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: Labixten meltlets double strength

Active Ingredient: Bilastine 20mg
Dosage Form: Orodispersible tablet

New Zealand Sponsor: A. Menarini New Zealand Pty Limited

Manufacturer: Faes Farma S.A, Leioa, Spain

Product: Trikafta 100/50/75

Component 1:

Active Ingredients: Elexacaftor 100mg

Ivacaftor 75mg
Tezacaftor 50mg
Oral grapules

Dosage Form: Oral granules

Component 2:

Active Ingredient: Ivacaftor 75mg

Dosage Form: Oral granules

New Zealand Sponsor: Pharmacy Retailing (NZ) Limited t/a Healthcare Logistics

Manufacturers: Almac Pharma Services Limited, Craigavon, United Kingdom Halo Pharmaceutical Inc, New Jersey, United States of America

Pharmaceutical Manufacturing Research Services Inc, Pennsylvania, United States of

America

Catalent Greenville Inc, North Carolina, United States of America

Product: Trikafta 80/40/60

Component 1:

Active Ingredients: Elexacaftor 80mg

Ivacaftor 60mg Tezacaftor 40mg

Dosage Form: Oral granules

Component 2:

Active Ingredient: Ivacaftor 59.5mg
Dosage Form: Oral granules

New Zealand Sponsor: Pharmacy Retailing (NZ) Limited t/a Healthcare Logistics

Manufacturers: Almac Pharma Services Limited, Craigavon, United Kingdom Halo Pharmaceutical Inc, New Jersey, United States of America

Pharmaceutical Manufacturing Research Services Inc, Pennsylvania, United States of

America

Catalent Greenville Inc., North Carolina, United States of America

Product: Wegovy

Active Ingredient: Semaglutide 0.68mg/mL
Dosage Form: Solution for injection

New Zealand Sponsor: Novo Nordisk Pharmaceuticals Limited

Manufacturers: Novo Nordisk A/S, Hovedstaden, Denmark

Novo Nordisk A/S, Hillerod, Denmark

Product: Wegovy (0.5mg FlexTouch)

Active Ingredient: Semaglutide 1.34mg/mL Dosage Form: Solution for injection

New Zealand Sponsor: Novo Nordisk Pharmaceuticals Limited

Manufacturers: Novo Nordisk A/S, Hovedstaden, Denmark

Novo Nordisk A/S, Hillerod, Denmark

Product:Wegovy (1mg FlexTouch)Active Ingredient:Semaglutide 1.34mg/mL

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NEW ZEALAND GAZETTE

Dosage Form: Solution for injection

New Zealand Sponsor: Novo Nordisk Pharmaceuticals Limited

Manufacturers: Novo Nordisk A/S, Hovedstaden, Denmark

Novo Nordisk A/S, Hillerod, Denmark

Product: Wegovy

Active Ingredient: Semaglutide 2.27mg/mL Dosage Form: Solution for injection

New Zealand Sponsor: Novo Nordisk Pharmaceuticals Limited

Manufacturers: Novo Nordisk A/S, Hovedstaden, Denmark

Novo Nordisk A/S, Hillerod, Denmark

Product: Wegovy

Active Ingredient: Semaglutide 3.2mg/mL Dosage Form: Solution for injection

New Zealand Sponsor: Novo Nordisk Pharmaceuticals Limited

Manufacturers: Novo Nordisk A/S, Hovedstaden, Denmark
Novo Nordisk A/S, Hillerod, Denmark

Dated this 14th day of March 2025.

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

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