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Department of Health
Therapeutic Goods Administration

Regulation impact statement

Proposed regulatory scheme for personalised medical devices, including 3D-printed devices

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Regulation



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Introduction

Technology changes have the potential to deliver significant benefits and opportunities to Australians. Recent advances are both disrupting and changing the health sector, where there is rapid change in the availability and type of medical devices intended to be personalised for individuals.

Sometimes, the treatment requirements of a particular patient cannot be met with commercially available mass-produced medical devices. In these cases, healthcare providers make, or provide specifications to a manufacturer to make, personalised devices to meet the patients' needs.

However, medical devices are not without risk, and there is increasing recognition globally of the patient safety issues that can arise with medical devices. Recent high-profile cases have brought into question the effectiveness of the existing medical device regulatory frameworks; as a consequence, regulators around the world are increasing their scrutiny of the manufacture of medical devices.

In Australia, there has recently been a review of the medicines and medical device regulation,¹ as well as a number of Senate inquiries on medical device regulation in recent years. In order to continue to provide a high level of stringent oversight, the regulation of personalised medical devices is one such area that requires increased focus.

This Regulatory Impact Statement is intended to support the decision on whether or not to introduce regulatory reforms for medical devices that are manufactured for particular patients (personalised medical devices). These are devices that are captured in the current regulatory framework under:

- the custom-made medical device definition, and its corresponding exemption (explained in more detail below);
- medical devices that are referred to in the definition of manufacturer under Section 41BG of the [Therapeutic Goods Act 1989](#) (the Act) as devices already supplied but intended to be assembled or adapted to suit an individual; and
- medical devices incorporating human-origin materials that are currently regulated as biologicals under the Act.

Current regulation of custom-made medical devices

The [Therapeutic Goods \(Medical Devices\) Regulations 2002](#) (MD Regulation) define a custom-made medical device as:

- made specifically in accordance with a request by a health professional specifying the design characteristics or construction of the medical device; and
- intended to be used only in relation to a particular individual, or to be used by the health professional to meet special needs arising in the course of his or her practice.

To import, export or supply a medical device in Australia, it must be included on the Australian Register of Therapeutic Goods (ARTG), unless an exemption applies. This is the approval required to market medical devices in Australia.

The safety, quality and performance of medical devices is established through conformity assessment. Conformity assessment is the systematic and ongoing examination by the manufacturer of evidence and procedures to determine that the safety of a medical device is

¹ Information on the Review of Medicines and Medical Devices Regulation is available at: <https://www.tga.gov.au/hubs/mmdr>

acceptable and that the device performs as intended and, therefore, conforms to the essential principles (which set out the fundamental design and performance requirements for medical devices²).

An applicant must be able to demonstrate that the appropriate conformity assessment procedure has been applied to their device in order to apply for inclusion of the medical device in the ARTG. This is generally demonstrated by providing certification or documentation issued to the manufacturer by an appropriate assessment body (e.g., the TGA or a [comparable overseas regulator](#)). This follows third-party (independent) assessment of the manufacturer's facilities and processes and, for higher-classed medical devices, an additional in-depth design examination (evaluation) of the medical device.

There are four significant differences in the way custom-made medical devices are regulated in comparison to other medical devices: the conformity assessment procedure for custom-made medical devices, compliance with the essential principles, exemption from inclusion in the ARTG, and record keeping and reporting.

Conformity assessment procedure

In Australia, medical devices are stratified in a regulatory classification ruleset from Class I at the low end of the spectrum, to Class III at the highest. Regulatory oversight is commensurate with this classification. Manufacturers of medical devices higher than Class I, that have a measuring function, or that are supplied sterile, must be certified by the regulator (or a specified third-party representing the regulator) to ensure the manufacturer's systems provide sufficient assurance of the devices' safety and performance prior to their supply on the Australian market.

For custom-made medical devices, third-party assessment is not required. Manufacturers of custom-made medical devices may instead make use of an exemption pathway, which largely only requires the manufacturer to:

- advise the TGA that they are supplying particular kinds of custom-made medical device³; and
- keep written records for each custom-made device supplied and notify the TGA of any adverse events or recalls related to the custom-made medical device (retained for at least 5 years)⁴

There is little or no monitoring of compliance with these requirements. At the time the regulations came into place in 2002, custom-made medical devices were generally bespoke devices or devices modified for a specific patient. Typical examples were dentures and dental crowns, or prescription spectacles. At that time, it was considered that as custom-made devices were generally quite low risk products produced as 'one-off' items, third-party review of the manufacturer's facilities and processes, and in-depth examination of the devices design, for each custom-made device supplied would have been too onerous and would have affected supply of custom made devices given that most were low risk products.

Essential principles

The essential principles set out the fundamental safety and performance principles for medical devices. There are six general essential principles that apply to all devices (relating to health and

² The essential principles are prescribed in the MD Regulations, Schedule 1.

³ Notification of manufacture or importation of custom-made medical devices is required under Regulation 10.3 of the [MD Regulations](#)

⁴ The [MD Regulations](#) prescribe procedures for medical devices used for a special purpose at Schedule 3, Part 7. Clause 7.2 deals with custom-made medical devices.

safety, including long-term safety, with benefits outweighing the risks), a principle that covers information that must be provided with a medical device, another principle that covers clinical evidence requirements, and a further seven essential principles about design and construction that apply to devices on a case-by-case basis. This principles-based regulatory framework caters for technological advances and changes in the development of new medical devices, and provides flexibility for manufacturers. It does not mandate the means by which a manufacturer must prove that they have met the essential principles.

Custom-made medical devices, unlike other medical devices, are not required to fully comply with all of the essential principles. The written records required for custom-made medical devices must include a statement that the device complies with the applicable provisions of the essential principles or, if the device does not comply with all applicable provisions of the essential principles, an explanation of which essential principles the device does not comply with and the reasons for the non-compliance.

This relates to the 'one-off' nature of custom-made medical devices. For example, requirements for information supplied with a non-custom-made device are quite extensive, but this may be less extensive for a one-off custom-made medical device.⁵ Normal requirements for clinical evidence can also be impossible to meet for 'one-off' custom-made medical devices, as approaches such as clinical trials and tracking of devices in use are not always possible with one-off custom-made medical devices.⁶

Exemption from inclusion

Custom-made medical devices are exempt from the requirement for medical devices to be included on the ARTG and, as a result, are also not subject to third-party assessment and approval of the medical device prior to supply.

Inclusion on the ARTG brings with it a range of obligations and responsibilities, which do not apply for custom-made medical devices. For example, manufacturers of implantable medical devices are required to report to the TGA annually for the first three years they are included on the ARTG, and this does not apply for custom-made implantable medical devices.

There is also a range of enforcement mechanisms and sanctions linked to ARTG inclusion that cannot be applied to custom-made medical devices. For example, suspension or cancellation of an ARTG entry, such as where there are safety or compliance concerns, effectively removes a kind of medical device from the Australian market; this does not apply to custom-made medical devices not included on the ARTG. Further, most criminal and civil sanctions available under the Act relate to inclusion in the ARTG or other approvals by TGA, and thus cannot be applied to custom-made medical devices or their manufacturers or suppliers.

Record keeping and reporting

As noted above, the manufacturer of a custom-made medical device is required to advise the TGA that they are supplying a kind of custom-made medical device, and keep written records for each custom-made device supplied (to be retained for at least 5 years).

Record-keeping and reporting requirements applying to devices other than custom-made medical devices are considerably more extensive. These requirements are conditions on the inclusion of a medical device on the ARTG, and non-compliance can result in the loss of marketing approval for the device (which is not applicable for custom-made medical devices, as these are not approved for supply, so the approval cannot be withdrawn). Further, records for

⁵ Essential principle 13 prescribes the information to be provided with medical devices

⁶ Essential principle 14 requires clinical evidence appropriate to the intended use for all medical devices

high class and implantable (non-custom-made) medical devices are required to be kept for longer than 5 years, reflecting the long expected lifetime for these devices. Manufacturers of higher class devices are additionally required to make annual reports to the TGA during the first few years they are supplied.

Current regulation of diagnostic imaging and anatomical models

The accuracy of images and anatomical models is very important in ensuring correct diagnosis, or effective investigation, of anatomy, physiology, or pathology (disease) of a person.

Classification rule 5.4^[1] specifies that non-active (non-energy using) medical devices used to record X-ray diagnostic images (such as X-ray film) are classified as Class IIa medical devices. Under another classification rule, 4.3, diagnostic scanning equipment—the X-ray machine, MRI, PET or CT scanner are also Class IIa (or higher). The Class IIa classification means that manufacturers must implement a formal system of quality control (termed a quality management system) and they must also be certified and inspected by a suitable third party (such as the TGA or a European Union notified body).

However, the diagnostic and interpretative image-recording software for use with X-ray, magnetic resonance imaging (MRI), positron emission tomography (PET), and computed tomography (CT) scans is usually classified at the lowest regulatory classification—Class I—rather than Class IIa like X-ray film and diagnostic image-scanning equipment, despite such software having the same importance when it comes to required diagnostic accuracy.

This is largely a product of the time the regulations were developed rather than the risk profile of these image-recording technologies.

Similarly, anatomical models used for diagnosis or investigation of the anatomy, or used to plan surgical procedures, are also usually Class I even though their accuracy is critical in planning surgery.

The rationale for classifying X-ray film at Class IIa also holds for other diagnostic image-recording and anatomical modelling technologies that perform a similar function to that of the X-ray film.

Current regulation of medical devices with human-origin components

At present, a subset of combination products (medical devices that include materials of non-viable animal, microbial, or recombinant origin) are regulated as Class III medical devices (the highest regulatory class), and are included on the ARTG as a medical device. These devices undergo a high level of regulatory assessment by the TGA. Both the medical device components and the other therapeutic materials are assessed together as part of a design examination assessment prior to inclusion on the ARTG.

However, medical devices that include human-origin materials (for example, an artificial mechanical kidney that uses another person's stem cells) are not regulated as medical devices but instead are regulated as Biologicals under the Biologicals regulatory framework under the Act and the [Therapeutic Goods Regulations 1990](#); this is at odds with how comparable overseas regulators regulate these products.

^[1] MD Regulations, Schedule 2, Classification Rule 5.4

The growth of ‘personalised medical devices’

Personalised medical device is a broad term used to describe all of the various types of medical devices that are intended to address the particular needs of an individual. As outlined above, these may be currently regulated as custom-made medical devices, medical devices assembled or adapted to suit an individual, and/or medical devices incorporating human-origin materials. Personalised medical devices range dramatically in type and form—from prosthetics and implants to devices made using emerging technologies and advanced manufacturing methods, for example, bones, ears, exoskeletons, windpipes, jaw bones, tissues, and organs, many of which have been described in a number of recent publications.⁷

Over the past two decades, advances in technology and materials science have delivered significant benefits to the health sector, including the application of emerging technologies to medical devices.

These technologies mean that it is now possible to manufacture medical devices personalised to the individual, using modern manufacturing systems, including design software, and additive manufacturing such as 3D printing, etc. This contrasts to the traditional bespoke production methods for custom-made medical devices, such as a dental laboratory technician or dentist individually fashioning a tooth crown by hand. The advanced technologies have (or will) enable an expansion in the types of custom-made medical devices available and accessibility of custom-made medical devices, a reduction in the cost of custom-made medical devices, and an increase in the percentage number of custom-made medical devices which can be supplied to the market.



Rapid advances made in technology and materials science in the last two decades have delivered great benefits to the health sector but medical device regulatory frameworks have not kept pace.

Two areas that have had a particular impact on personalised devices are medical-imaging technology and manufacturing technology. One example is 3-Dimensional (3D) printing, where it is now possible for a healthcare professional to custom-make implantable medical devices (such as a replacement hip), designed exactly to a patient’s specifications, using 3D-printing technology. Such a custom-made medical device, when produced by more traditional methods, would previously have been difficult to make, very expensive, and a rarely used option.

International response

The regulators of ten global medical device jurisdictions, including Australia, together form the International Medical Device Regulators Forum (IMDRF)⁸—an organisation established as the successor to the Global Harmonisation Taskforce (GHTF). This group’s goal is to develop a harmonised regulatory model that will be adopted by all member jurisdictions to ensure that patients have access to medical devices that meet appropriate safety and performance standards, and to facilitate global supply. The ten jurisdictions already have regulatory requirements which are similar to one another, and are based on the work of the GHTF, of which Australia was also a founding member.

In 2018, the IMDRF [established a personalised medical devices working group](#) to develop guidance that establishes definitions and regulatory pathways for regulatory authorities to consider in the regulation of medical devices that are intended for individuals. The goal was to

⁷ For example, *Medical Applications for 3D Printing: Current and Projected Uses*

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4189697/>, accessed on 15 November 2019

⁸ www.imdrf.org

promote global harmonisation in the terminology and premarket requirements for such devices. Australia chairs the working group, and has made significant contributions to the work in the space of the regulation of personalised medical devices.

The IMDRF describes personalised medical devices in one of three ways—*custom-made*, *patient-matched*, and *adaptable*. The IMDRF definitions and associated examples are provided in [Appendix 1](#).

These different types of personalised medical devices are introduced below, together with some examples of each.

Comparison and examples of the different types of medical device proposed

Personalised medical devices				
	Custom-made	Patient-matched	Adaptable	Non-adaptable mass-produced
Comment			A type of mass-produced medical device.	
Intended to be:	manufactured specifically to address one or more of the recipient's anatomical features physiological features a pathological condition	manufactured specifically to match a particular individual's anatomical features physiological features a pathological condition	adapted after supply to address a particular individual's anatomical features physiological features a pathological condition or adapted in order to be properly installed	used by individuals or healthcare institution where the standard sizes and designs are suitable for the individual or institution's needs.
Intended recipient	An individual patient or a healthcare professional, such as a surgeon	A particular individual	A particular individual or a healthcare institution	An individual or a healthcare institution (Note: not intended for any particular individual)
When manufactured	On demand, following request from a healthcare provider	On demand, following request of an individual (usually a healthcare provider but may also be a lay person depending on the device)	When the manufacturer predicts/estimates there will be a market for the device.	When the manufacturer predicts/estimates there will be a market for the device.

Personalised medical devices				
Overall responsibility for the device	Authorising healthcare professional	Manufacturer	Manufacturer	Manufacturer
Reason specific type of personalised device required	The health professional has determined that there is no other suitable device on the market in Australia (i.e., on ARTG) that meets the needs of the intended recipient	There is no suitable adaptable medical device available for the individual's needs. The individual's needs can be met with a device that can be manufactured within the design envelope of an existing design.	There are no non-adaptable mass-produced medical devices available that can meet the needs of the individual or healthcare institution. The designed adaptability of the adaptable medical device is sufficient to meet the needs of the individual or healthcare institution.	Not applicable. Not a personalised medical device.
Specifications	Design characteristics specified and provided by an authorised professional to the manufacturer. Manufacturer takes into account the specified design characteristics when manufacturing the device.	Design and design envelope determined by the manufacturer. Specifications relating to the individual (e.g., length of arm) provided to the manufacturer. Device manufactured according to those specifications so long as they are within the previously validated design envelope.	Dimensions and design determined by the manufacturer. Intended to be adapted or assembled after supply (by a surgeon, for example) in accordance with the manufacturer's validated instructions. Adaptations and modifications may be made to specifications determined by the intended recipient so long as they are within the	Dimensions and design determined by the manufacturer.

Personalised medical devices				
			allowable parameters specified by the manufacturer in its instructions for use.	
Typical number produced	One-off	Small to large volumes	Mass-produced	Mass-produced
Production process	Intended to be a one-off. It may or may not be possible to validate or verify certain elements of the design and production. Is not intended to be reproduced.	Capable of being validated, verified, and reproduced (within the constraints of the design envelope).	Capable of being validated, verified, and reproduced.	Capable of being validated, verified, and reproduced. Continuous production process or homogeneous batch.
Example	Example 1—Addressing the needs of a patient Following a car accident, a patient requires a new neck (cervical) disc. The surgeon undertakes diagnosis and assessment of the size of disc required. On reviewing the options available, the surgeon finds that the required disc is not available so the surgeon contacts a manufacturer and requests that a disc be produced	A hip joint that is manufactured to be the necessary length, thickness, and angle for an individual patient, where the manufacturer is using a template and has made sure that joints are made within the minimum and maximum dimensions that the manufacturer has previously validated as being safe and performing as intended.	Adjustable-length crutches. A mass-produced plastic (polymer) surgical implant for skull (cranial) reconstruction that is supplied to surgeons who then shape the device during surgery specifically to suit the patient's anatomy. The manufacturer provides instructions on how to shape the device.	Portable infusion pump

Personalised medical devices				
	<p>according to specifications that will accord with the patient's anatomy.</p> <p>Example 2—Addressing the needs of a healthcare professional</p> <p>A surgeon has unusually long fingers and finds that conventional surgical tools available on the market do not meet his/her needs. The surgeon designs the specifications and asks a manufacturer to make a set of surgical clamps.+</p>			

Problem

The widespread application of emerging technologies to medical devices was not envisioned in the early 1990s when the GHTF began documenting⁹ the principles that underpin device regulation in Australia and other comparable jurisdictions (such as the European Union (EU) and Canada).

Australia adopted the GHTF model as the basis for its medical devices regulatory framework in 2002. Changes since this time—rapid developments in advanced manufacturing and digital technologies, the expansion in the types of devices being produced in this way, and the increased availability of the technology—have meant that existing regulatory frameworks are not adequate to address these emerging technologies. This is not limited to personalised medical devices, and the TGA is also examining other emerging technology issues, such as software that is a medical device in its own right (including apps) and cyber security of medical devices.



The 2002 medical devices regulatory framework in Australia has not kept pace with how changes in technology and materials science has led to new types of personalised medical devices being made available.

Australia, and other jurisdictions, are now reviewing their legislative frameworks to ensure that the risks to patients associated with the emerging technologies and the personalisation of medical devices are appropriately mitigated, while still supporting the level of innovation and development that provides benefits to patients, the healthcare sector, industry, and the broader community.

Limitations with the framework in Australia

The TGA has undertaken a comprehensive review of the Australian medical devices framework as it applies to personalised medical devices and has identified a number of limitations:

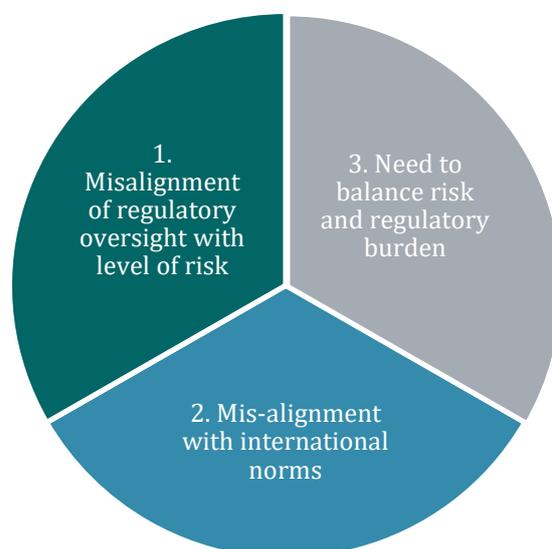
- devices which fall within the current definition of ‘custom-made medical device’ are *not* subject to regulation. This means that there is presently a large (and growing) proportion of the types of medical devices that are eligible for the custom-made exemption from regulation. This is far beyond the original intent which was, for largely lower class medical devices, to primarily shift to medical practitioners the burden of risk management of the quality, safety and performance of such devices.
- insufficient mechanisms for the Australian Government to have effective oversight and visibility of the personalised medical device sector. In addition to the risk to patient health and safety this presents, the effect is an inconsistent regulatory burden on devices falling outside the ‘custom-made’ exemption. Given the rate of growth in these kinds of devices, the significance of this problem is predicted to also grow.
- there are insufficient mechanisms for investigation or regulatory action following adverse events involving personalised (custom-made) medical devices. This is a result of the limited record-keeping requirements that currently exist.
- the current personalised medical devices framework is misaligned with the regulatory schemes in other countries for material of human-origin, medical device combination products. This means that a global industry is currently subject to different regulatory

⁹ GHTF documents can be accessed at <http://www.imdrf.org/ghtf/ghtf-archives.asp>

regimes in Australia versus other countries resulting in unnecessary regulatory burden for industry.

These limitations are three dimensions (Figure 1) of a single problem.

Figure 1—The three dimensions of the problem



Dimension 1. Misalignment of regulatory oversight with level of risk

As outlined above, any device that is made for a particular patient at the request of a health professional is considered to be a custom-made medical device. The device is therefore exempt both from the requirement of being included in the ARTG and the range of conformity assessment requirements that applies to other medical devices, such as inspections of manufacturers' premises and the requirement for third-party certification.

This contrasts sharply with the regulatory requirements for non-custom-made medical devices, where strict controls are imposed on manufacturers, and also separately on Australian sponsors (importers, exporters and suppliers) to ensure that the devices do not pose unnecessary risks to patients or other users, and that they will perform the clinical functions for which they are intended. Sponsors (official suppliers) of non-custom-made medical devices also have a range of post-market monitoring requirements, while their inclusion on the ARTG enables a number of compliance and enforcement mechanisms to be used by the TGA, including cessation of supply if compliance or safety issues arise.

There are no limits in the Australian framework on the types of devices that can be supplied under the custom-made exemption pathway. The full spectrum of risk categories of medical devices are supplied this way, ranging from simple non-invasive devices such as orthotics for shoes to treat foot abnormalities, which are typically Class I devices, all the way to hip implants for treating bone loss due to cancer, which are Class III—the highest classification.

At the time of development of the current regulatory framework for medical devices in Australia (1990–2002), the state of technology relating to personalised medical devices was significantly less advanced, and the regulatory exemption put in place for custom-made medical devices was premised on a number of assumptions, many of which no longer hold true:

- that the healthcare provider was taking on responsibility for the devices' performance, in the context of their clinical care for the patient;

- that affected devices would largely comprise low-risk products such as glass eyes, prosthetic limbs, prescription lenses, or an occasional high-risk product; and
- that the benefit of a patient being provided with a custom-made device rather than an inadequate mass-produced device, or not being provided with treatment at all, would outweigh the risk of no third-party oversight of the manufacturer of the device.

Present custom-made devices regulations only require a manufacturer to:

- notify the TGA of the specific kind of custom-made device they are supplying.
 - This is a one-time notification for the category of the device, not an individual notification every time one is supplied.
- complete a written statement about the device, including whether or not it complies with the essential principles.¹⁰
 - The information is not provided to the patient, which means that the patient may have no information about the device (unlike in the EU, where the manufacturer or authorised representative must also provide this information to the patient).

There is currently no requirement for any third-party assessment of custom-made devices or of their manufacture in Australia. The TGA may request information about the devices; however, the legislation does not provide the TGA with the power to enter and inspect manufacturing sites. Additionally, the manufacturer is only required to keep documentation about a custom-made device for five (5) years after supplying the device. This is considered to be an inadequate period of time for implantable devices due to their long expected lifetimes. Other jurisdictions, such as the EU, require that this documentation be kept for a period of fifteen (15) years.

Data limitations

The systemic risks presently presented by the *uniform* exemption of devices which meet the definition of ‘custom-made medical device’ from being regulated are clearly set out in this section.

The costs that changing this exemption to better manage patient safety risks are not possibly to quantify accurately. There is almost no data on the numbers of personalised devices that are proposed to be captured by any reform option such as manufacturing volumes and numbers of adverse events. That vacuum arises from the nature of the problem sought to be addressed by the proposed reforms—the exemption of custom-made medical devices from inclusion in the ARTG and third-party conformity assessment requirements.

TGA’s power to request information is linked to ARTG inclusion or applications for such inclusion or conformity assessment certification (which do not cover custom-made medical devices). As a result, the TGA holds only very limited notification information on currently available custom-made manufacturers. It is also thought to be incomplete.

Other possible data sources were also investigated, but it was evident that none of the potential sources had information on types, volumes or costs of custom-made devices:

- Inclusion on the [Prostheses List](#), which prescribes reimbursement requirements of private health insurers for implantable prostheses (such



¹⁰ The Essential Principles set out the safety and performance requirements for medical devices and are given in Schedule 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002*

as joint replacements, cardiac devices etc.). As listing on the Prostheses List requires inclusion of the device on the ARTG, there is no information on custom-made medical devices on this list.

- The Medicare Benefits Schedule (MBS) is a list of health professional services subsidised by the Australian Government, but reporting on the MBS largely does not capture information on the medical devices used in those services.
- Private and public hospitals hold information on procedures performed, but related medical device information, to the extent it is captured at all, is largely on individual patient records. Procurement systems also do not systematically collect information on custom-made medical devices procured.
- Healthcare sectors outside of hospitals may also use custom-made medical devices extensively, but data is unavailable on general use of medical devices, let alone custom-made medical devices. Dental, prosthetics, and orthotics health professionals are big users of custom-made medical devices, but other allied health sectors may also use custom-made medical devices, including physiotherapy and rehabilitation services, etc.
- Custom-made medical devices also cover a broad scope of devices—some are used for individual patients (and where implanted may be detailed in the patient files) but some are individual healthcare practitioners, such as custom-made instruments and equipment, which are unlikely to be captured by existing reporting mechanisms.

Classification framework

Under the Australian regulatory framework, devices are categorised in a regulatory classification framework that applies increasing levels of regulatory requirements and oversight as the Class increases. Examples of medical devices and how they are categorised into regulatory class (from highest risk to lowest risk) are provided in the table overleaf.

Currently, regardless of a device's safety and intended performance, each is eligible for the custom-made medical device exemption (see the column 'potentially exempt'). In addition to the obvious risk of absence oversight otherwise applicable to such devices, it creates a serious gap in regulation between regulation of other medical devices of the same kind. Some regulation of personalised medical devices will address risks without unnecessarily increasing regulatory burden. The present landscape may create a perverse incentive for manufacturers and sponsors to fall within the terms of the exemption.

Regulatory class/level	Example devices	Potentially exempt?
Class AIMD	Pacemakers Artificial hearts	Y
Class III	Prosthetic heart valves Absorbable surgical sutures	Y
Class IIb	Surgical lasers Diagnostic X-ray	Y

Regulatory class/level	Example devices	Potentially exempt?
Class IIa Class I(s) Class I(m)	Dental drills or ultrasound machines Sterile surgical gloves Clinical thermometer measuring body temperature	Y
Class I	Crutches Hospital beds	Y

Therefore, the existing requirements for custom-made medical devices do not distinguish between the quality, safety, and intended performance of the devices, and they are noticeably lighter than the requirements placed on manufacturers for medium and higher class mass-produced devices. Their application takes no account of the quality, safety and intended performance of the relevant device.

Regulatory requirement	Mass-produced	Custom-made
Current regulatory requirements for custom-made devices	N/A	Notify the TGA of the specific kind of device being supplied (one-time notification for the category of device) Create and retain (internal) a written statement about the device including whether it complies with each of the TGA's Essential Principles TGA may request information about the devices
Routine inspection of manufacturing sites	Yes	No
TGA inspection of manufacturing sites	Yes	Limited—only where there is an immediate public health risk and within Australia only
Information provided to patient	Yes	None
Nominated individual/organisation that is legally responsible under the Act for ensuring devices do not pose unnecessary risks to patients or other users, and that they will perform the clinical functions for which they are intended	Yes	No

Regulatory requirement	Mass-produced	Custom-made
Device must meet specific criteria related to its intended purpose, and be included on the ARTG before it can be supplied in the Australian market	Yes	No
Marketing approval of non-compliant devices can be removed from the market (suspended or cancelled from the ARTG)	Yes	No
Criminal and civil penalties can apply for non-compliance	Yes	No

Dimension 2. Misalignment with international norms

Australia, and its system of regulation of medical devices, does not operate in isolation. With just two percent of the world medical devices market, it is important for Australia to harmonise with international regulators, as it facilitates a viable domestic manufacturing base including for supply to international markets. It also makes Australia a more attractive market into which overseas manufacturers may supply their devices. The latter is critical for ensuring that the most appropriate medical devices are available to Australian patients.

Globally harmonised approaches to address the regulatory challenges associated with emerging technologies assist the delivery of standards and regulatory practices related to the safety, performance, and quality of medical devices; promote innovation; facilitate international trade; and reduce regulatory burden. Failure to so align creates a regulatory disjunct for Australia leaving both the domestic medical device market and Australians disadvantaged in the likely reduced pool of devices to which they may have access.

There exists an opportunity for Australia to adopt a strategic long-term regulatory position on personalised medical devices, by aligning its regulatory framework to that of the best-practice model advocated internationally by the IMDRF personalised medical devices working group. The beneficiaries are domestic medical device manufacturers and Australian patients.

Dimension 3. Need to balance risk with regulatory burden

The government's approach to regulating therapeutic goods is designed to ensure that regulation is only used where absolutely needed and, then, only to the extent needed to protect and advance public health. In practice, this means that the level of regulation—and the TGA's regulation and compliance efforts—is (in general) commensurate with the risks posed by particular therapeutic goods or types of technology, process, or material.

Personalised medical devices offer significant benefits to patients, the health system, and industry, but, as ever, there is a need to balance the benefits against the risks.

The Australian medical devices regulatory framework currently provides for the regulation of custom-made devices, which are devices intended to address an individual's needs where no other suitable device is available on the market. Oversight of custom-made medical devices for the most part lies with healthcare professionals who commission their manufacture. In this way, the risk associated with the custom-made device is managed, at least in part, by the health professional in exercising their clinical judgement. In comparison, manufacturers of mass-produced medical devices are the primary parties responsible for meeting safety, performance, and quality requirements when designing and manufacturing their medical devices.

In the context of the increasing technological complexity of, and higher risks of many custom-made medical devices, it is not appropriate that medical practitioners bear the primary risk of managing the quality, safety and performance of the device itself. This does not absolve the practitioner of responsibility for delivery of a high standard of care including to choose the medical device most suitable to meet the patient's needs. It is not, however, appropriate risk management, for example, for a medical practitioner to assume responsibility for assessment of the design and manufacture of a high-risk custom-made joint replacement made in a specialist and remote manufacturing facility, or a custom-made tooth crown made by a dental technician in a dental laboratory associated with their practice.

Implications for patients and management of the health system

Devices not performing as intended

No device is risk free, and complications and adverse events relating to failures in design or manufacturing can have significant implications both for individuals and for the health sector more broadly. This applies equally to personalised medical devices.

There have been a number of recent well-publicised issues with medical devices in recent years, with Senate Inquiries on ASR metal on metal hip replacement implants,¹¹ PIP breast implants¹² and vaginal mesh implants.¹³ These relate to mass-produced medical devices, but exemplify the potential harms associated with devices that do not perform as they should. The experiences of individuals can vary greatly, and can be life altering, or life ending. For example:

- [Chapter 3](#) of the Senate Inquiry report on the ASR metal on metal hip replacements notes that in addition to the failure and need for revision of the hip replacement, complications included severe pain, loss of mobility and a complex of physical and psychological effects due to shedding of cobalt and chromium ions from the implanted device.
- [Chapter 4](#) of the Senate Inquiry report on the PIP breast implants notes not only the physical complications experienced by patients who received these implants, but also the impacts of the associated anxiety and mental stress.
- [Chapter 2](#) of the Senate Inquiry report on vaginal mesh implants also details the severely adverse outcomes those women who have experienced complications following their surgery, and a list of [urogynaecological \(vaginal\) surgical mesh complications](#) was also published on the TGA's website. Complications include ongoing pelvic soft tissue trauma and infection, acute and/or chronic pain, extensive scarring, and in many of these cases the initial complaint (such as stress urinary incontinence or pelvic organ prolapse) has also recurred.

While the numbers of patients affected by failures of mass-produced devices will, at present, be higher than that for custom-made medical devices, the potential adverse effects resulting from personalised medical devices can be just as significant and costly on an individual basis. With increasing personalisation, the occurrence of these issues where personalised medical devices are involved will increase over time.

¹¹ Senate Standing Committee on Community Affairs, Inquiry - [The regulatory standards for the approval of medical devices in Australia](#) (2010-11)

¹² Senate Standing Committee on Community Affairs, Inquiry - [The role of the Government and the Therapeutic Goods Administration \(TGA\) regarding medical devices, particularly Poly Implant Prothese \(PIP\) breast implants](#) (2012)

¹³ Senate Standing Committee on Community Affairs, Inquiry - [Number of women in Australia who have had transvaginal mesh implants and related matters](#) (2017-18)

There can be significant individual harm and costs to the healthcare system when there is a failure of a medical device, including:

- the need for additional surgeries that may include explanting the device, followed by other surgery to address both the original problem and any problems caused by the faulty device;
- the cost of associated psychological impact of the failure of a device and steps required to remediate the failure;
- increased hospital stays, which puts additional strain on health systems and divert resources from other patients;
- inability to return to the previous employment, affecting potential future income and impacting the employer; and
- cost of litigation.

In addition to protecting patients from medical devices not performing as intended, a robust regulatory framework also assists the devices sector to manage risks.

Assurance of regulatory oversight

Regulatory oversight provides evidence-based assurance around the safety, quality and performance of medical devices. In addition to the fundamental role in ensuring devices perform as intended, this assurance is also relied upon across the health sector and by the broader community.

As outlined above, for custom-made devices, the clinical judgement exercised by the prescribing health professional is a key factor in managing the risks associated with the medical device. However, the increasing complexity and technology involved in producing these devices is changing the balance around the role for health professionals in this context. While health professionals continue to be best placed to identify the specific requirements for their individual patients, it is inappropriate risk management to require them to assume responsibility for ensuring the device is designed and manufactured appropriately. This is particularly so as the technological complexity of both the manufacturing process and the devices themselves becomes increasingly specialised.

The broader health sector also relies on the assurance provided by the medical device regulatory framework. While no medical device is without risk, approval of medical devices is relied upon as assurance of the safety, quality and performance of the device.

There are also broad effects at a more systemic level, such as for procurement (e.g., hospitals sourcing medical devices) and reimbursement (e.g., inclusion of a medical device on the ARTG is a requirement for all listings on the [Prostheses List](#) described above). While custom-made devices are currently prevalent in some sectors (such as dentistry), as the number of increasingly complex custom-made medical devices grows and becomes widely available in different specialities, health sector concerns about the regulation of custom-made medical devices is expected to grow.

Compliance with a robust regulatory framework also provides assurance to the medical device industry that they are appropriately managing their obligations to patients, medical practitioners, the health sector, and the community. It also provides a framework for internal assurance, including for governance (such as for company boards and shareholders).

Scale and scope of the problem

The following figures help to provide as much insight as is available into the potential scale and scope:

- the size of the 3D printing market; and
- the number of health practitioners/businesses in the market likely to already be using personalised medical devices

3D-printing in healthcare

In 2017, the global 3D printing in healthcare market was valued at \$797.7 million, and is estimated to grow at 18.3% compound annual growth rate from 2018–2023.¹⁴ North America is the leading market in the 3D-printing in healthcare market with 39.7% of the total share followed by Europe. 3D-printing in the healthcare market in the Asia Pacific region (APAC) is growing at a significant pace and the share of Europe and the APAC¹⁵ combined was 37% of the global market.

Some sources predict that between 2019–2024, the compound annual growth rate for the 3D-printing market will grow 12.8% and that the APAC region will be the fastest growing market.¹⁶

While 3D-printing technology is not the only manufacturing technique for custom-made medical devices, the emergence of this technology is instrumental in a shift from bespoke custom-made medical devices to large-scale production of personalised devices. 3D-printing has the potential to shift some types of medical interventions from custom-made medical devices being an exception, to personalised medical devices being routine. Detailed analysis of medical device sectors utilising 3D (and 4D¹⁷) printing technologies shows:¹⁸

- **Medical devices:** 3D printing of medical devices is at different stages of development, with the technology quite mature for prototyping (which has been in use for several decades by some manufacturers) and is being actively embraced by some non-implantable sectors where personalisation is the norm (external prosthetics, hearing aids and dental implants). It is early mainstream use for low volume medical devices, and in ‘adolescent’ development for custom-made medical devices and pre-surgical planning. It is estimated that there is around five (5) percent to twenty (20) percent market penetration for medical devices which might utilise 3D printing technology.
- **Surgical implants:** While still largely in the domain of top clinical research institutions (with an estimated 1% market penetration) the use of 3D technologies in this sector is expected to be among the faster-paced adoptions of medical technology. This is due to the potential impact on quality of life for patients given precision 3D printed implants and related items (such as personalised anatomical models, instruments and surgical plans), and the large

¹⁴ <https://www.industryarc.com/Report/1268/3D-printing-in-healthcare-market-analysis.html>. accessed on 15 November 2019

¹⁵ In the referenced paper, this included the following countries: China, Japan, Australia, South Korea, India, Taiwan, Malaysia, and Hong Kong

¹⁶ <https://www.mordorintelligence.com/industry-reports/global-3d-printing-market-in-healthcare-industry-industry> accessed on 15 November 2019

¹⁷ 4D printing uses the same techniques of 3D-printing through computer-programmed deposition of material in successive layers to create a three-dimensional object, but adds the dimension of transformation over time. For example, the printed product reacts with its environment (humidity, temperature, etc.) and changes its form (size, shape, structure).

¹⁸ Gartner, Hype Cycle for 3D printing

market for surgical implants (e.g. there were 122,500 joint replacement procedure in Australian in 2018¹⁹).

- **Dental devices:** Dental devices (from more straight-forward caps, crowns, braces, and implants, to reconstructive implants) are ideally suited to 3D-printing as these are personalised, unique items which cannot be mass-produced (and likely to already be produced as custom-made medical devices). 3D-printing has been used to create dental appliances for several years, primarily by laboratories that serve dentists. A transition is beginning to shift the technology directly into dentists' offices, but this is slow given the high investment costs and design and technological skills needed to master the technology. Current use of 3D technology is estimated at around 5% to 20%, and expected to continue to grow steadily.

Healthcare practitioners

The TGA employed an independent firm—Noetic²⁰—to undertake its regulatory costings in support of this RIS. In terms of the scale of businesses potentially using personalised medical devices (now or in the future), Noetic estimated that there are currently approximately 8,503 business, including:

- 7,500 dental practices
- 600 prosthetists/laboratories
- 116 orthotic/prosthetic practices
- 287 private hospitals

Each of these sectors already makes extensive use of custom-made medical devices. Although (as discussed above) data on the full range and number supplied is not available, custom-made medical devices in common use in these sectors include:

- dental practices: custom-made crowns, dentures, braces, implants
- prosthetists/laboratories: custom made prosthetics such as limbs
- orthotic/prosthetic practices: generally custom-made orthotics
- private hospitals: may make quite bespoke custom-made medical devices in in-hospital engineering labs, or source custom-made medical devices (including high-risk devices) from the device sector, including endovascular grafts, maxillofacial implants (for reconstruction of the face, skull, jaw, etc.) and patient-matched joint replacements.

Need for government action

There are three key reasons that government action is required on this issue:

- the rapid emergence of new technologies and rapid uptake of personalised medical devices
- the continued need for international alignment
- no other suitable mechanisms to manage issues with personalised medical devices

¹⁹ Australian Orthopaedic Association National Joint Replacement Registry, *2019 Annual Report: Hip, Knee & Shoulder Arthroplasty - September 1999 to December 2018*, <https://aoanjrr.sahmri.com/>

²⁰ See Appendix 2.

Emerging technology

The rapid development in the technological complexity of personalised medical devices, expansion well beyond the manufacturing techniques envisaged by the authors of the existing custom-made regulatory framework, and expected massive growth in the number of such personalised medical devices over the coming years, mean that changes are required in the way these devices are regulated to provide sufficient oversight to safeguard patient safety.

The world is seeing a shift towards more personalised medicine. Personalised medicine has the potential to deliver improved health outcomes for patients, and to lower consequential burden on the healthcare sector. Use of autologous (the individual's own) cells and tissues can result in improved outcomes for patients, and reduced adverse events, complications, or difficulties that stem from rejection of foreign material.

However, as outlined above, the shift towards the use of personalised medical devices brings with it significant challenges, including in how to best to regulate these new types of devices and associated technologies.

International alignment

The Australian medical device market is only a small fraction (around two percent) of the global market²¹ (4.3 billion US\$ out of approximately 400 billion US\$ globally) and the vast majority of medical devices supplied in Australia, even many custom-made devices, are increasingly manufactured by overseas entities and imported here. The regulatory framework for medical devices in Australia is necessarily aligned with the frameworks of other larger jurisdictions to ensure ease of importation, which allows access to the greatest number of safe medical devices for Australian patients. Regulatory marketing approvals gained in the EU, the USA, Canada and Japan can be used to support market authorisation in Australia.

Due to their unique nature, it can be difficult for manufacturers of personalised medical devices to validate their design, perform sufficient testing, and maintain the quality of manufactured parts. IMDRF member regulators have recognised the problems relating to the design and manufacture of personalised medical devices and are in agreement that action is needed.

Internationally aligned regulation of medical devices also facilitates access to medical devices, especially in Australia. Harmonisation of regulatory frameworks minimises duplication of regulatory oversight (such as reassessing the same device in multiple jurisdictions), while still assessing the safety, quality, and performance of medical devices. This can also apply for personalised medical devices.

In 2017, Australia proposed a new work item to address the specific challenges with personalised medical devices, resulting in the formation of the [IMDRF Personalized Medical Devices working group](#). The working group consulted internationally and then published definitions for personalised medical devices in 2018²². It has recently consulted internationally on a draft document that proposes regulatory pathways for each category of personalised medical device²³.

²¹ <https://www.export.gov/article?id=Australia-Medical-Devices>

²² <http://imdrf.org/docs/imdrf/final/technical/imdrf-tech-181018-pmd-definitions-n49.pdf>

²³ <http://imdrf.org/consultations/cons-pmd-rp.asp>



International regulators, through the IMDRF, have recognised the problems relating to the design and manufacture of personalised medical devices and have agreed that action is needed.

There is now an opportunity for Australia to implement regulatory reforms that are commensurate with the foreseen risks while ensuring minimal regulatory burden but also timely availability of personalised medical devices to individuals who need them. As the regulation of medical devices for supply into or out of Australia is undertaken at the federal level, changes to the medical device regulatory framework necessarily lies with the Australian Government²⁴.

Options

Criteria for assessment options

Some of the criteria used in assessing the various options included:

- the degree by which the option would likely address the three dimensions of the identified problem
- the overall regulatory burden (for example, a delayed implementation of an exemption would introduce unintended regulatory burden on the exempted group)
- equitable and proportionate regulation of 'main stream' and personalised medical devices to safeguard the health and wellbeing of the Australian public, while also providing access to emerging technologies and increased equivalence of regulatory burden on the device manufacturers and sponsors
- the potential for partial implementation to introduce unintended loopholes and gaps (which could possibly then be exploited)
- the additional benefits to be attained through early implementation of globally harmonised regulations
- the ability to address the recommendations in the Medicines and Medical Devices Review (specifically Recommendation 20, harmonisation with the EU)
- the TGA's capacity to effectively absorb any changes and still provide agreed service levels
- the complexity for stakeholders and the TGA in implementing these changes in a piecemeal fashion and timeframe

Options considered

A number of approaches and options for addressing the problem were considered, based on consultation over several years.

²⁴ The majority of the states and territories in Australia have invested the Australian Government with the power to regulate medical devices on their behalf within their respective jurisdictions

Three key options explored in this RIS

The three options explored in detail in this RIS are:

- Option 1—Maintain the status quo (no change)
- Option 2—Introducing a comprehensive package of regulatory reforms
- Option 3—Regulate custom-made medical devices in line with other medical devices

Alternative approaches also considered

In addition to the three options listed above, a number of alternative approaches were also considered but then discounted. They included: an exploration and preliminary analysis of alternative tools as education campaigns; introduction of voluntary codes of conduct; and alternative regulatory framework mechanisms (that is, beyond the current Act, such as Consumer Law). However, it became apparent that these alternatives not be able to address the limitations with the current regulatory framework. None of them adequately deals with the problem—the current uniform exemption of all devices falling within the terms of ‘custom-made medical device’ from both regulatory *requirements* and *oversight* applicable to devices with the same ‘risk profile’. Education campaigns will not require reporting to the TGA of the devices supplied by the manufacturer or sponsor, it will not allow inspection of premises at which the devices are made and would do nothing to ensure that each patient is assured of receipt of information about that device.

In the face of an existing robust regulation framework for medical devices which can easily be adapted to appropriately regulate personalised medical devices without unnecessarily increasing regulatory burden there is no compelling reason to allow for a voluntary code of conduct to apply to a subsection only of medical devices. Precisely who would promote such a conduct and settle on its terms is unclear.

Option 1—Status Quo

Under the status quo, as previously described, personalised medical devices are captured by the definition of custom-made medical device. This means that subsets of the custom-made category, i.e., those which are more like standard commercial devices than bespoke custom-made devices, are not regulated in the same way as commercial devices supplied in differing sizes. All custom-made devices, regardless of potential to cause harm to a patient, are exempt from the requirement to undergo third-party scrutiny of their associated evidence of safety and performance; and their manufacturers cannot be inspected by the TGA under the powers of the existing Act and associated regulations. The TGA would continue to have limited visibility of custom-made manufacturing and supply in Australia based on the current notification requirement under the existing regulations, with a limited ability to undertake compliance enforcement actions against unsafe devices.

In addition, there is no mechanism, under this option, to recognise the emerging point-of-care manufacturing systems that are being marketed to healthcare providers, and that are intended to allow healthcare providers to produce medical devices for treating their patients.

New methods for using personalised anatomical models for investigating the anatomy and planning surgeries would not be required to undergo third-party scrutiny, in contrast to the requirement applied to now out-of-date analogue methods for achieving the same aim, such as X-ray film.

Medical devices that include a human-origin material component, but that have a primary physical or mechanical function as a medical device, would still be required to be regulated under the Australian biologicals framework instead of the medical devices framework. The

medical devices framework already allows medical devices to have medicine components or animal-origin components, which are assessed by the relevant areas of the TGA, while the business process for certification follows the medical device pathway. This would not be expanded to allow the same consideration for medical devices that include human-origin material as is the case in other jurisdictions. Australia would remain out-of-step with other comparable international regulatory frameworks.

Ultimately, under the status quo, patients will continue to face an unmitigated potential for harm from an increasing number of medical devices that have insufficient regulatory oversight.

Impacts under Option 1

Under this option, industry and certain healthcare providers using personalised medical devices, including those using 3D-printed medical devices, would continue to operate as they currently do. Given the trajectory of technological development, the number of devices falling within the existing regulatory framework for custom-made medical device would expand rapidly over the next decade and beyond.

The current regulation would continue to apply, and appropriate regulations would not be available to provide regulatory oversight to custom-made devices and other personalised medical devices produced through new technology. Additionally, responsibilities of persons who choose to use medical devices in an off-label manner would remain unclear.

Under Option 1, there is no immediate change in direct compliance costs for industry. Over time, as some medical devices shift into the custom-made medical device space, administrative costs for those sponsors and manufacturers in respect of those products would drop, as third-party conformity assessment and inclusion on the ARTG would no longer be required (detailed in costs below). As the sponsors and manufacturers of custom-made medical devices would still be required to largely conform to the essential principles, their internal design, production, and oversight procedures should not diminish (although they would change as they shift to personalised versions of the medical devices being produced).

Unlike for devices included on the ARTG, there would be no independent assessment of this continued compliance with the essential principles. This may result in safety concerns emerging for some patients, as the existing risk-management strategy for custom-made medical devices (clinical judgement and oversight by the prescribing health professional) is likely to become less effective as custom-made medical devices of higher risk and increasingly greater technical complexity enter the market.

Costs and potential flow on effects

Administrative savings to industry

The rapid expansion in the use of personalised medical devices is expected to change the balance in mass produced and custom-made medical devices over time.

It is not possible to accurately estimate the number of custom-made medical devices which might emerge over coming years, or to know which of these would replace medical devices which are currently or would in the future be included in the ARTG.

Where a custom-made medical device would otherwise have been developed, a mainstream medical device would need to be included in the ARTG; under this option, the costs associated with regulatory compliance (seeking third-party certification of conformity assessment procedures, applying for inclusion in the ARTG, and maintaining that entry over time) would be saved.

On average, each ARTG entry not required (shifting product lines from mainstream to custom-made) would save industry administrative effort costing around:

- \$52,000 for conformity assessment application and assessment
 - This would apply to around eight percent of ARTG entries, where they seek TGA conformity assessment certification (the remainder reuse overseas certification to support their Australian application, which is not a cost incurred for Australian regulatory requirements)
- \$4,500 for each ARTG entry application and assessment, and a further \$1,000 to \$1,600 if the application is subject to audit (mandatory for high-class medical devices relying on overseas certification)
- \$2,400 per annum in ongoing compliance costs for ARTG entries, and a further \$6,200 to maintain TGA conformity assessment certification.

These costs are based on the time required to comply with application requirements (completing application forms, gather the evidence to support applications, etc.) and complying with ongoing requirements (such as adverse event reporting, annual reporting, maintaining required records, etc. for ARTG entries, and annual surveillance of manufacturers holding TGA conformity assessment).

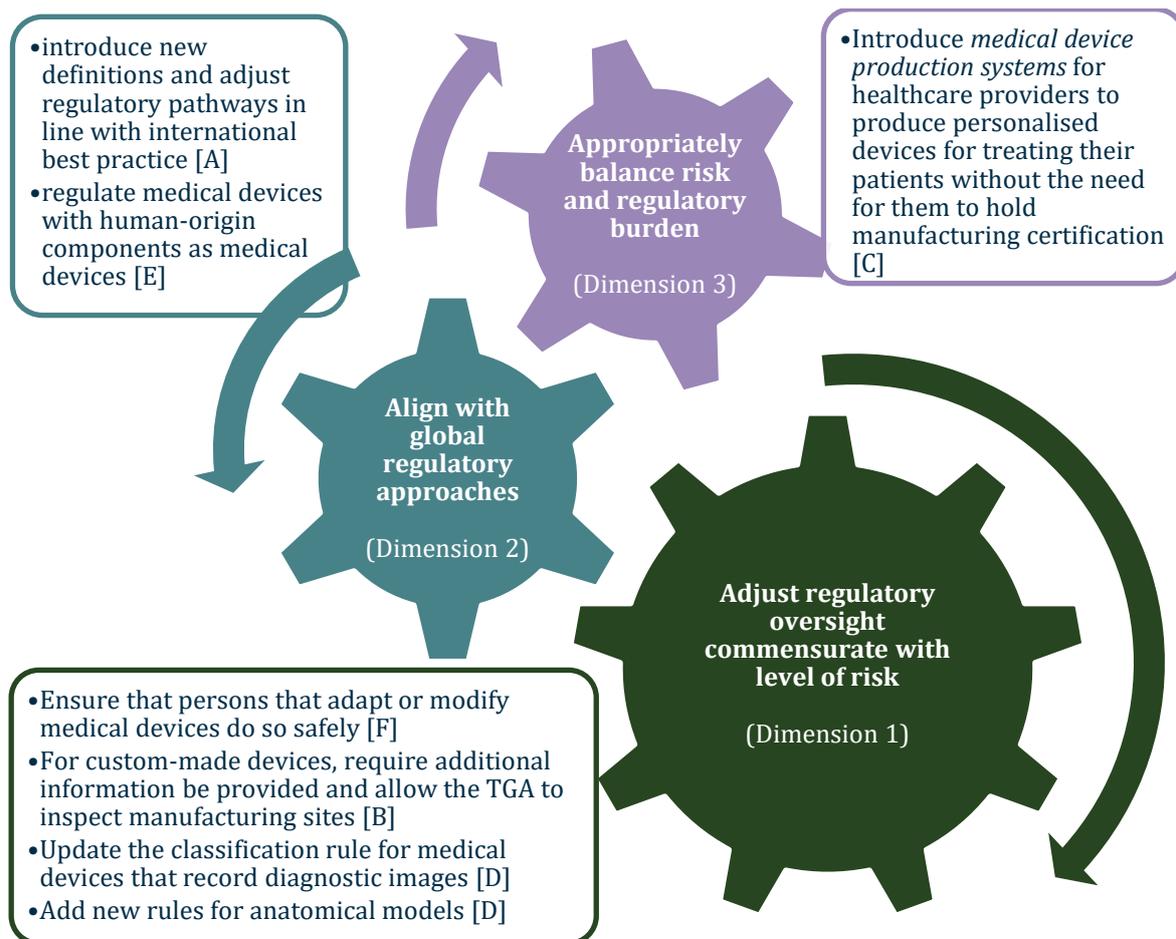
While there is no way to estimate how many devices might shift from mainstream medical devices to custom-made medical devices over the coming years should the status quo be maintained. However, the administrative cost of maintaining each ARTG entry and the related conformity assessment certification is significant.

These figures cover the average time by manufacturers and sponsors to establish and maintain their ARTG entry, and do not include the regulatory fees and charges they would also incur (which are not included in Regulatory Burden Estimate).

As outlined above, in addition to the incentives to develop personalised medical devices in terms of patient outcomes and market share, there are significant cost incentives for such devices to be regulated as custom-made, to decrease regulatory oversight and associated costs.

Option 2—Comprehensive package of regulatory reforms

Option 2 involves introducing a comprehensive package of reforms to the Australian medical device regulatory framework to address the three dimensions of the problem outlined above, whilst endeavouring to balance the benefits, risks, and regulatory burden. The proposed elements of the reform package are summarised in *Figure 2* below.

Figure 2—Addressing the three dimensions of the problem

The changes, supported by a change management plan including education on the changes to affected industry, comprise the following six elements:

- Introduction of new definitions for personalised medical devices;
- A change to the requirements for supplying custom-made medical devices in Australia, so that additional information must be provided to the TGA and to patients and, to allow the TGA to inspect manufacturing sites;
- Introduction of a framework for regulating a medical device production system that would allow healthcare providers to produce personalised devices for treating their patients, without the need for manufacturing certification;
- An update to the classification rule for medical devices that record diagnostic images so that it includes any device for this purpose and not just X-rays, for example, 3D-printed models of patient anatomy;
- A change to the regulation of medical devices with a human-origin component such that they are regulated as *medical devices with a biological component* rather than as pure *biologicals* (for example, a 3D-printed implant incorporating cells from a patient); and
- Clarification that any modifications or adaptations to personalise a medical device that has already been supplied must have been intended by the original manufacturer of the device.

These changes have been consulted publically with relevant stakeholders over a twenty four month period through various mechanisms²⁵ and have received strong stakeholder support. In addition, they represent harmonisation with global best practice.

Details of proposed changes

A. New definitions for personalised medical devices

What would change?

This change would involve adopting new definitions for personalised medical devices (custom-made, patient matched, and adaptable), aligned with those of the IMDRF.

What would this mean?

Adopting new definitions, aligned with the IMDRF definitions, would result in personalised medical devices being grouped into three categories:

- custom-made medical devices
- patient-matched medical devices
- adaptable medical devices

Custom-made medical device:

The revised definition to be included in the MD Regulations (aligned to the IMDRF definition²⁶) is more detailed than the existing custom-made definition:

custom-made medical device means a medical device that:

- (a) is intended by the manufacturer to be for:
 - (i) the sole use of a particular patient (the ***intended recipient***); or
 - (ii) the sole use of a particular health professional (the ***intended recipient***) in the course of the health professional's practice; and
- (b) is manufactured by the manufacturer in accordance with a written request of a health professional (the ***requesting health professional***) and with particular design characteristics specified by that health professional in the request (even if the design is developed in consultation with the manufacturer), where those design characteristics are intended to address:
 - (i) either or both of anatomical and physiological features of the intended recipient; or
 - (ii) a pathological condition of the intended recipient; and
- (c) the requesting health professional has determined is necessary to address the matters covered by paragraph (b) because there is no kind of medical device included in the Register to address those matters or to address those matters to an appropriate level.

Medical devices that fit the custom-made definition would still be eligible for exemption from being included on the ARTG (and associated third party assessment, fees and charges), and there would remain limited regulatory oversight applied to their manufacture as compared with non-exempt medical devices. However, the scale and scope of the devices that meet the new definition would be considerably reduced as compared to the current definition of 'custom

²⁵ Consultation has occurred through workshops, meetings, formal publications and has included healthcare professionals, hospitals, manufacturers, researchers, consumers and industry

²⁶ [IMDRF Document - Definitions for Personalized Medical Devices](#)—definition 4.2

made’—primarily as patient-matched medical devices will no longer fall within the scope of the custom-made exemption (more detail below).

The new custom-made definition would make it much clearer that the responsibility for the device lies more strongly with the healthcare professional than is the case with the current definition, and the package of reforms additionally includes the introduction of new requirements on manufacturers and sponsors of custom-made medical devices (detailed in Element B below).

Retaining the current exemption from inclusion on the ARTG is important for ensuring that individuals retain the option of accessing truly bespoke devices that would not otherwise be available. This approach balances access to these devices against the risks of reduced regulatory oversight by:

- reducing the scope of the custom-made medical device definition;
- re-balancing the responsibility closer to the healthcare professional (who is best placed to understand the specifics of the individual’s case); and
- increasing the requirements (outlined in element B below) place on manufacturers and sponsors of custom-made medical devices making use of the exemption pathway.

Patient-matched medical device:

A new definition of ‘patient-matched medical device’ (aligned with the IMDRF definition²⁷) would be included in the MD Regulations:

patient-matched medical device means a medical device that:

- (a) is manufactured by the manufacturer, within a specified design envelope, to match:
 - (i) either or both of anatomical and physiological features of a particular individual; or
 - (ii) a pathological condition of a particular individual; and
- (b) is designed by the manufacturer (even if the design is developed in consultation with a health professional); and
- (c) is manufactured using production processes that are capable of being:
 - (i) either or both validated and verified; and
 - (ii) reproduced.

The patient-matched category of devices, which currently falls under the custom-made definition in Australia, would no longer be eligible for this exemption²⁸, and instead would require third-party regulatory oversight according to the device risk classification.

Manufacturers of medical devices that meet the new definition for patient-matched medical devices would be required to apply standard conformity assessment procedures (not the special procedure for custom-made devices) according to the classification of their medical devices. This means that for devices that are classified above Class I, conformity assessment evidence from a recognised third-party (such as the TGA or a notified body) would be required. The manufacturer would be required to apply for this evidence and, once received, maintain its currency through complying with post-market requirements such as annual inspections by the issuing agency. These requirements are the same as those for mass-produced medical devices.

²⁷ [IMDRF Document - Definitions for Personalized Medical Devices](#)—definition 4.3

²⁸ *Therapeutic Goods (Medical Devices) Regulations 2002*, Schedule 4, Item 1.5

Australian manufacturers of, or sponsors importing, patient-matched medical devices would also be required to include their medical devices in the ARTG and to comply with the requirements for maintaining the inclusion, including compliance with the essential principles.

Adaptable medical devices

The regulation of adaptable medical devices would not change. A new definition of adaptable medical device (aligned with the IMDRF definition²⁹) would be included in the MD Regulations:

adaptable medical device means a mass-produced medical device that is intended by the manufacturer to be assembled or adapted after it has been supplied, in accordance with the manufacturer's instructions, to:

- (a) address either or both of anatomical and physiological features of a particular individual; or
- (b) address a pathological condition of a particular individual; or
- (c) otherwise perform as intended by the manufacturer.

An adaptable medical device is, by definition, a subset of a mass-produced medical device (albeit one that the manufacturer has designed and produced to be modified after supply) and is not eligible for exemption from inclusion on the ARTG.

Manufacturers of medical devices that meet the new definition for adaptable medical devices already apply the standard conformity assessment procedures (not the special procedure for custom-made medical devices) according to the classification of their medical devices because these types of devices are not eligible for the current custom-made device exemption. This means that for devices that are classified above Class I, they already hold appropriate conformity assessment evidence.

The new requirements would specify that manufacturers of adaptable medical devices should supply validated instructions for their devices to be adapted, assembled or adjusted to suit a particular individual. This should already be the case and so the new requirements would be an express confirmation of the existing arrangements.

Australian manufacturers of, or sponsors importing, adaptable medical devices would also be required to include their medical devices in the ARTG and to comply with the requirements for maintaining the inclusion. Again, this should already be the case. Accordingly, the requirements should not represent a change for this group of stakeholders. There are already many examples of adaptable medical devices included in the ARTG.

[Appendix 2—Regulatory Burden Costings](#) provides further assessment of this change element from page 16 (Change 1).

B. Additional requirements for custom-made medical devices

What would change?

This element would involve changing the requirements for supplying custom-made medical devices in Australia, so that additional information must be provided to the TGA and to patients and, to allow the TGA to inspect manufacturing sites

The proposed changes would require that:

- the manufacturer's statement about a custom-made medical device is provided to the patient receiving the device;

²⁹ [IMDRF Document - Definitions for Personalized Medical Devices](#)—definition 4.4

- the TGA be allowed to enter and inspect custom-made medical device manufacturing sites, in accordance with the authority it has to inspect all other medical device manufacturers;
- a manufacturer in Australia, or a sponsor of an overseas-manufactured custom-made medical device, provides an annual report to the TGA of the custom-made devices it has supplied; and
- documentation about an implantable custom-made medical device is retained for a minimum period of fifteen (15) years.

Note: It is envisioned that such inspections would not be routinely held but would be risk-based according to the implications for health and safety.

These additional requirements for custom-made medical devices aim to address current issues with oversight of these devices:

- **Notification of supply:** Current custom-made medical device regulations only require a manufacturer in Australia, or a sponsor of a manufacturer overseas, to notify the TGA of the specific kind of custom-made device they are supplying. This is a one-time notification for the category of the device, not an individual notification every time one is supplied.
- **Information for patients:** A written statement about the device, including whether or not it complies with the essential principles, must also be prepared and kept. The information is not provided to the patient, unlike in the EU, where the manufacturer or authorised representative must also provide this information to the patient.
- **Entry and inspection powers:** There is currently no requirement for any third-party assessment of custom-made devices or of their manufacture in Australia. The TGA may request information about the devices; however, the legislation does not provide the TGA with the power to enter and inspect manufacturing sites for custom-made devices.
- **Record keeping:** The manufacturer is only required to keep documentation about a custom-made device for five (5) years after supplying the device. The TGA considers this to be an inadequate period of time for an implantable device due to its long expected lifetime. Problems with implantable devices may not surface until after they have been implanted for more than five (5) years. It is important to have access to manufacturing records when something goes wrong with a medical device in order to investigate potential causes of the problem, which will inform decisions about how to manage the patient. Other jurisdictions, such as the EU, require the documentation to be kept for a period of fifteen (15) years.

These changes would give more transparency to patients receiving custom-made medical devices. Making the manufacturer's statement about the device available to a patient would assist with ensuring that the patient understands the custom-made nature of the device and may also improve the informed consent process. The other changes would provide the TGA with more information about the manufacture and supply of custom-made medical devices in Australia, thereby improving its ability to monitor the quality, safety and performance of these devices.

[Appendix 2—Regulatory Burden Costings](#) provides further assessment of this change element from page 16 (Change 2).

C. Production systems for healthcare professionals

This element would involve introducing a framework for regulating medical device production systems that would allow healthcare providers to produce personalised medical devices for treating their patients without the need for them to hold manufacturing certification.

A *medical device production system* (MDPS) is a collection of the raw materials and main production equipment specifically intended to be used together and by a healthcare provider, or

healthcare facility, to produce a specific type of medical device, for treating his, her or its patients. An MDPS includes the medical device it is intended to produce.

The MDPS may require the use of ancillary equipment or other specified input, however, all components must be validated as a production process to consistently produce the intended medical device with the use of the supplied instructions.

What would change?

MDPSs, like other systems, would be considered to be medical devices and would need to be included in the ARTG. They would be classified and assessed according to the device they are intended to produce. The production equipment and consumable raw materials used in an MDPS would not be considered to be medical devices on their own, unless they fit the definition of a medical device in their own right.

What would this mean?

Healthcare providers or healthcare facilities that use MDPSs to produce medical devices for treating their patients would not be manufacturers under the regulatory framework in relation to those systems. This means that healthcare providers would not need conformity assessment certification for manufacturing medical devices when they make use of an MDPS.

[Appendix 2—Regulatory Burden Costings](#) provides further assessment of this change element from page 30 (Change 3).

D. New classification rules for diagnostic imaging and anatomical models

The key diagnostic technology that was in place when the medical devices regulatory framework was first introduced was the X-ray. At the time the framework was introduced the following specific classification rule³⁰ for X-ray film was included to address the potential harm that could result from inaccurate diagnostic X-ray images:

5.4 Non active medical devices intended to record X-ray diagnostic images

A non-active medical device that is intended by the manufacturer to be used to record X-ray diagnostic images is classified as Class IIa.

Recent advances in technology in both digital (virtual) imagery (both 2D and 3D) as well as in advanced manufacturing (such as in 3D printing) have led to new methods of providing information to healthcare professionals for use in diagnosis and for the investigation of anatomy for the purpose of planning surgeries.

The accuracy of images and anatomical models then becomes very important in ensuring correct diagnoses and for the safe planning of surgeries. For instance, an anatomical model that misrepresented the location of a nerve to a surgeon could result in significant harm to a patient were that nerve inadvertently severed during surgery, which could be due to an inaccuracy in the anatomical model.

This change would involve:

- updating the current classification rule for medical devices that record non-visible light diagnostic images so that it includes any device for this purpose and not just X-rays.
- introducing new classification rules for anatomical models used for diagnosis or investigation (for example, for surgical planning)

³⁰ Schedule 2, Item 5.4.

What would change?

TGA is proposing that the same degree of regulatory oversight as that currently applied to X-ray film be applied to the newer technologies that are used to represent the equivalent information today—namely, software that records patient diagnostic images (in the non-visible spectrum), and virtual and physical anatomical models used for diagnostic or investigative purposes. The software used to generate the virtual models would also be the same class.

There have been significant increases in medical devices (both patient-matched and mass produced) relying on diagnostic imaging. Anatomical models for surgical planning have also increased, in support of increasingly ambitious surgical procedures. Consequently, newer methods of diagnostic imaging and the increase in use of anatomical models, are of critical importance.

What would this mean?

Manufacturers of anatomical models would be required to hold appropriate conformity assessment evidence for a Class IIa device. This requirement would apply only to manufacturers whose models are intended to be used for diagnosis or investigation of the anatomy. It would not apply to manufacturers of models that are intended purely for training or education purposes, as these are not considered to be medical devices. The requirement would not apply to hospitals or healthcare practitioners if they used a medical device production system (under element C) to produce the anatomical models for treating their patients, and the medical device production system was included in the ARTG.

Manufacturers of software that is intended to be used to record patient imaging for diagnosis or investigation of the anatomy would be required to hold appropriate conformity assessment evidence for a Class IIa device.

[Appendix 2—Regulatory Burden Costings](#) provides further assessment of this change element from page 42 (Change 4).

E. Regulation of medical devices with human-origin components as medical devices rather than as biologicals

This change would involve medical devices with a human-origin component, for example, a 3D-printed implant incorporating cells from the patient, being regulated as medical devices with a biological component rather than as pure biologicals. This change is included in this package to clarify arrangements and ensure such devices are regulated consistently. These medical devices may be patient-matched or more mainstream medical devices, and may be 3D printed or not.

3D ‘bioprinting’, or printing of patient-specific implants that incorporate human-origin material, is increasing. Some jurisdictions, including Canada, the EU and the USA, regulate medical devices with human-origin material as medical devices. In contrast, the Act specifies that any product that comprises, contains, or that is derived from human cells or human tissues is a *biological* and is thus regulated through the biologicals framework.

This arrangement is not ideal for 3D-printed implantable scaffolds with human materials, as they are analogous, from a design, engineering, production, and assessment perspective, to current implantable scaffolds with incorporated medicine, or animal-origin material, both of which are regulated as medical devices under the Act. The current regulatory arrangements in Australia means they are likely to be subject to different regulatory pathways in other jurisdictions. This can be confusing and costly for manufacturers facing different requirements on their regulatory submissions, for different regulators.

What would change?

Medical devices that contain as a component, but that are not wholly comprised of, human-origin material would not be regulated as biologicals; rather, they would be classified as Class III medical devices with a biological component. This change would mean that a medical device incorporating materials of human origin would be regulated as a medical device and not as a biological, more closely aligning the Australian framework with those of other jurisdictions.

This change would allow for the possibility of abridged assessment of the device components in accordance with current procedures. It is proposed that this change would apply to both viable and non-viable human-origin components because the TGA has the in-house expertise to evaluate both as a component of a medical device.

What would this mean?

Conformity assessment certification by the TGA would be required for medical devices that contain a biological (human origin) component, in line with the requirements for other combination products, including medical devices that contain medicinal, recombinant DNA, microbial, or animal-origin materials. Accordingly, the biological component would be required to meet all applicable regulatory requirements and a fee for the assessment of the biological component during the design-examination process would be applied.

Manufacturers would also need to comply with relevant regulatory requirements for the biological components of their devices relating to biological materials, such as therapeutic goods orders for controlling infectious-disease transmission. Note that manufacturers are already required to meet these requirements under the current biologicals framework.

At this stage, approximately 30 ARTG entries exist for biologicals with human-origin materials, none of which include a medical device component (so no changes will be needed for existing human-origin therapeutic goods). Following this change any medical devices with human-origin material would need to seek inclusion in the ARTG as medical devices.

[Appendix 2—Regulatory Burden Costings](#) provides further assessment of this change element from page 45 (Change 5).

F. Ensure that adaptations and modifications to medical devices are done so safely

This change clarifies requirements for the newly defined ‘adaptable medical device’, making it clear that any modifications or adaptations to personalise a medical device that has already been supplied must have been intended by the original manufacturer of the device.

Under the current definition of manufacturer in section 41BG(2) of the Act, a person is not considered the manufacturer of a medical device if:

- the person assembles or adapts the device for an individual patient
- the device has already been supplied by another person, and,
- the assembly or adaptation does not change the purpose intended for the device

An example where this exclusion is currently applied is in dental resins for treating patients in the repair of teeth, where the resin material is included in the ARTG. The TGA considers that the dentist will, in accordance with the manufacturer’s intention and instructions for mixing, forming, curing, etc. the resin, assemble and/or adapt the resin material for an individual patient. In this scenario, the dentist does not require conformity assessment certification for manufacturing a dental restoration. The regulatory obligations apply to the manufacturer and the sponsor of the resin material.

The assurance that the final assembled or adapted device will perform as intended comes from the validated instructions provided by the original manufacturer. This means that the manufacturer will have tested the performance of samples of its device, when adapted or assembled according to its instructions. In the dental resin example, the original manufacturer makes certain specifications for the use of its product, such as the mixing constituents, the mixing ratio, the type and size of defect to which the resin should be applied, and how long it needs to cure.

When the dentist follows these instructions, it is expected that the dental restoration will perform as intended by the manufacturer of the resin. A person who does not follow the original manufacturer's instructions will be considered a manufacturer and would assume all of the responsibilities of a manufacturer. This includes applying the appropriate conformity assessment procedure and meeting the appropriate compliance and enforcement regime. Regulations for noncompliance with the manufacturer's obligations will also apply because any modifications or adaptations outside of what has been specified by the original manufacturer may affect the device's compliance with the essential principles and might add risk to the health and safety of a patient.

Clarifying this issue in the context of 3D-printed devices is important because healthcare providers now have the option of 3D-printing medical devices, such as dental crowns. It is not considered appropriate that the same approach that is currently being applied to dental-resin material in the ARTG ought to be applied to raw materials for 3D printing, in that, we do not believe regulating the raw material for a 3D-printer is sufficient in ensuring that the final device will comply with the essential principles. This is because 3D-printing involves more than assembling or adapting a device for a particular patient. It is a complex multifactorial process that has an impact on the finished device's compliance with the essential principles. Moreover, a 3D-printing raw material, as with any other manufacturing raw material, is not a medical device, as it is not directly used for treating or diagnosing a patient. Some additional clarification around these issues is therefore required.

What would change?

Additional text would be added to the Act and/or MD Regulations to make clear that a person would not be considered a manufacturer where a medical device has been assembled or adapted for an individual patient and the assembly or adaptation is in accordance with validated instructions provided by the manufacturer of the relevant device. However, if an individual modifies or adapts a device which has already been placed on the market or put into service in such a way that compliance with the essential principles may be affected, that person shall be considered to be a manufacturer and shall assume the obligations incumbent on manufacturers. The person would be subject to the compliance and enforcement regime on that basis.

The need for the provision of validated instructions by the original manufacturer would also be reinforced.

What would this mean?

The effect of these changes would be to clarify the circumstances in which an entity holds responsibilities as a medical device manufacturer. It will also highlight the fact that changes made to a medical device, that are not intended by its original manufacturer, may impact the safety and performance of the device.

[Appendix 2—Regulatory Burden Costings](#) provides further assessment of this change element from page 46 (Change 6).

Impacts of the proposed reforms under Option 2

Modelling and quantification of the regulatory impact of the proposed changes to the regulation of personalised medical devices is presented in Appendix 2, TGA Regulatory Burden Costings – Personalised Medical Devices.

The average annual costs, resulting from the analysis of the impact of the proposed changes, are difficult to estimate for a number of reasons. These costs are primarily driven by the effort associated with hospitals in the private sector seeking certification for manufacturing activities and including their patient-matched medical devices in the ARTG. Hospitals have traditionally manufactured custom-made medical devices and the proposed reforms do not change this activity; that is, this can continue without the need for manufacturing certification under the proposed reforms. However, certification will be required under the proposed reforms if hospitals intend to undertake manufacture of the new proposed category of patient-matched medical devices.

The concept of a patient-matched medical device has recently emerged and, therefore, there is no empirical data on which to base any assumptions regarding sponsor/manufacturer behaviour in this area. That is to say, it is difficult to predict whether hospitals would seek certification for manufacturing patient-matched devices, or whether they would choose to purchase commercially produced patient-matched devices, or whether they would choose to limit their own production of patient-matched medical devices to those made with a regulated Medical Device Production System (the latter two options negating the need for certification).

Given that hospitals would have three options for proceeding with the use of patient-matched medical devices in their facilities, it is likely that only a percentage of hospitals who currently undertake manufacturing activities for custom-made devices would seek certification. The TGA sought comment from representatives from the private hospital sector on their strategies for patient-matched medical devices. While acknowledging that their strategies were still developing, the private hospital sector provided feedback to inform the regulatory burden estimate. Based on this, the regulatory burden of hospitals in the private sector seeking certification was modelled on 33% and 10% of the population with 1, 3, and 5 ARTG entries per hospital. The median result was then used. The outcome is reflected in the following Regulatory Burden Estimate Table.

Regulatory Burden Estimate Table

Average annual regulatory costs (from business as usual)				
Change in costs (\$ million)	Business	Community organisations	Individuals	Total change in costs
Total, by sector	\$1.261	\$	\$0.005	\$1.266

These costing are summarised in more detail in Tables 12 and 13 (p 48 to 49) at [Appendix 2—Regulatory Burden Costings](#). Note that the public sector is specifically excluded from the Regulatory Burden Framework. This includes the exclusion of TGA fees and charges from these costings.

Potential flow-on effects

As this is a globally emerging area in healthcare, at this early stage it is difficult to define or quantify the potential flow-on effects of implementation. While it is possible to identify what they might be, these are hypotheses only, and it is difficult to obtain or identify any supporting evidence.

The TGA has engaged with a number of stakeholders in order to try to analyse and assess potential flow-on effects across the broader health sector and community, including the potential for increased demand for medical devices and associated services. The potential areas considered were:

- increased pressure on point of care facilities, including hospitals;
- increased pressure on the health insurance sector;
- incentives for members of the health workforce to focus on the provision of personalised medical devices to the detriment of other important health functions;
- an increase in trailing obligations for medical practitioners associated with longer-term care of patients fitted with personalised medical devices;
- pressure on the health system from overseas consumers attracted to Australia by a more rigorous regulatory regime for devices (“medical tourism”); and
- increased costs for government, especially where there are Commonwealth/State implications.

The majority of the stakeholders engaged indicated either they believed there would not be any impact, or were unclear as to whether there would or wouldn't be an impact. Some indicated they have yet to conduct any research on the impact of newer technologies on the health care system. A number indicated that it is a topic that they can see value in exploring further.

An experienced medical devices industry expert indicated that growth in the medical tourism industry in Australia is unlikely to be driven by personalised medical device regulation. Personalised medical devices are not peculiar to Australia, and some other challenges that might impede that growth include paperwork, approval processes and that the hospital system is not currently geared for medical tourism.

Some private hospitals indicated that they are likely to outsource personalised medical devices, including aids to implement surgery, to third-party organisations that are already performing this function.

In addition, a number of mechanisms to deal with changes already exist. For example, pathways for reimbursement of prosthesis already exist (where the device is on the Prosthesis List and included in the ARTG). If the number of prosthesis that meet this criterion were to increase, that might place additional pressure on the health insurance sector. The Department of Health Medical Services Advisory Committee pathway exists for managing changes, including changes to surgeon operation times.

Option 3—Regulate custom-made medical devices in line with other medical devices

Under this option the exemption from inclusion on the ARTG for custom-made medical devices would be removed. This would mean manufacturers of custom-made medical devices would need to seek certification of their conformity assessment procedures, including demonstrating full compliance with the essential principles, to support the inclusion of these medical devices on the ARTG. Compliance with all the requirements of ARTG inclusion would also apply.

This would address the growing risks associated with the ‘light touch’ regulation of custom-made medical devices, including:

- **Improved visibility:** Inclusion on the ARTG would mean much greater TGA oversight of custom-made medical devices being supplied in Australia.

- **Improved oversight:** The requirement for conformity assessment certification would result in third party scrutiny of the conformity assessment procedure for all manufacturers of custom-made medical devices. These devices would also be required to comply with the essential principles (rather than the current requirement to document where they do not comply).
- **Responsibilities associated with ARTG inclusion:** Reporting of adverse events and annual reporting for high risk and implantable, record keeping requirements, powers of entry to manufacturer's premises and the compliance enforcement pathways (suspension or cancellation of an ARTG entry – which ceases the authority to supply the medical devices, and criminal and civil penalties under the Act) would all apply to these medical devices in full.

This option addresses **Dimension 1—Misalignment of regulatory oversight with level of risk** quite well, in that regulatory oversight would be aligned with the risk of the medical device as it is for all 'mass produced' medical devices. The existing classification rules effectively and efficiency class devices according to risk, and existing conformity assessment requirements provide oversight in proportion to that risk. While there is always room for improvement, TGA proactively reviews and amends elements of the framework to ensure continued relevance and appropriateness.

However, this option does not effectively address the other two dimensions:

- **Dimension 2—Misalignment with international norms:** The definitions and IMDRF definitions and examples (Appendix 1) is the emerging regulatory framework for personalised medical devices. In addition to being out of step with international regulatory norms, Australia represents only a small proportion of the global medical devices market (around 2 per cent). The Australian framework relies heavily on certification or approvals from comparable overseas regulators to facilitate access to medical devices, as eliminating duplicate assessment across jurisdictions reduces assessment costs significantly. Where Australian requirements vary significantly, even where manufacturers and sponsors could meet the Australian requirements, the cost of assessment to Australian specific requirements may be prohibitive.
- **Dimension 3—Need to balance risk with regulatory burden:** In practice while patient-matched medical device may seek inclusion in the ARTG, many 'bespoke' custom-made medical devices would not be included on the ARTG due to associated costs. Instead these would cease to be supplied, or alternative supply pathways (explained below) would be used. This is not an appropriate balance of risk with regulatory burden. Personalised medical devices offer significant benefits to patients, the health system, and industry as this option would compromise access to many very promising emerging technologies.

Conformity assessment seeks assurance of safety, quality and performance of devices through systematic assessment of the manufacturing procedures, so manufacturers of bespoke custom-made medical devices may find this difficult or impossible to meet given their relative lack of systematic manufacturing processes.

Some larger manufacturers of patient-matched medical devices may meet manufacturing requirements. A number of existing patient-matched medical device manufacturers already have ISO13485 certification (on which conformity assessment requirements are based) however they may struggle with some of the additional requirements for conformity assessment, especially in relation to clinical evidence requirements (depending on the technology, it can be difficult or impossible to undertake clinical trials for 'one-off' medical devices). For more specialised and low volume medical devices, compliance would become increasingly difficult.

Without the proposed *medical device production system* (MDPS) no mechanism exists to recognise the emerging point-of-care manufacturing systems that are being marketed to

healthcare providers, and that are intended to allow healthcare providers to produce medical devices for treating their patients.

Some personalised medical devices may be supplied under Special Access Scheme (SAS³¹) or Authorised Prescriber (AP) arrangements. SAS and AP allow health practitioners to access therapeutic goods that are not on the ARTG and are not otherwise exempt from being in the ARTG. Supply of custom-made medical devices through this pathway would result in more limited oversight than existing custom-made requirements, as these arrangements are intended for exceptional clinical circumstances and tend to be *ad hoc* in nature.

Option 3 also does not address some of the deficiencies of the current custom-made medical device regulation framework, including:

- Providing for personalised anatomical models for investigating the anatomy and planning surgeries currently being required to undergo third-party scrutiny, unlike the requirements applied to now out-of-date analogue methods for achieving the same aim, such as X-ray film (Option 2D above)
- Clarifying requirements for medical devices that include a human-origin material component (Option 2E above). The existing biological framework for medical devices with human origin is confusing and costly. In addition, a number of device aspects (engineering, production, device assessment) are not adequately covered where such medical devices are regulated as biologicals.

Potential flow-on effects

This option has significant limitations as outlined above, particularly in forcing many personalised medical devices from the Australian market. It does not satisfactorily address the problem as outlined above, or deliver against two of the three dimensions on which these options are being assessed.

In addition to the impacts on manufacturers and suppliers of existing and future products, the lack of access to emerging personalised medical device technologies would have a profound impact for patients, health care professionals, the health sector and community. This impact would grow over time, as emerging technologies continued to be developed but would remain largely inaccessible in Australia.

Benefits

Option 1—Status quo

The benefits of maintaining the status quo are limited. It will save the costs associated with changes where medical devices shift from mainstream (requiring ARTG inclusion) to custom-made (which are exempt). Option 1 also does not address any of the limitations of the current regulatory approach:

- Current custom-made medical device definition allows for a large (and growing) proportion of the types/categories of medical devices that are eligible for custom-made exemption—far beyond the original intent

³¹ Further information on SAS is available on the TGA website at <https://www.tga.gov.au/form/special-access-scheme>

- insufficient mechanisms for the Australian Government to have effective oversight and visibility of the personalised medical device sector, which is predicted to become more significant over time as the market moves further towards personalised medicine
- insufficient mechanisms for investigation following adverse events relating to or involving personalised (custom-made) medical devices, as a result of limited record-keeping requirements (particularly around record-retention timeframes)
- insufficient compliance and enforcement mechanisms for dealing with unsafe devices or manufacturers
- misalignment with international norms for human-origin material – medical device combination products, which results in unnecessary regulatory burden for industry

Option 2—Comprehensive package of regulatory reforms

Under Option 2, the proposed regulatory changes are intended to address the three dimensions of the stated problem, and additionally align with the objectives for regulating medical devices in general, which are:

- minimising public health and safety risks
- maintaining consumer confidence in the safety and performance of medical devices
- aligning, as far as possible, with international best practice
- minimising unnecessary regulatory burden

The proposed changes are expected to provide benefits to patients being treated with personalised medical devices and to healthcare providers who use personalised medical devices in their practices, primarily improved clinical outcomes for patients. The strengthening of regulation for personalised medical devices would ensure that an appropriate and consistent level of third-party oversight is in place, which would minimise the risk of harm to patients. This would also give healthcare providers more assurance that the medical devices will perform as intended.

Additionally, the proposed changes are expected to provide benefits to the regulated industry sector. Some devices currently covered under the Australian custom-made exemption would require third-party assessment to make them eligible for inclusion in the ARTG. This facilitates reimbursement processes for some devices and also provides a degree of public confidence in the products. The changes would also level the playing field for manufacturers by making the device categories and requirements clearer and more consistent. Manufacturers, particularly of patient-matched devices, who are already ensuring their devices comply with the essential principles for safety and performance, would not be unfairly competing against manufacturers who are not subject to the same degree of regulatory oversight.

Most of these proposed changes would move the regulation of personalised medical devices in the direction of international alignment. For example, regulatory oversight or approval of patient-matched medical devices is already required in multiple jurisdictions including the USA and Canada. Australian manufacturers who are currently using the custom-made exemption for their patient-matched medical devices may find that complying with the new arrangements opens up additional international markets for their products.

Finally, changing the Australian regulatory pathway for medical devices with human-origin material, such as 3D-bioprinted devices, would better align with other jurisdictions. This is expected to benefit manufacturers because it would reduce confusion about and the regulatory burden of complying with the requirements of multiple jurisdictions.

One of the key benefits for custom-made devices is the ability to custom-make a device to meet the specific needs of an individual patient, and the ability to provide a device where a mass-produced device is not available or would provide a less than optimal solution. The ability to create anatomically-correct models of a patient prior to surgery enables diagnosis, and also allows the surgical team to train and plan for surgeries, which may potentially reduce the risk of errors, reduce surgery time, make surgery possible at all, and reduce post-operative complications.

Option 2 offers potential benefits patients, health professionals, health care systems and the medical devices industry.³²

Benefits for patients

- Solution for an otherwise un-solvable problem (for example, patients of uncommon size or shape, or with a unique anatomical condition)
- Precise implant shapes
- Reduced surgery and recovery times (generally speaking the shorter the surgery duration to lower the risk to the patient (from infection and anaesthesia)
- Better aesthetic results
- Reduced post-operative complications.

Benefits for healthcare systems and health professionals

Healthcare systems include various facilities such as hospitals and dental surgeries, and the health care professionals who work within them.

- Visualisation and planning of procedures using anatomically correct models which may have the following benefits:
 - Better selection of devices and other surgical tools
 - Decreased surgical risk and increased accuracy (of incisions for example) and potentially resulting in less surgical errors and faster post-operative recovery
 - Better anticipation of difficulties that can potentially arise during surgery/procedures
- Other benefits potentially include:
 - Reduced post-operative complications
 - Decreased risk of soft tissue trauma
 - Decreased duration of surgical procedure time (less anaesthetic) due to reduced need, for example, to reshape a mass-produced implant
 - Less misplacements and errors during the procedure
 - Decreased radiological exposure during the procedure.

Industry

- Increased demand should continue to drive innovation and growth in the industry

³² Many of these come from a study by Martelli *et al* Advantages and disadvantages of 3 dimensional printing in surgery: A systematic Review. Surgery, June 2017

- The ability to meet the medical needs associated with the increasing geriatric population and an increasingly sedentary lifestyle will increase demand for certain orthopaedic and dental devices which will continue to drive the market

Option 3—Regulate custom-made medical devices in line with other medical devices

Regulating custom-made medical devices in line with other medical devices has the benefit of increasing visibility and oversight of these medical devices. It shifts these medical devices into an established and proactively managed regulatory framework with clearly outlined responsibilities and accountabilities for manufacturers and sponsors, and provides a range of compliance and enforcement mechanisms for the regulator not currently applicable to custom-made medical devices.

However, the significant limitations of this option, including forcing most personalised medical devices from forecast supply into the Australian market, mean this option is not realistically viable. The impact on patients, healthcare systems, health professionals and the medical devices industry could not be supported, and this option also does not address numerous aspects of the problems associated with the development and growth of personalised medical device technologies.

Consultation

Formal engagement for reforms to the personalised medical devices regulatory framework began in August 2017 at a targeted workshop for fifty invited participants including representatives from the medical device industry (both large and small organisations), hospitals, surgeons, researchers, patients, and government. There was consensus at the workshop on the need to reform the medical device regulatory frameworks for custom-made devices, especially high-risk (permanently implantable) devices, enabled by 3D-printing.

In November 2017, the TGA released a consultation paper—*Proposed regulatory changes related to personalised and 3D printed medical devices*.³³ The consultation was available through the TGA website for a six-week period and closed on 22 December 2017.

The paper included proposed ways to address the increasing trend for personalised medical devices. While the regulatory changes were not limited to 3D-printed medical devices, 3D-printing was one of the main themes, as this technology enables personalisation of medical devices in a fast and potentially up-scalable manner.

Results of 2017 consultation

The responses to the consultation paper³⁴ showed broad stakeholder support for the proposed reforms and a strong awareness of the need for improvements to the regulation of personalised medical devices. Twenty-four submissions were received, from industry and industry representatives, healthcare practitioners and organisations, government, universities and consumer representatives.

³³ 2017 consultation paper available on TGA website: <https://www.tga.gov.au/consultation/consultation-proposed-regulatory-changes-related-personalised-and-3d-printed-medical-devices>

³⁴ A summary and copies of responses to the 2017 consultation are available on the TGA website at: <https://www.tga.gov.au/submissions-received-proposed-regulatory-changes-related-personalised-and-3d-printed-medical-devices>

The submissions indicated that there was still need for greater clarity, in particular, regarding the proposed definitions. The need for clarification was especially evident regarding the boundary between the proposed 'custom-made' and the proposed 'patient-specific' definitions and there were multiple requests for explanatory examples. There were also several submissions indicating uncertainty, and requesting further explanation of what exactly would be seen as a medical device production system.

2019 consultation

In order to obtain additional feedback from affected stakeholders, the TGA publicly released another consultation paper on 11 February 2019, seeking submissions until 31 March 2019.³⁵ The document included an invitation to comment on the proposed options, specifically, seeking feedback on the suitability and potential impact that any proposed changes to the regulations might have.

The 2019 consultation included a proposal to align the new definitions for personalised medical devices in Australia with the IMDRF definitions that were published in November 2018. These definitions provided additional clarity when compared with those consulted on in Australia in 2017. The IMDRF definitions paper included examples for each of the different categories.

Twenty-four submissions were received. Overall, there was a strong consensus across all stakeholder groups, with a majority of respondents supporting the proposed changes to the regulatory framework for personalised medical devices. A number of submissions were complementary of the leading role that Australia was playing as Chair of the International Medical Device Regulators Forum personalised medical devices working group.

Submissions also focussed on ensuring a level playing field for manufacturers and hospitals that are manufacturing more than custom-made medical devices, international alignment, cost of compliance, and the need for clear guidance and education from the TGA. Some specific issues were identified through the consultation:

- A number of submissions were concerned about the proposed new medical device production system (MDPS), but it was clear that much of the feedback stemmed from a misunderstanding of how the regulations would apply both to these devices and to other types of manufacturing systems. Clarification on this misunderstanding was provided in the [outcomes summary](#) for the consultation.
- There were a number of responses from members of the low-risk assistive technologies sector who were concerned about increased regulatory burden. They mistakenly believe that their Class I products would require third-party certification if the proposals are implemented. They also believe that each and every device that is supplied would need an ARTG entry. In reality, there would **not** be any additional regulatory requirements in this sector. Many of the products in this sector are not medical devices and a current consultation on options to exclude certain products used for and by people with disabilities from regulation should alleviate these concerns.
- Some smaller Australian manufacturers who have been engaged in custom-made implantable medical devices also appear to have limited understanding of the medical devices regulatory framework. Stakeholder education for this cohort will be a priority for the TGA.
- Hospital respondents want the freedom to manufacture more than custom-made medical devices but have concerns about meeting the cost of regulatory compliance.

³⁵ 2019 consultation paper available on TGA website: <https://www.tga.gov.au/consultation/consultation-proposed-regulatory-scheme-personalised-medical-devices-including-3d-printed-devices>

Stakeholders responding to the consultation were:

- Manufacturers (8), Industry Associations / Organisations (6), Healthcare Representative Bodies (3), Healthcare Providers (3), Consumer Organisations (2), Not for Profit (1), University (1)

No respondents strongly opposed the proposed reforms. The small number of submissions that opposed one or some of the proposals also supported others and there was a misunderstanding of current regulatory requirements as noted above.

Some respondents opposed some parts of the proposals for application to all categories of devices, most notably there were several submissions that suggested potentially increased reporting requirements for custom-made medical devices should be limited to higher-risk devices.

International (IMDRF) consultations

In addition to the consultation conducted in Australia, the IMDRF personalised medical devices working group has conducted two formal international consultations. The first was to establish definitions for personalised medical devices, which were published in 2018³⁶ (see *Appendix 1*), and the second was undertaken in 2019 to establish regulatory pathways for each category of personalised medical device.³⁷ These international consultations received broad support and the proposed changes for Australia are aligned with the IMDRF approach.

Consultations with selected stakeholders

In addition to the consultation processes outlined above, bilateral consultations have been undertaken on particular aspects of the proposed changes with a range of stakeholders, including member of key consultative forums (the [RegTech Forum](#) and the [Advisory Committee on Medical Devices](#)), and discussions with a number of respondents to the TGA consultations on personalised medical devices and members of the healthcare sector, including public and private hospital peak bodies.

Preferred option

Option 2—Changes to better regulate personalised medical devices

The proposed changes to the regulatory framework under this option aligns with the approach of other regulators and the recommendations of the IMDRF working group for personalised medical devices. The proposed regulatory controls, based on the internationally harmonised approach, involves the introduction of three categories (*custom made*, *patient matched*, and *adaptable*) of personalised medical device, with associated regulatory controls applied commensurate with the risks and nature of the three categories. The risk of harm to patients would be minimised, and healthcare providers would have greater assurance that the medical devices they use would perform as intended.

³⁶ 2018 consultation paper available on the IMDRF website at <http://www.imdrf.org/consultations/cons-definitions-personalized-md-n49-180524.asp>

³⁷ 2019 consultation paper available on the IMDRF website at: <http://www.imdrf.org/consultations/cons-rar-cabc-mdrr.asp>

The introduction of the medical device production system (MDPS) would ensure ongoing safety of the production of medical devices, usually at the point of care, by healthcare professionals who would otherwise be required to obtain manufacturer certification. The introduction of this new approach would provide improved outcomes from systems that are currently not regulated in Australia, together with reducing the regulatory burden on those healthcare professionals who would otherwise be considered to be manufacturers under the Act. It would also align Australia with the internationally recognised best-practice (IMDRF) model for such systems.

The updates to the classification rules relating to anatomical models would result in the application of appropriate regulatory oversight of manufacturers who make models for the investigation of the anatomy and for the planning of surgeries. The new rules would ensure that the regulatory framework is updated so that oversight of new digital technologies is in line with the equivalent analogue technologies of the past (i.e., X-ray film).

The changes relating to the way medical devices with human-origin components are regulated would mean that the framework would be aligned with international norms, and would ensure that the human-origin components of combination medical device products are subject to appropriate regulatory scrutiny in the same way that other combination products are subject (such as medical devices with animal-origin material).

The new definition of 'adaptable medical device' and additional information on the boundaries associated with the adaptation of medical devices will improve clarity for the sector, and highlight the impact on the safety and performance of the device when adapting medical devices outside of the manufacturer's instructions.

There are additional benefits relating to Option 2 as follows:

- a levelling of the playing field for manufacturers which will narrow the scope of devices captured by custom-made definition, and ensure comparable patient matched and mass produced medical devices are regulated in a comparable way;
- improving TGA's visibility of the custom-made medical devices industry in Australia, so the size and scope of the sector can be monitored and any trends or emerging issues for individual devices or personalised medical devices more broadly, and addressed;
- opening up international markets to domestic manufacturers (who would be required to meet internationally harmonised requirements);
- facilitating sponsor access to reimbursement pathways (such as the inclusion of patient-matched medical devices on the Prostheses List, as discussed above);
- improving public confidence in the regulatory framework that applies to personalised medical devices;
- ensuring that patients are better informed about the custom-made medical devices they have been provided with; and
- improved post market monitoring and compliance and enforcement mechanisms.

Option 2 is a comprehensive package of interrelated reforms that provides for an alignment of the requirements for personalised medical devices with the objectives for regulating medical devices in general, namely the:

- minimisation of public health and safety risks;
- maintenance of consumer confidence in the safety and performance of medical devices;
- alignment, as far as possible, with international best practice; and
- minimisation of unnecessary regulatory burden.

Implementation and evaluation

Implementation

The implementation of the proposed reforms would require a significant education effort from the TGA. This would include engaging with all affected stakeholders in a range of fora, and developing guidance materials targeted for the different groups. The consultation period for this work, which commenced in 2017, has already resulted in increased understanding of affected stakeholders.

The proposed implementation trajectory begins with the proposed reforms coming into effect on 25 August 2020. Medical devices that are being supplied in Australia prior to this commencement date, and that would be affected by the proposed reforms, would have the benefit of a transition period as described below.

When designing the implementation and considering the transition approach, the TGA took the following considerations into account:

- The need to implement the changes as quickly as reasonable, whilst keeping in mind any additional regulatory burden the changes will impose;
- Wherever possible aligning new reporting requirements with existing time frames (so for example, manufacturers of custom-made medical devices are required to notify TGA within two (2) months of commencing supply, and annual reporting timeframes might be aligned to this initial notification date); and
- Allowing reasonable time for those manufacturers that are required to obtain full registration and compliance for their devices.

Currently included medical devices

All medical devices that are included in the ARTG prior to 25 August 2020 and that are subject to re-classification under the proposed reforms would be considered to be transitional devices. The current ARTG entry would allow continued supply until 1 November 2024 if the following requirement for notification to the Secretary is followed:

The sponsor of a transitional medical device notifies the Secretary prior to 25 February 2021 of:

- the ARTG number;
- the unique product identifier of all medical devices supplied under that number; and
- which devices would require new ARTG inclusions at the end of the transition period.

The manufacturers and sponsors of these medical devices would have until November 2024 to seek the appropriate certification for their devices and to apply for new ARTG inclusions at the re-classified level.

Custom-made medical devices

The proposed requirements for custom-made medical device manufacturers to provide the manufacturer's statement with a custom-made device, and to retain records for implantable devices for a longer period, would apply to custom-made medical devices manufactured on or after 25 August 2020.

The proposed annual reporting requirements would apply to custom-made medical devices manufactured in Australia, or imported into Australia, on or after 25 August 2020. This means

that the first annual reports, for custom-made medical devices manufactured in the preceding year, would be due on 1 October 2021.

The proposed ability for the TGA to inspect custom-made medical device manufacturing sites would apply on or after 25 August 2020.

Patient-matched medical devices

Patient-matched medical devices are currently captured by the custom-made medical device definition. The exemption from the requirement to be included in the ARTG for patient-matched devices that are currently considered to be custom-made devices, and are notified to the TGA in the custom-made data repository by 25 August 2020, would remain in force until 1 November 2024 for those devices that meet the following condition:

The sponsor or Australian manufacturer of a patient-matched medical device that has been notified to the TGA as a custom-made medical device prior to 25 August 2020, notifies the Secretary in writing of the following before 25 February 2021:

- (a) the name and address of the sponsor;
- (b) the name and address of the manufacturer;
- (c) the device nomenclature system code for the device;
- (d) the medical device classification of the device; and
- (e) the unique product identifier of the device.

Such devices would need to be included in the ARTG before 1 November 2024.

Adaptable medical devices

The new definition and clarification of requirements for not alter existing regulatory requirements. Advice to relevant stakeholders will be required under transitional arrangements (such as amended guidance).

Evaluation

The purpose of the evaluation will be to assess the impact of the regulatory changes, whether the benefits have been realised, the impact on key stakeholders, and patient safety. The evaluation approach, questions and data requirements will be defined and agreed prior to implementation in order to ensure that appropriate data is captured to facilitate the evaluation and communicate the approach to key stakeholders. In addition, lessons learnt from other regulatory changes will be incorporated into the implementation and evaluation processes.

Methods

Methods used for data gathering are likely to include:

- formal and informal engagement with stakeholders through consultation and bi-lateral discussions
- analysis of data held on ARTG
- analysis of calls to the TGA Information Line

Stakeholders

Stakeholders that will be consulted as part of the evaluation will include:

- other regulators (including IMDRF)
- industry associations and peak bodies
- industry—manufacturers and sponsors
- hospitals
- health insurers
- patients and consumers
- surgeons
- researchers
- other governments, the Department of Health, states and territories

Potential questions

Questions that the evaluation may consider or address include:

- Did the increase in regulatory scope encompass all of the anticipated devices/scenarios?
- Which stakeholders and stakeholder groups did the TGA expect to be impacted by the changes, and did this align with the actual results? For example, did the organisations that now are regulated conform to the regulatory requirements?
- How effective were the communication and education methods that were employed prior to, and during the implementation?
- How many devices are now included in the ARTG as a result of the changes?
- How many hospitals registered medical device production systems (MDPS)?
- What was the number of adverse events or recalls involving devices that are now registered on the Australian Therapeutic Goods Register (ARTG)?
- Did all of the manufacturers/sponsors that indicated they would seek registration complete the registration process?
- Were there any unintended consequences for patients or the hospital system? If so, what were they?
- Were there any unintended consequences for manufacturers or sponsors? If so what were they?
- Did the regulatory burden align with the estimates? If not, where did they differ?
- Was there a perceived change in consumer confidence in the safety and performance of medical devices as a result of the changes?
- How many inspections did the TGA carry out? What were the overall results of those inspections?
- What have the impacts been on the broader community – for example has this promoted the growth of Australian manufacturers and innovation in this area?
- What were the impacts on the manufacturing of medical devices that include human-origin material?

Timeframe

While many aspects of the evaluation will be conducted on an ongoing basis (for example, through the forums and regular stakeholder meetings the TGA conducts and participates in), the TGA anticipates two key formal evaluation timeframes.

The first will be around the initial implementation, and likely to follow the first date for annual reporting which is 1 October 2021. The results of the evaluation would therefore be likely to be released in Q1 2022.

The second would be as a follow up to assess the inclusion of patient-matched devices in ARTG. The current proposed implementation deadline for inclusion is 1 November 2024 which means the evaluation results are likely to be released in early 2025.

Appendix 1—IMDRF Definitions (and examples) for Personalised Medical Devices

See IMDRF Final Document: Definitions for Personalized Medical Devices ([IMDRF PMD WG/N49 FINAL: 2018](#))³⁸

Definitions

Personalised medical device

A generic term to describe any of the types of medical devices that are intended for a particular individual, which could be either a custom-made, patient-matched, or adaptable medical device.

Custom-made medical device

A medical device that, at a minimum, meets the following requirements:

- it is intended for the sole use of a particular individual (which could be a patient or healthcare professional); and
- it is specifically made in accordance with a written request of an authorized professional, which gives, under their responsibility, specific design characteristics; even though the design may be developed in consultation with a manufacturer; and
- it is intended to address the specific anatomic-physiological features or pathological condition of the individual for whom it is intended.

Note 1: Medical devices that are patient-matched, adaptable or mass-produced shall not be considered to be custom-made.

Note 2: A custom made device is intended for a case where an individual's specific needs cannot be met, or cannot be met at the appropriate level of performance, by an alternative device available on the market.

³⁸ <http://imdrf.org/docs/imdrf/final/technical/imdrf-tech-181018-pmd-definitions-n49.pdf>

Patient-matched medical device

A medical device that meets the following requirements:

- it is matched to a patient's anatomy within a specified design envelope using techniques such as scaling of the device based on anatomic references, or by using the full anatomic features from patient imaging; and
- it is typically produced in a batch through a process that is capable of being validated and reproduced; and
- it is designed and produced under the responsibility of a manufacturer even though the design may be developed in consultation with an authorized healthcare professional.

Note 1: A written request from an authorized healthcare professional may be present; but is not mandatory.

Note 2: The number and type of design inputs in consultation with a healthcare professional may vary depending on the medical devices to be manufactured.

Note 3: The design must remain within the validated parameters of the specified design envelope.

Adaptable medical device

A medical device that meets the following requirements:

- it is mass-produced; and
- it is adapted, adjusted, assembled or shaped at the point of care, in accordance with the manufacturer's validated instructions, to suit an individual patient's specific anatomo-physiologic features prior to use.

Batch

One or more components or finished devices that are produced using the same lot of raw material, the same method of manufacture, having the same probability of chemical or microbial contamination, and that are intended to have uniform characteristics and quality within specified limits.

DICOM files

Patient imaging files, typically produced by computed tomography (CT) or magnetic resonance (MR), that are saved in the Digital Imaging and Communications in Medicine format.

Homogenous batch

A production group of equivalent parts or materials manufactured and/or tested in the same manner, without interruption, typically on the same day or in the same time period, and produced by the same person, or with the same machine/equipment set-up and fulfil the same specifications [Ref MEDDEV 2.5/6 Rev. 1 <http://ec.europa.eu/DocsRoom/documents/10287/attachments/1/translations>].

Mass-produced medical device

A medical device that is:

- based on standardized dimensions/designs;

- not designed for a particular individual; and
- typically produced in a continuous production run or homogenous batch.

Specific design characteristics

Unique design specifications, necessary to produce custom-made devices, that are based on an individual's specific anatomic-physiological features and/or pathological condition; and that cannot be proposed by a manufacturer without the involvement of a healthcare professional.

For example, transmitting only dimensions/geometric parameters (such as DICOM files from CT scans) to a manufacturer prior to the production of a medical device, is not sufficient to be considered as giving specific design characteristics. Additional information, such as the thickness and trajectory of a plate, the number, type and positions of fixation screws, would also need to be provided.

Specified design envelope

Minimum and maximum dimensions, mechanical performance limits, and other relevant factors, that characterize a medical device for production purposes, which may be based on a standard device template model.

Examples

Custom-made medical devices

Artificial cervical disc replacement, requested by a spinal surgeon, for reconstruction of the cervical disc following cervical discectomy to treat cervical radiculopathy in a 7'2" male patient. In this example, the osseous dimensions of this patient's cervical spine exceed those which an available artificial cervical disc would accommodate; therefore the individual's specific needs cannot be met by an alternative device available on the market. The surgeon has provided, under his/her responsibility, unique design specifications that are based on the individual's specific anatomic-physiological features and pathological condition to the manufacturer.

An **acetabular cup implant** requested by an orthopaedist who, in addition to DICOM-compliant scan images, sends to a 3D printing implant manufacturer specific requirements for acetabulum reconstruction by bridging the areas of acetabular bone loss. These include the thickness and trajectory of the cup mounting flange, and the number, type and positions of fixation screws. In this example these requirements are outside of the manufacturer's validated design envelope for this type of device. The required dimensions for bridging exceed those that have been validated under worst case parameters; and the number and location of screw holes are also beyond the limits modelled and/or tested.

An **endoscope with a modified steering mechanism** requested by a gastroenterologist to address a loss in manual dexterity caused by a disability. In this example the individual's specific needs cannot be met by an alternative device available on the market. The relevant healthcare professional for the gastroenterologist provides under his/her responsibility shape and force design requirements to the endoscope manufacturer that address the special requirements related to the disability.

Patient-specific medical devices

Acetabular guide designed to assist a surgeon with pre-operatively planned placement of the acetabular cup component of a total hip replacement. The guide is based upon CT images of a

patient's specific anatomy and pre-operatively planned placement of the acetabular cup. The device manufacturing processes, as well as the pre-operative planning process upon which the design of the patient-specific guide is based, are validated within a certain range of anatomical parameters. In this example the guide is produced under the responsibility of the manufacturer in consultation with, and input from, the surgeon.

Mandibular implants produced by a 3D printing manufacturer, from a template model and DICOM files. In this example the manufacturer provides software to the healthcare professional for the development of the 3D print file of the implant (based on the DICOM file from patient CT scans). The surgeon has received training from the manufacturer to use the software to tailor the 3D model for the patient within validated parameters. The manufacturer uses the 3D print file to produce, under its responsibility, the implant.

An **externally worn orthosis to shape the skull of an infant to prevent plagiocephaly**, based on 3D external images of the patient's head. In this example the images are produced by a prosthetist and sent to a manufacturer. The manufacturer produces, under its responsibility, a patient specific helmet within validated parameters.

Adaptable medical devices

Thoracolumbar pedicle screw system, which consists of multiple mass-produced components from a single manufacturer, that allows the surgeon to build an implant system, at the point of care, to fit the patient's anatomical and physiological requirements in accordance with validated instructions provided by the manufacturer. In this example the surgeon assembles a combination of hooks, screws, longitudinal members (e.g., plates, rods, plate/rod combinations), transverse or cross connectors, and interconnection mechanisms (e.g., rod-to-rod connectors, offset connectors). Additionally, longitudinal members require intraoperative contouring, in accordance with the manufacturer's validated instructions, in order to fit the individual patient's spinal curvature.

Mass-produced polymer surgical implants for cranial reconstruction that are supplied sterile and are intended to be thermoformed during the surgical procedure. The manufacturer's validated instructions provide details for heating and shaping the implant to suit a patient's particular anatomy.

Mandibular advancement orthosis for the treatment of sleep apnoea, which is adapted to the dentition through thermoforming, and is adjusted by the patient in accordance with the manufacturer's validated instructions.

Appendix 2—TGA Regulatory Burden Costings— Personalised Medical Devices

See: [Regulatory Burden costing: Proposed Regulatory Framework for Personalised Medical Devices \(pdf,595kb\)](#)

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Medical Device Authorisations Branch	December 2019