharmaceuticals LP, Newark, USA Packaged by: AstraZeneca UK Limited, Macclesfield For: AstraZeneca UK Limited, UK	UK	Third Schedule
97060619T	Seroquel XR Extended-Release Tablets 200mg (New Manufacturing Site)	Manufactured by: AstraZeneca Pharmaceuticals LP, Newark, USA Packaged by: AstraZeneca UK Limited, Macclesfield For: AstraZeneca UK Limited, UK	UK	Third Schedule
97070619T	Seroquel XR Extended-Release Tablets 300mg (New Manufacturing Site)	Manufactured by: AstraZeneca Pharmaceuticals LP, Newark, USA Packaged by: AstraZeneca UK Limited, Macclesfield For: AstraZeneca UK Limited, UK	UK	Third Schedule
97080619T	Pulmicort Nebulising Suspension 0.5mg/ml Sterile Single-Dose Units (Additional Indication)	AstraZeneca AB, Södertälje	Sweden	Third Schedule
97090619T	Tagrisso Film Coated Tablets 40mg (Additional Indication)	AstraZeneca AB	Sweden	Third Schedule



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DAN	TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
97100619T	Tagrisso Film Coated Tablets 80mg (Additional Indication)	AstraZeneca AB	Sweden	Third Schedule
97110619T	Galvus Met Film-Coated Tablets 50mg/500mg (Change of Manufacturing and Packaging Source)	Novartis Pharma Produktions GmbH, Germany For: Novartis Pharma AG, Basel, Switzerland	Germany	Third Schedule
97120619T	Gilenya Hard Capsules 0.5mg (Additional Indication)	Manufactured by: Novartis Pharma Stein AG, Switzerland For: Novartis Pharma AG, Basel, Switzerland	Switzerland	Third Schedule
97130619T	Xolair Powder and Solvent for Solution for Injection 150mg (New Indication)	Novartis Pharma Stein AG, Switzerland For: Novartis Pharma AG, Basel, Switzerland	Switzerland	Third Schedule
97140619T	Aclasta Solution For Infusion 5mg (Additional Manufacturer and Source)	Manufactured by: Fresenius Kabi Austria GmbH, Graz For: Novartis Pharma AG, Basel, Switzerland	Austria	Third Schedule
97150619T	Myfortic Gastro-Resistant Tablets 180mg (Change of Manufacturing and Packaging Source and Change of Importer)	Manufactured by: Novartis Pharma Produktions GmbH, Wehr, Germany For: Novartis Pharma AG, Basel, Switzerland	Germany	Third Schedule
97160619T	Myfortic Gastro-Resistant Tablets 360mg (Change of Manufacturing and Packaging Site and Change of Importer)	Manufactured by: Novartis Pharma Produktions GmbH, Wehr, Germany For: Novartis Pharma AG, Basel, Switzerland	Germany	Third Schedule
97170619T	Zometa Concentrate for Solution for Infusion 4mg/5ml (Additional Source, Additional Presentation and Change of Importer)	Manufactured by: Fresenius Kabi Austria GmbH, Austria For: Novartis Pharma AG, Basel, Switzerland	Austria	Third Schedule
97180619T	Elidel Cream 1% (Change of Marketing Authorisation Holder, Change of Manufacturer, Additional Manufacturing Site, Change of Artwork, Change of Label and Change of Importer)	MEDA Manufacturing, France For: MEDA Pharma GmbH & Co. KG Germany	France	Third Schedule
97190619	No More Congestion Syrup (Additional Name of Product and Change of Artwork)	Bpi Genethics Limited	Trinidad and Tobago	Freely



DAN	TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
97200619	No More Allergies Syrup (Additional Name of Product and Change of Artwork)	Bpi Genethics Limited	Trinidad and Tobago	Freely
97210619	No More Nausea Syrup (Additional Name of Product, Change of Artwork and Change in Dosage)	Bpi Genethics Limited	Trinidad and Tobago	Freely
97220619	No More Pain & Fever Syrup (Additional Name of Product and Change of Artwork)	Bpi Genethics Limited	Trinidad and Tobago	Freely
97230619T	Revolade Film-Coated Tablets 25mg (Change of Marketing Authorisation Holder and Additional Indications)	Glaxo Operations UK Limited	United Kingdom	Third Schedule
97240619T	Revolade Film-Coated Tablets 50mg (Change of Marketing Authorization Holder and Additional Indications)	Glaxo Operations UK Limited	United Kingdom	Third Schedule
97250619T	Gemibine 200 Lyophilized Powder for Injection (Change in Formulation)	Intas Pharmaceuticals Ltd.	India	Third Schedule
97260619T	Gemibine 1000 Lyophilized Powder for Injection (Change in Formulation)	Intas Pharmaceuticals Ltd.	India	Third Schedule
97270619T	ARASID-100 Cytarabine Injection BP 100mg/ml, 1ml vial (Change in Formulation)	Intas Pharmaceuticals Ltd.	India	Third Schedule
97280619T	ARASID-500 Cytarabine Injection BP 100mg/ml, 5 ml vial (Change in Formulation)	Intas Pharmaceuticals Ltd.	India	Third Schedule
97290619T	ARASID-1000 Cytarabine Injection BP 100mg/ml, 10 ml vial (Change in Formulation)	Intas Pharmaceuticals Ltd.	India	Third Schedule
97300619T	BeneFIX Powder and Solvent for Solution for Injection 250IU (Change in Licence Holder, Change in Diluent Manufacturing Site)	Powder Manufacturer: Wyeth Farma, S.A., Madrid, Spain Solvent Manufacturer: Vetter Pharma-Fertigung GmbH & Co. KG, Langenargen,	Spain	Third Schedule



DAN	TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	and Change in Shelf-Life for Active Substance)	Gemany Secondary Packager: Wyeth Farma, S.A., Madrid, Spain License Holder: Pfizer Europe MA EEIG, Belgium		
97310619T	BeneFIX Powder and Solvent for Solution for Injection 500IU (Change in Licence Holder, Change in Diluent Manufacturing Site and Change in Shelf-Life for Active Substance)	Powder: Manufacturer: Wyeth Farma, S.A., Madrid, Spain Solvent: Manufacturer: Vetter Pharma-Fertigung GmbH & Co. KG, Langenargen, Gemany Secondary Packager: Wyeth Farma, S.A., Madrid, Spain License Holder: Pfizer Europe MA EEIG, Belgium	Spain	Third Schedule
97320619T	Eliquis Film-Coated Tablets 2.5mg (New Indication)	Manufactured by: Bristol-Myers Squibb Manufacturing Company, Puerto Rico EEUU Packager: Bristol-Myers Squibb S.r.L., Italy License Holder: Bristol-Myers Squibb/Pfizer EEIG, UK	Italy	Third Schedule
97330619T	Eliquis Film-Coated Tablets 5mg (New Indication)	Manufactured by: Bristol-Myers Squibb Manufacturing Company, Puerto Rico EEUU Packager: Bristol-Myers Squibb S.r.L., Italy License Holder: Bristol-Myers Squibb/Pfizer EEIG, UK	Italy	Third Schedule
97340619T	Xyntha Powder and Solvent for Solution for Injection 250IU (New Indication)	Powder: Manufactured by: Wyeth Pharma S.A., Madrid, Spain Secondary Packager: Wyeth Farma, S.A., Madrid, Spain Solvent: Manufacturer: Vetter Pharma-Fertigung GmbH & Co. KG, Germany Licence Holder: Wyeth Pharmaceuticals Inc. Philadelphia, USA	Spain	Third Schedule
97350619T	Xyntha Powder and Solvent for Solution for Injection 500IU (New Indication)	Powder: Manufactured by: Wyeth Pharma S.A., Madrid, Spain Secondary Packager: Wyeth Farma, S.A., Madrid, Spain	Spain	Third Schedule



DAN	TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
		Solvent: Manufacturer: Vetter Pharma-Fertigung GmbH & Co. KG, Germany Licence Holder: Wyeth Pharmaceuticals Inc. Philadelphia, USA		
97360619T	Enbrel Solution for Injection in Pre-Filled Pen 50mg (Additional Indication, Change in Manufacturer, Primary Packager and Pen Assembly, Change in Product License Holder, Change in Name of Product, Change of Artwork and Change of Label)	Manufacturer: Pfizer Manufacturing Belgium NV, Belgium Primary Packager: Pfizer Manufacturing Belgium NV, Belgium Secondary Packager: Wyeth Pharmaceuticals, UK License Holder: Pfizer Europe MA EEIG, Belgium	UK	Third Schedule
97370619T	Enbrel Solution for Injection in Pre-Filled Syringe 50mg (Change in Manufacturer and Primary Packager, Change of Product License Holder, Change in Name of Product, Change of Artwork and Change of Label)	Manufacturer: Pfizer Manufacturing Belgium NV, Belgium Primary Packager: Pfizer Manufacturing Belgium NV, Belgium Secondary Packager: Wyeth Pharmaceuticals, UK License Holder: Pfizer Europe MA EEIG, Belgium	UK	Third Schedule
97380619T	Actemra Solution for Subcutaneous Injection Pre Filled Syringe 162mg (Additional Indications)	Manufactured by: Vetter Pharma-Fertigung GmbH & Co. KG For: F. Hoffmann-La Roche Ltd., Basel, Switzerland	Germany	Third Schedule
97390619T	Mircera Solution for Injection Pre-Filled Syringes 50mcg/0.3ml - (Additional Packager, Change of Artwork and Change of Importer)	Made for: F. Hoffmann-La Roche Ltd Basel, Switzerland Manufacturer: F. Hoffmann-La Roche Ltd Kaiseraugst, Switzerland Primary Packager: F. Hoffmann-La Roche Ltd Switzerland Secondary Packager: Roche Diagnostics GmbH, Germany	Germany	Third Schedule
97400619T	Mircera Solution for Injection Pre-Filled	Made for:	Germany	Third Schedule



DAN	TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Syringes 75mcg/0.3ml (Additional Packager, Change of Artwork, Change of Importer and Change of Label)	F. Hoffmann-La Roche Ltd Basel, Switzerland Manufacturer: F. Hoffmann-La Roche Ltd Kaiseraugst, Switzerland Primary Packager: F. Hoffmann-La Roche Ltd. Switzerland Secondary Packager: Roche Diagnostics GmbH, Ger.		
97410619T	Mircera Solution for Injection Pre-Filled Syringes 100mcg/0.3ml (Additional Packager, Change of Artwork, Change of Importer and Change of Label)	Made for: F. Hoffmann-La Roche Ltd Basel, Switzerland Manufacturer: F. Hoffmann-La Roche Ltd Kaiseraugst, Switzerland Primary Packager: F. Hoffmann-La Roche Ltd Switzerland Secondary Packager: Roche Diagnostics GmbH, Germany	Germany	Third Schedule
97420619T	Mircera Solution for Injection Pre-Filled Syringes 200mcg/0.3ml (Additional Packager, Change of Artwork, Change of Importer and Change of Label)	Made for: F. Hoffmann-La Roche Ltd Basel, Switzerland Manufacturer: F. Hoffmann-La Roche Ltd Kaiseraugst, Switzerland Primary Packager: F. Hoffmann-La Roche Ltd Switzerland Secondary Packager: Roche Diagnostics GmbH, Germany	Germany	Third Schedule
97430619T	Mabthera Concentrate for Solution for Infusion 100mg/10ml (Additional Manufacturing Site)	Made for: F. Hoffmann-La Roche Ltd, Basel, Switzerland By: Genentech Inc., Hillsboro, Oregon, USA	USA	Third Schedule
97440619T	Mabthera Concentrate for Solution for Infusion 500mg/50ml (Additional Manufacturing Site)	Made for: F. Hoffmann-La Roche Ltd, Basel, Switzerland By: Genentech Inc., Hillsboro, Oregon, USA	USA	Third Schedule



DAN	TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
97450619T	Tamiflu 75mg Capsules (Change of Manufacturer's Name and Address, Additional Secondary Packaging Site and Change of Importer)	Manufactured by: Delpharm Milano S.r.l., Italy Packed by: F. Hoffmann-La Roche Ltd., Switzerland For: F. Hoffmann-La Roche Ltd., Basel, Switzerland	Switzerland	Third Schedule
97460619T	Pulmozyme Solution for Inhalation 2500U (2.5mg) 2.5ml (Additional Primary Packaging Site, Additional Secondary Packaging Site, Change of Artwork, Change of Importer, Change of Packaging and Change of Label)	Made for: F. Hoffmann-La Roche Ltd Basel, Switzerland, By: Genentech Inc., South San Francisco, United States Packed by (Primary): Catalent Pharma Solutions, Woodstock, Illinois, United States Packed by (Secondary): F. Hoffmann-La Roche Ltd Kaiseraugst, Switzerland	Switzerland	Third Schedule
97470619T	Pantecta Tablets P20 (Change of Marketing Authorisation Holder, Artwork, Label and Additional Distributor)	Manufactured by: Takeda GmbH-Lehnitzstrasse Germany Packaged by: Takeda México S.A. de C.V., Mexico Distributor: Aspen Panama S.A. Panama	Mexico	Third Schedule
97480619T	Pantecta Tablets 40mg (Change of Marketing Authorisation Holder, Artwork, Label and Additional Distributor)	Manufactured by: Takeda GmbH-Lehnitzstrasse Germany Packaged by: Takeda México S.A. de C.V., Mexico Distributor: Aspen Panama S.A. Panama	Mexico	Third Schedule
97490619T	Pantecta IV Lyophilized Powder for Solution for Injection 40mg (Change of Marketing Authorisation Holder, Artwork, Label and Additional Distributor)	Manufactured by: Takeda GmbH-Lehnitzstrasse Germany Packaged by: Takeda México S.A. de C.V., Mexico Distributor: Aspen Panama S.A. Panama	Mexico	Third Schedule
97500619T	Alevian Duo Capules 100mg/300mg (Change of Marketing Authorisation Holder, Artwork, Label and Additional Distributor)	Manufactured by: Gelcaps Exportadora de México Packaged by: Takeda México S.A. de C.V.	Mexico	Third Schedule
97510619T	Diprivan 10mg/ml (1%) Emulsion for Injection or Infusion - Pre-Filled Syringe 50ml (Change in Marketing Authorisation	Manufactured by: Corden Pharma SpA Italy Packed by: AstraZeneca UK Ltd. For: Aspen Labs S.A. de C.V., Mexico	UK	Third Schedule



DAN	TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Holder, Change of Artwork and Change of Label)			
97520619T	Diprivan 10mg/ml (1%) Emulsion for Injection or Infusion – Ampoules (Change of Marketing Authorisation Holder, Change of Artwork and Change of Label)	Manufactured by: Corden Pharma SpA Italy Packed by: AstraZeneca UK Ltd. For: Aspen Labs S.A. de C.V., Mexico	UK	Third Schedule
97530619T	Diprivan 20mg/ml (2%) Emulsion for Injection or Infusion – vials (Change of Marketing Authorisation Holder, Change of Artwork and Change of Label)	Manufactured by: Corden Pharma SpA Italy Packed by: AstraZeneca UK Ltd. For: Aspen Labs S.A. de C.V., Mexico	UK	Third Schedule
97540619T	Fraxiparine 2850IU AXA/0.3ml Solution for Injection (S.C.) in Pre-Filled Syringe (Change of Marketing Authorisation Holder, Change in Name of Manufacturing Site, Change of Artwork, Change of Importer and Change of Label)	Manufactured by: Aspen Notre Dame de Bondeville, France For: Aspen Labs S.A. de C.V., Mexico	France	Third Schedule
97550619T	Fraxiparine 5700IU AXA/0.6ml Solution for Injection (S.C.) in Pre-Filled Syringe (Change of Marketing Authorisation Holder, Change in Name of Manufacturing Site, Change of Artwork, Change of Importer and Change of Label)	Manufactured by: Aspen Notre Dame de Bondeville, France For: Aspen Labs S.A. de C.V., Mexico	France	Third Schedule
97560619T	Nimbex Solution for Injection or Infusion 2mg/ml (5mg in 2.5ml) (Change of Marketing Authorisation Holder, Change of Artwork, Additional Presentation, Change of Importer and Change of Label)	Manufactured by: GlaxoSmithKline Manufacturing S.p.A., Pharma, Italy For: Aspen Labs S.A. de C.V., Mexico	Italy	Third Schedule



DAN	TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
97570619T	Nimbex Solution for Injection or Infusion 2mg/ml (10mg in 5ml) (Change of Marketing Authorisation Holder, Change of Artwork, Additional Presentation and Change of Importer)	Manufactured by: GlaxoSmithKline Manufacturing S.p.A., Pharma, Italy For: Aspen Labs S.A. de C.V., Mexico	Italy	Third Schedule
97580619T	Mivacron Injection 2mg/ml (5mg/2.5ml) (Change of Marketing Authorisation Holder, Change of Artwork, Additional Presentation and Change of Importer)	Manufactured by: GlaxoSmithKline Manufacturing S.p.A., Pharma, Italy For: Aspen Labs S.A. de C.V., Mexico	Italy	Third Schedule
97590619T	Mivacron Injection 2mg/ml (10mg/5ml) (Change of Marketing Authorisation Holder, Change of Artwork, Additional Presentation, Change of Importer and Change of Label)	Manufactured by: GlaxoSmithKline Manufacturing S.p.A., Pharma, Italy For: Aspen Labs S.A. de C.V., Mexico	Italy	Third Schedule
97600619	Phillips' Milk of Magnesia Original Liquid (Change of Manufacturing Site, Change of Artwork and Change of Label)	Manufactured by: Aspen Mexico S.de R.L de C.V., Mexico For: Aspen Caricam S.A. San Jose Costa Rica	Mexico	Freely
97610619	Phillips' Milk of Magnesia Mint Liquid (Change of Manufacturing Site, Change of Artwork and Change of Label)	Manufactured by: Aspen Mexico S.de R.L de C.V., Mexico For: Aspen Caricam S.A. San Jose Costa Rica	Mexico	Freely
VeterinaryProducts				
97620619VP	Dectomax Injection 1% (Change of Name of Manufacturer)	Manufactured by: Inovat Industria Farmaceutica Ltda. Distributed by: Zoetis Industria de Productosm Vereinaros Ltda.	Brazil	Veterinary Prescription Only
97630619VP	Revolution Topical Solution (for cats) 45mg/0.75ml (Change of Name of Manufacturer)	Zoetis Inc.	USA	Veterinary Prescription Only
97640619VP	Revolution Topical Solution (for dogs) 60mg/0.50ml	Zoetis Inc.	USA	Veterinary Prescription Only



DAN	TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	(Change of Name of Manufacturer)			
97650619VP	Revolution Topical Solution (for dogs) 240mg/2.0ml (Change of Name of Manufacturer)	Zoetis Inc.	USA	Veterinary Prescription Only
97660619	Zimecterin Gold Oral Paste (Change of Name of Manufacturer)	Boehringer Ingelheim Animal Health do Brazil, Ltda.	Brazil	Freely
97670619VP	Ivomec Injection (Change of Name of Manufacturer)	Boehringer Ingelheim Animal Health do Brazil, Ltda.	Brazil	Veterinary Prescription Only
97680619VP	Eqvalan Paste (Change of Name of Manufacturer)	Boehringer Ingelheim Animal Health do Brazil, Ltda.	Brazil	Veterinary Prescription Only
97690619VP	Recombitek C4 (Change of Name of Manufacturer)	Boehringer Ingelheim Animal Health USA Inc.	USA	Veterinary Prescription Only
97700619VP	Recombitek C6 (Change of Name of Manufacturer)	Boehringer Ingelheim Animal Health USA Inc.	USA	Veterinary Prescription Only
97710619VP	Recombitek C6/CV (Change of Name of Manufacturer)	Boehringer Ingelheim Animal Health USA Inc.	USA	Veterinary Prescription Only
97720619VP	Heartgard Plus Chewables 68mcg Ivermectin and 57mg Pyrantel (Change of Name of Manufacturer)	Boehringer Ingelheim Animal Health Puerto Rico LLC.	USA	Veterinary Prescription Only
97730619VP	Heartgard Plus Chewables 136mcg Ivermectin and 114mg Pyrantel (Change of Name of Manufacturer)	Boehringer Ingelheim Animal Health Puerto Rico LLC.	USA	Veterinary Prescription Only
97740619VP	Heartgard Plus Chewables 272mcg Ivermectin and 227mg Pyrantel (Change of Name of Manufacturer)	Boehringer Ingelheim Animal Health Puerto Rico LLC	USA	Veterinary Prescription Only
97750619VP	Nexgard Chewable Tablets 11.3mg (Change of Name of Manufacturer)	Boehringer Ingelheim Animal Health do Brazil Ltda.	Brazil	Veterinary Prescription Only
97760619VP	Nexgard Chewable Tablets 28.3mg (Change of Name of Manufacturer)	Boehringer Ingelheim Animal Health do Brazil Ltda.	Brazil	Veterinary Prescription Only
97770619VP	Nexgard Chewable Tablets 68mg (Change of Name of Manufacturer)	Boehringer Ingelheim Animal Health do Brazil Ltda.	Brazil	Veterinary Prescription Only
97780619VP	Nexgard Chewable Tablets 136mg (Change of Name of Manufacturer)	Boehringer Ingelheim Animal Health do Brazil Ltda.	Brazil	Veterinary Prescription Only



DAN	TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
97790619T	Heparin Injection BP 5000IU/5ml (Additional Manufacturing Site)	Gland Pharma Limited	India	Third Schedule
97800619T	Heparin Injection BP 25000IU/5ml (Additional Manufacturing Site)	Boehringer Ingelheim Animal Health do Brazil Ltda.	Brazil	Veterinary Prescription Only
97810619	Cerumol Ear Drops (Change of Importer)	Thornton and Ross Limited UK	UK	Freely
97820619	Seven Seas Cod Liver Oil Plus Omega Fish Oil 150ml, 170ml, 300ml, 450ml (Change of Manufacturing and Packaging Site)	Laleham Health and Beauty Limited	United Kingdom	Freely
97830619T	Dolo-Neurobion XR Extended Release Film Coated Tablets (Change of Marketing Authorization Holder)	Merck S.A. de C.V. Mexico For: Procter & Gamble Interamericas de Guatemala LTDA, Guatemala	Mexico	Third Schedule
97840619T	Dolo-Neurobion N Film Coated Tablets (Additional Indication and Change of Marketing Authorization Holder)	Merck S.A. de C.V. Mexico For: Procter & Gamble Interamericas de Guatemala LTDA, Guatemala	Mexico	Third Schedule
97850619T	Neurobion Film Coated Tablets (Change of Marketing Authorization Holder)	Merck S.A. de C.V. Mexico For: Procter & Gamble Interamericas de Guatemala LTDA, Guatemala	Mexico	Third Schedule
97860619T	Dolo-Neurobion Injection - Dual Chamber Pre-Filled Syringe (Change of Marketing Authorization Holder and Additional Indication)	Merck S.A. de C.V. Mexico For: Procter & Gamble Interamericas de Guatemala LTDA, Guatemala	Mexico	Third Schedule
97870619	Iliadian Nasal Decongestant Solution Pediatric Drops 0.01% (Change of Marketing Authorization Holder)	Merck S.A. de C.V. Mexico For: Procter & Gamble Interamericas de Guatemala LTDA, Guatemala	Mexico	Freely
97880619T	Cosopt Ophthalmic Solution 2%/0.5% (Change of Artwork and Change of Marketing Authorization Holder)	Laboratories Merck Sharp & Dohme - Chibert	France	Third Schedule



DAN	TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
97890619T	Trusopt Ophthalmic Solution 2% (Change of Marketing Authorization Holder)	Laboratories Merck Sharp & Dohme - Chibert	France	Third Schedule
97900619T	Timoptic Ophthalmic Solution 0.5% (Change of Marketing Authorization Holder)	Laboratories Merck Sharp & Dohme - Chibert	France	Third Schedule
97910619T	Timoptic XE Ophthalmic Solution 0.5% (Change of Marketing Authorization Holder)	Laboratories Merck Sharp & Dohme - Chibert	France	Third Schedule
97920619T	Saflutan Eye Drop Solution 15mcg/ml (Change of Marketing Authorization Holder)	Laboratoire Unither	France	Third Schedule
97930619T	Victoza Solution for Injection in a Pre-Filled Pen 6mg/ml (Additional Indications and Additional Packaging Site)	Novo Nordisk A/S	Denmark	Third Schedule
97940619T	Levemir FlexPen Solution for Injection 100U/ml, 3ml pre-filled pen (Additional Manufacturing Site)	Novo Nordisk Produção Farmacêutica do Brasil Ltda	Brazil	Third Schedule
97950619T	NovoRapid FlexPen Solution for Injection 100U/ml, 3ml pre-filled pen (Additional Manufacturing Site)	Novo Nordisk Produção Farmacêutica do Brasil Ltda	Brazil	Third Schedule
97960619T	NovoMix 30 FlexPen Solution for Injection 100U/ml, 3ml pre-filled pen (Additional Manufacturing Site)	Novo Nordisk Produção Farmacêutica do Brasil Ltda	Brazil	Third Schedule
97970619T	Novolin 70/30 Penfill Suspension for Injection, 100U/ml, 3ml cartridge (Additional Manufacturing Site)	Novo Nordisk Produção Farmacêutica do Brasil Ltda	Brazil	Third Schedule
97980619T	Trajenta Tablets 5mg (Additional Indications)	Boehringer Ingelheim Promeco, S.A. de C.V.	Mexico	Third Schedule
97990619T	Twynsta 80/5mg Tablets (Additional Packaging Site)	Rottendorf Pharma GmbH	Germany	Third Schedule



DAN	TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
98000619T	Twynsta 80/10mg Tablets (Additional Packaging Site)	Rottendorf Pharma GmbH	Germany	Third Schedule
98010619T	Spiriva Respimat Solution for Inhalation 2.5mcg (Additional Indication)	Boehringer Ingelheim Pharma GmbH & Co. KG	Germany	Third Schedule
98020619	Pepto Bismol Liquid (Change of Formulation and Change of Label)	The Procter & Gamble Company	USA	Freely
98030619T	ProVisc Ophthalmic Viscosurgical Device (Additional Manufacturing Site)	Manufactured by: Lifecore Biomedical, LLC, For Alcon Laboratories Inc. USA	USA	Third Schedule
98040619T	Viscoat Ophthalmic Viscosurgical Device (Change of Name of Product and Additional Manufacturing Site)	Manufactured by: Lifecore Biomedical, LLC, For Alcon Laboratories Inc. USA	USA	Third Schedule
98050619T	Buscopan Tablets 10mg (Change of Distributor and Marketing Authorization Holder and Change of Label)	Boehringer Ingelheim Promeco S.A. de C.V. For Sanofi- Aventis de Panama	Mexico	Third Schedule
98460619	Vit-B-Denk Film Coated Tablets 100mg + 200mg (Additional Packaging Site)	Denk Pharma GmbH & Co. KG, Germany	Germany	Freely
98470619T	Clotri-Denk 1% Cream (Change of Manufacturer)	C.P.M. ContractPharma GmbH Germany	Germany	Third Schedule
98480619	Para-Denk 125 Suppository, 125mg (Alternative Manufacturer and Change of Packaging)	bene-Arzneimittel GmbH Germany	Germany	Freely
98490619	Para-Denk 250 Suppository, 250mg (Alternative Manufacturer and Change of Packaging)	bene-Arzneimittel GmbH Germany	Germany	Freely
98500619T	Amlo-Denk 5 Tablet 5mg (Additional Packaging Site)	Denk Pharma GmbH & Co. KG, Germany	Germany	Third Schedule
98510619T	Amlo-Denk 10 Tablet 10mg (Additional Packaging Site)	Denk Pharma GmbH & Co. KG, Germany	Germany	Third Schedule
98520619T	Synagis Solution for Injection 100mg/ml (Change of Marketing Authorisation Holder)	Manufacturing Site: Boehringer Ingelheim Pharma GmbH & Co. KG Germany Secondary Packager: Abbvie S.r.L. Italy	Germany	Third Schedule



DAN	TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
		For: Abbvie & Co. KG Deutschland GmbH Germany		
98530619T	Lexapro® (Escitalopram) Film-Coated Tablets 20mg (Change of Marketing Authorisation Holder)	H. Lundbeck A/S, Valby, Denmark For: Lundbeck America Central, S.A., Panama City, Republic of Panama	Denmark	Third Schedule
98540619	Kalms Day 84 Tablets & 200 Tablets (Change of Formulation and Change of Label)	G.R. Lane Health Product Limited, United Kingdom	United Kingdom	Freely
98550619T	Blopress Tablets 8mg (Change of Packaging and Change of Label)	Abbott Laboratories Argentina S.A., Argentina	Argentina	Third Schedule
98560619T	Blopress Tablets 16mg (Change of Packaging and Change of Label)	Abbott Laboratories Argentina S.A., Argentina	Argentina	Third Schedule
98570619T	Blopress Plus Tablets 16mg/12.5mg (Change of Packaging and Change of Label)	Takeda Ireland Ltd., Ireland Packaged by: Abbott Laboratories, Argentina S.A., Argentina	Argentina	Third Schedule
98580619T	Avonex 30mcg/0.5ml Solution for Injection (Change of Formulation, Change of Packaging, Change of Label and New Manufacturing Site)	Vetter Pharma-Fertigung, GmbH & Co. KG, Langenargen, Germany	Germany	Third Schedule
98590619T	Cytax 30 Paclitaxel Injection USP Concentrate 30mg/5ml (Change of Packaging)	Intas Pharmaceuticals Limited	India	Third Schedule
98600619T	Cytax 100 Paclitaxel Injection USP Concentrate 100mg/16.7ml (Change of Packaging)	Intas Pharmaceuticals Limited	India	Third Schedule
98610619T	Cytax 300 Paclitaxel Injection USP Concentrate 300mg/50ml (Change of Packaging)	Intas Pharmaceuticals Limited	India	Third Schedule
98620619T	Accentrix Solution for Injection 10mg/ml (Change of Marketing Authorisation Holder, Change of Indications for Use and Change of Label)	Novartis Pharma Stein AG	Switzerland	Third Schedule
98630619T	Voltaren Emulgel 1.16% (Change of Manufacturing	Manufactured by: GSK Consumer Healthcare S.A.,	Switzerland	Third Schedule



DAN	TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Site Name and Change of Label)	Switzerland For: GlaxoSmithKline Costa Rica, S.A., Costa Rica		
98640619T	Procto-Glyvenol Suppositories (Change of Product License Holder and Change of Label)	Manufactured by: Delpharm Huningue S.A.S, France For: GlaxoSmithKline, S.A., Costa Rica	France	Third Schedule
98650619T	Procto-Glyvenol Cream (Change of Product License Holder, Change of Manufacturing Site Name and Change of Label)	Manufactured by: GSK Consumer Healthcare S.A., Switzerland For: GlaxoSmithKline Costa Rica, S.A., Costa Rica	Switzerland	Third Schedule
98660619T	Lamisil Dermgel 1% (Change of Product License Holder, Change of Name of Manufacturing Site, Change of Packaging and Change of Label)	Manufactured by: GSK Consumer Healthcare S.A., Switzerland For: GlaxoSmithKline Costa Rica, S.A., Costa Rica	Switzerland	Third Schedule
98670619T	Lamisil Cream 1% (Change of Product License Holder, Change of Manufacturing Site Name and Change of Label)	Manufactured by: GSK Consumer Healthcare S.A., Switzerland For: GlaxoSmithKline Costa Rica, S.A., Costa Rica	Switzerland	Third Schedule
98680619T	Lamisil Spray 1% (Change of Product License Holder and Change of Label)	Manufactured by: Delpharm Huningue S.A.S, France For: GlaxoSmithKline Costa Rica, S.A., Costa Rica	France	Third Schedule
98690619	Otrivin Nasal Spray Nebulizer Solution 0.1% (Change of Name of Manufacturing Site and Change of Label)	Manufactured by: GSK Consumer Healthcare S.A., Nyon, Switzerland For: GlaxoSmithKline Costa Rica, S.A., Costa Rica	Switzerland	Freely
98700619	Otrivin Nasal Drops Solution 0.1% (Change of Name of Manufacturing Site and Change of Label)	Manufactured by: GSK Consumer Healthcare S.A., Nyon, Switzerland For: GlaxoSmithKline Costa Rica, S.A., Costa Rica	Switzerland	Freely
98710619	Otrivin Metered Dose Nasal Spray 0.1% (Change of Name of Manufacturer and Change in Primary Packaging and Change of Label)	Manufactured by: GSK Consumer Healthcare S.A., Nyon, Switzerland For: GlaxoSmithKline Costa Rica, S.A., Costa Rica	Switzerland	Freely
98720619	Otrivin Nasal Drops Solution 0.05% Children	Manufactured by: GSK Consumer Healthcare S.A.,	Switzerland	Freely



DAN	TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	(Change of Name of Manufacturing Site and Change of Label)	Nyon, Switzerland For: GlaxoSmithKline Costa Rica, S.A., Costa Rica		
98730619	Panadol Extra Strength with Optizorb Film Coated Tablets (Change of Name of Product, Change of Artwork and Change of Label)	Manufactured by: GlaxoSmithKline Dungarvan Ltd., Ireland Packed by: GlaxoSmithKline Panama S.A., Panama	Panama	Freely
98740619	Panadol Day Non-Drowsy Tablets (Change of Name of Product, Change of Artwork and Change of Label)	Manufactured by: GlaxoSmithKline Dungarvan Ltd., Ireland Packed by: GlaxoSmithKline Panama S.A., Panama	Panama	Freely
98750619	Panadol Multi-Symptom Tablets (Change of Name of Product, Change of Artwork and Change of Label)	Manufactured by: GlaxoSmithKline Dungarvan Ltd., Ireland Packed by: GlaxoSmithKline Panama S.A., Panama	Panama	Freely
98760619	Panadol Sinus Tablets (Change of Name of Product, Change of Artwork and Change of Label)	Manufactured by: GlaxoSmithKline Dungarvan Ltd., Ireland Packed by: GlaxoSmithKline Panama S.A., Panama	Panama	Freely
98770619	Panadol Woman Tablets (Change of Artwork and Change of Label)	Manufactured by: GlaxoSmithKline Dungarvan Ltd., Ireland Packed by: GlaxoSmithKline Panama S.A., Panama	Panama	Freely
98780619	Andrews Salts Original Effervescent Powder (Additional Source, Change of Artwork and Change of Label)	Manufactured by: GlaxoSmithKline Argentina S.A., Argentina	Argentina	Freely
98790619	Andrews Salts Lemon (Change of Formulation, Additional Source, Change of Artwork and Change of Label)	Manufactured by: GlaxoSmithKline Argentina S.A., Argentina	Argentina	Freely
98800619	Benjamins Relief Diphenhydramine Elixir (Change of Name of Product, Change of Artwork and Change of Label)	Manufactured by: P.A. Benjamin Mfg. Co. Ltd. 97 East Street, Kingston, Jamaica	Jamaica	Freely



DAN	TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
98810619	Benjamins Relief Diphenhydramine Elixir – Cherry Flavour, Sugar Free, Alcohol Free (Change of Name of Product, Change of Artwork and Change of Label)	Manufactured by: P.A. Benjamin Mfg. Co. Ltd. 97 East Street, Kingston, Jamaica	Jamaica	Freely
98820619	Benjamins Relief Diphenhydramine Elixir – Grape Flavour, Sugar Free, Alcohol Free (Change of Name of Product, Change of Artwork and Change of Label)	Manufactured by: P.A. Benjamin Mfg. Co. Ltd. 97 East Street, Kingston, Jamaica	Jamaica	Freely
98830619	Benjamins Relief Diphenhydramine Expectorant (Change of Name of Product, Change of Artwork, Change of Packaging and Change of Label)	Manufactured by: P.A. Benjamin Mfg. Co. Ltd. 97 East Street, Kingston, Jamaica	Jamaica	Freely
98840619	Benjamins Relief Diphenhydramine – Expectorant – Cherry Flavour, Sugar Free, Alcohol Free (Change of Name of Product, Change of Artwork, Change of Packaging and Change of Label)	Manufactured by: P.A. Benjamin Mfg. Co. Ltd. 97 East Street, Kingston, Jamaica	Jamaica	Freely
98850619	Benjamins Relief Diphenhydramine – Expectorant – Grape Flavour, Sugar Free, Alcohol Free (Change of Name of Product, Change of Artwork, Change of Packaging and Change of Label)	Manufactured by: P.A. Benjamin Mfg. Co. Ltd. 97 East Street, Kingston, Jamaica	Jamaica	Freely
98860619T	Kytril Film-Coated Tablets 1mg (Change of Marketing Authorisation Holder, Change of Name of Manufacturer, Change of Artwork, Change of Importer and Change of Label)	Manufactured by: Delpharm Milano S.r.l., Italy Packaged by: Ivers-Lee A.G., Switzerland For: Atnahs Pharma UK Limited UK	Switzerland	Third Schedule



DAN	TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
98870619T	Kytril 3mg/3ml I.V. Injectable Solution (Change of Marketing Authorisation Holder, Change of Artwork, Change of Importer and Change of Label)	Manufactured & Packaged by: Cenexi SAS, France For: Atnahs Pharma UK Limited, UK	France	Third Schedule
98880619T	Bondronat Film-Coated Tablets 50mg (Change of Marketing Authorisation Holder, Change of Artwork, Additional Source, Change of Importer, Change of Packaging and Change of Label)	Manufacturer and Primary Packager: Penn Pharmaceutical Services Limited, Tredegar, UK Secondary Packager: Waymade PLC, UK For: Atnahs Pharma UK Limited, UK	UK	Third Schedule
98890619T	Bondronat Concentrate for Solution for Infusion 6mg/6ml (Change of Marketing Authorisation Holder, Change of Artwork, Additional Packager, Change of Importer, Change of Packaging and Change of Label)	Manufacturer and Primary Packager: Roche Diagnostics GmbH, Germany Secondary Packager: Waymade PLC, UK For: Atnahs Pharma UK Limited, UK	UK	Third Schedule
98900619T	Bonviva Solution for I.V. Injection 3mg/3ml – Pre-Filled Syringe (Change of Marketing Authorisation Holder, Change of Artwork, Change in Secondary Packager, Change of Importer, Change of Packaging and Change of Label)	Manufacturer and Primary Packager: Vetter Pharmaceutical Manufacturing GMBH & CO KG, Germany Secondary Packager: Waymade PLC, UK For: Atnahs Pharma UK Ltd., UK	UK	Third Schedule
98910619T	Bonviva Film-Coated Tablets 150mg (Change of Marketing Authorisation Holder, Artwork, Additional Packager, Change of Importer, Packaging and Label)	Manufacturer and Primary Packager: Vetter Pharmaceutical Manufacturing GMBH & CO KG, Germany Secondary Packager: Waymade PLC, UK For: Atnahs Pharma UK Ltd., UK	Uk	Third Schedule
98460619	Vit-B-Denk Film Coated Tablets 100mg + 200mg (Additional Packaging Site)	Denk Pharma GmbH & Co. KG, Germany	Germany	Freely



DAN	TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
98470619T	Clotri-Denk 1% Cream (Change of Manufacturer)	C.P.M. ContractPharma GmbH Germany	Germany	Third Schedule
98480619	Para-Denk 125 Suppository, 125mg (Alternative Manufacturer and Change of Packaging)	bene-Arzneimittel GmbH Germany	Germany	Freely
98490619	Para-Denk 250 Suppository, 250mg (Alternative Manufacturer and Change of Packaging)	bene-Arzneimittel GmbH Germany	Germany	Freely
98500619T	Aml-Denk 5 Tablet 5mg (Additional Packaging Site)	Denk Pharma GmbH & Co. KG, Germany	Germany	Third Schedule
98510619T	Aml-Denk 10 Tablet 10mg (Additional Packaging Site)	Denk Pharma GmbH & Co. KG, Germany	Germany	Third Schedule
98520619T	Synagis Solution for Injection 100mg/ml (Change of Marketing Authorisation Holder)	Manufacturing Site: Boehringer Ingelheim Pharma GmbH & Co. KG Germany Secondary Packager: Abbvie S.r.L. Italy For: Abbvie & Co. KG Deutschland GmbH Germany	Germany	Third Schedule
98530619T	Lexapro® (Escitalopram) Film-Coated Tablets 20mg (Change of Marketing Authorisation Holder)	H. Lundbeck A/S, Valby, Denmark For: Lundbeck America Central, S.A., Panama City, Republic of Panama	Denmark	Third Schedule
98540619	Kalms Day 84 Tablets & 200 Tablets (Change of Formulation and Change of Label)	G.R. Lane Health Product Limited, United Kingdom	UK	Freely
98550619T	Blopress Tablets 8mg (Change of Packaging and Change of Label)	Abbott Laboratories Argentina S.A., Argentina	Argentina	Third Schedule
98560619T	Blopress Tablets 16mg (Change of Packaging and Change of Label)	Abbott Laboratories Argentina S.A., Argentina	Argentina	Third Schedule
98570619T	Blopress Plus Tablets 16mg/12.5mg (Change of Packaging and Change of Label)	Takeda Ireland Ltd., Ireland Packaged by: Abbott Laboratories, Argentina S.A., Argentina	Argentina	Third Schedule
98580619T	Avonex 30mcg/0.5ml Solution for Injection (Change of Formulation, Change of Packaging,	Vetter Pharma-Fertigung, GmbH & Co. KG, Langenargen, Germany	Argentina	Third Schedule



DAN	TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Change of Label and New Manufacturing Site)			
98590619T	Cytax 30 Paclitaxel Injection USP Concentrate 30mg/5ml (Change of Packaging)	Intas Pharmaceuticals Limited	Germany	Third Schedule
98600619T	Cytax 100 Paclitaxel Injection USP Concentrate 100mg/16.7ml (Change of Packaging)	Intas Pharmaceuticals Limited	India	Third Schedule
98610619T	Cytax 300 Paclitaxel Injection USP Concentrate 300mg/50ml (Change of Packaging)	Intas Pharmaceuticals Limited	India	Third Schedule
98620619T	Accentrix Solution for Injection 10mg/ml (Change of Marketing Authorisation Holder, Change of Indications for Use and Change of Label)	Novartis Pharma Stein AG	India	Third Schedule
98630619T	Voltaren Emulgel 1.16% (Change of Manufacturing Site Name and Change of Label)	Manufactured by: GSK Consumer Healthcare S.A., Switzerland For: GlaxoSmithKline Costa Rica, S.A., Costa Rica	Switzerland	Third Schedule
98640619T	Procto-Glyvenol Suppositories (Change of Product License Holder and Change of Label)	Manufactured by: Delpharm Huningue S.A.S, France For: GlaxoSmithKline, S.A., Costa Rica	France	Third Schedule
98650619T	Procto-Glyvenol Cream (Change of Product License Holder, Change of Manufacturing Site Name and Change of Label)	Manufactured by: GSK Consumer Healthcare S.A., Switzerland For: GlaxoSmithKline Costa Rica, S.A., Costa Rica	Switzerland	Third Schedule
98660619T	Lamisil Dermgel 1% (Change of Product License Holder, Change of Name of Manufacturing Site, Change of Packaging and Change of Label)	Manufactured by: GSK Consumer Healthcare S.A., Switzerland For: GlaxoSmithKline Costa Rica, S.A., Costa Rica	Switzerland	Third Schedule
98670619T	Lamisil Cream 1% (Change of Product License Holder, Change of Manufacturing Site Name and Change of Label)	Manufactured by: GSK Consumer Healthcare S.A., Switzerland For: GlaxoSmithKline Costa Rica, S.A., Costa Rica	Switzerland	Third Schedule



DAN	TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
98680619T	Lamisil Spray 1% (Change of Product License Holder and Change of Label)	Manufactured by: Delpharm Huningue S.A.S., France For: GlaxoSmithKline Costa Rica, S.A., Costa Rica	France	Third Schedule
98690619	Otrivin Nasal Spray Nebulizer Solution 0.1% (Change of Name of Manufacturing Site and Change of Label)	Manufactured by: GSK Consumer Healthcare S.A., Nyon Switzerland For: GlaxoSmithKline Costa Rica, S.A., Costa Rica	Switzerland	Freely
98700619	Otrivin Nasal Drops Solution 0.1% (Change of Name of Manufacturing Site and Change of Label)	Manufactured by: GSK Consumer Healthcare S.A., Nyon Switzerland For: GlaxoSmithKline Costa Rica, S.A., Costa Rica	Switzerland	Freely
98710619	Otrivin Metered Dose Nasal Spray 0.1% (Change of Name of Manufacturer, Primary Packaging and Label)	Manufactured by: GSK Consumer Healthcare S.A., Nyon, Switzerland For: GlaxoSmithKline Costa Rica, S.A., Costa Rica	Switzerland	Freely
98720619	Otrivin Nasal Drops Solution 0.05% Children (Change of Name of Manufacturing Site and Change of Label)	Manufactured by: GSK Consumer Healthcare S.A., Nyon, Switzerland For: GlaxoSmithKline Costa Rica, S.A., Costa Rica	Switzerland	Freely
98730619	Panadol Extra Strength with Optizorb Film Coated Tablets (Change of Name of Product, Change of Artwork and Change of Label)	Manufactured by: GlaxoSmithKline Dungarvan Ltd., Ireland Packed by: GlaxoSmithKline Panama S.A., Panama	Panama	Freely
98740619	Panadol Day Non-Drowsy Tablets (Change of Name of Product, Change of Artwork and Change of Label)	Manufactured by: GlaxoSmithKline Dungarvan Ltd., Ireland Packed by: GlaxoSmithKline Panama S.A., Panama	Panama	Freely
98750619	Panadol Multi-Symptom Tablets (Change of Name of Product, Change of Artwork and Change of Label)	Manufactured by: GlaxoSmithKline Panama S.A., Panama	Panama	Freely
98760619	Panadol Sinus Tablets (Change of Name of Product, Change of Artwork and Change of Label)	Manufactured by: GlaxoSmithKline Panama S.A., Panama	Panama	Freely



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DAN	TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
98770619	Panadol Woman Tablets (Change of Artwork and Change of Label)	Manufactured by: GlaxoSmithKline Panama S.A., Panama	Panama	Freely
98780619	Andrews Salts Original Effervescent Powder (Additional Source, Change of Artwork and Change of Label)	Manufactured by: GlaxoSmithKline Argentina S.A., Argentina	Argentina	Freely
98790619	Andrews Salts Lemon (Change of Formulation, Additional Source, Change of Artwork and Change of Label)	Manufactured by: GlaxoSmithKline Argentina S.A., Argentina	Argentina	Freely
98800619	Benjamins Relief Diphenhydramine Elixir (Change of Name of Product, Change of Artwork and Change of Label)	Manufactured by: P.A. Benjamin Mfg. Co. Ltd. 97 East Street, Kingston, Jamaica	Jamaica	Freely
98810619	Benjamins Relief Diphenhydramine Elixir – Cherry Flavour, Sugar Free, Alcohol Free (Change of Name of Product, Change of Artwork and Change of Label)	Manufactured by: P.A. Benjamin Mfg. Co. Ltd. 97 East Street, Kingston, Jamaica	Jamaica	Freely
98820619	Benjamins Relief Diphenhydramine Elixir – Grape Flavour, Sugar Free, Alcohol Free (Change of Name of Product, Change of Artwork and Change of Label)	Manufactured by: P.A. Benjamin Mfg. Co. Ltd. 97 East Street, Kingston, Jamaica	Jamaica	Freely
98830619	Benjamins Relief Diphenhydramine Expectorant (Change of Name of Product, Change of Artwork, Change of Packaging and Change of Label)	Manufactured by: P.A. Benjamin Mfg. Co. Ltd. 97 East Street, Kingston, Jamaica	Jamaica	Freely
98840619	Benjamins Relief Diphenhydramine – Expectorant – Cherry Flavour, Sugar Free, Alcohol Free (Change of Name of Product, Change	Manufactured by: P.A. Benjamin Mfg. Co. Ltd. 97 East Street, Kingston, Jamaica	Jamaica	Freely



DAN	TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	of Artwork, Change of Packaging and Change of Label)			
98850619	Benjamins Relief Diphenhydramine – Expectorant – Grape Flavour, Sugar Free, Alcohol Free (Change of Name of Product, Change of Artwork, Change of Packaging and Change of Label)	Manufactured by: P.A. Benjamin Mfg. Co. Ltd. 97 East Street, Kingston, Jamaica	Jamaica	Freely
98860619T	Kytril Film-Coated Tablets 1mg (Change of Marketing Authorisation Holder, Change of Name of Manufacturer, Change of Artwork, Change of Importer and Change of Label)	Manufactured by: Delpharm Milano S.r.l., Italy Packaged by: Ivers-Lee A.G., Switzerland For: Atnahs Pharma UK Limited UK	Switzerland	Third Schedule
98870619T	Kytril 3mg/3ml I.V. Injectable Solution (Change of Marketing Authorisation Holder, Change of Artwork, Change of Importer and Change of Label)	Manufactured & Packaged by: Cenexi SAS, France For: Atnahs Pharma UK Limited,UK	France	Third Schedule
98880619T	Bondronat Film-Coated Tablets 50mg (Change of Marketing Authorisation Holder, Change of Artwork, Additional Source, Change of Importer, Change of Packaging and Change of Label)	Manufacturer and Primary Packager: Penn Pharmaceutical Services Limited, Tredegar, UK Secondary Packager: Waymade PLC, UK For: Atnahs Pharma UK Limited, UK	UK	Third Schedule
98890619T	Bondronat Concentrate for Solution for Infusion 6mg/6ml (Change of Marketing Authorisation Holder, Artwork, Importer, Packaging, Label and Additional Packager)	Manufacturer and Primary Packager: Roche Diagnostics GmbH, Germany Secondary Packager: Waymade PLC, UK For: Atnahs Pharma UK Limited, UK	UK	Third Schedule
98900619T	Bonviva Solution for I.V. Injection 3mg/3ml – Pre-Filled Syringe (Change of Marketing Authorisation	Manufacturer and Primary Packager: Vetter Pharmaceutical Manufacturing GMBH & CO KG, Germany	UK	Third Schedule



DAN	TRADE NAME AND FORM	MANUFACTURER	COUNTRY OF ORIGIN	CONDITION OF SALE
	Holder, Change of Artwork, Change in Secondary Packager, Change of Importer, Change of Packaging and Change of Label)	Secondary Packager: Waymade PLC, UK For: Atnahs Pharma UK Ltd., UK		
98910619T	Bonviva Film-Coated Tablets 150mg (Change of Marketing Authorisation Holder, Change of Artwork, Additional Packager, Change of Importer, Change of Packaging and Change of Label)	Manufacturer and Primary Packager: Penn Pharmaceutical Services Limited Tredegar, UK Secondary Packager: Waymade PLC, UK For: Atnahs Pharma UK Ltd.	UK	Third Schedule



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