



Australian Government

Department of Health

COVID-vaccine related fraud and security risks

Submission from the Department of Health to the
Parliamentary Joint Committee on Law Enforcement

APRIL 2021

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Executive summary

The Department of Health welcomes the opportunity to make a submission to the *Parliamentary Joint Committee on Law Enforcement* Inquiry into COVID-vaccine related fraud and security risks. At the request of Services Australia this submission also includes information provided by that agency.

This submission addresses the Inquiry's terms of reference in respect of the Department's roles and responsibilities for fraud relating to COVID vaccines. It should be emphasised, however that as of the time of writing (26 April 2021) there was little evidence of significant fraud related to the production, distribution or provision of COVID-19 vaccines. While there is evidence of some promotion of COVID-19 vaccines on the dark web and in some social media, it is comparatively limited and in the case of social media channels such as Facebook also actively monitored and blocked. Due to communication and educational activities managed by the department on behalf of the government, there is also widespread recognition that the COVID-19 vaccines and vaccinations are provided for free and cannot be purchased privately in Australia.

While there have been some overseas reports, there is also little evidence of vaccine counterfeits in the Australian supply chain. This is due to the tight management and close oversight of shipping and distribution of both imported and locally-manufactured vaccines by the manufacturers, commercial sponsors (vaccine companies) and the logistics companies involved in distribution of vaccines. The Department maintains records of all batches of vaccines manufactured and/or released for use in Australia as well as detailed records of all batches of vaccines provided to states and territories, vaccination centres, aged and primary care.

However, the Department, in collaboration with several collaborating departments, local and international law enforcement agencies, vaccine manufacturers and suppliers and the logistics providers contracted to government, has a strong focus on detecting potential telecommunications and internet fraud relating to COVID vaccinations and potential criminal activity around the supply of fake or black market vaccines, through both intelligence assessment and monitoring and response activities. Maintenance of the physical security of the supply chain was integral to the commercial arrangements struck by the Department in vaccine distribution contracts.

Regarding our immediate region, the Department of Foreign Affairs and Trade has partnered with the Therapeutic Goods Administration within the Department of Health to support countries with their regulatory decision-making, including vaccine approval and safety monitoring (pharmacovigilance). If South Pacific or South East Asian nations consider they may be experiencing significant COVID-vaccine fraud, the Department has undertaken to provide advice through the Regulatory Compliance Branch and establish connections through the Department's Australia Government and global law enforcement networks.

Considering the broader implications of a fraud or security incident

When considering COVID-vaccine relation fraud and security risks, it is important to consider broader implications if such risks did materialise. For example, while a fraud or security incident is in itself a negative outcome, such an incident could also precipitate an erosion of public trust in a specific vaccine, the vaccination program, or public administration more broadly.

This has the potential to have negative, and long-lasting, effects on our national COVID vaccination efforts; however, it may also impact on Australia's National Immunisation Program (NIP).

It could also lead to an increase in the rate of people who withdraw consent for their vaccination-related information stored on the Australian Immunisation Register (AIR) to be shared with third parties such as vaccination providers

The World Health Organisation's publication Vaccination and Trust provides some useful information on the role of trust in the success of vaccination programs

www.euro.who.int/_data/assets/pdf_file/0004/329647/Vaccines-and-trust.PDF.

Term of Reference a) - Telecommunications and internet fraud relating to COVID vaccinations

Intelligence assessment

The Department of Health maintains a specialised intelligence function for medicines, vaccines and other therapeutic goods within the Regulatory Compliance Branch of the Health Products Regulation Group. A significant number of staff in that Branch have a policing or intelligence background and work across government, including the Australian Border Force and Commonwealth and State and Territory law enforcement agencies.

Fraud and scam activity is likely to be the biggest illicit COVID-19 vaccine issue to impact Australia. Scammers exploit public anxiety to target vulnerable members of the community for financial gain or personal information. Activity such as non-delivery scams, where vaccines are listed for sale with no intent to supply after payment, will be most common.

Organised crime groups will almost certainly attempt to profit from the high global demand for COVID-19 vaccines. In some countries they may play a role in the production of, and trade in, illicit COVID-19 vaccines internationally, and engage in vaccine-related scam activity. However, the Australian Government's wide distribution of vaccines at no cost to all those who wish to be vaccinated mitigates the organised crime threat in Australia.

Fraud and scams targeting potential buyers of COVID-19 vaccines will likely be a mix of non-delivery and vaccine-themed phishing activity. In non-delivery scams, sellers will advertise vaccines, including on websites, social media platforms and darknet marketplaces, take money or personal information, but not supply the product. Vaccine-themed phishing activity will likely comprise social engineering attempts in which vaccines are offered for sale, but only with the intent of harvesting personal information from the victim.

Monitoring and response

The Department of Health (the Department) is a member of the whole-of-government COVID-19 vaccine Joint Intelligence Group (JIG) and Joint Analyst Group (JAG) co-ordinated by the Department of Home Affairs. These groups were established to monitor and respond to any online sales of COVID-19 vaccines with an Australian nexus. The Department of Home Affairs provide darknet and clearnet monitoring capability which is analysed by the JIG/JAG cohort. Any advertising of illicit COVID-19 vaccines through an Australian platform is provided to the Department for assessment and possible investigation for breaches of the *Therapeutic Goods Act 1989*.

The Department is also an active participant in INTERPOL's 'Operation Vigilant' — a targeted global operation against the illicit production and marketing of illicit COVID-19 vaccines and COVID related products. Information about global COVID-19 vaccine fraud is regularly disseminated to participant countries to raise awareness of the type of scam activity that is occurring and improve detection capability. INTERPOL, the World Health Organization and member countries use this construct to report any COVID-19 vaccine fraud and anything with an Australian connection will be referred to the Regulatory Compliance Branch of the Department for assessment and action.

Current threat environment

As of late April 2021, the Department had not received any intelligence reports or allegations of online COVID-19 vaccine scam activity occurring within Australia.

The Department's assessment remains that consumer interest in accessing COVID-19 vaccines outside of the Australian Government rollout is low. Low instances of COVID-19 cases in Australia, and the availability of a free vaccine (and free vaccination service) are assessed to be the main factors driving consumers away from illegally accessing vaccines. There has also been media coverage involving senior Departmental officers advising Australian consumers of the risks associated with buying COVID-19 vaccines online.

It is possible that any restriction to vaccine accessibility, mistrust in the Australian Government vaccine rollout or an increase in COVID-19 cases could drive consumers towards accessing vaccines through an illegal pathway and we continue to monitor this through the JIG/JAG and international partners.

Term of Reference b) - Criminal activity around the supply of fake vaccines, black market vaccines and/or fake vaccine certifications and the acquisition of certificates

Intelligence assessment

Based on the Department's intelligence assessment, incursion of counterfeit COVID-19 vaccines into the legitimate supply chain in Australia is highly unlikely. Supply chain security for therapeutic goods, including vaccines, is the responsibility of the company undertaking the import, export or supply of the good. Reputation, economic and regulatory factors mean vaccine producers are highly motivated to protect the integrity of their supply chains and will almost certainly apply security best practice. This is complemented in the case of COVID-19 vaccines by the Australian Government's commitment to track and trace all doses of the vaccine within Australia.

One potential supply chain vulnerability is corruption of trusted personnel, with the risk being highest in transport, logistics and wholesale companies. Supply chain insiders may become vulnerable to organised crime exploitation via financial incentive or pressure tactics. This vulnerability grows as the size and complexity of the supply chain increases. Should Australia use a greater variety of vaccines, the vulnerability will increase proportionately.

Within Australia, the most likely supply chain breach is theft or diversion of approved vaccines to the black market. Diverted vaccines are those stolen from the global supply chain, including those approved by foreign regulators but not by the Therapeutic Goods Administration for distribution outside of the regulated system. Counterfeits may be developed to replace the stolen legitimate product if diverted mid-supply, though vaccines may be stolen without replacement in transit, or from supply chain end-points such as medical clinics and pharmacies. The most likely vaccines to be diverted and distributed are those not requiring cold storage. However, black market vendors might also falsely claim their products had unbroken cold storage, or that their particular vaccine did not require it.

Counterfeit vaccines are those created specifically to mimic existing products available in the lawful supply chain. The ability to produce or acquire packaging identical or similar to that of the genuine article will likely facilitate the proliferation of COVID-19 vaccine counterfeits. Counterfeits are most likely to be sold via the black market; however, the regulated supply chain is at risk of incursion. As with diverted vaccines, the most likely to be counterfeited are those not requiring highly-temperature controlled supply chains.

Fake vaccines are those created to appear as if they could be real, while not being copies of products available in the lawful supply chain. These products are likely to require similar production capability to that used for counterfeits; however, as they do not need to mimic a genuine article, they are both easier to create, and possibly less subject to the scrutiny of enforcement bodies and industry members. Fake vaccines are most likely to appear in markets or settings traditionally subject to shortages, subject to weaker regulation and enforcement, and that are not Government funded or subsidised.

Suppliers of illicit vaccines will typically demonstrate criminal intent motivated by the potential for profit. Due to the integrity and accessibility of the supply chain in Australia, such criminals will face a limited market; however, a small number of products resulting from overseas criminal

activity will likely enter the country. Possible suppliers will be well-intentioned family members or community contacts seeking to share vaccines with their relatives or diaspora in Australia.

The likely routes for illicit vaccines entering Australia are international mail, international passenger baggage, air cargo and sea cargo. The most likely scenario is for non-temperature controlled vaccines to be sent in small numbers via international mail, although given the widespread recognition that all vaccines currently supplied require transport and storage at refrigeration temperatures or colder, shipping of any vaccines at room temperature through mail may lead to suspicion in the purchaser.

Monitoring and response

The Department works closely with the Australian Border Force (ABF) to detect and interdict illegal imports of COVID-19 vaccines. The ABF has well-established methodologies for monitoring goods entering Australia through the cargo and international pathways and applies this on the Department's behalf to detect illegal therapeutic goods, including COVID-19 vaccines. Any detection is referred to the Department for assessment and the Department will instruct the ABF to destroy any therapeutic goods deemed to be unlawfully imported.

The Department has agreed referral thresholds with the AFP for detections of illicit COVID-19 vaccine imports and/or supply. Any illicit activity not considered to be of a serious criminal nature will be investigated and responded to in accordance with the *Therapeutic Goods Act 1989*. Under the Act, Infringement Notices and civil penalties may be pursued as well as criminal penalties.

Current threat environment

As of late April 2021, the Department had not received any intelligence reports or allegations regarding import and/or supply of fake or black market COVID-19 vaccines in Australia.

Any changes to vaccine accessibility, mistrust in the Australian Government vaccine rollout or an increase in COVID-19 cases may drive consumers towards accessing vaccines through an illegal pathway. A change to the threat environment may result in an increase in criminal conduct, such as:

- imports of unapproved COVID-19 vaccines for commercial supply
- counterfeiting or manufacture of fake vaccines for onshore supply, and
- diversion of legitimate vaccines for onshore supply or export.

The Department has established controls for detecting this activity, including:

- online marketplace monitoring through the JIG/JAG
- assessment of adverse event reports from the public and medical practitioners
- complaints portal for referring non-compliant therapeutic goods
- cargo profiling
- engagement with state and federal police, and
- reporting from international regulators and law enforcement agencies.

Services Australia

Services Australia is delivering components of the COVID-19 vaccination national rollout relating to the Australian Immunisation Register (AIR) and proof of vaccination.

The AIR is the national register that records all vaccines given to people of all ages in Australia, including vaccines given under the National Immunisation Program through school programs and privately, such as for flu or travel.

Proof of vaccination can be viewed on an individual's existing Immunisation History Statement (IHS).

Proof of vaccination in the form of an IHS has been around and used for many years in settings like school or child care and changed more recently to be used as proof to support government policies including No Jab No Pay.

On 27 March 2021, the IHS was enhanced to increase the level of assurance by:

- a. Introducing a Commonwealth Coat of Arms watermark feature, making it harder to replicate,
- b. Making the COVID-19 immunisation status more prominent, and
- c. Including a person's Individual Healthcare Identifier.

The Agency is also working to develop a COVID-19 specific immunisation record, which is quick and simple to access. Options to strengthen assurance of the digital record and minimise fraud risk are being investigated, including:

- a. Live image detection, such as a shimmering watermark, making the digital record difficult to replicate, and
- b. Presenting vaccination certification using more advanced technology offerings, for example a secure digital wallet or through biometric anchoring, which could be delivered by leveraging the Government's myGov and/or Digital Identity system

Services Australia works closely with vaccination providers to verify their provider status and register them to report vaccination data to the AIR. The Provider Digital Access (PRODA) system allows secure access to government online services, including the AIR, via a username, password and verification code log on, to ensure privacy and security of Australians' health information, and to maintain the quality and accuracy of data held in the AIR.

Services Australia is actively monitoring for potential scam activity, in particular impersonation scams designed to steal personal and financial information. They are also supporting the AIR to deliver the COVID-19 vaccine rollout and has state-of-the-art cybersecurity in place to protect personal information, including a 24/7 Cyber Security Operations Centre.

Term of Reference c) - Risks to Australia regarding fraud and integrity of COVID vaccines in South Pacific nations and support for these nations to address issues relating to fraud and integrity risks

Regional Vaccine Access and Health Security Initiative

In October 2020, the Government announced a \$500 million Initiative to provide safe and effective COVID-19 vaccines and support health security in the Pacific and Southeast Asia. Through this Regional Health Security and Vaccine Access Initiative, Australia will help ensure the countries of the Pacific and Timor-Leste are able to achieve full COVID-19 immunization coverage (as defined by partner governments, and assuming that the first 20% of population coverage is provided through the COVAX Facility). Australia's funding will be used to procure and deliver COVID-19 vaccines and support related technical assistance in Fiji, Kiribati, Nauru, Papua New Guinea, Samoa, Solomon Islands, Timor-Leste, Tonga, Tuvalu and Vanuatu.

The Government will ensure that any vaccines purchased and delivered will have met Australian or other internationally accepted standards of safety and efficacy. This means that vaccines supplied will have received emergency use authorisation from the World Health Organization (WHO) or approval from the Therapeutic Goods Administration (TGA), which is designated by WHO as a Stringent Regulatory Authority (SRA), or possibly another comparable SRA such as the US FDA or European Medicines Agency.

A central tenet of the Initiative is that it will make Australia's world-class scientific and public health expertise available to our region to support partner countries in preparing to safely and effectively deliver COVID-19 vaccines without disrupting wider health service delivery. To do so, the Department of Foreign Affairs and Trade has partnered with the TGA to help support target countries with their regulatory decision-making, including vaccine approval and safety monitoring (pharmacovigilance). If South Pacific or South East Asian nations consider they may be experiencing significant COVID-vaccine fraud, the Department has undertaken to provide advice through the Regulatory Compliance Branch and establish connections through the Departments Australia Government and global law enforcement networks. The National Centre for Immunisation Research and Surveillance (NCIRS) has also been engaged to help provide expertise in policy and planning for immunisation services.

As of late April 2021, TGA has already partnered with PNG and Timor Leste on the provision of Australian manufactured vaccines and support for COVAX facility vaccines, and will commence collaboration with at least three other Pacific Island Countries in the coming weeks. The TGA has also thus far provided COVID-19 vaccine regulatory support for Thailand, Indonesia and the Philippines, including technical advice to facilitate the local manufacture of vaccines for several South East Asian countries within Thailand.

Term of Reference d) - Physical security in the production, transport and supply of COVID vaccines in Australia

Limiting the risk to physical security in the production, transport and supply of COVID vaccines in Australia will minimise criminal risks to the supply chain, including in handling, shipping and storage measures to steal or divert vaccines. Measures include:

- Government collaboration with logistics providers

The Department is working with reputable logistics providers to ensure the security of the vaccines through the supply chain is maintained. This incorporates employment of trusted personnel.

- Government collaboration with vaccine administration

Ensuring Australians have access to free, safe and effective COVID-19 vaccines through awareness of government endorsed clinics and locations for vaccination will limit the risk of stolen or diverted vaccines.

The Department has worked with vaccine manufacturers to ensure that safety procedures at acceptance points are maintained. This includes, but is not limited to, identity and organisation verification at point of vaccine collection.

The Department is also working to ensure that the security of the vaccine is preserved through secure waste and packaging disposal.

- Government collaboration with pharmaceutical companies

Pharmaceutical companies have implemented notification and clearance of vaccine products at multiple stages within purpose built process models. This has significantly enhanced the security of the vaccine supply chain, which is highly likely to deter criminal actors by limiting opportunities.

For example, one of the two major providers of COVID-19 vaccine in Australia, Pfizer has stood up 24/7 global assistance and provided the following to aid in the secure delivery of the vaccine:

- Images and information regarding the expected packaging appearance and weight
- Inclusion of GPS device in each packaged box that will detect deviations and monitor temperature and light
- Specifically designed temperature controlled shippers utilising dry ice to maintain recommended temperature storage conditions
- Onshore quality control
- 24/7 Global Security Operational Center and Senior Director contact details
- Pfizer staff monitoring of online scam activity

Term of Reference e) - Measures to prevent and protect against COVID vaccine-related fraud and security risks

The Department's fraud prevention team has been working with the Attorney-General's Department Commonwealth Fraud Prevention Centre on the key fraud and corruption risks that may affect the COVID-19 Vaccination Program. This is based on experiences reported with the UK and US vaccine program rollout. This will:

- Combat COVID-19 related misinformation and disinformation through effective health messaging
 - Identify and counter myths and misconceptions and with evidence based facts
 - Seek communication to the public through health experts
 - Avoid emphasising any misinformation or myths
 - Communicate the importance of getting information from credible sources
- Reduce risk to vaccine hesitancy through use of URLs in public SMS communication guidance

The Department continues to work closely with the Australian Competition and Consumer Commission (ACCC) on content on scams and provided social media responses to:

- warn followers about not clicking on links that do not end '.gov.au';
- report any scams brought to the attention of the department to ACCC; and
- advise other government departments and jurisdictions if the department intends to use SMS as a messaging channel.

Term of Reference f) - Any related matters

Nil