Is my software regulated?

In Australia, software and apps that meet the definition of a medical device are regulated by the TGA. Some examples of software or apps that are medical devices are:

- An app that organises and tracks a person's health information, and analyses this information to diagnose diabetes, or provide a percentage risk of the user having diabetes.

- Software that analyses skin images to screen for melanoma

Recent reforms have been implemented to clarify the requirements of regulated software based medical devices, including introducing a number of exclusions and exemptions for specific types of software products:

- Excluded products are not medical devices, and are not subject to any TGA regulatory requirements.

- Exempt software is a medical device, but is not subject to all regulatory requirements. Upcoming guidance on Clinical Decision Support Software will provide detailed guidance on the exemption, including which products are covered, and which requirements still apply.

The purpose of this document is to guide developers and users of software to decide which software and apps are medical devices (as defined by Therapeutic Goods Regulations) and which are general health management and fitness software.

How do I know if my software is a medical device?

The following flowcharts show which software products are regulated as a medical device, and those that are not.

What if I need more information?

Please see the following guidance for detailed information on:

- How the TGA regulates software based medical devices

- Examples of regulated and unregulated (excluded) software based medical devices

- Regulatory changes for software based medical devices

- Clinical Decision Support Systems

If you have further questions, you can contact the TGA via digital.devices@health.gov.au

Is my software regulated?

Software that analyses data obtained from an IVD is regulated as IVD software. See Software as in vitro diagnostic medical devices (IVDs) for more information.

Software (including apps)

⚠ Software can be part of a medical device. This software is sometimes referred to as SiMD (software in a medical device). The TGA regulates this software as part of that medical device.

Yes

Is its purpose likely to be medical? (see page 3) — No → Does it work in combination with a medical device? — No → It is not a medical device

This software is not regulated by the TGA. See Examples of regulated and unregulated (excluded) software based medical devices for more information.

Yes

Is it excluded? (see page 4) — Yes

No

Does it work directly with data obtained in vitro? — Yes → It is an *in vitro* diagnostic (IVD) medical device

Yes (combination) → Does it enable or assist with the function of that medical device? — No → It is not a medical device

No

Does it support clinical decisions? — No

Yes (enable/assist) → It is an accessory (regulated as a medical device)

This software is an accessory. An *accessory* to a medical device is something that its manufacturer specifically intends to be used with a medical device to enable or assist it to be used as intended.

An accessory to a medical device is regulated as a medical device, and must be entered on the ARTG prior to supply. See How the TGA regulates software based medical devices for more information.

Yes

Is the clinical decision support software exempt? (see page 6) — No → It is a medical device

This software is a medical device and must be entered on the ARTG prior to supply. See How the TGA regulates software based medical devices and Examples of regulated and unregulated (excluded) software based medical devices for more information.

Yes → It is an exempt medical device

This software is exempt clinical decision support software. See Clinical Decision Support Software for more details on how exempted CDS is regulated.

For more detail see the following pages:

- Medical Purpose - Page 3
- Excluded software - Page 4 and page 5
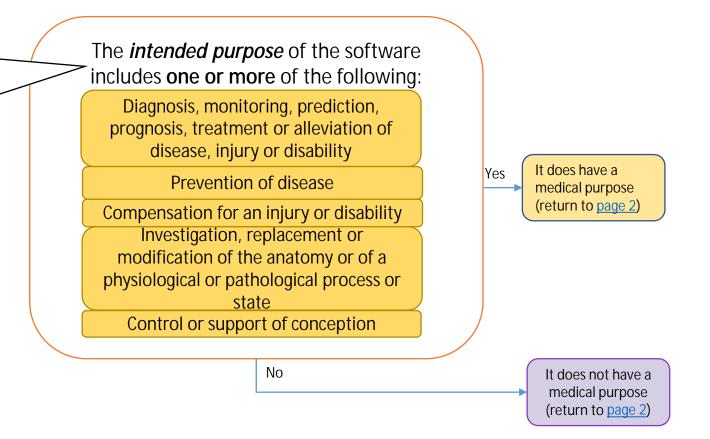- Exempted clinical decision support software - Page 6

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Is its purpose likely to be medical?

Software has a medical purpose if it is intended to be used in one of the ways shown below.

Therapeutic Goods (Medical Devices) Regulations 2002:

intended purpose what the manufacturer intends it to be used for. This is usually described in:
a) information provided with the device; or
b) instructions for use; or
c) any advertising material; or
d) any technical documentation.

The ***intended purpose*** of the software includes **one or more** of the following:

- Diagnosis, monitoring, prediction, prognosis, treatment or alleviation of disease, injury or disability
- Prevention of disease
- Compensation for an injury or disability
- Investigation, replacement or modification of the anatomy or of a physiological or pathological process or state
- Control or support of conception

Yes → It does have a medical purpose (return to page 2)

No → It does not have a medical purpose (return to page 2)

Is it excluded?

Does it have any of these functions (see page 5 for details):

> Consumer health products – prevention, management and follow up devices that do not provide specific treatment or treatment suggestions

> Digital Mental Health

> Enabling technology intended to support telehealth, remote diagnosis, healthcare or dispensing

> Digitisation of paper based or other published clinical rules or data including simple dose calculators and Electronic Patient Records

> Population based analytics that do not drive outcomes for individuals

> Laboratory Information Management Systems –systems to automate workflows, integrate instruments, manage orders and samples and associated information.

Yes → **It may be excluded**

Therapeutic Goods (Excluded Goods) Determination 2018:

Software that is limited to performing certain functions has been excluded from regulation.

These products are therefore not medical devices. Many of these products are likely to be subject to Australian Consumer Law.

For more detail on what would be excluded refer to:

Examples of regulated and unregulated (excluded) software based medical devices guidance document.

No → **No, it is not excluded (return to page 2)**

Is it excluded?

Consumer health products – prevention, management and follow up devices that do not provide specific treatment or treatment suggestions:
- Software intended for self-management of an existing disease or condition that is not serious (without providing specific treatment or treatment suggestions)
- Consumer health and wellness products (may be software or a combination of non-invasive hardware and software), excludes serious conditions
- Behavioural change or coaching software intended to be used to improve general health or wellness factors (such as weight, exercise, sun exposure or dietary intake) that does not provide information to the consumer that would generally be accepted to require the interpretation of a health professional
- PROMs (patient recorded outcome measures) and patient surveys (including those that form part of an electronic health record)

Digital mental health tools – (including a cognitive behaviour therapy tools) based on established clinical practice guidelines that are referenced and displayed in the software.

Enabling technology intended to support telehealth, remote diagnosis, healthcare or dispensing:
- Communication software that enables telehealth consultations, including the transmission of patient information, for the purposes of supporting the delivery of health services.
- Software intended to administer or manage health processes or facilities, rather than patient clinical use cases
- Systems that are intended only to store or transmit patient images
- Software intended to provide alerts or additional information to health professionals in relation to patient care. The health professional can exercise their own judgement in determining whether to action the alert or information.
- Software embedded in delivery of health services (clinical workflow management software)
- Middleware that does not control IVD instruments or medical devices, and does not recommend a diagnosis or make treatment decisions.

Digitisation of paper based or other published clinical rules or data including simple dose calculators and Electronic Patient Records:
- Simple calculators that use relevant published clinical standards or authoritative sources to make calculations or display calculations and outputs so they may be validated by the user, but do not control the administration of a calculated dosage.
- Electronic Patient Records (EMRs) and Electronic Health Records (EHRs) that use relevant published clinical standards or authoritative sources to make calculations or display calculations and outputs so they may be validated by the user, but do not control the administration of a calculated dosage.

Population based analytics that do not drive outcomes for individuals - Data analytics that are for the collection and analysis of class, group or population data that are not intended to be used for clinical use cases for individuals

Laboratory Information Management Systems – Software that automates workflows, integrates instruments, manages samples, reports results of assays - but is not intended to manipulate information or data to generate new, diagnostic outputs (other than automating simple calculations or generating report comments)
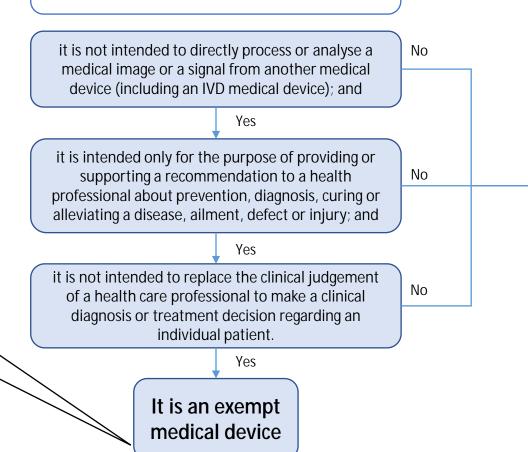
Is the clinical decision support software exempt?

Does the clinical decision support software meet **all 3** of these criteria:

it is not intended to directly process or analyse a medical image or a signal from another medical device (including an IVD medical device); and

No →

↓ Yes

it is intended only for the purpose of providing or supporting a recommendation to a health professional about prevention, diagnosis, curing or alleviating a disease, ailment, defect or injury; and

No →

↓ Yes

it is not intended to replace the clinical judgement of a health care professional to make a clinical diagnosis or treatment decision regarding an individual patient.

No →

↓ Yes

It is an exempt medical device

Therapeutic Goods (Medical Devices) Regulations 2002:

Some medical devices are exempt from the requirement to be entered on the ARTG. Clinical decision support systems are only exempt if they meet these 3 criteria.

Exempt devices must still comply with certain regulatory requirements. See Clinical Decision Support Software for more details on how exempted CDSS is regulated

This software is a medical device, and requires entry in the ARTG (it is not exempt). See How the TGA regulates software based medical devices and See Examples of regulated and unregulated (excluded) software based medical devices for more information.