Response to the Therapeutic Goods Administration (TGA) - Clarifying and strengthening the regulation of Artificial Intelligence

October 2024

Introduction

Formerly known as the Society of Hospital Pharmacists of Australia (SHPA), Advanced Pharmacy Australia (AdPha) is the progressive voice of Australian pharmacists and technicians, built on 80 years of hospital innovation that puts people and patients first. AdPha supports all practitioners across hospitals, transitions of care, aged care and general practice to realise their full potential. We are the peak body committed to forging stronger connections in health care by extending advanced pharmacy expertise from hospitals to everywhere medicines are used.

AdPha welcomes the opportunity to provide feedback to the Therapeutic Goods Administration (TGA) consultation titled – Clarifying and strengthening the regulation of Artificial Intelligence (AI).

AdPha convenes various Specialty Practice Groups, including Pharmacy Informatics and Technology, of which members from this group have provided their expert insights to inform AdPha's response to this consultation.

If you have any queries or would like to discuss our submission further, please contact Jerry Yik, Head of Policy and Advocacy at jyik@adpha.au.

Potential changes to the Act - Definition and Language

Question 1: Do you broadly agree that a review of the definitions in the Therapeutic Goods Act 1989 and subordinate legislation is needed to clarify responsibility for the development, deployment and use of AI models and systems?

AdPha agrees that the language utilised in the *Therapeutic Goods Act 1989* should reflect contemporary AI models and systems that are utilised in practice, specifically to encompass activities involving AI that are not always conducted by human beings. To strengthen and clarify regulation, the Act should clearly define and identify that the various AI models and systems exist, and will continue to emerge, that are either conducted by human beings or programmed to perform activities based on complex algorithms. By reviewing the definition, further regulatory restrictions should be considered to acknowledge who is accountable for AI models and systems that are not conducted by human beings.

Question 2: Are there specific definitions that should be clarified? If yes, what are they?

No comment.

Question 3: Are there specific activities you are concerned would not be appropriately regulated using the existing legislation? If yes, what are they?

AI models and systems that perform by complex algorithms require strict, routine input and output validation strategies that mitigate potential risk that can arise due to a lack of current, evidence-informed information being utilised. As stated in the consultation, accountability for output by AI models and systems that perform based on complex algorithms requires close attention and continual validation. If these types of AI models and systems are not routinely monitored for credibility of their purpose and function, the regulation of these devices will be complex as accountability for breaching the Act or other laws will be confounded. More importantly, if these types of AI models and systems lead to patient harm owing to inconsistent validation and monitoring of output data, currently the regulation would not account for these concerns.

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Potential changes to medical device regulation

- **Classification rules**

Question 4. Do you agree that programmed or programmable medical devices or software that is a medical device for use in providing a prediction or prognosis in relation to a disease or condition should be reclassified under classification rules 4.5(1) and 4.5(2)? Why or why not?

Yes. AdPha broadly agrees that programmed or programmable medical devices or software that is a medical device for use in providing a prediction or prognosis in relation to a disease or condition should be reclassified under classification rules 4.5(1) AND 4.5(2).

As digital health evolves, these technological advancements and the use of AI to provide a prediction or prognosis for a disease or condition and assist health care professionals with finetuning treatment and management plans will be more prevalent. Therefore, the classification rules must reflect these advancements and align with the evolving use of AI in health care settings as it can impact patient harm if not appropriately risk classified.

Classification 4.5(2) encompasses the broader use of AI, where it will assist with critical reasoning for the purpose of assisting the health professional making a diagnosis of a disease or condition, based on a prediction or prognosis provided by AI. If the prediction or prognosis for a disease or condition is not accurate, this can impede appropriate clinical decision making and pose significant, direct harm to the patient. AI models and systems should not be confined to Class 1 medical devices as their advancements will directly impact patient care, but conversely, lead to patient risk and harm. During episodes of care where AI will be utilised to improve efficiencies and provide timely and quality care whilst having appropriate human oversight these possible risks that can emerge which need to be identified and classed as outlined in Schedule 2 of the Therapeutic Goods (Medical Devices) Regulations 2002.

Question 5. Are all other classification rules in Schedule 2 of the Therapeutic Goods (Medical Devices) Regulations 2002 appropriate for the risks associated with the use of medical devices that are, or incorporate, AI models and systems? Why or why not?

AdPha believes other classification rules in Schedule 2 of the Therapeutic Goods (Medical Devices) Regulations 2002 to an extent accounts for the risks associated with the use of medical devices, specifically a programmed or programmable medical device or software that is a medical device.

As reported in Pharmacy Forecast Australia 2024, AI tools can serve to improve efficiencies in current health care setting workflows and optimise human expertise by enabling opportunities to advance scope of practice and support sustainability of the

workforce as administrative, repetitive, burdensome tasks can be automated by AI.[1] Utilising AI breeds risks, and the classification rules in Schedule 2 acknowledges majority of the risks, and as mentioned above, by reclassifying 4.5(1) and 4.5(2) to include prediction or prognosis in relation to a disease or condition will capture most risks.

Nonetheless, classification 4.7 discusses the potential for medical devices that incorporate AI to recommend a treatment or intervention to a health professional who will then, is assumed to use their own clinical judgement, to decide about the treatment or intervention. This adopts a similar purpose to clinical decision support software (CDSS) such that the software will facilitate, support and enable clinical practice. Therefore, AdPha inquires the need for guardrails to ensure that a programmed or programmable medical device or software that meets the definition of a medical device does not have coercive influence upon a healthcare professionals' clinical judgement which will have direct, significant impact on patient care. Additionally, classification 4.7 has been risk classified as class IIb or less, which is concerning as AI tools incorporated within software that is intended to recommend a treatment of intervention imposes significant patient risk.

Question 6. Should there be specific classification rules for devices that are, or incorporate, AI systems or models? If yes, what are they and why should they be introduced?

Given the emerging advancements across the AI landscape and the continual improvements to current AI models, specific classification rules for medical devices that incorporate AI models and systems should be considered by the TGA. The level of risk associated with AI incorporated medical devices need to be classed differently, beyond the degree of invasiveness in the human body, the duration and location of use, and whether the device relies on a source of energy other than the body or gravity. As AI incorporated medical devices can improve efficiencies and decrease burdens on healthcare professionals, stricter classification rules are necessary to ensure patient safety is not compromised and the quality of care delivered through utilisation of advancing digital health systems remains of utmost importance with adequate human oversight.

Coupled with transparency, classification rules should identify and reflect the specific component of a medical device that incorporates AI. Not all medical devices that incorporate AI into improving its performance relies on solely AI generated inputs for it to meet its intended purpose. Therefore, when utilising classification rules, it is imperative that manufacturers are transparent with regards to which specific aspect of their medical device incorporates AI and whether this will directly impact patient care thus potentially lead to harm. As patient complexities prolific, clinical guidelines and standards of practice synchronously evolve and adapt to meet the demands. Similarly, digital health advancements must swiftly align with the rapidly evolving modifications in clinical

practice and be reflected in a timely manner across medical devices that utilise AI based on clinical practice guidelines and standards to provide an output. These nuances embedded across medical devices that incorporate AI must be closely monitored to ensure they are not overlooked such that patient safety could be compromised. The source of information and inputs that these medical devices utilise to perform its intended purpose and whether this aspect is reliant on AI requires greater transparency to ensure classification rules will be appropriately assigned.

- **Essential Principles**

Question 7. Are the current requirements in essential principle 12.1 (Attachment B) sufficient to address the risks emerging from the complexity of the different subtypes of AI?

AdPha broadly supports the current requirements in essential principle 12.1, however, with the emerging complexities from subtypes of AI and the various uses of AI in healthcare settings, it is important to ensure there is strict governance and oversight of the algorithms and information processed by AI models and systems. Given these AI models and systems are used for providing a diagnosis for a disease or condition, screen for a disease or a condition, provide a prediction or prognosis in relation to a disease or condition and provide this information to a health professional for the purpose of the health professional making a diagnosis of a disease or condition, evidence-informed, up to date practice is crucial.

As mentioned above, the health landscape continues to transform and patient complexity intensifies in the modern world, practice standards and guidelines rapidly adapt to evolving health care needs. A similar adoption strategy is necessary and must be translated and captured in a timely manner within AI tools that are used to assist with informing patient care. Therefore, AdPha believes essential principle 12.1 (f) should be revised to capture evidence-informed and current information is maintained in these AI tools to provide quality, person-centred care that upholds contemporary practice in health care settings.

Similar to robust quality assurance and regulatory processes in place for registering a medicine in Australia, a comparable process must be adopted prior to utilising advancing digital health practices including AI incorporated medical devices.

Medicines undergo thorough assessment and clinical trial phases which surface inconsistencies between success in research conditions and when used in phase 2 of a clinical trial. AdPha queries the regulation and processes in place for registering medical devices that incorporate AI and whether it accurately reflects the broad impact that utilisation of AI will have on direct patient care. If the intended purpose of the medical device that incorporates AI fails to be achieved in active healthcare environments, this

must be detected prior to implementation and registering of medical devices, similar to medicines. There must be an equilibrium between fostering digital health innovation and ensuring robust, research and development processes are strictly followed to implement evidence-based advancements that are credible and justifiable to uphold patient safety.

AdPha believes that to effectively utilise digital and technological advancements, robust governance and collaboration between health care providers, technology developers and regulatory bodies is crucial. This will foster establishment of equitable and safe AI tools, which are interoperable and encompass digital health strategies that meet the demands and needs across dynamic health environments.

The current essential principles should specify that sponsors of programmed or programmable medical devices must embed robust governance and collaboration with end users of tools such as AI models and systems to ensure utilisation of these advancing digital health innovations are effective, interoperable and standardised to aid the delivery of quality care. This will serve a culture of data stewardship and provide guardrails to mitigate potential risks that can emerge, if suppliers are aware of the risks to avoid, by adopting a proactive approach. For AI tools to be fit for purpose, suppliers and manufacturers must collaborate with health care providers and regulatory bodies to ensure all safeguards are adhered to and the medical device achieves its intended purpose in a safe manner.

Question 8. Are additional provisions required to address specific kinds of AI? (adaptive AI, generative AI, machine learning, etc) If yes, what provisions and under which circumstances?

No comment.

Question 9. Should there be additional provisions to ensure the ongoing performance of open-source software that is incorporated in medical devices? If yes, please provide details.

Yes. One of the main concerns discussed with respect to the use of AI is not related to the technology itself but the disinformation of health information provided from open sources that are not strictly governed or regulated. AdPha believes that additional provisions are required to ensure consumers are protected from accessing misinformed health advice. Clear standards for health advice platforms and benchmarking must be in place by governments to lay the foundational requirements for providing health advice to consumers from open-source software's. If medical devices have open-source software incorporated, additional provisions defining the potential safety considerations is essential and should be something the manufacturer of the medical device explicitly articulates. Similar to the above, ensuring the information incorporated in medical devices from open-source software is evident-informed, relevant and reflective of contemporary

practice must be strictly followed. Therefore, the manufacturer of the medical device must take accountability for utilising open-source software within the medical device and be well versed with the performance of the device aided by open-source software by accepting the risks that can occur.

Question 10. Should there be a requirement in the essential principles to identify when AI is incorporated in a medical device? (Check all that apply)

- When it is standalone AI as a medical device.
- When it is used as part of the device achieving it's intended purpose.
- Where a specific kind of AI is being used (generative AI, adaptive AI, etc).
- Medical devices that are an AI system or model should be identified on the labelling and/or in the instructions for use.
- Medical devices that use an AI system or model to generate data or make decisions about the care of a patient should be identified on the labelling and/or in the instructions for use.
- Other circumstances (please elaborate).

Transparency of using AI tools, especially when these models and systems can influence decision making related to patient care is of utmost important. Consumers should be made aware that decisions made about their care could be informed by data and information derived from AI models and systems. Following this, consumers must be equipped to entrust the provision of information provided by AI tools that aid patient care and this requires transparent, continual communication and collaboration with the consumers of healthcare. Partnering with consumers is a priority area and key standard set by the Australian Commission on Safety and Quality in Health Care (ACSQHC). [2] The standard highlights the importance of including consumers in all aspects of clinical decision making, thereby, emphasising the quality of care that can be provided through strong collaboration, transparency and communication. By identifying the use of AI across medical devices and providing comprehensive information, consumers can better understand the implications of AI in their care and most importantly be aware of the benefits and risks that follow AI tools. Evidence suggests partnering with consumers delivers better clinical outcomes, safety and quality and the patient experience is improved, and community perceptions of healthcare delivery and organisations are shifted.

AdPha agrees that there should be a requirement in the essential principles that clearly articulate when AI is incorporated in a medical device there must be transparency of its use, for both the clinician and patient/end-user.

Question 11. Are there other risks associated with the use of AI that should be addressed with additional labelling requirements? If yes, please provide information about what the risks are and what additional labelling requirements should be introduced.

Additional risks associated with the use of AI should be addressed through other platforms and means rather than including this as an additional labelling requirement. The risk of misinformation or inaccurate performance from the use of AI needs to be communicated to clinicians and healthcare providers through education and effective awareness strategies that highlight the benefits and risks related to the increasing use of AI across healthcare settings.

By providing the foundational understanding of the use of AI across healthcare and the benefits and the risks, labelling is a good way of identifying AI-integrated medical devices. Strict governance of labelling is crucial and must parallel clear, regulatory oversight of the labelling requirements to determine who is responsible for the content, accuracy, and updating of AI-related labelling.

Without defined governance, there is a risk of inconsistent or inaccurate information being provided to clinicians and ultimately patients, which could compromise patient safety and hinder effective clinical decision-making. If regulations and legislation are amended for the use of AI tools in healthcare, labelling must reflect this in a timely manner.

Another concern is the possibility of labelling being copied or misappropriated. If labelling content is duplicated without proper validation or authorisation, it will falsely lead to the dissemination of outdated or incorrect information that is construed to be derived from AI tools.

To mitigate these risks, AdPha recommends implementing a strategy similar to the Therapeutic Goods Administration (TGA) system of listing medicines with AUST R (Registered) and AUST L (Listed) numbers in Australia. This provides healthcare providers and consumers' confidence that the medical device that incorporates AI has been approved by the TGA for its use. Assigning unique identifiers or registration numbers to AI systems and models used in medical devices can:

- **Ensure Traceability:** Unique identifiers allow for tracking of specific AI models and systems, facilitating monitoring and management throughout the devices lifecycle.
- **Enhance Accountability**: Manufacturers would be required to maintain up-to-date information associated with each AI model and system, ensuring any changes or updates are appropriately documented and communicated.
- **Promote Transparency**: Clear labelling with standardised identifiers helps healthcare professionals and consumers easily recognise the involvement of AI in

medical devices, understand its role, and access detailed information about its function and governance.
- **Facilitate Regulatory Oversight**: Potential regulators can more effectively oversee AI technologies in medical devices, ensuring compliance with safety standards and enabling swift action if issues arise.

Adopting a robust labelling framework for AI tools would address governance concerns and reduce the risk of misinformation due to copied or inaccurate labelling. It would also align with best practices for transparency and patient safety, fostering trust in AI-integrated medical devices among healthcare providers and patients.

Software exclusions

Question 12. Do you think the existing software exclusions to carve out certain products from the Medical Devices Regulations remain appropriate?

a. **Consumer health products**
b. **Digital mental health tools**
c. **Software that is a calculator**
d. **Laboratory information management systems**

If no, what measures do you consider most appropriate for the identified exclusions? If yes, why?

As stated in the consultation paper, one of the software-based exclusions from TGA's oversight were made on the basis that these products were very low risk to users. AdPha and its members from the Pharmacy Informatics and Technology Specialty Practice Group query the definition of 'very low risk' and seek clarity regarding how risk was assessed and whether a similar approach to the classification rules were adopted. To this end, the existing software exclusions to carve out certain products from the Medical Devices Regulations is not appropriate as the term 'very low risk' requires further explanation and must be defined with clear objective criteria. Acknowledging the TGA adopts a principles-based regulation approach to provide flexibility, AdPha believes there are certain aspects that require an objective rules-based approach to prevent ambiguity.

- Digital mental health tools (DHMTs)

There are professional bodies and regulatory frameworks in place to protect consumers in the healthcare sector from unregulated operators. These protections are essential to ensure that health services and products are safe, effective, and reliable. The exclusion of DMHTs from the TGA regulation contradicts these protections, especially considering that the individuals seeking mental health support are often among the most vulnerable

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populations who should be provided with accurate, evidence-informed and credible information. Patients using DMHTs who may be suffering from mental health conditions are at a high risk of harm, including suicidal ideations and self-induced harm. This heightens the importance of ensuring these tools are regulated and reviewed such that they are effective and verified for its intended purpose.

Carving DMHTs, software-based products, owing to reliance on a voluntary accreditation process managed by the ACSQHC via the National Safety and Quality Digital Mental Health (NSQDMH) Standards is not appropriate. Accreditation to the NSQDMH Standards is voluntary and this simply negates the mere concept of utilising the Standards to guide safety and quality in DMHTs if there is no routine accreditation process to assess whether the tools adhere to the Standards. If accreditation to the NSQDMH standards was not voluntary, this would ensure there was greater governance and oversight of DMHTs that ensures safety and quality is upheld such that end-users receive evidence-informed, contemporary practice aligned advice and information.

Moreover, these tools are assumed to be based on established clinical practice guidelines that are referenced and displayed in the software. However, AdPha queries whether any safeguards are currently in place to ensure DMHTs tools do base their products based on current clinical practice guidelines and whether DMHTs are updated in a timely manner to reflect contemporary practice. Dynamic health complexities mean clinical practice guidelines are being updated and reviewed more frequently to align current population characteristics and evolution. The vulnerability of the population cohort who may utilise DMHTs heightens the urgency to ensure these software products provide information and advice that is current and reflective of updated clinical practice guidelines.

Unregulated DMHTs should not be classed as a product that is very low risk to users. Leaving these tools unregulated could lead to unsafe outcomes, where users rely on unproven or unreliable digital interventions which can lead to rippling effects and increased presentations across health care settings. Therefore, it is crucial that DMHTs be included in the TGA Medical Devices Regulations to ensure they meet the necessary standards of safety, efficacy, and quality, similar to other medical devices. Regulating these tools would ensure that they are subject to clinical validation, ongoing oversight, and patient protection mechanisms, aligning with the broader goals of protecting public health and safety.

- Consumer health products:

Specified good 14B in the Therapeutic Goods (Excluded Goods) Determination 2018 requires further clarification and refinement of its intended purpose. A software, or a combination of software and non-invasive hardware that is:

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(a) intended by its manufacturer to be used by a consumer to promote or facilitate general health or wellness by measuring or monitoring (through non-invasive means) a physical parameter, such as movement, sleep, heart rate, heart rhythm, temperature, blood pressure or oxygen saturation;

(b) not intended by its manufacturer to be used:

i. in clinical practice; or

ii. for the purpose of diagnosis, screening, prevention, monitoring, prediction, prognosis, alleviation, treatment, or making a recommendation or decision about the treatment, of a serious disease or a serious condition, ailment or defect

will most likely be used for the purpose of prediction of a serious disease or serious condition, ailment of defect. AdPha agrees with the issues listed in the consultation that these goods continue to emerge across varying environments and provide information well beyond health and wellness, with a greater focus on diagnostic and monitoring functionalities. AdPha supports utilisation of digital health applications and remote monitoring devices as this facilitates empowerment and active patient engagement across their health care management. However, to support active engagement from patients, it is crucial that this is complemented by regulating these applications and software products that are being utilised to monitor whether the devices performance meets its intended purpose. Patients who utilise consumer health products and are empowered to take accountability for their health should be provided with transparency of the goods they use as many may believe these products have undergone robust testing and quality assurance processes to ensure they are fit for purpose. Many patients are relying on these software products to monitor their health status and perceive many of these devices are reliable health information sources.

To this end, consumer health products are increasingly enhancing their functionalities to deceitfully be used for the purpose of diagnosis, prediction, monitor and make recommendation or decision about the treatment of, a disease, condition, ailment or defect. These consumer health products must be regulated, and strict governance is essential to oversee the utilisation and use of these software products which are supposedly stating are not intended to diagnose, screen for, monitor, predict, make a prognosis of, alleviate, treat, or make a recommendation or decision about the treatment of, a disease, condition, ailment or defect.

Additionally, if consumer health products are regulated by the TGA it is important to provide transparency with regards to the software products that do not meet the regulatory inclusions. By providing this level of transparency and communicating with end users and consumers of software products these can be safeguards implemented to protect patients such that they receive safe, quality care from utilising these software products.

- Software that is a calculator

There are many software products that are calculators replacing paper-based guides and resources which are utilised in healthcare settings, including, but not limited to, therapeutic drug monitoring and dosing, renal impairment calculations and opioid conversion calculators. It is required that a software that is a calculator uses relevant published clinical standards or authoritative sources to make calculations or displays calculations and outputs in a manner that may be validated by the user. Similar to DMHTs, AdPha queries how the use of current and relevant clinical standards and authoritative sources are verified and validated for use in health care settings in a timely manner. Analogous to evolving clinical practice guidelines and standards, these calculators must be programmed to reflect current practice that accounts for emerging complexities.

- Laboratory information management systems

Due to increasing digital health advancements and AI incorporated models and systems, laboratory information management systems may have the functionality to trigger automated ordering of certain laboratory results based on an assay that is examined. This becomes a prescriptive response, which would historically be determined by a clinician for the clinical need to order certain tests. AdPha acknowledges the National Association of Testing Authorities (NATA), Australia accredits organisations to perform testing. However, if AI is incorporated into these systems, it is important to clarify to what extent clinicians will have sufficient oversight and influence over ordering appropriate clinical laboratory tests in practice. AdPha believes accrediting these systems should be managed by NATA, however, these evolving complexities must be addressed during accreditation processes.

Question 13. Are there other software exclusions you consider inappropriate? If yes, what are they?

No comment.

International harmonisation

Question 14. What risks and/or advantages do you see to maintaining international harmonisation?

Although international harmonisation in AI regulation is preferred, allowing for seamless integration of products across borders and avoiding high costs for manufacturers, it is essential to recognise that it may not always align with Australia's legislation and regulation. Therefore, while aligning with major frameworks such as the IMDFR (International Medical Device Regulators Forum) should be a priority, Australia must retain the flexibility to act in situations where patient safety is compromised. By balancing international alignment and maintaining high safety standards, Australia can ensure timely access to innovative AI solutions while safeguarding patient care, as this must be of utmost priority.

To ensure alignment with advancing digital health innovation globally, Australia needs to develop a sovereign capability for assessing and monitoring the safe use of medical devices that incorporate AI. Similar to the robust processes and quality assurance procedures in place to register a medicine in Australia, medical devices that incorporate AI require a comparable approach. As mentioned above, a strategy similar to the Therapeutic Goods Administration (TGA) system of listing medicines with AUST R (Registered) and AUST L (Listed) numbers should be adopted for a medical device that incorporates AI. Additionally, AI models and systems, like medicines, require ongoing post-marketing surveillance to ensure updated models and enhancements maintain safety and efficacy and adhere to Australia's legislation and regulations. A structured approach to regulating AI tools based on a risk matrix must be considered as variations between nations stemming from legislation and regulations must be acknowledged and addressed when discussing international harmonisation.

Question 15. Are there circumstances where the risk posed by the use of AI models and systems should override international harmonisation?

See above.

Transparency

Question 16. Should therapeutic goods be labelled or identifiable as having met the TGA's regulatory requirements?

If yes, how should therapeutic goods be labelled? (Please check all that apply)

- **With a simple mark or symbol that shows that it is "TGA approved".**
- **With the ARTG inclusion number.**
- **Through a publicly available database.**
- **Other (please explain).**

As mentioned above, AdPha recommends implementing a strategy similar to the Therapeutic Goods Administration (TGA) system of listing medicines with AUST R (Registered) and AUST L (Listed) numbers in Australia. This provides healthcare providers and consumers' confidence that the medical device that incorporates AI has been approved by the TGA for its use. Assigning unique identifiers or registration numbers to AI systems and models used in medical devices can:

- **Ensure Traceability:** Unique identifiers allow for tracking of specific AI models and systems, facilitating monitoring and management throughout the devices lifecycle.
- **Enhance Accountability**: Manufacturers would be required to maintain up-to-date information associated with each AI model and system, ensuring any changes or updates are appropriately documented and communicated.
- **Promote Transparency**: Clear labelling with standardised identifiers helps healthcare professionals and consumers easily recognise the involvement of AI in medical devices, understand its role, and access detailed information about its function and governance.
- **Facilitate Regulatory Oversight**: Potential regulators can more effectively oversee AI technologies in medical devices, ensuring compliance with safety standards and enabling swift action if issues arise.

However, medical devices that incorporate AI that do not meet the TGA's regulatory requirements, or have an exemption, should be just as easily identifiable by health care providers and end-users. There must be greater oversight and governance of the medical devices that do not meet the regulatory requirements to ensure they are not being utilised in practice and potentially causing patient harm. Transparency is paramount in the regulation of AI incorporated medical devices to ensure patient safety and uphold public trust. For devices operating under exemptions, there must be robust monitoring and evaluation processes in place. This should include a comprehensive and accessible register that documents these exemptions, and those medical devices that do not meet

the regulations, including the specific conditions and timeframes under which they were granted. This visibility allows stakeholders to monitor for when a devices functionality may expand beyond its original exempted purpose without appropriate oversight. By keeping a detailed log of exempted and unregulated devices, developers and regulators can ensure that any changes in the device's application are met with corresponding clinical rigor and regulatory review. If issues or complaints arise, transparent records enable a clear understanding of the exemption's basis and facilitate timely re-evaluation and action. Establishing systematic processes and maintaining transparency around exemptions and unregulated medical devices not only enhance accountability but also reinforce the increasing responsibility to oversee these evolving AI-incorporated technologies effectively in a timely manner.

Question 17. Are there other measures the TGA should implement to improve transparency about the use of AI models and systems in therapeutic goods? If yes, what are they?

No comment.

Guidance, education, information and communication

Question 18. Is the use of AI models and systems adequately covered by the current guidance and information available on the TGA website? If no, what changes or additional material are required?

Factsheets should be utilised to disseminate further education and awareness regarding the use of medical devices that incorporate AI. These factsheets should be concise, easy to read, and written in simple language yet detailed enough to translate relevant information to key stakeholders, including health care providers, manufacturers, sponsors and patients. It is important to ensure patients are aware of their rights when it comes to the care they receive, especially when medical devices that incorporate AI have been utilised. Improving patient engagement and empowering them to be involved in decision-making related to their own care is essential. Whether this means targeted factsheets to patients are developed, this can be a consideration.

When providing education and awareness regarding regulating medical devices that utilise AI, the importance of continual and sustainable change management processes must be considered. AI is an evolving technology, and ensuring stakeholders are aware of the changes in a timely manner is crucial. Change management must be ingrained into the regulatory framework so that updates to AI algorithms, intended purposes, or potential risks are monitored consistently, ensuring devices operate safely and ethically throughout their lifecycle. These changes need to be communicated to stakeholders in a timely, easily accessible manner.

Moreover, accessing resources, guidelines and clinical practice updates related to medical devices that incorporate AI should be easily accessible on the TGA website and communication platforms. Communication should be sent to key stakeholders for awareness and means of notification.

Question 19. Are there places other than the TGA website where information about the regulation of therapeutic goods should be made available?

Please see below a list of places other than the TGA website this information should be made available:

- State government websites
- Australian Commission on Safety and Quality in Health Care resource library
- Fact sheets to be disseminated to health care settings
- Primary care settings
- Events and conferences

Question 20. Are there specific resources that should be developed to support clinicians and consumers? If yes, what are they and where should they be provided?

No comment.

References

[1] Advanced Pharmacy Australia. (2024). Pharmacy Forecast Australia 2024. Australia. Available from: https://adpha.au/publicassets/e8fad6b2-576e-ef11-913f-005056964190/Pharmacy-Forecast-Australia-2024.pdf

[2] The Australia Commission On Safety And Quality In Health Care. (2024). Partnering with Consumers Standard. Australia. Available from: https://www.safetyandquality.gov.au/standards/nsqhs-standards/partnering-consumers-standard

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