**EXPLANATORY STATEMENT**

***Australian Immunisation Register Act 2015***

***Australian Immunisation Register Amendment (Reporting) Rules 2024***

**Purpose and operation**

The *Australian Immunisation Register Amendment (Reporting) Rules 2024* (Amendment Rules) amends the *Australian Immunisation Register Rule 2015* (AIR Rule) to introduce two reporting requirements for recognised vaccination providers from 1 March 2024. Firstly, for a recognised vaccination provider administering a Japanese encephalitis virus vaccine to report to the Australian Immunisation Register (AI register) information about the route of administration. Secondly, for a recognised vaccination provider administering a relevant vaccine prescribed by the AIR Rule to report to the AI register information about the vaccine type.

The requirement to report route of administration of the Japanese encephalitis virus vaccine (under the Amendment Rules) is needed to identify if the vaccine was given intradermally or subcutaneously. Intradermal administration has been recommended to ease supply constraints in the event of a Japanese encephalitis virus outbreak, as this route of administration uses less vaccine than the subcutaneous route of delivery. Reporting route of administration will also provide the ability to monitor vaccine effectiveness, and any safety and adverse effects. The Amendment Rules will also add the requirement to report information about the vaccine type. This information will be used for the ongoing management of the National Immunisation Program (NIP).

In general, both amendments will improve reporting to the AI register to ensure individuals have a complete record of their vaccinations and better inform program delivery and performance. It will also assist with monitoring the effectiveness of vaccines and vaccination programs and to identify parts of Australia at risk during disease outbreaks.

**Background**

Section 10A of the *Australian Immunisation Register Act 2015* (AIR Act) requires recognised vaccination providers to report certain vaccinations administered within a particular period and in the required manner to the AI register as prescribed by the rules. The current rules are dictated by theAIR Rule. Under section 9(a) of the AIR Rule, a recognised vaccination provider must report to the AI register: COVID-19 vaccines, influenza vaccines, vaccines given under the NIP and Japanese encephalitis virus vaccines. Subsection 9(e) of the AIR Rule prescribes the required information to be reported by the recognised vaccination provider for inclusion in the AI register including patient details, provider details and vaccine details.

It is important to note that the Amendment Rules do not make vaccination mandatory. It is only mandatory to report to the AI register the additional information relating to vaccinations.

In addition, under subsection 10A(2) of the AIR Act, a recognised vaccination provider is not required to comply with these reporting requirements where the recording of information is likely to pose a risk to the health or safety or an individual. A person who fails to comply with their reporting obligations under subsections 10A(1) or (3) of the AIR Act may be liable to a civil penalty of 30 penalty units in accordance with subsection 10A(5).

**Authority**

Subsection 31(1) of the AIR Act provides that the Minister may, by legislative instrument, make rules prescribing matters required or permitted by the AIR Act to be prescribed by the rules; or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

**Reliance on subsection 33(3) of the *Acts Interpretation Act 1901***

Subsection 33(3) of the *Acts Interpretation Act 1901* provides that where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character (including rules, regulations or by-laws), the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument.

**Commencement**

The Amendment Rules commence on 1 March 2024.

**Consultation**

The Department of Health and Aged Care (the department) consulted with Services Australia and Jurisdictional Immunisation Coordinators in each state and territory on the proposed amendments to the AIR Rule. Stakeholders are supportive of the proposed amendments.

The department and Services Australia will undertake communication activities to ensure that key stakeholders, including vaccination providers, are aware of the new mandatory reporting requirements for vaccinations resulting from the Amendment Rules.

**General**

The Amendment Rules are a legislative instrument for the purposes of the *Legislation Act 2003*.

Details of the Amendment Rules are set out in **Attachment A**.

The Amendment Rules are compatible with the human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment B**.

**ATTACHMENT A**

**Details of the *Australian Immunisation Register Amendment (Reporting) Rules 2024***

**Section 1 – Name**

Section 1 provides the name of the instrument is the *Australian Immunisation Register Amendment (Reporting) Rules 2024* (Amendment Rules).

**Section 2 – Commencement**

Section 2 provides the Amendment Rules commence on 1 March 2024.

**Section 3 – Authority**

Section 3 provides the Amendment Rules are made under subsection 31(1) of the *Australian Immunisation Register Act 2015.*

**Section 4 –Schedules**

Section 4 provides each instrument that is specified in a Schedule to the Amendment Rules is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule has effect according to its terms.

**Schedule 1 – Amendments**

**Item 1 – Paragraph 9(e)(vii)**

Item 1 repeals paragraph 9(e)(vii) of the AIR Rule to remove requirements to report the serial number of administered COVID-19 vaccines. This paragraph is being repealed as this field is not utilised and is covered within the requirement to report batch numbers under paragraph 9(e)(vi).

The requirement to report serial numbers for COVID-19 vaccine is replaced with the requirement to report the route of administration for Japanese encephalitis virus vaccine. Japanese encephalitis virus vaccine administration is mandatory to report under paragraph 9(a)(iv) of the AIR Rule.

**Item 2 – At the end of paragraph 9(e)(vii)**

Item 2 amends subsection 9(e) of the AIR Rule to add a new reporting requirement to be able to differentiate between relevant vaccines prescribed under the AIR Rule and the vaccine type information. **ATTACHMENT B**

**Statement of Compatibility with Human Rights**

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

***Australian Immunisation Register Amendment (Reporting) Rules 2024***

This disallowable 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**

Section 31 of the *Australian Immunisation Register Act 2015* (AIR Act) provides that the Minister may, by legislative instrument, make rules prescribing matters required or permitted by the AIR Act to be prescribed by the rules; or necessary or convenient to be prescribed for carrying out or giving effect to the AIR Act.

Section 10A of the AIR Act requires recognised vaccination providers to report certain vaccinations administered within a particular period and in the required manner to the Australian Immunisation Register (AI register) as prescribed by the rules. The current rules are the *Australian Immunisation Register Rule 2015* (AIR Rule). Under subsection 9(a) of the AIR Rule, a recognised vaccination provider must report to the AI register: COVID-19 vaccines, influenza vaccines, vaccines given under the National Immunisation Program (NIP) and Japanese encephalitis virus vaccine. Subsection 9(e) of the AIR Rule outlines required information to be reported by the recognised vaccination provider for inclusion in the AI register including patient details, provider details and vaccine details.

The *Australian Immunisation Register Amendment (Reporting) Rules 2024* (Amendment Rules) amend the AIR Rule to introduce two reporting requirements for recognised vaccination providers from 1 March 2024. Firstly, for a recognised vaccination provider administering a Japanese encephalitis virus vaccine to report to the AI register information about the route of administration. Secondly, for a recognised vaccination provider administering a relevant vaccine prescribed by the AIR Rule to report to the AI register information about the vaccine type.

The requirement to report route of administration of the Japanese encephalitis virus vaccine (under the Amendment Rules) is needed to identify if the vaccine was given intradermally or subcutaneously. Intradermal administration has been recommended to ease supply constraints in the event of a Japanese encephalitis virus outbreak, as this route of administration uses less vaccine than the subcutaneous route of delivery. Reporting route of administration will also provide the ability to monitor vaccine effectiveness and safety/adverse effects. The Amendment Rules will also add the requirement to report information about the vaccine type. This information will be used for the ongoing management of the NIP.

In general, both amendments will aim to improve reporting to the AI register to ensure individuals have a complete record of their vaccinations and to better inform program delivery and performance. AI register data is used to monitor the effectiveness of vaccines and vaccination programs and to identify parts of Australia at risk during disease outbreaks. It is important to note that these amendments do not make vaccination mandatory. It is only mandatory to report the additional information relating to vaccinations.

In addition, under subsection 10A(2) of the AIR Act, a recognised vaccination provider is not required to comply with these reporting requirements where the recording of information is likely to pose a risk to the health or safety or an individual. A person who fails to comply with their reporting obligations under subsections 10A(1) or (3) of the AIR Act may be liable to a civil penalty of 30 penalty units in accordance with subsection 10A(5).

**Human Rights implications**

The Amendment Rules engage the following human rights.

Article 12 of the Right to Health under International Covenant on Economic, Social and Cultural Rights (ICESCR)

The Amendment Rules engage Article 12 of the 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 reporting of the route of administration for Japanese encephalitis virus vaccine will provide the ability to monitor vaccine effectiveness, safety, and adverse effects for all Australians. This information is also relevant for clinical care (to be accessible by other healthcare workers other than the original vaccination provider, as necessary).

The reporting of information about the vaccine type will be used for the ongoing management of the NIP. In general, both amendments will improve reporting to the AI register to ensure individuals have a complete record of their vaccinations and better inform program delivery and performance. It will also assist with monitoring the effectiveness of vaccines and vaccination programs and to identify parts of Australia at risk during disease outbreaks.

Enhancing vaccination reporting will contribute to enriched monitoring and will provide invaluable statistics on health-related issues. This is a positive step towards attaining the highest standard of health for all Australians.

Article 17 of the Right to protection of privacy and reputation under International Covenant on Civil and Political Rights (ICCPR)

The Amendment Rules engage Article 17 of the ICCPR, which is concerned with the right to privacy and reputation.The Amendment Rules require the reporting of personal information of the person being vaccinated, and the person who administered the vaccine, to the AI register.

However, this information is subject to the secrecy provisions in Part 4 of the AIR Act. Section 23 of Part 4 creates an offence where a person makes a record of, discloses, or uses protected information in a way that is not authorised by section 22 of the AIR Act. Relevantly, protected information includes personal information and relevant identifying information obtained under the AIR Act (section 4 of the AIR Act). Section 22 authorises a person to collect, make a record of, disclose, or otherwise use protected information for the purposes of including such information in the AI register. This provision also authorises the recording, disclosure, and use of protected information in other circumstances, including disclosure to specified recipients and for specified purposes.

One of these circumstances is where the Minister authorises handling protected information for a specified purpose. The Minister may only authorise the disclosure of protected information in response to a disclosure request where the Minister is satisfied it is in the public interest. All disclosure requests are considered in line with the secrecy provisions in Part 4 of the AIR Act and other relevant legislation, such as the *Privacy Act 1988*, specifically balancing the purpose of the disclosure against the privacy impact of disclosure on the affected individual.

Additionally, vaccination providers have the capacity under subsection 10A(4) of the AIR Act to decline to report the administration of a vaccination where they consider it would likely pose a risk to the health or safety of an individual to do so.

The Amendment Rules do not impact or change the protections afforded to individuals under the above provisions.

**Conclusion**

The Amendment Rules are compatible with human rights. The Amendment Rules promote the right to health. The reporting of additional information to the AI register aims to protect the health of the community. The Amendment Rules also limit the right to privacy however, this limitation is reasonable and necessary, and information reported to the AI register is protected by the secrecy provisions in the AIR Act.

**The Hon Mark Butler MP**

**Minister for Health and Aged Care**