Avant
By doctors for doctors

Avant Mutual Group Limited
ABN 58 123 154 898

Registered office
Level 6, Darling Park 3
201 Sussex Street, Sydney NSW 2000

Postal address
PO Box 746 Queen Victoria Building
Sydney NSW 1230

DX 11583 Sydney Downtown

avant.org.au

Telephone 02 9260 9000 **Fax** 02 9261 2921
Freecall 1800 128 268 **Freefax** 1800 228 268

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Therapeutic Goods Administration
Department of Health and Aged Care

By email: digital.devices@tga.gov.au

Avant submission to the TGA's consultation: proposed clarification of how Clinical Decision Support System Software is regulated

Avant's submission is attached.

Please contact me on the details below if you require any further information or clarification of the matters raised in the submissions.

Yours sincerely

Georgie Haysom

Georgie Haysom
General Manager, Advocacy, Education and Research
Email: georgie.haysom@avant.org.au

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Avant Submission to the consultation: proposed clarification of how Clinical Decision Support System Software is regulated

Avant is a member-owned doctors' organisation and Australia's largest medical indemnity insurer, committed to supporting a sustainable health system that provides quality care to the Australian community. Avant provides professional indemnity insurance and legal advice and assistance to more than 86,000 healthcare practitioners and students around Australia (more than half of Australia's doctors). Our members are from all medical specialities and career stages and from every state and territory in Australia.

We assist members in civil litigation, professional conduct matters, coronial matters and a range of other matters. Our Medico-legal Advisory Service provides support and advice to members and insured medical practices when they encounter medico-legal issues. We aim to promote quality, safety and professionalism in medical practice through advocacy, research and medico-legal education.

Members have begun approaching us for advice on the use of artificial intelligence (AI) in healthcare, particularly the use of AI tools for documentation. Some of these include CDSS products. It can be difficult for medical practitioners to assess the quality, safety and performance of tools and to understand how they work, particularly where they use AI. It is our understanding that in general these AI documentation tools fall outside the scope of the TGA's regulatory framework, and so are not subject to regulatory oversight.

Avant supports a national, risk-based, approach to regulation of AI, and we agree that higher risk products should be subject to greater regulation.

It is in this context that we provide comments on the proposals outlined in this consultation.

Proposal 1: Introduce a definition for "Clinical Decision Support System (CDSS) software"

Do you agree with the inclusion of the proposed CDSS definition in the Regulations? Why or why not?

We agree that clarity is needed around the scope of the exemption for CDSS. We are particularly concerned about CDSS products that include AI. While some AI tools used in healthcare are reasonably well established and supported by evidence, others are new and untested and may not be subject to any regulatory oversight. We agree with the comments in the consultation paper that healthcare professionals have an inability to assess the performance of a CDSS product, both generally, and where AI is used.

We agree with the inclusion of the proposed CDSS definition in the regulations because:

- if a CDSS product is to be exempted from the need to undergo the registration process, there should be clear criteria that must be met.

- given the rapid developments in technology it is important that there be a focus on consistency of definition.
- we agree that where possible there should be a focus on achieving international consistency because of the potential for products to be developed internationally and introduced into the Australian market.

We note that the proposed definition includes that the requirements in subparagraphs (a) to (c) are those "intended by the manufacturer". Where a CDSS product uses AI, and machine learning in particular, we would be concerned if the intended purpose of the product could change with machine learning, such that it morphs from a decision-support tool to a decision-making tool, beyond the manufacturer's intentions. If this happens the CDSS product would no longer be exempt and would need to be approved by the TGA and included in the ARTG.

We suggest that it would also be helpful for the regulations and/or the guidance to include unambiguous statements that:

- to be exempt, the health professional must have autonomy and responsibility for evaluating and applying the findings of the software to their clinical practice; and
- software that reaches conclusions and/or provides recommendations without the direct involvement of a health professional will not be exempt.

Proposal 2: Amend Schedule 4 Item 2.15 in the Regulations

Do you agree with the amendment of the description of exempt CDSS software in Schedule 4 Item 2.15? Why or why not?

Avant agrees with the inclusion of information that provides clarification of the criteria for exemption, thereby reducing confusion for health practitioners and manufacturers.

Proposal 3: Amend the conditional exemption for CDSS software

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?

Why or why not?

Avant agrees with the proposal to amend the conditional exemption in schedule 4 2.15 for CDSS software as described to include verification information. This would allow the health practitioner to have information to understand the basis upon which the CDSS recommendation is made so they can:

- cross check that the recommendations made by the CDSS are accurate.
- explain to the patient why or why not the practitioner agrees with the recommendations made by the CDSS.

If the practitioner does not agree, the practitioner must be able to explain why their opinion differs from the CDSS recommendation.

As the technology develops over time the criteria upon which the recommendations are being made will need to be updated. While we appreciate that the TGA's regulatory framework aims to be technology neutral, if the CDSS product uses AI, it would be helpful to make this clear. This would assist in health practitioners in their assessment and verification of the product and its recommendations, and consideration of whether it is fit for its intended purpose.

Proposal 4: Improve guidance for stakeholders

Question 4 What changes to guidance materials would be helpful for stakeholders to understand their regulatory obligations?

What format or content would be useful?

The examples in the current guidance are useful. We suggest that further examples be provided referring to CDSS products that use AI, as it is currently unclear whether some of these products are exempt or are subject to TGA oversight.

It would also be helpful to include in the guidance information about:

- when a CDSS product might move from being exempt to requiring regulatory oversight.
- the importance of manufacturer needing to monitor the operation of their products to ensure that the intended use does not change (particularly given that the proposed definition is based on the manufacturer's intended use).

Additionally, it would be helpful if guidance materials could incorporate clear statements that:

- there may be regulatory outcomes for practitioners who use software that is not exempt or approved.
- there may be regulatory outcomes for manufacturers/sellers who promote and/or provide software that is not exempt or approved.

Avant Mutual
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