

## **EXPLANATORY STATEMENT**

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

*National Health Act 1953*

*National Health (Immunisation Program – Designated Vaccines) Determination 2014  
(No.1)*

### **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.

### **Purpose**

This Determination revokes and replaces the *National Health (Immunisation Program – Designated Vaccines) Determination 2012 (No.1)*.

The purpose of the *National Health (Immunisation Program – Designated Vaccines) Determination 2014 (No.1)* (the New Determination) is to designate vaccines in accordance with subsection 9B(2) of the Act, and specify circumstances in which designated vaccines may be provided.

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 New Determination.

### **Background**

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.

In November 2009, PBAC recommended the listing of Agrippal<sup>®</sup>, and in March 2010 the PBAC recommended the listing of Fluvirin<sup>®</sup> on the NIP, to allow for the sponsor to participate in future national tenders.

In July 2008, PBAC agreed that measles-mumps-rubella-varicella (MMRV) or MMR and varicella vaccine (VV) at 18 months of age, in case of a shortage of MMRV vaccine, be listed.

### **Instrument Description**

The *National Health (Immunisation Program - Designated Vaccines) Determination 2012 (No.1)* (the Previous Determination) was made on 24 September 2012, came into effect on 28 September 2012, and was last amended on 15 June 2013.

The Legislative Instrument is substantively the same as the previous Determination, with the addition of two new Trivalent Influenza Vaccines Agrippal<sup>®</sup> and Fluvirin<sup>®</sup>, and the addition of additional circumstances for the provision of the MMR vaccines Priorix and MMR-II.

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

The instrument commenced on the day after it was registered on the Federal Register of Legislative Instruments.

### **Consultation**

The Office of Best Practice Regulation considers that regulatory amendments that update the listing of vaccines on the National Immunisation Program and their associated price to be machinery in nature. Therefore in accordance with section 18(a) of the Legislative Instruments Act it has been determined that further consultation is unnecessary.

## **NOTES ON SECTIONS**

### **Section 1 – Name of Declaration**

This section provides that the title of the Determination is the *National Health (Immunisation Program – Designated Vaccines) Determination 2014 (No.1)*.

### **Section 2 – Commencement**

This section provides for the Determination to commence the day after it is registered.

### **Section 3 – Repeal**

This section repeals the previous Determination which was made on 24 September 2012, came into effect on 28 September 2012, and was last amended on 15 June 2013.

### **Section 4 – Definitions**

This section provides for defined terms to be used in the Determination and gives shortened reference to the *National Health Act 1953*.

### **Section 5 – Designated vaccines**

This section sets out the list of designated vaccines for the purpose of section 9B(2) of the National Health Act. This list will replace the previous list of vaccines that was last amended on 15 June 2013.

### **Section 6 – Circumstances in which designated vaccines may be provided**

This section sets out the circumstances under which designated vaccines may be provided, for the purpose of section 9B(5) of the National Health Act. This list will replace the previous list of vaccines that was last amended on 15 June 2013.

### **Section 7 – Circumstances in which designated vaccines may be provided – particular vaccines**

This section sets out the circumstances under which particular designated vaccines may be provided, for the purpose of section 9B(5) of the National Health Act. This list will replace the previous list of vaccines that was last amended on 15 June 2013.

## **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) Determination 2014 (No.1)**

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

The Legislative Instrument is substantively the same as the Previous Determination, with the addition of two new Trivalent Influenza Vaccines Agrippal<sup>®</sup> and Fluvirin<sup>®</sup>, and the addition of additional circumstances for the provision of the MMR vaccines Priorix and MMR-II.

#### **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 National Immunisation Program (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, by protecting individuals and the community against vaccine preventable disease. Efficient operational arrangements for the NIP support effective administration of the Program.

The NIP is also consistent with 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 as outlined above.

**Julianne Quaine**  
**Assistant Secretary**  
**Office of Health Protection**  
**Department of Health and Ageing**