

3 August 2023

The Digital Technology Taskforce
Technology and Digital Division, Technology Strategy Branch
Department of Industry, Science and Resources
Ngunnawal Country, Industry House,
10 Binara Street (GPO Box 2013)
Canberra ACT 2601 Australia

Re: Consultation on Supporting Responsible Al

Thank you for the opportunity to provide input into evolving policy for the safe and responsible use of AI.

This submission is made on behalf of the Australian Alliance for AI in Healthcare (AAAiH), a national community of practice with over 100 member organisations drawn from industry, health service providers, academia and consumer organisations.

Background

AAAiH and its partners including the Australasian Institute of Digital Health (AIDH) and the Digital Health CRC (DHCRC), are currently engaged in a policy development program for the safe and effective use of AI in healthcare.

The process began with a national consultation on AI priorities for healthcare in 2021, which attracted 152 responses. That body of work is documented in the AAAiH's AI RoadMap for Healthcare, which is attached to this submission as an appendix. The Roadmap identified 8 priority areas, covering issues such as AI safety and security, industry development and workforce, and made 24 specific recommendations

More recently we have undertaken to refresh and sharpen this work, with a focus on identifying core policy targets over the next few years. We will hold a Chatham House Rules workshop in Sydney on August 15 to explore an updated draft set of policy recommendations, and will have attendees from DISR, as well as Federal and State Departments of Health, and representatives from key stakeholder and regulatory bodies. We intend to launch the final policy recommendations emerging from the workshop later this year.

Our submission for this consultation is a draft set of policy recommendations, developed with the assistance of the AAAiH membership, the DHCRC and the AIDH. These draft recommendations will be given consideration at our August workshop. We therefore anticipate the recommendations will evolve over the next few months. We would welcome

the opportunity to update the Department of Industry, Science and Resources over this period, as our recommendations take their final form.

The draft AAAiH Policy recommendations

The policy recommendations in our current proposal cover 3 areas:

- 1. Safety, Quality, Ethics and Security governance for healthcare AI
- 2. Supporting the development of a healthcare AI industry in Australia
- 3. Building the capabilities of the healthcare workforce and consumers to be effective users of Al

In developing these proposals, we have sought to build on current regulatory structures that are healthcare specific, and to focus on those challenges which require healthcare-specific policy development.

Healthcare requires specific policy attention for a number of reasons:

- General purpose foundation models such as large language models (LLM) are currently not designed to be 'medical grade' but are increasingly being used to support healthcare. While the Therapeutic Goods Administration would regulate healthcare specific AI that included an LLM to ensure it was safe, the clinical use of general AI such as ChatGPT currently avoids scrutiny because the system is not explicitly marketed for healthcare.
- Safety standards are industry specific. Safety requirements in healthcare to not harm patients will typically result in more stringent governance than many other sectors. Healthcare also has a strong model of post-market surveillance for actual harms not reflected in other large industries. "Moving fast and breaking things" is not a good strategy in health.
- The higher burden of regulatory compliance in healthcare is therefore essential but poses a substantial barrier to industry. Consequently, healthcare may need to find ways of supporting industry as it meets its stringent regulatory standards.
- Privacy requirements are shaped by industry specific as well as general laws. There
 are strict requirements to obtain consent and protect personal information in
 healthcare, which for example may prohibit cross-border transfer of data (e.g. to an
 LLM run by a foreign corporation) where its re-use is not controllable, and may
 breach local laws.
- Al models can perform very differently across clinical settings because of patient, service and workflow differences. Al model localisation will be needed for the routine use of many Al systems in healthcare and will inevitably require specific governance such as provider organisation accreditation.

The attached discussion paper outlines potential policy options that should assist in dealing with the specific challenges of using AI safely, effectively and privately in healthcare, and explores how healthcare AI companies can be best supported.

We are strongly supportive of the Government's active interest in developing industry appropriate policy and governance for AI and welcome the opportunity to provide further assistance if that is required.

On behalf of the AAAiH

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<u>Attachments</u>

- 1: Discussion paper: A National Policy Agenda for AI in Healthcare
- 2: The AAAiH Roadmap for AI in Healthcare