SHPA response to TGA's proposed clarification of how Clinical Decision Support System (CDSS) software is regulated, May 2024

The Society of Hospital Pharmacists of Australia (SHPA) is the national professional organisation for more than 6,100 hospital pharmacists, and their hospital pharmacy intern and technician colleagues working across the Australian's health system. Hospital pharmacists are core to medicines management and optimising the safe and quality use of medicines in all settings.

SHPA convenes a Pharmacy Informatics and Technology Specialty Practice Group with over 800 pharmacists and technicians, whose Leadership Committee have contributed to the development of this submission. SHPA's Pharmacy Informatics and Technology Specialty Practice Group is a network of members who have an interest in or work to optimise patient care and outcomes when deploying, building or analysing data or using digital systems such as electronic medication records, e-prescribing, dispensing software, automated dispensing systems, smart pumps and pharmacy robots.

SHPA welcomes the opportunity to be consulted on how clinical decision support system software is regulated, given they have long been a critical element of pharmacy practice. The health software ecosystem also continues to grow rapidly as technological progress is made to support the capacity and efficiency of our healthcare practitioners, as well as make healthcare safer. This does not come without risks, and the inappropriate or incorrect use of some software or digital systems, or insufficient training of use, has already been implicated in a number of coronial inquiries or inquests into preventable deaths in the healthcare system. With artificial intelligence software already being used in Australian healthcare delivery and expected to gather pace, regulation of these emerging technologies is necessary to safeguard the public from unintentional harm or unsafe care. SHPA offers the following comments on the four proposals in the discussion paper.

Proposal 1: Introduce a definition for CDSS software

Clinical decision support system (CDSS) software *are software technology-based products intended by the manufacturer to:*

a) *assist clinicians by aggregating, analysing and displaying data from within electronic medical records (EMRs) or clinical information systems to provide prompts, reminders and recommendations at the point of care; and/or*
b) *assist in implementing evidence-based clinical practice guidelines and*
c) *may improve efficiency, reduce errors and adverse events, and enhance the overall quality and availability of effective care.*

Do you agree with the inclusion of the proposed CDSS definition in the Regulations?

Yes.

Why or why not?

SHPA believes that the inclusion of the proposed CDSS definition in the Regulations is an improvement that aligns with current international based definitions of CDSS and is fit-for-purpose for knowledge based CDSS software.

However, it is essential to note that this definition does not address the need to protect consumers from products that are not intended to function as a CDSS, but are, or can be used in clinical practice. The consultation paper identifies all large language models (LLMs) as CDSS software, yet the proposed definition – which says "*intended by the manufacturer"* – would likely exclude LLMs from regulation as a CDSS software since it is not the *intent* of the manufacturer for it to be used clinically or as outlined in this definition.

Additionally, consideration should be given to scenarios where CDSS software is developed by an agency rather than a manufacturer. For example, most government health service organisations have considerable informatics teams that support and maintain the electronic medical records (EMRs). More recently, these teams have began employing data scientists and other persons able to supplement and create technologies that are not available or that have too many constraints within the utilised software. The proposed definition does not clarify how an internally developed CDSS, that is not intended to be marketed or commercialised, would be categorised. We suspect that approvals for the development of these models and CDSS applications sit with human research and ethics groups who are unlikely to be aware of the broader considerations in CDSS software, artificial intelligence (AI) and technology that are required.

As the use of CDSS software increases, particularly with AI and machine learning technologies, it is anticipated by SHPA that the ethical and professional considerations on clinically acting on advice and recommendations from these software will be raised by healthcare stakeholders. The TGA alone, based on its remit, is unable to be the sole regulator in this emerging area of practice. To protect the public and support safe and high-quality care, there is very likely a role for professional practice standards, health practitioner regulators, local health services and others, who will have influence in where and how these software are or are not used in patient care. SHPA recommends that the TGA stays ahead of this regulatory environment as a principal regulator of CDSS in Australia.

Proposal 2: Amend Schedule 4 Item 2.15 in the Regulations

Stakeholders have provided feedback to the TGA indicating that clarification is needed to deliver certainty about the scope of exempt CDSS software products, particularly with respect to:

- *diagnostic software (including IVD software); and*
- *ensuring stakeholders understand that processing a medical image includes compression and decompression.*

Therefore, the proposed amendment is to add the following wording to Schedule 4 Item 2.15:
(d) not intended to provide a diagnosis or treatment decision, including IVD software.

Do you agree with the amendment of the description of exempt CDSS software in Schedule 4 Item 2.15?

Yes.

Why or why not?

SHPA supports this proposed amendment as it will support the need for greater regulation and oversight of products that declare themselves as CDSS software.

However, as was the case with Proposal One, this proposal only targets products aimed at the medical software industry and does not cover consumer grade tools. For example, consumers have access to pseudo-CDSS software through the utilisation of LLMs such as chatbots/GPT, creating a challenge for these regulations. An LLM like ChatGPT is not marketed or intended to be used as a CDSS software, however, it could very easily be employed for that use by a consumer, or have an open source plug-in created to do so.

SHPA does not suggest that the TGA alone should be expected to regulate all AI systems, however, there is a need to consider intent and capability as separate but related elements that require a system to be subject to regulations. Failing to provide an avenue to exert influence and regulate tools capable of acting as a CDSS

software will put consumers at risk of harm. The power and ability of LLMs to create health disinformation is well documented[1], as are the lack of guardrails in place to prevent bypassing any current protections.[2] Greater vigilance is required to manage potential risks and safeguard public health.

Proposal 3: Amend the conditional exemption for CDSS software

In order to ensure transparency for practitioners and professionals, and to provide clarity on the requirement to allow for verification by a healthcare professional, we are proposing to amend the current criteria for exemption of certain CDSS software products described in Schedule 4 Item 2.15 to include the following:

(e) displays within the product, details of clinical practice guidelines, calculations or logic used by the CDSS software to the health professional to enable verification of any recommendations made by the product, where such verification is of a nature that can be realistically performed in the intended clinical context of use.

Do you agree with the amendments to the criteria for exemption of certain CDSS software to enable verification of any recommendations made by the product?

Yes.

Why or why not?

SHPA supports this proposal to amend the criteria for exemption of certain CDSS software. It is important for oversight of products that market themselves as CDSS software and addresses the current loopholes that can lead to distrust and ambiguity.

Liability for decision making supported by CDSS software is a major concern for the healthcare industry[3], this proposal creates visibility as to what is the guideline versus the operationalisation of the guideline through technology. The likely impact of this amendment is that all AI-based CDSS software will be subject to regulation, since in many cases foundational models will be unable to articulate the logic of the model.

Proposal 4: Improve guidance for stakeholders

In addition to developing new material to explain any changes made to the Regulations following this consultation, the TGA are also seeking feedback from stakeholders on the existing guidance documents below, to identify any areas where stakeholders would benefit from additional information, examples or materials.

- *TGA's general guidance on CDSS software*
- *TGA's guidance on the exemption for certain CDSS software*

What changes to guidance materials would be helpful for stakeholders to understand their regulatory obligations?

SHPA recommends that the guidelines include more information on the current and future state and how systems with the capability to act as a CDSS software are viewed.

What format or content would be useful?

N/A.

References

[1] Menz BD, Modi ND, Sorich MJ, Hopkins AM. (2024). Health Disinformation Use Case Highlighting the Urgent Need for Artificial Intelligence Vigilance: Weapons of Mass Disinformation. *JAMA Intern Med.* 2024; 184(1):92–96. doi:10.1001/jamainternmed.2023.5947

[2] Menz B D, Kuderer N M, Bacchi S, Modi N D, Chin-Yee B, Hu T et al. (2024). Current safeguards, risk mitigation, and transparency measures of large language models against the generation of health disinformation: repeated cross sectional analysis *BMJ 2024;* 384 :e078538 doi:10.1136/bmj-2023-078538

[3] Caroline Jones, James Thornton, Jeremy C Wyatt. (2023). Artificial intelligence and clinical decision support: clinicians' perspectives on trust, trustworthiness, and liability, *Medical Law Review*, Volume 31, Issue 4, Autumn 2023, Pages 501–520, https://doi.org/10.1093/medlaw/fwad013