**EXPLANATORY STATEMENT**

**Issued by the Authority of the delegate of the Minister for Health**

***National Health Act 1953***

***National Health (Immunisation Program – Designated Vaccines) Variation Determination 2012 (No.3)***

**Legislation**

Section 9B(1) of the *National Health Act 1953* (the Act) states that the Minister may provide, or arrange for the provision of, designated vaccines and goods or services that are associated with, or incidental to, the provision or administration of designated vaccines. Section 9B(2) provides that the Minister may, by legislative instrument, determine that a specified vaccine is a designated vaccine for the purposes of this Act. Section 9B(5) provides that in addition to specifying a vaccine, a determination under subsection (2) may specify the circumstances in which the vaccine may be provided. The *National Health (Immunisation Program – Designated Vaccine) Determination 2012 (No.1)* (the Principal Determination) designates vaccines in accordance with subsection 9B(2) of the Act and specifies circumstances in which designated vaccines may be provided.

**Purpose**

The purpose of this Determination is to vary the Principal Determination to update the composition of the trivalent influenza vaccines (which are *Vaxigrip®, Fluvax®, Influvac®* and *Fluarix®* and *Vaxigrip Junior®* )for the 2013 and future influenza seasons.

As the composition of the influenza vaccine may change every one to two years the amendment removes the requirement for the Pharmaceutical Benefits Advisory Committee (PBAC) to provide advice on the addition of the new composition of listed trivalent influenza vaccines on each occasion that the vaccine composition is altered to reflect strain changes of circulating influenza viruses.

It also varies the circumstances for use of *Fluvax* which is no longer registered for use in children less than 5 years of age. This variation in circumstances removes *Fluvax Junior ®* from the Determination, as it was only for use in children between the ages of 6 months and 3 years.

**Background**

These trivalent influenza vaccines are designated vaccines in accordance with subsection 9B(2) of the Act.

A designated vaccine may be provided free of charge to eligible people under the National Immunisation Program (NIP), in the circumstances set out in the Principal Determination.

Section 9B(7) of the Act provides that a vaccine must not be specified in a determination under section 9B(2) unless the Pharmaceutical Benefits Advisory Committee (PBAC) has recommended to the Minister for Health that it be a designated vaccine.

Influenza viruses undergo frequent changes in their surface antigens. This is responsible for the annual outbreaks and epidemics of influenza and is the reason that the composition of influenza vaccines requires annual review. The World Health Organization (WHO) convenes technical consultations in February and September each year to recommend viruses for inclusion in seasonal influenza vaccines for both the northern and southern hemispheres. The Australian Influenza Vaccine Committee (AIVC) considers WHO’s recommendation in providing its advice to the Therapeutic Goods Administration (TGA) on the composition of the vaccine to be used Australia. The TGA’s decision on the composition of the trivalent seasonal influenza vaccine to be used each year is published on its website at: www.tga.gov.au

This Instrument does not vary the designated seasonal influenza vaccines.

**Instrument Description**

Items 205 and 206 in Schedule 1, Part 1 have been amended to remove reference to the composition of the trivalent influenza vaccine.

The composition of the vaccine is determined by the TGA following advice from WHO and the AIVC.

It also varies the circumstances for use of *Fluvax Junior* which is no longer registered for use in children less than 5 years of age.

As a result of the amendments, other minor formatting amendments have been made.

This instrument is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

The instrument will commence on the day after it is registered on the Federal Register of Legislative Instruments.

**Consultation**

The Department of Health and Ageing has consulted with the TGA in relation to the changes in composition of the seasonal influenza vaccine which result from the different strains of influenza. The PBAC has also been consulted on the amendments to the Determination. The PBAC has agreed that is not necessary for it to consider variations in the composition of the brands of seasonal influenza vaccines already included on the Determination. The variation to the listing for Fluvax is also appropriate as this vaccine is not approved for use in children under 5 years of age.

**Statement of Compatibility with Human Rights**

*Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011*

**National Health (Immunisation Program – Designated Vaccines) Variation
Determination 2012 (No.3)**

This legislative instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

**Overview of the legislative instrument**

The legislative instrument varies the *National Health (Immunisation Program – Designated Vaccines) Determination 2012 (No.1)*(the Principal Determination) which designates vaccines in accordance with subsection 9B(2) of the Act, and specifies circumstances in which designated vaccines may be provided.

This instrument varies the Principal Determination by updating the seasonal influenza strains for 2013 as recommended by the World Health Organization (WHO).

**Human rights implications**

This legislative instrument engages Articles 2 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) by assisting with the progressive realisation by all appropriate means of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

The NIP assists the advancement of this human right by providing free access for eligible people to designated vaccines. This is a positive step towards attaining the highest standard of health for all Australians. Efficient operational arrangements for the NIP support effective administration of the Program.

The NIP also assists the advancement of Article 1 of the ICESCR. Since vaccination is not mandatory in Australia this enables the right to self-determination.

**Conclusion**

This legislative instrument is compatible with human rights because it advances the protection of human rights.

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