Australian Government
Department of Health
Therapeutic Goods Administration

Regulation of medical software and mobile medical 'apps'

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Software is becoming increasingly important in medical devices; however, its rapid evolution, particularly in relation to mobile technology, presents new and complex challenges for the TGA and regulatory agencies internationally.

The following is intended to provide guidance on the regulatory arrangements pertaining to medical software and mobile medical apps by addressing some questions frequently put to the Therapeutic Goods Administration (TGA).

Are medical software products considered to be medical devices?

A software product is considered a medical device if it fits the definition in section 41BD of the *Therapeutic Goods Act 1989*.

> A ***medical device*** is:
>
> 1. any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:
>   1. diagnosis, prevention, monitoring, treatment or alleviation of disease;
>   2. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability;
>   3. investigation, replacement or modification of the anatomy or of a physiological process;
>   4. control of conception;
>   5. and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means.

Software that satisfies this definition may include programs or operating instructions that control the functioning of an electronic device, such as:

- Smart phone apps that measure blood glucose levels and patient body temperature
- X-ray image-processing software
- Diagnostic software

Such software may be used with or in devices such as:

- Computers*
- Mobile phones*

- Tablets*
- Analysers used for pathology/detection of disease
- Patient monitors
- Pacemakers (which are medical devices themselves)
- Infusion pumps (which are medical devices themselves)

*NB a mobile phone, computer or tablet not intended by its manufacturer to be used for therapeutic purposes would not meet the definition of a medical device.

Are all medical software products considered to be medical devices?

Not all forms of 'medical software' come within the definition of a medical device. A software product that is limited to managing and presenting information - such as a medical records management system or a dosage calculator - would not usually come within the definition unless it also incorporates a therapeutic or diagnostic function.

Many mobile apps are simply sources of information. The TGA does not have a role in regulating advice to health professionals or consumers other than when it relates to the advertising of therapeutic goods, or labelling and instructions for use.

However products that have a role in diagnosing or managing illness using software that analyses clinical data, such as the results of blood tests or ECGs, would, if they come within the definition above, be considered to be medical devices and would therefore be subject to TGA's regulatory oversight.

The TGA already regulates medical device software used for therapeutic purposes under the medical devices regulatory framework. Mobile apps would be considered within this framework.

How is medical device software classified?

Medical device software that is intended to control a device, or influence the functions of a device will generally fall into the same classification as that device.

However, medical device software intended as an accessory to a medical device is classified separately from the device with which it is used.

Medical device software products that use a source of electrical energy to perform their functions are considered to be active medical devices under the classification rules contained in Chapter 4 of the Therapeutic Goods (Medical Devices) Regulations 2002.

How is medical device software (including mobile medical apps) regulated in Australia?

As with all other medical devices, the regulation of medical device software and mobile medical apps that are medical devices is **risk-based**. This means that the level of scrutiny and oversight by the TGA applied to a product will vary according to the level of risk that the product represents to the patient or healthcare professional using it. The potential risks arising from medical devices can be minor, or very significant indeed, depending on the nature of the device and its intended purpose.

Applications for inclusion of medical device software on the Australian Register of Therapeutic Goods (ARTG) are reviewed in accordance with the manufacturer's intended purpose and the manner in which the product is to be supplied to health care professionals and the Australian public.

The therapeutic goods legislation requires manufacturers of medical device software products (other than those

which are classified as Class 1 - the lowest risk classification) to obtain Conformity Assessment certification, while all medical devices, irrespective of classification, are expected to meet the Essential Principles for safety and performance.

The regulations make no distinction between different forms of software; all forms of software that meet the definition of a medical device must conform to the Essential Principles. For further information, please refer to Section 13 in Part 2 of the Australian Regulatory Guidelines for Medical Devices (ARGMD).

What is happening overseas?

Internationally, regulatory agencies are monitoring developments in medical software that might be used in diagnostic tools and other medical devices.

The TGA acknowledges the enormous complexity involved in attempting to regulate this area and continues to keep abreast of advancements in medical device technology.

The TGA is a founding member of the International Medical Device Regulators Forum (IMDRF), a group of medical device regulators from around the world who meet regularly to accelerate international medical device regulatory harmonisation and convergence.

Where IMDRF publishes guidance on an aspect of medical device regulation, each member jurisdiction, including Australia, then considers the appropriateness of that guidance in the context of its own regulatory framework.

IMDRF members have recognised that existing regulatory frameworks are not necessarily well structured to address the potential public health risks posed by standalone medical device software. As a result, in 2013 IMDRF established a dedicated working group tasked with developing and harmonising approaches to the regulation of standalone medical device software (including mobile medical apps). The TGA is actively participating in this working group.

Once the outcomes of the IMDRF working group are developed, the TGA may update this guidance in light of the Working Group's ultimate recommendations.

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