Medicines Australia submission to the Department of Industry, Science and Resources' consultation on Supporting Responsible AI

26 July 2023

Medicines Australia welcomes the opportunity to respond to the Department of Industry, Science and Resources' consultation on artificial intelligence (AI). As the peak body representing the innovative pharmaceutical industry in Australia, our response will focus primarily on AI in healthcare.

AI has the potential to significantly improve the lives of Australians in many ways, not the least of which is in the diagnosis, treatment and management of health conditions. However, as with all technologies used to improve or maintain health, AI not only has the potential for great benefit but also the risk of harm, which needs to be mitigated. In addition to the already-identified risks associated with AI more generally, AI use in healthcare carries with it additional risks. For example, an algorithm designed to help diagnose or categorise a health condition and thereby direct treatment decisions, has the benefit of being able to synthesise significant amounts of information quickly to accurately treat more people than doctors alone, but also to have significant negative consequences if the algorithm is incorrect and subsequently results in incorrect treatment decisions. For this reason, Medicines Australia supports the appropriate use of AI in healthcare, but also advocates for appropriate checks and balances for any AI technologies used in the healthcare setting, including human oversight and regular checks and updates as the diagnosis and treatment landscape evolves.

As a set of overarching principles, we support those outlined on page 14 ('Box 3', replicated below) of the 'Safe and responsible AI in Australia' discussion paper provided as part of this consultation. We also draw the Department's attention to the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Artificial Intelligence Ethics Principles (2022),[1] which, as an IFPMA member, Medicines Australia supports, and which also reflect the principles outlined in Box 3 below.

These principles should guide the development, governance and implementation of any AI technology used in Australia, including those employed in the diagnosis, management and treatment of Australians' health. Factored into these principles and any resulting governance of AI in the healthcare setting should be:

- quality assurance of AI technologies
- consideration of the benefits as well as the risks of AI as part of a risk–benefit analysis
- sufficient support for timely access to new, innovative AI technologies that will benefit Australians.

It should be noted that this consultation comes at a time when access to new healthcare options is under evaluation more generally as part of a review of the health technology assessment system in

[1] IFPMA Artificial Intelligence Principles 2022. Available at https://www.ifpma.org/publications/ifpma-artificial-intelligence-principles/. Accessed 20 July 2023.

Australia, under the Strategic Agreement between Medicines Australia and the Commonwealth.[2] A shared goal of the Strategic Agreement is 'reducing time to access for Australian patients so that they can access new health technologies as early as possible'. Any governance implemented relating to AI used in healthcare, particularly as it relates to access to medicines and other technologies for the treatment of medical conditions, should take this goal into account and ensure that timely access to new health technologies is not impeded.

Box 3: Australia's AI Ethics Principles

1. **Human, societal and environmental wellbeing:** AI systems should benefit individuals, society and the environment.
2. **Human-centred values:** AI systems should respect human rights, diversity, and the autonomy of individuals.
3. **Fairness:** AI systems should be inclusive and accessible, and should not involve or result in unfair discrimination against individuals, communities orgroups.
4. **Privacy protection and security:** AI systems should respect and uphold privacy rights and data protection, and ensure the security ofdata.
5. **Reliability and safety:** AI systems should reliably operate in accordance with their intended purpose.
6. **Transparency and explainability:** There should be transparency and responsible disclosure so people can understand when they are being significantly impacted by AI, and can find out when an AI system is engaging with them.
7. **Contestability:** When an AI system significantly impacts a person, community, group or environment, there should be a timely process to allow people to challenge the use or outcomes of the AI system.
8. **Accountability:** People responsible for the different phases of the AI system lifecycle should be identifiable and accountable for the outcomes of the AI systems, and human oversight of AI systems should be enabled.

Source: 'Safe and responsible AI in Australia' discussion paper. Available at https://storage.googleapis.com/converlens-au-industry/industry/p/prj2452c8e24d7a400c72429/public_assets/Safe-and-responsible-AI-in-Australia-discussion-paper.pdf. Accessed 18 July 20

Responses are provided to select questions below.

Definitions

1. Do you agree with the definitions in this discussion paper? If not, what definitions do you prefer and why?

Medicines Australia supports the definitions outlined in the consultation.

Potential gaps in approaches

2. What potential risks from AI are not covered by Australia's existing regulatory approaches? Do you have suggestions for possible regulatory action to mitigate these risks?

Medical diagnosis and management are only as good as the data inputted. For example, the risk of misdiagnosis due to limited understanding of non-traditional presentations of diseases is significant.

[2] Commonwealth of Australia and Medicines Australia. Strategic Agreement in relation to reimbursement, health technology assessment and other matters. Available at https://www.pbs.gov.au/general/medicines-industry-strategic-agreement-files/MA-Strategic-Agreement-Signed.pdf. Accessed 18 July 2023.

MA supports AI used to oversee the diagnosis and management of patients being overseen by humans.

Further, TGA regulations[3] cover regulation of software and apps that are defined as medical devices, but do not cover other medical technologies that employ AI, such as those that can synthesise large amounts of data to determine patterns, scan images to assist diagnosis and subsequently guide treatment decisions. Any governance of AI in Australia, whether general or specific to healthcare, should be robust enough to ensure that the quality of AI used in the healthcare setting is safe, that quality assurance is maintained and that bias is eliminated to ensure that risks to patients are minimised.

3. Are there any further non-regulatory initiatives the Australian Government could implement to support responsible AI practices in Australia? Please describe these and their benefits or impacts.

Education and training of AI technology operators is imperative to ensure that these technologies are used as intended and should be guided by the Government with support from private industry.

Education of the general public in data literacy and understanding of the benefits as well as the risks of AI could also assist with uptake and governance.

4. Do you have suggestions on coordination of AI governance across government? Please outline the goals that any coordination mechanisms could achieve and how they could influence the development and uptake of AI in Australia.

Responses suitable for Australia

5. Are there any governance measures being taken or considered by other countries (including any not discussed in this paper) that are relevant, adaptable and desirable for Australia?

Target areas

6. Should different approaches apply to public and private sector use of AI technologies? If so, how should the approaches differ?

Both public and private sector use of AI should be transparent to allow people interacting with these technologies to understand how they work and what will happen to any information gathered by the technology. However, additional considerations should be given to private use of AI with respect to commercially confidential information about the technology itself. Any restrictions on the use or implementation of these technologies should not stifle innovation.

7. How can the Australian Government further support responsible AI practices in its own agencies?

8. In what circumstances are generic solutions to the risks of AI most valuable? And in what circumstances are technology-specific solutions better? Please provide some examples.

9. Given the importance of transparency across the AI lifecycle, please share your thoughts on:

[3] Therapeutic goods Administration. Medical devices reforms: Medical device software regulation https://www.tga.gov.au/how-we-regulate/supply-therapeutic-good/supply-medical-device/medical-devices-reforms/medical-devices-reforms-medical-device-software-regulation. Accessed 18 July 2023.

a. where and when transparency will be most critical and valuable to mitigate potential AI risks and to improve public trust and confidence in AI?

Transparency will be critical at all stages of the process to ensure that recipients of these technologies are informed, consenting, and aware of the risks and benefits of these technologies, particularly in the healthcare setting.

b. mandating transparency requirements across the private and public sectors, including how these requirements could be implemented.

Transparency is paramount in ensuring that people are aware of the risks and benefits of AI technologies. Transparency could be mandated across both private and public sectors, providing that the transparency does not extend to commercially confidential information that could restrain innovation. For example, the details of the algorithm employed by an AI technology such as coding could remain confidential, while still making transparent the impact and outcomes of that algorithm.

10. Do you have suggestions for:

a. Whether any high-risk AI applications or technologies should be banned completely?

b. Criteria or requirements to identify AI applications or technologies that should be banned, and in which contexts?

11. What initiatives or government action can increase public trust in AI deployment to encourage more people to use AI?

- Education
- Transparency
- Clarity on governance
    - how privacy concerns relating to these technologies have been addressed
    - assurance that information held by or generated by AI will not result in discrimination, inequities or harms.

Implications and infrastructure

12. How would banning high-risk activities (like social scoring or facial recognition technology in certain circumstances) impact Australia's tech sector and our trade and exports with other countries?

13. What changes (if any) to Australian conformity infrastructure might be required to support assurance processes to mitigate against potential AI risks?

Risk-based approaches

14. Do you support a risk-based approach for addressing potential AI risks? If not, is there a better approach?

Yes, provided that the risk matrix also considers the potential benefits as part of a risk–benefit analysis. This sort of approach is already used in assessing new treatment technologies via health technology assessment and could also be applied to AI used in healthcare.

15. What do you see as the main benefits or limitations of a risk-based approach? How can any limitations be overcome?

A risk-based approach is beneficial in that it aims to protect recipients from harms associated with AI-based technologies. However, it is limited in that it doesn't consider the potential benefits of a new technology. This should also be considered, particularly for AI technologies used in healthcare. Ensuring that a full risk–benefit analysis is considered for each new technology will help to prevent potentially beneficial uses of AI from being banned or limited. A risk-based approach should also consider whether the risks can be overcome through education, informed consent by recipients, human oversight or other means.

16. Is a risk-based approach better suited to some sectors, AI applications or organisations than others based on organisation size, AI maturity and resources?

17. What elements should be in a risk-based approach for addressing potential AI risks? Do you support the elements presented in Attachment C?

We support the measures outlined in Attachment C. However, there does not appear to be any consideration of oversight of quality control for AI technologies as a means of risk mitigation. Whether this should be through self-assessment, guidance or regulation should be discussed, but assessment of the quality of the technology should be added to any risk-based approach.

18. How can an AI risk-based approach be incorporated into existing assessment frameworks (like privacy) or risk management processes to streamline and reduce potential duplication?

AI use in healthcare could be incorporated into the existing TGA, PBAC and MSAC processes to ensure that it is evaluated for quality, safety, efficacy, and value in alignment with more traditional healthcare technologies.

19. How might a risk-based approach apply to general purpose AI systems, such as large language models (LLMs) or multimodal foundation models (MFMs)?

20. Should a risk-based approach for responsible AI be a voluntary or self-regulation tool or be mandated through regulation? And should it apply to:

a. public or private organisations or both?

b. developers or deployers or both?