TGA Consultation: Clarifying and Strengthening the Regulation of Artificial Intelligence

In October 2024, Cancer Council completed a submission to the Therapeutic Goods Administration (TGA) consultation on Clarifying and Strengthening the Regulation of Artificial Intelligence. This consultation sought feedback on proposals identified for mitigating risks and leveraging opportunities associated with using Artificial Intelligence (AI) models and systems across the regulatory environment.

Cancer Council's submission included the following areas:

- The requirement for international harmonisation on the definitions of the types of AI-based software as a medical device (SaMD) and aligning regulations with other regulators.
- The need for legislation and regulatory guidance to clarify liability and responsibility for risk management, data governance, safety, and quality monitoring of the implementation of AI technologies in healthcare settings.
- The need for a comprehensive consultative process with all relevant stakeholders, developers, healthcare professionals and providers, and consumers to inform proposed legislative and regulatory reform for AI regulation in healthcare.
- Development of a risk-based and holistic regulatory framework for assessing the safety and quality of AI-based SaMD.
- Specific regulation, compliance and awareness building on the importance of safety and data privacy when using generative AI as a tool in healthcare settings.
- The establishment of a National AI in Healthcare Agency to provide oversight of the safety, effectiveness, ethics and security of AI-based SaMD. They should develop essential principles for the development and use of AI models in healthcare settings.
- Ongoing regulatory review and approval throughout the lifecycle of AI-based SaMD products to ensure appropriate monitoring when deployed in clinical settings and review safety and performance over time.
- Appropriate labelling and certification of AI-based SaMD to ensure awareness and understanding of the information around the approved indication, information about how to use it in clinical practice, limitations, and clinical validation process.
- The need for Australian regulation around the appropriate access, use and storage of personal health information to maintain data privacy in AI tools used in healthcare settings.
- The need for more information and resources provided by the TGA for developers and end-users (consumers and healthcare professionals) to inform the responsible use of AI-based tools in healthcare.

Information about the progress of the consultation can be found on the TGA's consultation webpage: https://consultations.tga.gov.au/tga/clarifying-and-strengthening-the-regulation-of-ai/