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:	Kisqali
Active Ingredient:	Ribociclib succinate 254.4mg equivalent to ribociclib 200mg
Dosage Form:	Film coated tablet
New Zealand Sponsor:	Novartis New Zealand Limited
Manufacturers:	Novartis Singapore Pharmaceutical Manufacturing Pte Limited, Singapore Novartis Pharmaceutical Manufacturing LLC, Ljubljana, Slovenia
	Novartis Filarinaceuticai Manufacturing EEC, Ejubijana, Siovenia
Product:	Riximyo
Active Ingredient:	Rituximab 10mg/mL
Dosage Form:	Concentrate for infusion
New Zealand Sponsor:	Sandoz New Zealand Limited
Manufacturers:	Lek Pharmaceuticals d.d., Ljubljana, Slovenia
	Novartis Pharmaceutical Manufacturing LLC, Ljubljana, Slovenia
Product:	Zolgensma (8.3mL vial)
Active Ingredient:	Onasemnogene abeparvovec 20TVG/mL
Dosage Form:	Solution for infusion
New Zealand Sponsor:	Novartis New Zealand Limited
Manufacturer:	Novartis Gene Therapies, Inc., North Carolina, United States of America
Product:	Zolgensma (5.5mL vial + 8.3mL vial)
Active Ingredient:	Onasemnogene abeparvovec 20TVG/mL
Dosage Form:	Solution for infusion
New Zealand Sponsor:	Novartis New Zealand Limited
Manufacturer:	Novartis Gene Therapies, Inc., North Carolina, United States of America

Dated this 4th 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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