

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 set out in the Schedule hereto:

Schedule

Product: **AdiraMedica Docusate Sodium & Senna Tablets**
Active Ingredients: Docusate sodium 50mg Sennoside A+B calcium 40mg equivalent to Sennosides B 8mg
Dosage Form: Film coated tablet
New Zealand Sponsor: AdiraMedica Pty Limited
Manufacturer: Sunglow Lifescience Private Limited, Uthiramerur Taluk, India

Product: **Jemperli**
Active Ingredient: Dostarlimab 50mg/mL
Dosage Form: Solution for infusion
New Zealand Sponsor: GlaxoSmithKline NZ Limited
Manufacturers: Glaxo Operations UK Limited t/a Glaxo Wellcome Operations, Barnard Castle, United Kingdom
 Ajinomoto Althea Inc, California, United States of America

Product: **Omlyclo (75mg/0.5mL)**
Active Ingredient: Omalizumab 150mg/mL
Dosage Form: Solution for injection
New Zealand Sponsor: Celltrion Healthcare New Zealand Limited
Manufacturer: Celltrion Pharm Inc, Cheongju-si, South Korea

Product: **Omlyclo (150mg/1mL)**
Active Ingredient: Omalizumab 150mg
Dosage Form: Solution for injection
New Zealand Sponsor: Celltrion Healthcare New Zealand Limited
Manufacturer: Celltrion Pharm Inc, Cheongju-si, South Korea

Product: **Terlipressin Acetate AFT**
Active Ingredient: Terlipressin acetate 0.12mg/mL equivalent to terlipressin 0.1mg/mL
Dosage Form: Solution for injection
New Zealand Sponsor: AFT Pharmaceuticals Limited
Manufacturer: Hainan Poly Pharma Co. Limited, Haikou, China

Dated this 1st day of April 2025.

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