# PARLIAMENTARY INQUIRY QUESTION ON NOTICE

## Department of Health

## Senate Select Committee on COVID-19

## Inquiry into Australian Government's response to the COVID-19 pandemic

## Written Question on Notice, 29 January 2021

**PDR Number:** IQ21-000020

**Vaccination records, access and My Health Record linkage**

**Written**

**Senator:** Rachel Siewert

**Question:**
For consumers, where will the record of their vaccination be kept? Who will have access to that information? Will vaccination records be automatically linked to My Health Record?

**Answer:**
Records of consumer vaccinations will be kept in the Australian Immunisation Register (AIR), which is administered by Services Australia. The AIR is a national, whole-of-life register that captures all vaccines administered to those living in Australia. Legislative amendments recently passed by Parliament will make it mandatory for healthcare providers to record all COVID-19 vaccinations into the AIR.

The AIR Immunisation History Statement (IHS) displays all vaccinations an individual has received that are recorded on the AIR. Individuals can access their own IHS via Medicare Online, as well as the IHS of dependents aged up to 13. This access is linked through myGov or through the Medicare Express Plus App.

Due to privacy laws, those aged 14 years old or older must get their own IHS. Young people aged 14 years or older can give Services Australia permission for their parents to access their IHS on their behalf. General practitioners or other vaccination providers can access their patients' IHS on the AIR, and they can also print a copy of an individual's IHS on their behalf.

My Health Record (MHR) also allows Australians to view their immunisation history. Services Australia is an approved data repository to My Health Record.

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## Department of Health

## Senate Select Committee on COVID-19

## Inquiry into Australian Government's response to the COVID-19 pandemic

## Written Question on Notice, 29 January 2021

**PDR Number:** IQ21-000021

**Proof of vaccination**

**Written**

**Senator:** Rachel Siewert

**Question:**
How will consumers be able to demonstrate proof of vaccination if required? Is the Government considering a vaccine passport?

**Answer:**
COVID-19 vaccinations encounters will be reported to the Australian Immunisation Register, operated by Services Australia. Following their vaccination, individuals will be able to access their Immunisation History Statement (IHS) through their Medicare Online account, the Medicare Express Plus app, myGov or their My Health Record. If these channels are not suitable, they can request their immunisation history by phoning Services Australia. Healthcare providers can also print an IHS on behalf of their patient.

The Australian Government is considering mechanisms for recognising an international immunisation certificate for COVID-19 (digital or otherwise), however there are a number of considerations which still need to be addressed before this can be implemented safely and effectively.

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## Department of Health

## Senate Select Committee on COVID-19

## Inquiry into Australian Government's response to the COVID-19 pandemic

## Written Question on Notice, 29 January 2021

**PDR Number:** IQ21-000023

**Assurances by the Government on vaccine safety**

**Written**

**Senator:** Rachel Siewert

**Question:**
In the case of adverse events, how will the Government provide assurances to the community about vaccine safety?

**Answer:**

A vaccine will only be approved by the Therapeutic Goods Administration (TGA) if the benefits of its use are considered to significantly outweigh its potential risks. As part of this process, TGA's technical experts and the independent Advisory Committee on Vaccines carefully assess detailed safety information for each vaccine. This includes clinical trials with thousands of participants followed up for months after their second dose of vaccine, in addition to animal studies and real-world safety information. If approved, the sponsor of the vaccine is also required to continue to submit vaccine safety data to the TGA which is assessed on an ongoing basis.

For any approved vaccine, information about adverse events seen in clinical trials and post-market experience will be highlighted to health professionals and consumers in the Product Information and Consumer Medicines Information.

Following regulatory approval, the TGA continues to monitor the safety of vaccines. If the TGA identifies a significant safety concern, it can respond to address the risk, such as by requiring new warnings or instructions for use be included in the Product Information for the vaccine, requiring changes to labelling or packaging, providing safety alerts to health professionals and consumers, and even removing the vaccine from the market.

The existing national surveillance system for vaccines has well-established, robust procedures to quickly detect, investigate and respond to potential safety issues as they arise. The TGA is strengthening the monitoring processes for collecting and analysing

reports of suspected adverse events relating to COVID-19 vaccines. The TGA's safety monitoring processes for vaccines also include:

- requiring pharmaceutical companies to have risk management plans for the vaccines they supply, which describe how the companies will monitor for and mitigate the known and potential risks of the vaccines
- working with international regulators to assess significant adverse events detected overseas
- working with state and territory health departments and clinical experts to ensure a coordinated approach
- reviewing medical literature and other potential sources of new safety information.

Under the *Therapeutic Goods Act 1989*, pharmaceutical companies supplying vaccines are legally responsible for reporting serious adverse events and significant safety issues to the TGA. As a condition of their registration, pharmaceutical companies supplying COVID-19 vaccines will also be required to submit monthly summaries of worldwide safety data for evaluation by the TGA. GPs who will vaccinate patients in phase 1b are also required to give an undertaking that they will report all adverse events.

Like other medicines regulators around the world, the TGA collects reports of suspected adverse effects from health professionals and consumers and analyses them to detect signals for possible safety issues for investigation.

Adverse event reports that the TGA receives are entered into the TGA Adverse Event Management System. The information is used to help identify safety signals. A safety signal is a 'flag' for a possible safety concern. When the TGA identifies a signal, it undertakes a detailed evaluation to establish the possible role of the vaccine in causing the adverse event.

To support public confidence in COVID-19 vaccines and encourage uptake of immunisation, a weekly safety monitoring report will be published on TGA’s website. The report will support improved transparency, increased community engagement and communication. The objective is to reassure the public that the TGA is actively monitoring the safety of COVID-19 vaccines. Safety information published on the TGA website during the week, including information about emerging overseas safety issues, will be highlighted in the report.