



New Zealand Gazette

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Departmental Notice

Health

Medicines Act 1981

Suspension of Consent to the Distribution of a New Medicine

Pursuant to section 35 of the Medicines Act 1981, the Minister of Health hereby suspends the consent to the distribution in New Zealand of the new medicine set out in the Schedule hereto:

Schedule

<i>Product:</i>	Vaxigrip vaccine
<i>Active Ingredients:</i>	Influenza virus A/Wellington/1/2004(H3N2)-like strain 15µg/0.5mL dose Influenza virus B/Shanghai/361/2002-like strain 15µg/0.5mL dose Influenza virus haemagglutinin type A/New Caledonia/20/99 H1N1-like strain 15µg/0.5mL dose
<i>Dosage Form:</i>	Injection, solution
<i>New Zealand Sponsor:</i>	Aventis Pharma Limited
<i>Manufacturer:</i>	Sanofi Pasteur SA France.

Dated this 10th day of April 2005.

DON MATHESON, Deputy Director-General, Public Health (pursuant to delegation given by the Minister of Health on 6 July 2001).

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Provisional Consent to the Distribution of a New Medicine

Pursuant to section 23 of the Medicines Act 1981, the Minister of Health hereby provisionally consents to the sale, supply or use in New Zealand of the new medicine set out in the Schedule hereto:

Schedule

<i>Product:</i>	Vaxigrip vaccine
<i>Active Ingredients:</i>	Influenza virus A/Wellington/1/2004(H3N2)-like strain 10µg/dose Influenza virus B/Shanghai/361/2002-like strain 15µg/dose Influenza virus haemagglutinin type A/New Caledonia/20/99 H1N1-like strain 15µg/dose
<i>Dosage Form:</i>	Solution for injection
<i>New Zealand Sponsor:</i>	Aventis Pharma Limited

Manufacturers: Aventis Pasteur SA, Marcy L'Etoile, France
Aventis Pasteur SA, Val-De-Reuil Cedex, France

Note: This consent is given subject to the following conditions:

- The vaccine is approved as a single dose of vaccine for administration to individuals age under 65 years who are at low-risk from either influenza infection or the complications of influenza infection.
- The vaccine must be distributed with an appropriate and agreed "Dear Doctor" letter.

Note: This consent is valid until 31 March 2006.

Dated this 11th day of April 2005.

DON MATHESON, Deputy Director-General, Public Health (pursuant to delegation given by the Minister of Health on 6 July 2001).

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