PLATYPUS TECHNICAL CONSULTANTS

# Response to TGA Consultation

## Scope of regulated software-based products

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# 1. Introduction

Governments and medical device regulators around the world have an ongoing challenge in defining their approach to regulating medical device software, including Software as a Medical Device (SaMD). Australia's Therapeutic Goods Administration (TGA), and the Australian Government in general, is no different. The International Medical Device Regulators Forum (IMDRF), of which Australia is a member, has done already done considerable work in developing internationally harmonised approaches to some of the challenges associated with regulating medical device software, but there is still a way to go.

The Australian Government has recently revised medical device legislation to better regulate medical devices software, including SaMD, based on its potential to cause harm to patients. This is an improvement in Australia's medical device regulation, but there is still confusion about which software products are medical devices and which are not.

In this consultation, the TGA has asked for feedback on which products might be excluded from regulation or exempt from inclusion in the Australian Register of Therapeutic Goods (ARTG). The TGA has also asked for feedback on where there may be duplicate regulation of medical device software, and what evidence is needed to exclude or exempt medical devices from regulation.

Unfortunately, some of the options discussed in the consultation paper would lead to more complex regulation. For example, moving regulation of some medical devices away from the TGA, or excluding some products based on their form rather than their purpose. The medical device industry is challenging enough to enter without adding further complexity, which will reduce innovation and patient access to new technology. The focus should be on looking for ways to simplify regulation without reducing the safety and performance of the medical devices available in Australia.

## 1.1. Need for regulatory guidance

Although the TGA's consultation paper states:

> *"The clarification of what is in and what is out of scope of the medical devices regulatory framework can be achieved via an exclusion and/or exemption (or a combination or both)."*

Exclusion and exemption are ***not*** goods tools for clarification of what is in and out of scope, they are tools to reduce the regulation applied to specific products. A product that is not subject to the medical device legislation cannot be subject to exclusions or exemptions from that legislation, which makes these legislative measure unsuitable for clarifying what is out of scope.

A better tool for clarifying what is in and out of scope is clear regulatory guidance. Because it is not legislation it can provide detailed information on the Government's position on what is and is not captured by the legislation, the TGA's current approach to regulating particular products, and highlight any known challenges with particular types of medical devices. Regulatory guidance can also provide information about what the common approaches are for particular kinds of medical devices.

With new regulations coming into effect in August 2020, clear regulatory guidance is urgently needed to explain to manufacturers, sponsors and other stakeholders:

- which software products are captured by Australia's medical device regulatory framework,
- the TGA's current interpretation of the regulation, and
- how conformity assessment procedures are typically applied.

Regulatory guidance is particularly import because of the number of new manufacturers currently entering the medical device industry with software products. How the regulatory framework applies to software medical devices is challenging enough for experienced medical devices manufacturers, but with the rapid increase in digital health products many small and medium businesses are entering the medical devices industry with a software product as their first medical device. Furthermore, patients and users of software medical devices don't' have a clear understanding of what is regulated, or how it is regulated.

# 2. The TGA's Questions

## 2.1. What kinds of software-based products should be exempted from inclusion in the ARTG? What are they and why should they be exempted?

Platypus Technical considers exemption from inclusion in the ARTG to be a good option for medical devices that can be shown to have negligible potential to cause harm to patients. This is because exemption from inclusion in the ARTG reduces the regulatory burden but does not exclude them from TGA oversight.

Software that is only involved in storing, transferring, encoding, decoding or retrieving clinical test results or medical images are and kinds of software that might be considered here. However, to claim the exemption there should be a requirement of conformity to a recognised technical standard.

Storage, transmission and encoding of data usually has clearly defined standards that are prescriptive, and if a product is conforming to those standards the risk of data corruption (caused by the medical device itself) should be very low. However, the risk is not zero and corruption of medical data will have a big impact on clinical decision making, so these products should still be required to comply with the essential principles[i].

If a product uses a new method for encoding or transmitting medical data, it would be unable to conform to a recognised technical standard and would therefore be required to be included in the ARTG. This is appropriate because the TGA is then giving more oversight to the higher risk products that are using unproven methods. Over time as these methods are proven and adopted, standards will be developed, and they might be added to the exemption.

## 2.2. What kinds of software-based products should be excluded from regulation by the TGA? What are they and why should they be excluded?

Software products that meet the legislated definition of a medical device[ii] should not be excluded from the regulatory framework. Furthermore, medical devices should not be excluded based on their form.

Exclusion prevents the TGA's oversight of that product and means that the product is not required to comply with the essential principles of safety and performance. All medical devices carry some risk, even if it's a low risk, and many of the software medical devices coming onto the market are novel which means

that understanding of them is low. They should be required to comply with the essential principles and be subject to post-market oversight.

The internationally harmonised approach to medical device regulation is that medical devices are regulated based upon their *intended use*, the form of the product is of limited importance. In summary, this is because what the product is used to treat, the decision it informs, or the result it produces is where the risk to patients and users is. For example, a software product that is used to calculate an insulin does has the same potential to cause harm as a hardware insulin calculator. Because of this, excluding products based on their form creates inconsistent regulation and the potential for loopholes in the future as new products are developed. The TGA does make note of this in the consultation paper

If the TGA pursues the exclusion of some kinds of medical device software it should be based on the intended use, not the form of the product. This will minimise the risk of creating loopholes and ensure that regulation remains consistently applied across the market.

## 2.3. Please provide details of any existing regulatory oversight that you consider would negate the need for the TGA to regulate particular software-based products

Platypus Technical does not believe that there is any existing regulatory oversight that negates the *TGA's* need to regulate any kinds of medical devices. If there is genuine duplication of regulation for particular kinds of medical devices, then it is the non-TGA regulation that is negated.

The TGA administers the *Therapeutic Goods Act 1989*, which includes Australia's legal definition of a medical device. The TGA is also our representative on IMDRF working groups, standards committees, holds much of Australia's expertise in medical devices and is part of our Commonwealth Government. This gives the TGA access to the best expertise, collaboration with other medical device regulators, the ability to regulation with a nationally uniform approach and a holistic view of medical device technology, the industry and the challenges in regulating them. They are best placed to regulate medical devices in Australia.

Duplication of regulation and regulatory assessment should be reduced where possible, but if the TGA passes off the regulation of some medical devices to other organizations then the regulation of the industry becomes fractured and gaps will form. Presumably the TGA would continue to regulate all medical devices that are not regulated by another organisation, which will create two classes of regulation for some kinds of products and therefore an inconsistent approach. It will also create gaps in the regulatory framework that some products slip through because of the uncertainty of who the regulator is.

Note that this is different to the TGA using assessment by other organisations as evidence of compliance with Australian legislation. For example, the TGA will accept a conformity assessment certificate from a notified body as evidence of conformity assessment. They may also accept accreditation against certain standards as evidence of compliance against specific regulatory requirements. However, the TGA is still applying the medical device regulatory framework. Regulatory guidance would be a good way for the TGA to inform industry, patient, doctors, consumers and other stakeholders about what evidence may streamline they assessment processes.

Medical device regulation should remain centralised with the TGA so that there is one clear regulator for the industry and uniform requirements for medical devices (e.g. conformity assessment; the essential principles). This way it is clear to manufacturers and sponsors of medical devices who they are accountable to. It also means that the data about the risk of kinds of medical devices can be centralised, which is important for post-market monitoring of safety.

If there is duplication of the regulation for some kinds of medical devices, then Commonwealth and State governments should be taking action to reduce the non-TGA regulation and make it clear that those kinds of medical devices are subject to the *Therapeutic Goods Act 1989*.

## 2.4. Please describe what evidence or product characteristics could be used to determine that particular types of software pose no potential for significant harm to an individual.

Physical characteristics (form) should not be used alone to determine if a product has the potential to cause harm. The intended use must be considered.

Expert advice and post-market evidence (including clinical evidence) are both key requirements for making this decision. Expert advice can inform the potential for harm, and post-market evidence provides the occurrence rate and actual outcomes. Both are needed to consider the risk to patients and users. A new product with no post-market evidence would therefore need a strong expert consensus that there was no potential for harm, and a mature product will over time collect evidence of safety and also influence expert opinion. Innovative kinds of medical devices are often inherently higher risk because of their lack of history and therefore would receive more regulatory oversight until they are proven to be lower risk. This is consistent with Australia's (internationally harmonised) approach of risk-based medical device regulation.

Relevant clinical expertise will always be an important source of expertise because health and medical practitioners have a good understanding of the potential for harm to their patients. However, with software products other advice is needed to supplement clinical expertise.

Clinical software engineers are needed because they understand the inner workings of software, best practice software engineering, and the systems that software runs on. This puts clinical software engineers in a good position to understand the risk associated design and manufacturing of products that are or include software. Clinical engineers also understand the interaction with clinical practice including how the supporting infrastructure operates.

The medical sciences will be relevant in some cases. For example, medical physicists could contribute to decisions relating to the potential harm of medical imaging technologies and software, psychologists could advise on the potential harm related to behavioural therapies.

## 2.5. Which approaches from international jurisdictions, if any, should be used to inform the Australian approach to this issue?

Platypus Technical supports the TGA continuing its work with the IMDRF to develop internationally harmonised medical device guidelines, which are to inform Australian medical device regulation. This facilitates Australian manufacturers accessing international markets as well as Australians accessing

medical devices that are manufactured overseas. IMDRF guidelines and frameworks should continue to inform Australia's approach to regulation of medical devices software.

Where the IMDRF framework itself is insufficient, the TGA should be considering the approaches of IMDRF members who are closely aligned with Australia's medical devices framework (e.g. Europe).

This means care is needed in using the approach of the US FDA to inform the Australian approach because they are less aligned with the IMDRF framework. In some regards the US FDA is a good source and ahead of us. For example, they have some excellent guidance and have taken some clear action on some types of software products. However, they differ fundamentally in their approach to medical device regulation. The US FDA framework for medical devices focusses on the product and they are only just starting to introduce manufacturer certification. In contrast, Australia, Europe, and other IMDRF regulators established their medical device frameworks based on manufacturer certification and so it is a fundamental part of our frameworks.

# 3. Conclusion

Unfortunately, how the regulation of medical device software works in Australia is still not clear to most stakeholders. Businesses and innovators entering the industry need a clear understanding of whether their product is regulated or not. Both new and established businesses need a clear understanding of what is required of them, and patients and users of medical devices need to understand what the rules are for manufacturers, and where to report incidents. More guidance for stakeholders on how the regulatory framework works and the TGA's current regulatory position is urgently needed. Waiting until reform is complete is not acceptable because reform is slow and until it is complete industry is regulated under the current rules.

With regard to future reform of the software regulation, the TGA should continue to regulate products based on intended use, which is the internationally harmonised approach. Where possible, internationally harmonised regulation should be the goal and the IMDRF framework and guidelines should be used to inform Australia's approach to regulating medical device software, including SaMD.

The TGA should not be introducing exclusions or exemptions that are based on form, this will complicate the regulation and create gaps. For similar reasons, the Government should not be looking to move aspects of medical device regulation away from the TGA. Multiple regulators with different requirements and expectations complicates the regulations and creates gaps, including making it unclear to patients and consumers where to report incidents. Increased complication also makes the industry difficult to enter, which reduces innovation and patient access to new technology.

[i] Schedule 1, *Therapeutic Goods (Medical Devices) Regulations 2002*.
[ii] Section 41BD, *Therapeutic Goods Act 1989*.