**Phase 1A of the COVID-19 Vaccine Strategy**

Privacy Impact Assessment

 Agency Response

Department of Health

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# Context

This document has been prepared by the Department of Health (**Health)**. It is intended to respond to the recommendations provided by Maddocks in their COVID-19 Vaccine and Treatment Strategy Privacy Impact Assessment (PIA) Report dated 20 February 2021.

| Maddocks Recommendation 1:  | Privacy by Design |
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| We **recommend** that Health continues to take a ‘privacy-by-design’ approach as the implementation of the Vaccine Strategy progresses, and ensure that:* the privacy risks and issues discussed in this Stakeholder Consultation Document are continually monitored and reviewed;
* the initial period of implementation with Partners (including any co-design activities), which we understand has been occurring in parallel with the PIA process, is used to further explore the identified Information Flows, and the associated handling of personal information. This should include clarifying responsibility for the de-identification of Vaccine Strategy Information in the EDW before it is extracted into the VDS, and determine that appropriate de-identification processes will be used (including by seeking appropriate technical advice as required); and
* Health continues to seek and consider privacy advice as required. For example, if there are any changes to the types of Vaccine Strategy Information to be collected by an entity, Health should satisfy itself that each of the pieces of Vaccine Strategy Information that will be collected (particularly where that information will be subsequently collected by Health) will be reasonably necessary for, or directly related to, the functions and activities of the collecting entity in connection with the Vaccine Strategy. This will assist Health in complying with the data minimisation principle.

In addition, as implementation of the Vaccine Strategy further progresses, we **recommend** that Health continue to review its Privacy Policy, to ensure that it reflects any new or changed handling of personal information by Health as a result of the Vaccine Strategy. If appropriate, Health could also consider developing and publishing a separate Privacy Policy specific to the handling of personal information in connection with the Vaccine Strategy. |
| Response | Agreed. The rollout of the COVID-19 vaccine is a national priority and Health is taking a ‘privacy by design’ approach in implementing the Vaccine Strategy. Health understands that there may be privacy concerns in relation to the rollout and will continually monitor privacy risks to ensure they are mitigated appropriately.Collection of data is important to facilitate the rollout, manage supplies and reduce wastage. The provider and patient information required to be collected for the vaccine is consistent with information currently collected within the Australian Immunisation Register (AIR). Other information on logistics collected is essential for informing the reporting on the ordering and tracking of the vaccines.Health will leverage existing robust controls in place for de-identifying information in its Enterprise Data Warehouse (EDW), that is, the data repository that will be holding vaccine administration, before de-identified data is transferred to other platforms (such as the Vaccines Data Solution (VDS)). Additionally, Health’s information security policies and frameworks are designed to provide a secure operating environment that enables the department to achieve its business objectives while maintaining its obligations under the *Privacy Act 1988* (Cth) (Privacy Act).As recommended, Health will implement a range of privacy protections prior to phase 1a commencing. These include publishing key sections of the PIA, this response, and a targeted [Privacy Notice](https://health.gov.au/about-us/privacy-notice-for-covid-19-vaccinations) outlining handling of personal information for anyone receiving a COVID-19 vaccine. Health has committed to reviewing and updating its public privacy information in conjunction with future phases. Our approach to prioritizing privacy is also demonstrated by the imminent publication of key elements of a PIA that reviewed privacy impacts of the *Australian Immunisation Register Amendment (Reporting) Act 2021*. Health also intends to publish a privacy policy aimed for individuals whose information is uploaded onto the Australian Immunisation Register.Further updates to the Vaccine Strategy PIA Summary and additional Privacy Notices will be published in conjunction with future phases of the rollout. |

| Maddocks Recommendation 2:  | Develop a communication strategy |
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| We **recommend** that Health ensure that is has developed a broad public communication strategy which details how Vaccine Strategy Information will be handled, and how the privacy of Patients and other individuals will be protected. Such a strategy could include:* relevant information being made publicly available on Health’s website, which clearly explains the different Information Flows, the entities that will be handling personal information as part of those Information Flows, and the privacy protections that are in place (which could include a copy of the finalised PIA report, or an appropriate summary);
* distribution of training or guidance material (for example, a ‘privacy hand out’) for entities participating in the Vaccine Strategy, which reminds them of their privacy obligations and privacy best practice. We recognise that the level of detail may vary depending on the nature and identity of the entity (for example, Health could reasonably expect general practices to have a good understanding of their privacy and professional medical obligations). Such material could outline:
	+ Health’s expectations about the handling of personal information, including when Collection Notices are to be provided to the relevant individuals;
	+ that Vaccine Providers should only collect the minimum amount of Patient Information necessary to administer the vaccine (i.e. in accordance with the data minimisation principle); and
	+ that each entity should review its Privacy Policy and other publicly available information (e.g. on the entity’s website), to ensure that it accurately reflects any handling of personal information in connection with the Vaccine Strategy; and
* taking steps to ensure that Patients, and other individuals, are made aware of how their Vaccine Strategy Information will be handled (see Recommendation 3 below).
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| Response | Agreed. Health continues to work closely with other entities, including Commonwealth, State and Territory agencies, and industry representatives to ensure information is readily available regarding the vaccine program. The communications strategy encompasses several types of media to ensure broad reach across Australia. It provides clear information on the progressive rollout of the Vaccine Strategy, how personal information is being handled, and how the privacy of individuals will be managed. Communications materials (such as posters or information sheets) developed for people receiving the vaccine will include a link to COVID-19 pages, including the Vaccine Strategy Privacy Notice and important privacy information on the Health website. Guidance materials and training modules have been developed for vaccine providers, and include links to find further privacy information on the Health website that can be provided to patients. It should be noted that Health’s Partners in implementing the Vaccine Strategy, the training provider, and the workforce providers contracted by the Commonwealth must comply with the Privacy Act as per their contracts. For phase 1a, Health expects that the large-scale jurisdictional vaccine providers will follow current immunisation practice in collecting necessary information. All healthcare providers who will administer the vaccine are expected to maintain patient confidentially as part of being a registered healthcare professional.A summary of this PIA will be published along with further updates in conjunction with the upcoming phases of the implementation of the Strategy. |

| Maddocks Recommendation 3:  | Awareness about handling of Vaccine Strategy Information |
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| To ensure compliance with APP 5, we **recommend** that Health take steps to ensure that Patients, Vaccinators and Provider Personnel, and Distribution Chain Personnel, are aware of how their personal information will be handled.***Patients***This should include steps to ensure that Patients are aware: * of the reasons why their personal information is being collected in connection with the Vaccine Strategy, what the information will be used for, and who it may be disclosed to;
* that the *Australian Immunisation Register Act 2015* (Cth) (AIR Act) authorises (and requires) the collection of the personal information, explaining that if they consent to receiving the vaccine, it will be mandatory for their personal information to be reported to the Australian Immunisation Register (AIR), but that they can opt-out from having their information disclosed to other entities from the AIR (and they should also be made aware of how to do so, and of any consequences that flow on as a result);
* of the relevant contact details of the collecting entities (including that Health may collect their personal information from other entities in connection with the Vaccine Strategy);
* of how they can make a complaint and access or correct their personal information; and
* of whether or not the individual’s personal information is likely to be disclosed to any overseas entity.
* The relevant information should:
* be easy to understand and delivered in plain English; and
* to the extent possible and practicable, meet best practice accessibility requirements, to facilitate those with a disability, or those from culturally and linguistically diverse communities, being able to understand the information provided to them. Health could consider tailoring the relevant information, taking into account the needs of different groups in the community (such as Patients in aged care).

We **recommend** that Health, taking into account what is possible and practicable from an operational perspective, either: * develop and implement a consistent form of Collection Notice that will be provided to all Patients (for example, by requiring Vaccine Providers to provide this Collection Notice to all Patients). We consider that this option would represent privacy best practice, and could be implemented, for example, by:
	+ a separate form of Collection Notice being developed by Health, with Vaccine Providers instructed (during the onboarding process) to provide a copy to the Patient:
		- ideally, at the first point of collection, being the time that the Patient makes a booking with the relevant Vaccine Provider (i.e. through the Vaccine Provider’s booking system); or
		- if this is not practical in the circumstances, at the time of administering each dose of the vaccine; or
	+ if other information must be provided to Patients by Vaccine Providers, a Collection Notice being included in that material (e.g. as part of information about the vaccine possible side-effects and what to do in the event of an adverse reaction, or in a form used to obtain a Patient’s consent to receive the vaccine, which Health makes available to Vaccine Providers). We note that it may not be practical for a lengthy notice to be included in that material, but Health could adopt a ‘layered’ approach, as contemplated by the APP Guidelines. Such an approach would involve the material including a brief notice, with a reference (such as a website address or QR code) to a more comprehensive notice containing additional information about the APP 5.2 matters; or
* adopt a range of other strategies that are reasonable in the circumstances to ensure that Patients are made aware of how their Patient Information will be handled in connection with the Vaccine Strategy. This could include Health, for example:
	+ advising Vaccine Providers that they should inform Patients about how their Patient Information will be handled in connection with the Vaccine Strategy, for example through the Vaccine Provider’s booking system, or by oral or written means when the Patient attends their appointment;
	+ ensuring that Vaccine Providers are given appropriate training about what Patients should be told in relation to the handling of their Patient Information, and how the message should be communicated to Patients;
	+ developing and distributing material for Patients that contains the relevant information, for example, standardised content developed by Health for Vaccine Providers to provide to Patients;
	+ issuing Vaccine Providers with guidance that includes a reminder for them to provide the relevant information to Patients (this may include, for example, a clear explanation of their obligations under the Privacy Act, including to provide Patients with appropriate Collection Notices);
	+ including the relevant information on its website (which could also potentially include a Vaccine Strategy specific Privacy Policy, as discussed in **Recommendation** **1**); and
	+ ensuring that appropriate public communication strategies are implemented (as discussed in relation to **Recommendation** **2**).

***Vaccinators and Provider Personnel, and Distribution Chain Personnel***We **recommend** that Health take steps to ensure that Vaccinators, Provider Personnel, and Contact Personnel also understand how their personal information will be handled. This could involve a Collection Notice or other relevant information (as discussed in relation to Patients) being provided to:* Vaccinators and Provider Personnel – we suggest that this could be done as part of the onboarding process for the Vaccine Strategy (such as when they receive any relevant training to administer the COVID-19 vaccine, or use associated systems connected with the Vaccine Strategy); and
* Distribution Chain Personnel – we suggest that the details of who is to be responsible for providing the Collection Notice or relevant information should be determined as part of transition-in activities under the Logistics and Distribution Partner Contract or the relevant Supply Agreement.
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| Response | Agreed. As mentioned in the response to Recommendation 2, Health will ensure awareness among patients through a broad ranging communications strategy and layered approach to privacy matters. This includes publishing training and guidance materials to immunisation providers and aged care facilities as well as information sheets for people receiving the vaccine. [Information for providers](https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/information-for-covid-19-vaccination-providers) has been made publicly available on the Health website. Health has included guidance on seeking informed consent. This has been prepared by the Australian Technical Advisory Group on Immunisation (ATAGI) including a template consent form. Training modules developed by Health remind providers to discuss privacy with patients. Health communications materials for patients include a link to the Health website for further information regarding privacy. The process of recording informed consent by immunisation providers does not need to differ from usual practice.Health acknowledges the view that collection begins at the time of an individual utilising the booking systems. In Phase 1.a, the Commonwealth will not be providing booking systems. As part of future phases, Health will consider the privacy requirements of such booking systems (including through an updated PIA process). In addition, the department is implementing strategies to ensure patient awareness of privacy protections. Guidance materials and training modules for vaccine providers will continue to be updated with relevant privacy-related information as the implementation of the Strategy progresses. For phase 1a, Health notes that Vaccine providers are large-scale jurisdictional sites, rather than individuals. Use and handling of Vaccinator information is consistent with current practices in the Australian Immunisation Register. Health will consider this carefully in future phases of the rollout.Health has ensured clarity in roles and responsibilities in contracts with entities supporting the implementation of the Strategy, and will regularly review for compliance against contractual requirements.  |

| Maddocks Recommendation 4:  | Partner Contracts |
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| We **recommend** that Health regularly reviews the privacy and security obligations in its Partner Contracts to ensure that they are appropriate, including whether any changes are needed to reflect any new or changed collections, uses or disclosures of personal information by the relevant Partner (including because of the introduction of new processes or system functionalities). |
| Response | Agreed. Health will regularly review contracts to ensure protection of personal information is considered, and that contracts contain the appropriate information with clarifying roles and responsibilities regarding appropriate security and data handling. |

| Maddocks Recommendation 5:  | Contractual and other arrangements with other entities handling Vaccine Strategy Information |
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| We **recommend** that, as Health further progresses implementation of the Vaccine Strategy, Health consider and ensure that all entities who are not Partners but will collect personal information:* are clearly identified (so that it is clear whether or not they are an APP entity and subject to the Privacy Act);
* have functions and activities which are consistent with the collection of the relevant personal information;
* have entered into appropriate contractual or other administrative arrangements as required (depending on the identity and nature of the entity and their role in the Vaccine Strategy);
* only collect or have access to identified information if this is necessary (or whether, for example, information in any reports received by that entity could be included in a properly de-identified form); and
* if it is necessary for identified information to be provided, that the entity is subject to appropriate privacy obligations (e.g. under State or Territory privacy legislation or contractual arrangements).

We **recommend** that Health design contractual or other administrative arrangements with other entities to appropriately specify or limit the subsequent use or disclosure of personal information, which may include:* appropriate restrictions on the use and disclosure of personal information for the purposes of direct marketing;
* appropriate permissions or restrictions in relation to the use and disclosure of government-related identifiers;
* minimum security requirements (including restriction on transferring personal information to, or permitting access from, overseas); and
* any appropriate requirements for deletion or de-identification of the personal information.

For example, we suggest that Health ensure that the relevant Supply Agreements contain appropriate clauses to restrict each Supplier’s use and disclosure of personal information to the provision of the services under the relevant agreement, and include appropriate confidentiality, security and privacy clauses.We also **recommend** that Health ensure that contractual and other arrangements with entities other than Partners involved in the Vaccine Strategy contain obligations designed to facilitate Health’s ability to be open and transparent about the handling of personal information (such as, if applicable, a requirement to provide any information about the handling of Vaccine Strategy Information to individuals, as required or directed by Health). |
| Response | Agreed. Health has been ensuring this occurs in its contracts with entities, which are consistent with existing practices within the Department. Health will continue to implement appropriate arrangements with entities to clarify roles and responsibilities regarding the handling of information. The personal information of individuals receiving a vaccine is protected under existing legislation and processes. Only de-identified information will be used in Health’s Vaccine Data Solution (VDS) platform.  |

| Maddocks Recommendation 6:  | Testing and security of solutions handling Vaccine Strategy Information |
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| Given the sensitive nature of the Vaccine Strategy Information, we **recommend** that Health:* ensure that sufficient time and resources are allocated during the initial period of implementation with Partners (including during any co‑design activities) to satisfy itself that the de-identification, testing and quality assurance processes for transfer of Vaccine Strategy Information between entities and their systems are sufficient and appropriate to ensure that no inappropriate changes have occurred to the relevant Vaccine Strategy Information during the transmission process; and
* take reasonable steps (including obtaining relevant cybersecurity advice as required) to:
	+ specify minimum functional and non-functional security requirements for each solution that may store or handle Vaccine Strategy Information;
	+ minimise access to Vaccine Strategy Information to the minimum number of persons who have a legitimate ‘need to know’ that information, and who meet minimum security requirements specified by Health; and
	+ implement ongoing testing for security vulnerabilities for any solutions which store Vaccine Strategy Information.
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| Response | Agreed. Health has worked and continues to work closely with Partners and key stakeholders to safely and effectively roll out COVID-19 vaccines, including co-design, developing and testing cycles. Robust processes are in place for carrying out testing and quality assurance of systems developed to identify security vulnerabilities and ensure appropriate security arrangements are in place. In implementation of the Vaccines Data Solution and its related systems, Health has completed various processes and engaged relevant expertise through the Chief Information Security Officer, including resources from the Australian Cyber Security Centre (ACSC), a security assessor certified through the ACSC Information Security Registered Assessors Program (IRAP) and independent assurance services to ensure that the Solution meets the requirements of the Protective Security Policy Framework. There are various artefacts being developed including Security Plans, Threat Assessments, Data Protection Plans, Incident Response Plan, Penetration Test Report and a Final Security Report. Existing Data Governance Frameworks are being utilised to ensure strict arrangements are in place for who can access the information. |

| Maddocks Recommendation 7:  | Measures in relation to Health’s use and disclosure of Vaccine Strategy Information |
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| If Health considers it is likely that it will disclose any *identified* Vaccine Strategy Information to other entities, we **recommend** that Health consider whether there are steps it should take to further enhance public confidence in the handling of Vaccine Strategy Information, such as:* complying with Health’s usual data management and governance processes if it wishes to use and disclose Vaccine Strategy Information held by it (to consider and ensure that any uses and disclosures will comply with the requirements of APP 6, and the requirements of the AIR Act); and
* ensuring that any entities that do receive identified Vaccine Strategy Information will comply with their obligations under the Privacy Act or otherwise handle any Vaccine Strategy Information provided to them in an appropriate manner. For example, Health may wish to consider:
	+ agreeing clearly documented agreements or other arrangements with the recipient entities, which set out how these entities may handle Vaccine Strategy Information provided to them in connection with the Vaccine Strategy;
	+ including appropriate terms and conditions of use, to which authorised individuals of the recipient entities would need to agree before being provided with access to the Vaccine Strategy Information; and/or
	+ issuing guidance material to the recipient entities (which could be in letter form), which provides guidance about how these entities should handle Patient Information provided to them in connection with the Vaccine Strategy.
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| Response | Agreed. Identified Vaccine Strategy information will only be disclosed consistent with the provisions of the *Australian Information Register Act 2015*, and the *Privacy Act 1988*, as appropriate, and in line with departmental data governance processes. Health will provide entities receiving identified Vaccine Strategy information with the necessary guidance on handling and using personal information provided. Health will regularly monitor compliance against contractual requirements, including protection of personal information. |