Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

# Consultation: Proposed clarification of how Clinical Decision Support System software is regulated

Version 1.0, March 2024

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All submissions received will be placed on the TGA's Internet site, unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked "IN CONFIDENCE". Reasons for a claim to confidentiality must be included in the space provided on the TGA submission form. For submission made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA's Internet site. In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission form.

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# Introduction

The Therapeutic Goods Administration (TGA), as part of the Australian Government Department of Health and Aged Care, regulates therapeutic goods including medicines, medical devices, and biologicals to help Australians stay healthy and safe.

Ongoing reforms are undertaken by the TGA to ensure the regulatory oversight of all therapeutic goods remains appropriate. The objective of the reforms is to ensure the sustainability of the Australian regulatory system for therapeutic goods while delivering safe and timely access to the products the TGA regulates.

In February 2021, the Australian Government agreed a number of clarifications to the Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations) for software-based medical devices. The clarifications aimed to improve the regulation of software-based medical devices, and specifically to:

- consider measures that would clarify the boundary for software-based products that are captured under the regulatory framework for medical devices in Australia; and
- ensure that sponsors and manufacturers of software-based products are not subject to unnecessary regulatory oversight.

In considering what could potentially be carved out from regulation (including through a conditional exemption), the following principles were followed:

- Align internationally where appropriate
- Work to reduce or remove unnecessary regulatory burden:
  - by not regulating products where there is minimal-to-no risk to safety (a no-harm principle).
  - by not regulating twice (that is, where suitable frameworks for product or system oversight are already in place) including products recognised as Clinical Decision Support System (CDSS) software.

Since then, stakeholders, including industry, have raised questions and sought additional clarification on matters including:

- what CDSS software is
- how the conditional exemption applies to certain CDSS software
- what regulatory obligations need to be met to supply CDSS software products in Australia.

Additionally, the TGA has received feedback and questions from some external stakeholders indicating there are issues with the misuse of the CDSS software exemption.

Some of the exempt CDSS software notifications received by the TGA relate to software that may not meet the criteria for conditional exemption. This introduces unacceptable risks to public health.

This consultation paper is intended to seek feedback on what additional regulatory clarifications may need to be made, in addition to the development of more information and guidance, to address emerging concerns about the safety and performance of available CDSS software products.

# Background

The TGA is responsible for evaluating, approving, and monitoring products that are therapeutic goods. It regulates products that meet the legislative definition of a therapeutic good under the *Therapeutic Goods Act 1989* (the Act).

The TGA regulates software-based medical devices, including:

- software that functions as a medical device in its own right;
- software that controls or interacts with a medical device, either from within the device or externally; and
- artificial intelligence (AI)-enabled software.

If a software-based product is a medical device, the sponsor (supplier) generally needs to seek pre-market approval and the software-based product needs to be included in the Australian Register of Therapeutic Goods (ARTG) before it can be imported, exported, or supplied. The application for inclusion in the ARTG must be supported by manufacturer's evidence. Manufacturer's evidence consists of documents (including certification issued by independent bodies) demonstrating that the device is safe and fit for its intended purpose.

The 2021 regulatory amendments provided for some software-based medical devices (including certain CDSS software) to be exempt from ARTG inclusion and excluded other software from the TGA's regulatory framework. While exempt CDSS software is not required to have pre-market approval by the TGA nor be included in the ARTG, it must still:

- comply with the Essential Principles;
- comply with advertising requirements; and
- have had appropriate conformity assessment procedures applied.

Sponsors are also required to report adverse events associated with exempt CDSS software to the TGA.

## What is CDSS software?

CDSS software are software-technology products that perform a broad range of functions facilitating, supporting or enabling clinical practice. Usually CDSS software aggregates, analyses and displays data from a range of inputs including electronic medical records (EMRs) or clinical information systems (CISs). The CDSS software provides prompts, reminders, and recommendations to assist health professionals in implementing evidence-based clinical guidelines and/or hospital procedures.

CDSS software products include, but are not limited to:

- mobile apps
- artificial intelligence – any kind, including generative AI such as chatbots and large language models
- software as a service (cloud)
- websites and browser-delivered products
- more traditional software platform architectures.

The General practice data and electronic clinical decision support issues paper and related consultation regulatory impact statement published by the Department of Health and Aged Care in 2021 & 2022 similarly describes clinical decision support.

While CDSS software may take different forms, and function in different ways, a consistent feature of CDSS software is that it provides information to support a health practitioner in making a diagnosis but **does not make a diagnosis itself**.

Examples of CDSS software products include:

- a web-based application that provides information about particular diseases or conditions, based on a health practitioner's input of search terms.
- part of an electronic medical record (EMR) that provides prompts for treatment pathway options, based on a clinical practice guideline.
- an app that aggregates a patient's test results, prescriptions, and immunisation records, and makes reminders about missed immunisations or suggests additional tests, based on those already ordered, in line with a clinical knowledge database.

## Conditional exemption for certain CDSS software

In 2021 the TGA introduced a **conditional exemption** from inclusion in the ARTG for certain CDSS software. Not all CDSS software is exempt. A CDSS is only exempt from inclusion in the ARTG where it is:

- intended by its manufacturer to be for the sole purpose of providing or supporting a recommendation to a health practitioner about preventing, diagnosing, curing, or alleviating a disease, ailment, defect, or injury in persons; and
- not intended by its manufacturer to directly process or analyse a medical image or signal from another medical device; and
- not intended by its manufacturer to replace the clinical judgement of a health practitioner in relation to making a clinical diagnosis or decision about the treatment of patients.

In addition to meeting **all three** of these exemption criteria, a CDSS software will only be exempt if the sponsor provides a notice of supply to the TGA within 30 working days of commencing supply.

The manufacturer and/or sponsor of an exempt CDSS software product must still meet all other regulatory requirements for medical devices including:

- ensuring it meets the relevant Essential Principles for safety and performance
- reporting adverse events to the TGA, and
- complying with advertising requirements for therapeutic goods.

## Non-exempt software

Software that does not meet the exemption criteria must be included in the ARTG. These kinds of software include but are not limited to:

- consumer or patient-facing products
- IVD software or software-related diagnostic products
- Products labelled as CDSS software that:
  - make a diagnosis or treatment decision.
  - process signals or medical images from other medical devices, and/or use opaque methods that are not accessible or interpretable by a health professional to enable them to make an informed clinical decision.

# The problem

The nature of software innovation means that deployment and uptake of products into the market is taking place far more quickly than for other kinds of medical devices. This means that novel software products (including those using AI) can rapidly enter the market in large numbers. For example, a single product using an AI model that diagnoses tumours from images could process millions of patient images over a two-year period.

Any errors or issues associated with these kinds of products are therefore likely to manifest quickly and affect large numbers of people before reporting and action can occur. Ensuring only CDSS software devices that meet the exemption criteria are able to be supplied without undertaking a pre-market assessment and approval process is therefore critical to ensuring robust public health outcomes.

Feedback and questions from some external stakeholders indicate there are issues with the presentation of some CDSS software that are leading to misuse of the exemption, thereby introducing unacceptable levels of risk to patients as a result.

Reported issues include:

- **Application of the term “clinical decision support” (CDS):** The term “CDS has been used by suppliers in their marketing materials or product descriptions for software products and other kinds of medical devices that have functions including direct diagnosis, monitoring or treatment decision making, meaning these products go beyond decision support. If a software product is making

direct diagnosis and treatment decisions, then the product's function goes beyond the low risk functions of decision support. The TGA recognises that substantial innovation has taken place in software since the exemption was introduced. The use of this terminology whether deliberate, accidental, or misguided is contributing to confusion amongst end users of these devices.

Additionally, where the software product is supplied without an ARTG inclusion and presented as exempt, under the mistaken belief or assertion by the supplier that the product is exempt, an unacceptable increase in risks for patients arises. This is due to the lack of pre-market assessment by the TGA before these devices are supplied in Australia.

- **Incorrect application of the conditional exemption to in vitro diagnostic medical device (IVD) software:** IVD software is a diagnostic product and does not meet the current CDSS software exemption criteria. While these products may meet at least one of the exemption criteria, they do not meet all three criteria as required, and may not be notified to the TGA within 30 days of supply.
- **Inability to assess the performance of a CDSS software product:** Healthcare professionals and their representative bodies have indicated that the current CDSS software exemption (as provided in the Regulations) is concerning for some CDSS software that may not fully meet the exemption criteria.

  Healthcare professionals consider the possible misapplication of the exemption has introduced new risks to patients and clinicians where it may not be possible to verify the software is performing correctly, but it is assumed that the health professional can verify the product, particularly when used in a clinical setting. In some cases this passes the risk of error to the clinician.

# Proposals for change

The TGA is not intending to change the intent of the current CDSS software policy which was developed using the following principles:

- Align internationally where appropriate.
- Work to reduce or remove unnecessary regulatory burden by not:
  - regulating products where there is not a risk to safety (a no-harm principle)
  - regulating twice (that is, where suitable frameworks for product or system oversight are already in place) including products recognised as clinical decision support system (CDSS) software.

This consultation aims to clarify interpretation of the Regulations and guidance applicable to CDSS software with a view to refining Australia's current requirements for exempt CDSS software only.

Based on feedback and questions from some external stakeholders who have indicated changes are required to provide clarity and additional information about exempt CDSS, we have identified the following proposals for change:

1. Introduce a definition for "Clinical Decision Support Systems (CDSS) software"
2. Amend Schedule 4 Item 2.15 in the Regulations
3. Amend the conditional exemption for CDSS software
4. Improve guidance for stakeholders

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

The TGA is proposing to include the following definition in the Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations):

***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.*

This definition aligns with definitions used in other jurisdictions including the US Centers for Disease Control and Prevention. The intent of introducing the definition will be to:

- provide clarity to the scope of products commonly referred to as CDSS software, removing perceived ambiguity for stakeholders; and
- assist stakeholders in interpreting when a tool is a clinical decision support tool and when the tool provides features that are beyond the definition of CDSS software.

**Question 1**

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

**Why or why not?**

# Proposal 2: Amend Schedule 4 Item 2.15 in the Regulations

Currently the kinds of CDSS software medical devices that are subject to exemption are described in Schedule 4 Item 2.15 in the Regulations as follows:

*Medical device that is clinical decision support system software that is:*

*(a) intended by its manufacturer to be for the sole purpose of providing or supporting a recommendation to a health professional about preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; and*
*(b) not intended by its manufacturer to directly process or analyse a medical image or signal from another medical device; and*
*(c) not intended by its manufacturer to replace the clinical judgement of a health professional in relation to making a clinical diagnosis or decision about the treatment of patients*

Stakeholders have provided feedback 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.

We are therefore proposing to amend Schedule 4 Item 2.15 to the following:

*Medical device that is clinical decision support system software that is:*

*(a) intended by its manufacturer to be for the sole purpose of supporting a recommendation to a health professional about preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; and*
*(b) not intended by its manufacturer to process, compress, decompress or analyse a medical image or signal from another medical device; and*
*(c) not intended by its manufacturer to replace the clinical judgement of a health professional in relation to making a clinical diagnosis or decision about the treatment of patients; and*
*(d)* ***not intended to provide a diagnosis or treatment decision, including IVD software.***

**Question 2**

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

**Why or why not?**

# Proposal 3: Amend the conditional exemption for CDSS software

A key component of risk mitigation for exempt CDSS software is the ability for a healthcare practitioner or professional to have oversight of the datasets, information or evidence underpinning the prompts, reminders and/or recommendations made by the product. Oversight of, or insight into, how these outcomes are reached is intended to support the practitioner or professional with making a sound clinical decision.

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.***

**Question 3**

**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?**

# Proposal 4: Improve guidance for stakeholders

Sponsors and manufacturers rely on TGA's general guidance on CDSS software and guidance on the exemption for certain CDSS software to provide detailed interpretations and definitions relating to the products they are proposing to supply in Australia. These documents also provide detailed examples demonstrating how real-world products, including CDSS software, are regulated under the existing framework.

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

**Question 4**

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

**What format or content would be useful?**

# What we invite you to do

In your submission, we ask you to consider and respond to the questions outlined above, and to provide comments on the issues outlined in this consultation paper.

# What happens next?

While the proposals outlined in this consultation do not change the current policy position or approach to the regulation of CDSS software, we recognise that there are non-compliant CDSS software products currently available that will need to move to meeting regulatory requirements as soon as possible. Our approach to compliance activity is based on the following key principles including:

- we promote high levels of voluntary compliance by effectively engaging with and educating the regulated community, with clear guidance on how to comply
- our compliance and enforcement actions are evidence-based and adjust to respond to the nature and seriousness of the alleged non-compliance, and the potential risk to public health and safety.

For CDSS software, our main focus in 2024 will remain on assisting stakeholders to understand and meet their regulatory obligations. Compliance activities will initially be limited to higher risk CDSS software with an increasing focus on CDSS software devices planned for 2025.

## How to submit your feedback

Your input and feedback will help inform changes to the Regulations relevant to CDSS software. In addition to the scope of this consultation, we welcome feedback on our consultation process.

You can review the consultation on our consultation hub and submit your feedback by using our online survey tool [https://consultations.tga.gov.au/] or email your response to digital.devices@tga.gov.au Participation and feedback provided during this consultation is greatly appreciated. Following internal review of feedback received, the consultation outcomes will be published on the TGA website. This is expected to occur in mid-2024.

Please direct any queries via email to digital.devices@tga.gov.au.

**This survey closes at 23:59pm on 6 May 2024**

# Version history

| Version | Description of change | Author | Effective date |
|---|---|---|---|
| V1.0 | Original publication | Devices Emerging Technology Section | March 2024 |

**Therapeutic Goods Administration**

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au  Phone: 1800 020 653  Fax: 02 6203 1605
**https://www.tga.gov.au**

Reference/Publication #