

Consent to the Distribution of New Medicines

Pursuant to section 20 of the Medicines Act 1981, the Minister of Health hereby consents to the distribution in New Zealand of the new medicines which were referred to the Minister of Health under the provisions of section 24(5) of the Act and are set out in the Schedule hereto:

Schedule

Product: **Kadcyla**
Active Ingredient: Trastuzumab emtansine 100mg
Dosage Form: Powder for infusion
New Zealand Sponsor: Roche Products (NZ) Limited
Manufacturers: Patheon Manufacturing Services LLC, North Carolina, United States of America
 F Hoffmann-La Roche Limited, Kaiseraugst, Switzerland

Product: **Kadcyla**
Active Ingredient: Trastuzumab emtansine 160mg
Dosage Form: Powder for infusion
New Zealand Sponsor: Roche Products (NZ) Limited
Manufacturers: Patheon Manufacturing Services LLC, North Carolina, United States of America
 F Hoffmann-La Roche Limited, Kaiseraugst, Switzerland

Product: **Spiriva Respimat**
Active Ingredient: Tiotropium bromide monohydrate 3.125mcg equivalent to tiotropium 2.5mcg/dose
Dosage Form: Solution for inhalation
New Zealand Sponsor: Boehringer Ingelheim (NZ) Limited
Manufacturer: Boehringer Ingelheim Pharma GmbH & Co KG, Ingelheim am Rhein, Germany

Product: **Sustanon 250**
Active Ingredients: Testosterone decanoate 100mg/mL
 Testosterone isocaproate 60mg/mL
 Testosterone phenylpropionate 60mg/mL
 Testosterone propionate 30mg/mL
Dosage Form: Solution for injection
New Zealand Sponsor: Pharmacy Retailing (NZ) Limited t/a Healthcare Logistics
Manufacturers: NV Organon, Oss, Netherlands
 EVER Pharma Jena GmbH, Jena, Germany

Product: **Uptravi**
Active Ingredient: Selexipag 200mcg
Dosage Form: Film coated tablet
New Zealand Sponsor: Janssen-Cilag (New Zealand) Limited
Manufacturer: Excella GmbH & Co KG, Feucht, Germany

Product: **Uptravi**
Active Ingredient: Selexipag 400mcg
Dosage Form: Film coated tablet
New Zealand Sponsor: Janssen-Cilag (New Zealand) Limited
Manufacturer: Excella GmbH & Co KG, Feucht, Germany

Product: **Uptravi**
Active Ingredient: Selexipag 600mcg
Dosage Form: Film coated tablet
New Zealand Sponsor: Janssen-Cilag (New Zealand) Limited
Manufacturer: Excella GmbH & Co KG, Feucht, Germany

Product: **Uptravi**
Active Ingredient: Selexipag 800mcg
Dosage Form: Film coated tablet

NEW ZEALAND GAZETTE

New Zealand Sponsor: Janssen-Cilag (New Zealand) Limited
Manufacturer: Excella GmbH & Co KG, Feucht, Germany

Product: **Uptravi**
Active Ingredient: Selexipag 1000mcg
Dosage Form: Film coated tablet
New Zealand Sponsor: Janssen-Cilag (New Zealand) Limited
Manufacturer: Excella GmbH & Co KG, Feucht, Germany

Product: **Uptravi**
Active Ingredient: Selexipag 1200mcg
Dosage Form: Film coated tablet
New Zealand Sponsor: Janssen-Cilag (New Zealand) Limited
Manufacturer: Excella GmbH & Co KG, Feucht, Germany

Product: **Uptravi**
Active Ingredient: Selexipag 1400mcg
Dosage Form: Film coated tablet
New Zealand Sponsor: Janssen-Cilag (New Zealand) Limited
Manufacturer: Excella GmbH & Co KG, Feucht, Germany

Product: **Uptravi**
Active Ingredient: Selexipag 1600mcg
Dosage Form: Film coated tablet
New Zealand Sponsor: Janssen-Cilag (New Zealand) Limited
Manufacturer: Excella GmbH & Co KG, Feucht, Germany

Dated this 14th day of October 2019.

CHRIS JAMES, Group Manager, Medsafe, Ministry of Health (pursuant to delegation given by the Minister of Health on 11 September 2013).