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: FluQuadri

Active Ingredients: Influenza virus A/California/7/2009 (H1N1) – like strain 15mcg

Influenza virus A/Victoria/361/2011 (H3N2) - like strain 15mcg

Influenza virus B/Brisbane/60/2008 - like strain 15mcg Influenza virus B/Massachusetts/2/2012 - like strain 15mcg

Dosage Form: Suspension for injection

New Zealand Sponsor: sanofi-aventis new zealand limited

Manufacturer: Sanofi Pasteur Inc, Pennsylvania, United States of America

Product: FluQuadri Junior

Active Ingredients: Influenza virus A/California/7/2009 (H1N1) – like strain 7.5mcg

Influenza virus A/Victoria/361/2011 (H3N2) – like strain 7.5mcg Influenza virus B/Brisbane/60/2008 – like strain 7.5mcg Influenza virus B/Massachusetts/2/2012 – like strain 7.5mcg

Dosage Form: Suspension for injection

New Zealand Sponsor: sanofi-aventis new zealand limited

Manufacturer: Sanofi Pasteur Inc, Pennsylvania, United States of America

Product: Levoclear

Active Ingredient: Levocetirizine hydrochloride 5mg

Dosage Form: Film coated tablet

New Zealand Sponsor: AFT Pharmaceuticals Limited

Manufacturer: Zaklad Farmaceutyczny Adamed Pharma S.A., Ksawerow, Poland

Product: Xeomin

Active Ingredient/s: Botulinum toxin type A 50LD50 Units

Dosage Form: Powder for injection

New Zealand Sponsor: New Zealand Medical & Scientific Limited

Manufacturers: Merz Pharma GmbH & Co KGaA, Dessau-Rosslau, Germany

IDT Biologika GmbH, Dessau-Rosslau, Germany

Product: Xeomin

Active Ingredient: Botulinum toxin type A 100LD50 Units

Dosage Form: Powder for injection

New Zealand Medical & Scientific Limited

Manufacturers: Merz Pharma GmbH & Co KGaA, Dessau-Rosslau, Germany

IDT Biologika GmbH, Dessau-Rosslau, Germany

Product: Zaltrap

Active Ingredient: Aflibercept 25mg/mL (100mg/4mL)

Dosage Form: Concentrate for infusion

New Zealand Sponsor: sanofi-aventis new zealand limited

Manufacturer: Sanofi-Aventis Deutschland GmbH, Frankfurt, Germany

Product: Zaltrap

Active Ingredient: Aflibercept 25mg/mL (200mg/8mL)

Dosage Form: Concentrate for infusion

New Zealand Sponsor: sanofi-aventis new zealand limited

Manufacturer: Sanofi-Aventis Deutschland GmbH, Frankfurt, Germany

Dated this 12th day of December 2014.

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

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