Regulatory Burden costings

Proposed Regulatory Framework for Personalised Medical Devices

Therapeutic Goods Administration

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Executive Summary

Background

Rapid advances in computing technology and additive materials manufacturing have driven exponential change in medical imaging and manufacturing technology and consequently medical devices technology. The current regulatory framework for custom-made medical devices was based on a historical premise that these devices would largely comprise low-risk products such as glass eyes, prosthetic limbs, prescription lenses etc. More recently, custom-made devices encompassed a small number of high-risk devices where there were no other options to treat a patient.

The scale of production of custom-made medical devices (including at point of care) and increasing number of uses has resulted in recognition by the Therapeutic Goods Administration (TGA) and industry that the current regulatory requirements for personalised medical devices were too broad and no longer fit-for-purpose. Furthermore, the current regulations can result in significant risks for patients receiving high risk custom-made devices, such as permanent implants, as they do not have the same level of regulatory oversight as similar conventionally-manufactured devices. Specifically, manufacturers and sponsors of custom-made medical devices are currently exempt from rigorous pre- and post-market regulatory oversight, including inspections of manufacturers' premises and the requirement for third-party certification of the device's safety and performance.

Consequently, a review (incorporating public consultation) was undertaken into the efficacy of the current regulatory oversight of custom-made medical devices. This review resulted in a number of proposed changes to the existing regulatory framework for medical devices to introduce appropriate regulatory controls for the emerging field of personalised medical devices.

Summary of proposed regulatory changes

Below are the proposed changes for the regulation of personalised medical devices:

1) introduce new definitions for personalised medical devices;

2) change 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;

3) introduce a framework for regulating a medical device production system which will allow healthcare providers to produce lower risk personalised devices for treating their patients, without the need for manufacturing certification;

4) update 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;

5) regulate medical devices with a human origin component, for example a 3D-printed implant incorporating cells from the patient, as medical devices with a biological component rather than as pure biologicals; and

6) clarify 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.

Purpose of this Report

The purpose of this report is to provide a quantification of the regulatory impact of the proposed changes to the regulation of personalised medical devices to inform a Regulation Impact Statement (RIS) prepared by the Department of Health (the Department).

Approach

The modelling detailed in this report was conducted in accordance with the Office of Best Practice Regulation (OBPR) guidance for the calculation of regulatory costs and the approach was briefed and agreed in principle by the OBPR. The Noetic Group (Noetic) did not engage directly with industry in determining the time taken to undertake the activities associated with the implementation of the proposed regulatory changes. Rather, Noetic relied on advice provided by the Department and previous regulatory costings for the quantification of existing regulatory activities (albeit applied to a new population of sponsors and manufacturers).

Conclusion

As per OBPR guidance, regulatory costs are projected over a 10 year period and then averaged to arrive at an average annual regulatory cost. The table below provides the average estimated regulatory compliance costs.

Table ES1 Summary of estimated regulatory compliance costs

Average annual regulatory costs (from business as usual) ($million)				
Change in costs	Business$	Community Organisation$	Individual$	**Total change in costs**
Option A				
Status quo: Current Regulatory framework is appropriate - no change is required				
Option B				
Amended the regulatory framework for personalised medical devices in accordance with the 6 proposed regulatory changes	$1.261		$0.005	**$1.266**

General

Background

Need for regulatory changes for personalised medical devices

Rapid advances in computing technology and additive materials manufacturing have driven exponential change in medical imaging technology, manufacturing technology and consequently medical devices technology. The current regulatory framework for custom-made medical devices was based on the premise that these devices would largely comprise low-risk products such as glass eyes, prosthetic limbs, prescription lenses etc. More recently, custom-made devices encompassed a small number of high-risk devices where there were no other options to treat a patient.

However, the scale of production of custom-made medical devices (including at point of care) and increasing number of uses has resulted in a recognition by the Therapeutic Goods Administration (TGA) and industry that the current regulatory requirements for personalised medical devices were too broad and no longer fit-for-purpose under the current provisions for custom-made devices. Furthermore, the current regulations can result in some significant risks for patients receiving high risk custom-made devices such as permanent implants, as they do not have the same level of regulatory oversight as similar, conventionally-manufactured devices.[1] Specifically, manufacturers and sponsors of custom-made medical devices are exempt from rigorous pre and post-market regulatory oversight, including inspections of manufacturers premises and the requirement for third-party certifications of their devices' safety and performance.

Consequently, a review (incorporating public consultation) was undertaken into the efficacy of the current regulatory oversight of custom-made medical devices. This review resulted in a number of proposed changes to the existing regulatory framework for medical devices to introduce appropriate regulatory controls for the emerging fields of personalised medical devices.

[1] 3D-printed mass-produced medical devices do not meet the current definition of custom-made medical devices and therefore are not considered 'exempted' products under the medical devices regulatory framework.

Summary of proposed regulatory changes

Below are the proposed changes for the regulation of personalised medical devices:

1) introduce new definitions for personalised medical devices;

2) change 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;

3) introduce a framework for regulating a medical device production system which will allow healthcare providers to produce lower risk personalised devices for treating their patients, without the need for manufacturing certification;

4) update 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;

5) regulate medical devices with a human origin component, for example a 3D-printed implant incorporating cells from the patient, as medical devices with a biological component rather than as pure biologicals; and

6) clarify 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.

International regulatory harmonisation

Custom-made medical devices are currently defined in the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations) as medical devices that:

- are made specifically in accordance with a request by a health professional specifying the design characteristics or construction of the medical device; and
- are intended:
  - to be used only in relation to a particular individual; or
  - to be used by a health professional to meet special needs arising in the course of his or her practice.[2]

TGA is proposing to introduce new definitions to harmonise with those published by the International Medical Device Regulators Forum (IMDRF) at the end of 2018.[3]

[2] *Therapeutic Goods (Medical Devices) Regulations 2002,* Regulation 1.3 (Dictionary).

[3] IMDRF PMD WG/N49 FINAL: 2018.

Personalized 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[4]

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);
- 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 anatomo-physiological features or pathological condition of the individual for whom it is intended.

Patient-matched medical device[5]

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;
- 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.

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.

[4] Notes: Medical devices that are patient-matched, adaptable or mass-produced shall not be considered to be custom-made. 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.

[5] Notes: A written request from an authorised healthcare professional may be present; but is not mandatory. The number and type of design inputs in consultation with a healthcare professional may vary depending on the medical device to be manufactured. The design must remain within the validated parameters of the specified design envelope.

Transition period

TGA has advised that the transition period for the proposed changes to the regulatory framework of personalised medical devices will commence on 24 August 2020 and continue until 30 November 2024.

Purpose of this Report

The purpose of this report is to provide a quantification of the regulatory impact of the proposed changes to the regulation of personalised medical devices to inform a Regulation Impact Statement prepared by the Department.

Approach

The modelling detailed in this report was conducted in accordance with the OBPR guidance for the calculation of regulatory costs and the approach was briefed and agreed in principle by the OBPR. Noetic Group did not engage directly with industry in determining the time taken to undertake the activities associated with the implementation of the proposed regulatory changes. Rather, Noetic relied on advice provided by the Department and previous regulatory costings for the quantification of existing regulatory activities (albeit applied to a new population of sponsors and manufacturers).

Specifically, Noetic has provided this in the form of regulatory costings for each of the options listed below:

- Option A (Status Quo Option): No change to the Therapeutic Goods (Medical Devices) Regulations 2002 is required; the current TGA medical devices regulatory framework is appropriate.
- Option B (Information Option): Amended the regulatory framework for personalised medical devices in accordance with the 6 proposed regulatory changes.

The requirement for an 'appropriate' level of consultation is clearly articulated in the OBPR guidance. Noetic and the Department collaborated to achieve the required level of consultation, including the following activities:

- The Department undertook public consultations and conducted public forums in 2017 and 2018 to understand the impact that the proposed regulatory changes will have on the medical devices industry, healthcare professionals and patients. A further public consultation was undertaken from February to March 2019. Noetic reviewed all publicly released submissions to the consultation papers.
- Regular engagement (including a number of workshops) occurred with Department staff in the Medical Devices Branch to discuss and obtain feedback on progress; seek advice or direction regarding assumptions, qualifications and inputs; and communicate and resolve challenges.

- One meeting with the OBPR (attended by both Noetic and the Department) to confirm the proposed approach and seek advice or direction regarding assumptions, qualifications and inputs.

1. The Regulatory Costing

Costing Model

Overview

The development of the regulatory costing model was undertaken in accordance with the OBPR Guidance Note: 'Regulatory Burden Measurement Framework', dated February 2016. Costs were estimated for administrative compliance costs only. No substantive costs were identified, as it was considered that regulated entities would already have the necessary record management systems. Delay costs (application and approval delays) were determined to be out-of-scope.

The labour cost formula was used to determine these administrative compliance costs: price x quantity (or in its more expanded version: (Time required × Labour cost) × (Times performed × Number of businesses or community organisations × Number of staff)).

As detailed earlier in this report, workshops were held with Department staff to assist with the determination of the impacted population and the touch points arising from the proposed regulatory changes.

The options being considered by the Department

Table 1 details the regulatory options being considered by the Department.

Table 1. Regulatory options for personalised medical devices

Option A (Status Quo)	No change to the Therapeutic Goods (Medical Devices) Regulations 2002 is required; the current TGA medical devices regulatory framework is appropriate.
Option B	Amend the regulatory framework for personalised medical devices in accordance with the 6 proposed regulatory changes

Option A: Is the status quo and provides the cost base from which to calculate the change in regulatory burden for Option B.

Option B: The change in regulatory burden will mainly be realised by Manufacturers/Sponsors of custom-made devices, manufacturers and sponsors of medical device production systems, and manufacturers and sponsor of medical devices and associated software used to record diagnostic images. There will also be a slight increase in the regulatory burden of patients and healthcare providers associated with the need to provide patients the manufacturer's statement for custom-made medical devices.

Given the inter-related nature of the individual reform measures within the package of reforms, and which by their very nature relate directly to proposed actions to be undertaken by regulated bodies, a single regulatory option (Option B) has been costed.

Transition arrangements

The proposed reforms will come into effect on 25 August 2020, subject to the following transitions.

- **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 are considered to be transitional devices. The current ARTG entry will 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 must notify 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 will require new ARTG inclusions at the end of the transition period.
- **Custom-made medical devices.** Provision of the manufacturer's statement with the device and record retention requirements apply to custom-made medical devices manufactured on or after 25 August 2020. Annual Reporting requirements apply to custom-made medical devices manufactured in Australia, or imported into Australia, on or after 25 August 2020. First annual reports will be due 1 October 2021. Ability for TGA to inspect custom-made manufacturing sites applies on or after 25 August 2020.
- **Patient-matched medical devices.** 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, will remain in force until 1 November 2024 for those devices that meet the following condition:
  - The sponsor or Australian manufacturer must, before the notification date of 25 February 2021, notify the Secretary in writing of the following:
    - the name and address of the sponsor;
    - the name and address of the manufacturer;
    - the device nomenclature system code for the device;
    - the medical device classification of the device; and
    - the unique product identifier of the device.

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

For the purposes of quantifying changes in the regulated population, the regulatory costing has been undertaken over the period FY 2020/21 to FY 2030/31. Where population changes have been able to be determined, Noetic has factored this into the regulatory costing.

Labour cost

The Australian Bureau of Statistics (ABS) publishes 'Average Weekly Earnings' semi-annually. As at 26 August 2019, the latest dataset is May 2019.[6] Given that sponsors or manufacturers could be based in any state/territory, the national dataset was used. The relevant table of the data is Table 10H ('Average Weekly Earnings, Industry, Australia (Dollars) - Original - Persons, Full Time Adult Total Earnings' (includes overtime)). Two Australian and New Zealand Standard Industrial Classification (ANZSIC) divisions were considered by Noetic as being relevant to the particular activities being costed:

1 Professional, Scientific and Technical Services (ANZSIC Division M).

- Industry subdivisions are: Professional, Scientific and Technical Services (Except Computer System Design and Related Services), and; Computer System Design and Related Services.
- For May 2019, the figure for weekly earning is $1958.10.

2 Health Care and Social Assistance (ANZSIC Division Q).

- Industry subdivisions are: Hospitals; Medical and Other Health Care Services; Residential Care Services, and; Social Assistance Services.
- For May 2019, the figure for weekly earning is $1626.40.

It was assessed by Noetic that the Professional, Scientific and Technical Services was the more appropriate industry division because it is the industry division most likely to include the regulatory staff who would undertake the sponsor/manufacturer activities being costed.

For May 2019, the figure for weekly earnings is therefore $1958.10. To determine the average hourly cost, this figure is divided by the average number of total hours worked (includes overtime) for full-time, non-managerial employees (the 'All Industries' category has been used) (39.40 hours).[7] In accordance with OBPR guidance, a multiplier of 175 was used to account for the non-wage labour on-costs and overhead costs. The arising calculation is shown below.

$$(\$1958.10/39.40)*175 = \$86.97^{8}$$

An individual's (patient's) time, while not in paid employment (such as during leisure time), has been costed at $32.00 per hour, as per OBPR guidance. In accordance with OBPR guidance a multiplier is not applied to this figure.

[6] Australian Bureau of Statistics, 6302.0 - Average Weekly Earnings, Australia, May 2019, viewed 26 August 2019, <https://www.abs.gov.au/ausstats/abs@.nsf/0/7F76D15354BB25D5CA2575BC001D5866?Opendocument >.

[7] Australian Bureau of Statistics, 6306.0 - Employee Earnings and Hours, Australia, May 2018, viewed 26 August 2019,<https://www.abs.gov.au/AUSSTATS/abs@.nsf/DetailsPage/6306.0May%202018?OpenDocument >.

[8] By way of comparison, the suggested hourly labour rate by OBPR is $73.05 as compared to a value of $86.97 as calculated above.

Overview of changes

Changes 1 and 2 – New definitions for personalised medical devices and changed requirements for supply custom - made devices

Proposed changes

Manufacturers and sponsors of medical devices that fit the harmonised definition of custom-made, which is more restrictive than the current Australian status, will still be exempt[9] from being included in the Australian Register of Therapeutic Goods (ARTG). Custom-made medical devices will still be subject to limited regulatory oversight, though there will be an increase of regulatory requirements from the status quo, as detailed in the following table.

[9] In accordance with Schedule 4 of the Regulations.

Table 2. Proposed changes to the regulatory framework for custom-made medical devices

Current Regulatory Requirements	Proposed Regulatory Requirements	Likely Regulatory Impact
The manufacturer of a custom-made medical device that is manufactured in Australia must, within 2 months after the medical device is first manufactured in Australia, give the following information about the device to the Secretary: · the manufacturer's name and business address; and · a description of the kinds of medical devices being custom-made by the manufacturer (including the device nomenclature system code for any such devices).[10] The sponsor of a custom-made medical device that is imported into Australia must, within 2 months after the medical device is first imported into Australia, give the following information about the device to the Secretary: · the sponsor's name and address; · the manufacturer's name and business address; and · a description of the kinds of medical devices being custom-made by the manufacturer (including the device nomenclature system code for any such devices).[11] This notification is undertaken via an online notification form. Note that a separate form is required for each Global Medical Device Nomenclature (GMDN) code/ classification.	That a manufacturer in Australia, or a sponsor of an overseas manufactured custom-made device, provides an annual report to the TGA regarding the custom-made devices they have supplied in the preceding year.	Each manufacturer or sponsor would need to provide an annual report. The exact data fields of this report are still to be determined but it is likely to replicate a number of fields that are currently provided on the online notification form. The Department has advised that patient information will not be sought but that it is possible that the name and business address of the health professional who provided the specification for the higher-risk (Class IIb and Class III) custom-made device may be required. The necessary steps would include the capture of the information over the course of the year, the consolidation of the information for reporting purposes, the checking of the information prior to submission, and the actual submission. It should be noted that requirement to provide the TGA with the initial notification of the manufacture of a custom-made devices remains and is addition to the annual report. There is currently a civil penalty (e.g. penalty units) for not notifying the TGA of the manufacture of custom-made medical devices. Although many custom-made manufacturers have not provided this notification, this is an existing regulatory requirements and therefore is excluded from this regulatory costing.

[10] Regulation 10.3(1).

[11] Regulation 10.3(2).

Current Regulatory Requirements	Proposed Regulatory Requirements	Likely Regulatory Impact
The manufacturer of the device must prepare a written statement in relation to each custom-made medical device including the following: · the name and business address of the manufacturer; · sufficient information to enable the user to identify the device or, if relevant, the contents of packaging; · a statement to the effect that the device is intended by the manufacturer to be used only in relation to a particular individual or health professional; · the name of the individual in relation to whom the device is intended to be used; · the name and business address of the health professional who provided the specification for the device; · the particular design characteristics or construction of the device as specified by the health professional who provided the specification for the device; and · a statement to the effect 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, a statement explaining which provisions of the essential principles the device does not comply with and the reasons for the non-compliance.[12] The manufacturer must prepare, and keep up-to-date, documentation in relation to the device, including information in relation to the design, production and intended performance of the device.[13] Unlike in Europe, the regulations require that the manufacturer only keeps this statement and are not required to provide this information to the patient.	The manufacturer's statement about a custom-made device is to be provided to the patient receiving the device. This change would result in greater transparency for 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 understood the custom-made nature of the device and may also contribute to the informed consent process.	It should be noted that there is an existing requirement to prepare a written statement in relation to each custom-made medical device. This is an existing regulatory requirements and therefore is excluded from this regulatory costing. A small number of custom-made device manufacturers may already have contextualised this statement to make it suitable to be provided to a patient; however, this number was assumed to be not material to the calculation of the regulatory costing. It has been assumed that most patients will read the manufacturer's statement.

[12] Schedule 3, s. 7.2(2).

[13] Schedule 3, s. 7.2(4).

Current Regulatory Requirements	Proposed Regulatory Requirements	Likely Regulatory Impact
The manufacturer must notify the Secretary as soon as practicable after becoming aware of: · information relating to: o any malfunction or deterioration in the characteristics or performance of the device; or o any inadequacy in the design, production, labelling or instructions for use of the device; or o any use in accordance with, or contrary to, the use intended by the manufacturer of the device; that might lead, or might have led, to the death of a patient or a user of the device, or to a serious deterioration in his or her state of health; or · information relating to any technical or medical reason for a malfunction or deterioration of a kind mentioned in paragraph (a) that has led the manufacturer to take steps to recall a device that has been distributed.[14]	No change	Nil

[14] Schedule 3, s. 7.2(6).

Current Regulatory Requirements	Proposed Regulatory Requirements	Likely Regulatory Impact
In relation to records: · The manufacturer must keep the statement and documentation required under the relevant clause of this Schedule in relation to a medical device to which the conformity assessment procedures in this Part have been applied. · The manufacturer must keep the statement and documentation for at least 5 years after the manufacture of the last medical device to which the statement and documentation relates. [The Department considers this an inadequate period of time for an implantable device due to its long-expected lifetime – in Europe manufacturers of custom-made medical devices are required to keep the documentation for 15 years]. · On request from the Secretary, the manufacturer must make the statement and documentation available to the Secretary.[15] (Note the legislation does not provide the Department with the power to enter and inspect manufacturing sites for custom-made devices]. There is currently no requirement for any third-party assessment of custom-made devices or of their manufacturer.	That the TGA be allowed to enter and inspect custom-made device manufacturing sites, in accordance with the authority it has to inspect all other medical device manufacturers. This change would provide greater transparency to the TGA about the manufacture and supply of custom-made medical devices in Australia, improving the Department's ability to monitor quality, safety and performance of these devices. It is envisaged that such inspections will not be routinely held but will be risk-based according to the implications for health and safety. That documentation about an implantable custom-made device is retained for a minimum period of fifteen (15) years; as the current specification of a five (5)-year retention period is considered inadequate.	The Department has advised Noetic that the regulatory power to enter and inspect the premises of custom-made device manufacturing sites will be rarely used, with the key selection criteria being the reporting of adverse events or experimental custom-made medical devices (either type of device or manufacturing process). It is estimated that there will be no more than 5 inspections conducted per year. It is envisaged that the regulatory impact of inspections would be to receive notification of the inspection, prepare documentation of the inspection, undergo inspection, and respond to any follow-up matters arising from the inspection. As it is considered that most records will be maintained electronically rather than hard copy, the requirement to retain records for an additional 10 years will require some minor changes to a manufacturer's document management system as well as an annual check by staff to ensure the archival processes are being followed.

The patient-matched category of devices, which currently falls under the custom-made definition in Australia, will no longer be eligible for the existing exemption, and instead will require third party regulatory oversight according to the device risk classification. This will level the playing field for manufacturers as all will now be required to ensure that their devices comply with the essential principles for safety and performance rather than this being a voluntary requirement.

[15] Schedule 3, s. 7.6.

The listing of patient-matched medical devices on the ARTG[16] will provide a simplified pathway for inclusion on the Prostheses List. Inclusion on the list provides reimbursement for patients with private health insurance who receive the medical device, which is generally assumed to lead to increased usage of the device.[17] The likely candidate section of the Prostheses List is Part A (excludes prosthesis that include human tissue (Part B), and insulin infusion pumps and a number of cardiac prosthesis (Part C)). However, in addition to having to be entered on the ARTG, other legislative criteria for Part A include being provided to a person as part of an episode of hospital treatment or hospital-substitute treatment and a Medicare Benefit must be payable in respect of the professional service associated with the provision of the product (or the provision of the product is associated with podiatric treatment by an accredited podiatrist). When viewed as a whole, the inclusion criteria would likely restrict the number of patient-matched medical devices that make their way onto the Prosthesis List due to eligibility criteria.[18] In addition, the decision to submit an application to be included on the Prosthesis List is entirely at the discretion of the sponsor (i.e. it is not a regulatory requirement). Therefore, this will be a business decision, cognisant of the anticipated uplift in sales arising from inclusion in the list as well as taking into account the arising fees ($600 application and $400 per year ongoing listing fee) as well as the administrative burden in completing the application and providing the supporting evidence. While it is possible that some sponsors of patient-matched medical devices will apply for inclusion on the Prosthesis List, many and perhaps even the majority of sponsors will not. For the reasons listed above, the administrative burden associated with an application for inclusion on the Prosthesis List has not been included in the overall regulatory costing (noting also that activities by the public sector organisations are specifically excluded from a regulatory costing).

The regulation of adaptable medical devices will not change. Rather the definitional change is focussed on providing clarity as to which devices are in this category and by extension, which are not (e.g. a patient-matched medical device).

[16] Criterion 1 for listing in Part A of the Prostheses List is that 'The product must be entered and current on the Australian Register of Therapeutic Goods' (refer to Department of Health, 'Prostheses List: Guide to listing and setting benefits for prostheses', February 2019 (updated 13 June 2019), p.14).

[17] It is also noted that the listing on the ARTG facilitates procurement of the medical device by the public health sector, again leading to an expected increase in sales.

[18] For example, Medicare doesn't cover most dental care, dental procedures, or supplies, like cleanings, fillings, tooth extractions, dentures, dental plates, or other dental devices

Regulatory impact

Currently, the authoritative data set for sponsors and manufacturers of custom-made medical devices is contained within the Custom-made Device Repository (a database which contains the data entered via the online Custom-made medical devices notification form). Following data cleansing activities[19], there was approximately 245 unique records contained within the repository. It is noted that of these 245 records, 83 or approximately 1/3 could be identified as dentists or in related fields.[20] Other specialist fields that could be determined from the dataset included providers of prosthetics (limb and ocular) and orthotics.

The Department has advised Noetic that the number of practices represented in the repository is most likely a severe underrepresentation of the number of healthcare providers currently supplying custom-made medical devices to patients. For example, it is understood by Noetic that most dental practices would undertake activities that fall within the current regulatory definition of manufacturing a custom-made medical device. The latest statistical reporting by the Dental Board of Australia[21] details that there are 23,060 practising general and specialist dentists.[22] Noting custom-made medical devices regulatory requirements relate to a practice rather than an individual, the Australian Dental Association has advised the Department that there are approximately 7500 dental practices in Australia[23], which equates to approximately three dentists per practice. In addition, there are approximately 1264 dental prosthetists[24], whose peak body is the Australian Dental Prosthetists Association (some of these prosthetists will be part of a wider dental team though many are likely to work in separate practices). A separate group of specialists (dental technicians as

[19] Data cleansing activities included removing rows that contained incomplete information and consolidating the 'Name' field (which may pertain to either a Sponsor or a Manufacturer) to account for spelling errors and variations of a company name (for example, listed with or without 'Pty Ltd').

[20] This was determined by searching for 'dent' (for denture, dental, dentist etc.) in the sponsor/manufacture name. It is acknowledged that this is likely an understatement of the number of dentists or related specialist represented in this list as sponsor names may be of specific individuals or broader medical supply companies and therefore will not contain 'dent' in their provided sponsor name.

[21] Dental Board of Australia: Registrant Data, Reporting Period: 1 April 2019 to 30 June 2019, < https://www.dentalboard.gov.au/About-the-Board/Statistics.aspx>.

[22] Refer to Table 6.2 Dental practitioners – registration type by age group (figure represents sum of 'General', 'General and Specialist' and 'Specialist' columns) – note this figure includes dental prosthetists (currently 1264 are registered).

[23] Department advice to Noetic on 17 October 2019.

[24] Dental technicians are not registered by the Dental Board of Australia.

well as dental prosthetists) are represented by the Oral Health Professionals Association, the peak body for dental laboratories. If we assume an average of two dental prosthetists per practice, this equates to approximately 600 separate practices (which equates to approximately 1 dental prosthetists/ dental laboratory per 12 dental practices).

In relation to orthotic/ prosthetic providers, the peak professional body (The Australian Orthotic Prosthetic Association) states on their webpage that they have 480 certified practitioners as members, and this represents 80% of the profession nationally[25] (therefore 600 practitioners). Furthermore, the association publishes a listing of Australian Orthotic/ Prosthetic Practices in Australia. The latest edition (2019)[26], details 93 practices which, assuming the same ratio of practitioners to practices for non-members becomes 116 practices across the entire population of 600 practitioners.

Noting that the public sector is specifically excluded from the Regulatory Burden Measurement Framework, the remaining category of custom medical device providers includes private sector hospital biomedical engineering laboratories, who wish to maintain the flexibility of producing custom-made medical devices rather than using a Medical Device Production System – detailed under Change 3. The Department of Health maintains a list of declared hospitals, as required under the provisions of the *Private Health Insurance Act 2007* . The current list [27] details 1317 declared hospitals of which 638 are in the private sector and 679 in the public sector. Noting that government-to-government regulation is specifically excluded from the Regulatory Burden Measurement Framework[28], then the number of private hospitals that currently produce custom-made medical devices that will be impacted by these changes will be a sub-set of the 638 private hospitals. The Department has completed a line-by-line analysis of a large sample (over 85%) of each of the listed declared private hospitals. The Department's analysis reveals that approximately 45% of hospitals are likely to fall under the category of a custom-made medical device. manufacturer. When this figure is extrapolated over the entire population (638) t hen this gives a figure of 287.

In relation to the growt h of the regulated population, the Australian Dental association advised the Department that there is anticipated growth in the number of registered dentists of approximately 1000 per year. Noting there is approximately 18,000 existing active dentists in A ustralia (as per Dental Board of Australia reporting) , this represents a growth factor of approximately 5%. In the absence of growth data for the number of dental prosthetists/dental laboratories and orthotic/prosthetic providers ,

[25] The Australian Orthotic Prosthetic Association, 'About Us', viewed 26 August 2019, < https://www.aopa.org.au/about-us/about-us>.

[26] https://www.aopa.org.au/documents/item/726.

[27] See < https://www1.health.gov.au/internet/main/publishing.nsf/Content/hospitals2.htm>, viewed 21 October 2019.

[28] Department of the Prime Minister and Cabinet, Office of Best Practice Regulation, 'Guidance Note: Regulatory Burden Measurement Framework', February 2016, p.5.

Noetic has applied the same growth factor. The latest Australian Institute of Health and Welfare (AIHW) report on hospitals ('Hospitals at a glance 2017-2018') details a 2.3% (so 2%) increase in the number of private hospitals over the period 2012-13 to 2016-17.

The projected growth in the number of custom-made medical devices practices is detailed in the table below.

Table 3. Growth in number of custom-made medical devices practices over the period 2019/20 to 2030/31

Transition	Year	Dental Practices	Prosthetists/ Laboratories	Orthotic/ Prosthetic Practices	Private Hospitals
Yearly Growth Factor		1.05	1.05	1.05	1.02
Data Year	19/20	7,500	600	116	287
Data Year + 1	20/21	7,875	630	122	293
Year 1	20/21	8,269	662	128	299
Year 2	21/22	8,682	695	134	305
Year 3	22/23	9,116	729	141	311
Year 4	23/24	9,572	766	148	317
Year 5	24/25	10,051	804	155	323
Year 6	25/26	10,553	844	163	330
Year 7	26/27	11,081	886	171	336
Year 8	27/28	11,635	931	180	343
Year 9	28/29	12,217	977	189	350
Year 10	30/31	12,828	1,026	198	357
Total growth	(Year 10 – Year 1)	4,559	365	71	58
				Total	5052

Number of surgical procedures involving custom-made medical devices

Noetic has assumed that the number of in-scope surgical procedures equates to the number of occasions that a patient will be impacted by the regulatory change relating to the provision of the manufacturer's statement for a custom-made medical device.

The AIHW is the definitive source of information on healthcare facility activities in Australia, such as the number of surgical procedures conducted in public and private hospitals each year.

Of particular relevance to this regulatory costing are the AIHW's hospitals statistics. Noetic assessed that, within this collection of statistical data, the AIHW report 'Admitted patient care 2017-18' would be the most relevant. Chapter 6 of this report contains data on the number of procedures by Australian Classification of Health Interventions (ACHI) (as well as the total number of separations). This data incorporates emergency and elective surgery for both public and private hospitals and is broken down into 20 high-level Procedure Chapters based on the procedure type (see the table below). In this instance, as the regulatory burden being calculated relates to an individual rather than a public sector employee, the Government-to-Government exclusion to the Regulatory Burden Measurement Framework does not apply.

Table 4. Number of interventions and total separations 2017-18

ACHI chapter		Public hospitals	Private hospitals	Total
1–86	Procedures on nervous system	117,641	328,085	445,726
110–129	Procedures on endocrine system	10,986	11,815	22,801
160–256	Procedures on eye and adnexa	224,640	555,568	780,208
300–333	Procedures on ear and mastoid process	34,274	48,233	82,507
370–422	Procedures on nose, mouth and pharynx	110,087	206,927	317,014
450–490	Dental services	96,230	288,201	384,431
520–572	Procedures on respiratory system	199,124	60,557	259,681
600–777	Procedures on cardiovascular system	320,885	294,912	615,797
800–817	Procedures on blood and blood-forming organs	47,539	32,730	80,269
850–1011	Procedures on digestive system	783,841	1,385,135	2,168,976
1040–1129	Procedures on urinary system	1,465,656	556,394	2,022,050
1160–1203	Procedures on male genital organs	48,557	85,331	133,888
1240–1299	Gynaecological procedures	240,530	390,960	631,490
1330–1347	Obstetric procedures	604,255	170,698	774,953
1360–1580	Procedures on musculoskeletal system	411,851	604,477	1,016,328
1600–1718	Dermatological and plastic procedures	401,461	492,437	893,898
1740–1759	Procedures on breast	26,921	69,158	96,079
1786–1800	Radiation oncology procedures	15,399	7,623	23,022
1820–1923	Interventions, n.e.c.	6,889,753	5,969,476	12,859,229
1940–2016	Imaging services	68,655	51,792	120,447
	Interventions reported	**12,118,359**	**11,610,511**	**23,728,870**
	No intervention or not reported[(b)]	1,638,395	213,460	1,851,855
Total separations		**6,726,775**	**4,526,500**	**11,253,275**

Source: AIHW, Admitted patient care 2017-18: Australian hospital statistics, Table 6.1 titled 'Number of interventions, by ACHI chapter, public and private hospitals, 2017-18, p.102.

An additional publication supports the interpretation of this data: the AIHW data cube Procedures and healthcare interventions (ACHI 10th edition), Australia, 2017-18 (referred to throughout as the data cube). The most recently published version of the data cube (2017-18) was accessed by Noetic via the AIHW website as it provides the most granular detail of Procedure Chapters, whereby they are broken down into Subchapters, then Blocks, then by the actual Procedures (see the table below - using a subset of 'Chapter 6: Dental Services' as an example).

Table 5. Categorisation schema for procedures utilised by AIHW

Row Labels	Sum of Procedures
⊞01 Procedures on nervous system	445726
⊞02 Procedures on endocrine system	22801
⊞03 Procedures on eye and adnexa	780208
⊞04 Procedures on ear and mastoid process	82507
⊞05 Procedures on nose, mouth and pharynx	317014
⊟06 Dental services	384431
⊞0450-0452 Diagnostic Dental Services	7130
⊞0453-0455 Preventative Dental Services	62505
⊞0456 Periodontic Interventions	5512
⊞0457-0461 Oral Surgery	192604
⊞0462-0464 Endodontics	9389
⊞0465-0469 Restorative Dental Services	97107
⊟0470-0477 Prosthodontics	8055
⊟0470 Crown	5152
97613-00 Full crown, nonmetallic, indirect	340
97615-00 Full crown, veneered, indirect	106
97618-00 Full crown, metallic, indirect	14
97627-00 Preliminary restoration for crown, direct	3436
n.p.	1256
⊟0471 Bridge	112
97632-00 Provisional bridge, per pontic	21
97633-00 Provisional implant abutment, per abutment	41

Source: AIHW, National Hospital Morbidity Database, Procedures and healthcare interventions (ACHI 10th edition), Australia, 2017-18 < https://www.aihw.gov.au/reports/hospitals/procedures-data-cubes/contents/data-cubes >.

The Department has provided Noetic with the following analysis of in-scope procedures (at the Procedure Sub-Chapter). This was determined by the Department undertaking key word searches of procedure codes. The Department has advised Noetic that approximately 0.5% of the total of in-scope procedures (therefore 290,801* 0.005 = 1454) will likely involve a custom-made medical device.

Table 6. In-scope medical procedures for custom-made medical devices

Procedure Sub-Chapter	Sum of Procedures 2017-18
0001-0028 Skull, Meninges and Brain	2676
0029 -0059 Spinal Canal and Spinal Cord Structures	1901
0160-0165 Eyeball	100
0241-0250 Ocular Adnexa - Lacrimal System	1740
0307 -0316 Eardrum and Middle Ear	5383
0321-0328 Mastoid and Temporal Bone	1093
0370 -0381 Nose	29815
0416-0422 Pharynx	20
0450 -0452 Diagnostic Dental Services	165
0456 Periodontic Interventions	139

Procedure Sub-Chapter	Sum of Procedures 2017-18
0470 - 0477 Prosthodontics	40
0520 - 0531 Larynx	536
0532 - 0542 Trachea	42
0559 - 0567 Chest Wall, Mediastinum and Diaphragm	204
0621 - 0624 Heart - Aortic Valve	6506
0625 - 0630 Heart - Mitral Valve	3176
0631 - 0635 Heart - Tricuspid Valve	774
0636 - 0638 Heart - Pulmonary Valve	126
0667 - 0681 Coronary Arteries	45943
0694 - 0720 Arteries	2476
0721 - 0739 Veins	106
0740 - 0777 Other vascular sites	13452
0850 - 0869 Oesophagus	991
0891 - 0903 Small Intestine	543
0904 - 0925 Large Intestine	347
0928 - 0942 Rectum, Anus	96
0957 - 0973 Gall Bladder and Biliary Tract	9256
0974 - 0982 Pancreas	1099
0983 - 1004 Abdomen, Peritoneum and Omentum	15490
1040 - 1064 Kidney	1271
1065 - 1088 Ureter	51489
1112 - 1125 Urethra	467
1160 - 1170 Prostate and Seminal Vesicle	10
1171 - 1176 Scrotum and Tunica Vaginalis	206
1381 - 1393 Spine (Vertebral Column)	8
1408 - 1419 Humerus and Elbow	65
1439 - 1474 Hand, Wrist	127
1476 - 1493 Pelvis, Hip	14
1495 - 1524 Knee Joint, Leg	40415
1526 - 1548 Ankle, Foot	83
1600 - 1660 Skin and Subcutaneous Tissue	1301

Procedure Sub-Chapter	Sum of Procedures 2017-18
1740-1759 Breast	10679
1786-1800 Radiation Oncology Procedures	23022
1867-1908 Therapeutic Interventions	5061
1923 Interventions Not Elsewhere Classified	12348
Total	290 ,801

Regulatory impact of changes in separations over the ten-year period

The AIHW reported in *Admitted patient care 2017-18: Australian hospital statistics* that the average growth rate in the number of hospital separations between 2013-14 and 2017-18 was 3.8% (see table below). Assuming that the growth in the number of separations involving the use of a custom-made medical device is growing at the same rate as the total number of separations, this figure has been used to estimate growth over the ten-year period.

Table 7. Growth in number of separations (2013-14 to 2017-18)

						Change (%)	
	2013–14	2014–15	2015–16	2016–17	2017–18	Average since 2013–14	Since 2016–17
Public hospitals[(b)]							
Public acute hospitals	5,702,106	5,967,265	6,256,986	6,570,727	6,709,418	4.2	2.1
Public psychiatric hospitals	12,764	13,073	15,495	16,621	17,357	8.0	4.4
Total public hospitals	*5,714,870*	*5,980,338*	*6,272,481*	*6,587,348*	*6,726,775*	*4.2*	*2.1*
Private hospitals							
Private free-standing day hospital facilities	875,529	940,703	959,743	939,950	975,943	2.8	3.8
Other private hospitals	3,106,376	3,229,326	3,367,544	3,486,517	3,550,557	3.4	1.8
Total private hospitals	*3,981,905*	*4,170,029*	*4,327,287*	*4,426,467*	*4,526,500*	*3.3*	*2.3*
All hospitals	**9,696,775**	**10,150,367**	**10,599,768**	**11,013,815**	**11,253,275**	**3.8**	**2.2**

Source: AIHW, Admitted patient care 2017-18: Australian hospital statistics, Table 2.1: Separations, public and private hospital, 2013-14 to 2017-18, p.10.

As the data for the number of procedures (as provided by the Department) was for 2017-18 and the start year for the calculation is 2020/21, there is a need to compound this figure by the annual growth for two years (see table below).

Table 8. Projected growth in number of in-scope surgical procedures

Transition	Year	Number of Procedures
Yearly Growth Factor		1.038
Data Year	17/18	1,454
Data Year + 1	18/19	1,509
Data Year + 2	19/20	1,567
Year 1	20/21	1,626
Year 2	21/22	1,688
Year 3	22/23	1,752
Year 4	23/24	1,819
Year 5	24/25	1,888
Year 6	25/26	1,959
Year 7	26/27	2,034
Year 8	27/28	2,111
Year 9	28/2 9	2,191
Year 10	29/30	2,275
Total over 10-year period		**19,343**

Regulatory costing

Annual Report on custom-made medical devices

Key assumptions

- The majority of the information required for the compilation of the annual report to the Department (submitted via a web-form) is captured as part of usual business practices (e.g. the name and the business address of the health professional who requested the custom-made medical device). The increase in regulatory burden is therefore limited to the need to consolidate this information in a report, to check the report, and then submit to the Department. The time required to complete this process over the course of a year is estimated to be 1 hour.
- All existing custom-made devices manufacturers will likely continue to be custom-made devices manufacturers (noting that some may also become patient-matched medical devices manufacturers).
- The time taken to be aware of the regulatory changes is an additional regulatory burden for the current population only, after which it is considered to form part of the general regulatory requirements that new sponsors/manufacturers will need to be aware of.

Inputs

- Number of businesses: 7500 dental practices, 600 prosthetists/laboratories, 116 orthotic/prosthetic practices, and 287 private hospitals = 8503
- Number of businesses adjusted for growth factor to Year 1 = 9357
- Number of new business over the ten-year period of the regulatory costing = 5052
- Time taken to compile and submit annual report to the TGA = 60 minutes
- Time required to become aware of regulatory changes = 5 minutes
- Total time= 65 minutes

Current population

Step 1 Calculate total time in minutes to fulfil regulatory requirement: 9357 x 65 = 608,205 minutes

Step 2. Calculate total time in hours to fulfil regulatory requirement: 608,205 x 60 = 10,137 hours

Step 3. Apply the hourly rate to determine overall regulatory compliance cost): 10,137 x 86.97 = **$881,593.15**

Future population (over the ten-year regulatory costing period)

Step 1 Calculate total time in minutes to fulfil regulatory requirement: 5052 x 60 = 303,120 minutes

Step 2. Calculate total time in hours to fulfil regulatory requirement: 303,120/60 = 5052 hours

Step 3. Apply the hourly rate to determine overall regulatory compliance cost): 5052 x 86.97 = **$439,372.44**

Manufacturers Statement provided to patient

Key assumptions

- Due to the nature of custom-made devices, the manufacturer (albeit this may be the healthcare provider) will likely deal directly with the patient (rather than through a third-party healthcare provider). It is likely that they will just hand over the manufacturers' statement without providing a detailed explanation of its purpose to the patient. Therefore no additional regulatory burden has been factored in for the healthcare provider.

Inputs

- Number of patients who will receive the manufacturers' statement over the ten-year period of the regulatory costing = 19,343
- Time taken by patients to read the manufacturer's statement: 5 minutes

Population over the ten-year period (averaged over ten-years)

Step 1. Calculate total time in minutes to fulfil regulatory requirement: 19,343 x 5 = 96,715 minutes

Step 2. Calculate total time in hours to fulfil regulatory requirement: 96,715/60 = 1612 hours

Step 3. Apply the hourly rate to determine overall regulatory compliance cost): 1612 x 32.00 = **$51,581.33**

Step 4. Divide by 10 to determine average annual cost = **$5,158.13**

Annual inspection

Key assumptions

- No more than 5 inspections will be conducted each year. As the amount of inspections to be conducted per year is not affected by population growth, then the average figure is the same as the Year 1 figure for a regulatory costing.

Inputs

- Number of inspections per year = 5
- Time required to prepare for inspection = 120 minutes
- Time taken to support the conduct of an inspection (accompanying the inspector(s)) = 900 minutes (2 days at 7.5 hours per day)
- Total time per inspection (preparation and conduct) = 1020 minutes

Current population (same for each year)

Step 1 Calculate total time in minutes to fulfil regulatory requirement: 5 x 1020 = 5100 minutes

Step 2. Calculate total time in hours to fulfil regulatory requirement: 5100/60 = 85 hours

Step 3. Apply the hourly rate to determine overall regulatory compliance cost): 85 x 86.97 = **$7,392.45.**

Change 3– Medical Device Production Systems (MDPS)

Proposed change

A subset of medical devices currently classified as custom-made medical devices will now meet the new definition for patient-matched medical devices and will be required to apply the standard conformity assessment procedures (not the special procedures for custom-made devices) according to the classification of the medical devices (low risk medical devices only up to Class IIa). Therefore, for devices classified above Class I (including Class 1M and Class 1S), conformity assessment evidence from a recognised third party (such as the TGA or a notified body) will be required. The manufacturer will 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. Essentially, they will need to meet the regulatory requirements of mass-produced medical devices. Australian manufacturers of patient-matched medical devices (or the sponsor for imported medical devices) will also be required to include their medical devices in the ARTG and to comply with the requirements for maintaining the inclusion.

A key definitional element of a patient-matched medical device is that it is 'typically produced in a batch through a process that is capable of being validated and reproduced'. A new regulatory concept proposed by the TGA is regulating medical devices at the level of a medical device production system (MDPS). The MDPS is a

collection of the raw materials and main production equipment (such as a 3D dental printer), as well as potentially ancillary equipment, intended to be used by a healthcare provider to produce a specific type of medical device at the point of care. All components must be validated as a production process to consistently produce the intended medical device by reference to the validated instructions of the original manufacturer. This will also provide healthcare providers with greater assurance that the medical devices will perform as intended.

MDPSs would be regulated as medical devices and hence included in the ARTG (as well as complying with the requirements for maintaining the inclusion) – the listing is either the responsibility of the Australian manufacturer or the sponsor for imported devices. A MDPS would be classified according to the highest classification of the final device its manufacturer intends it to produce (see figure below). The production equipment and consumable raw materials used in a MDPS would not be considered to be medical devices on their own, unless they fit the definition of medical device in their own right.

Healthcare providers that use MDPSs to produce medical devices for treating their patients would not be considered as manufacturers under the proposed regulatory framework in relation to those systems. This means healthcare providers would not need conformity assessment certification for producing medical devices using a MDPS.

Regulatory impact

It is envisaged that, given the large regulatory burden (over $50,000 (see table below) to obtain a listing on the ARTG) that will be associated with the manufacturing of patient-matched medical devices not using a MDPS, most healthcare providers will seek to produce these devices using a MDPS. However, the expectation is that healthcare providers who have previously been producing custom-made medical devices will now need to inform themselves of the changes in the regulatory framework. Although some investigation of potential MDPS manufacturers is likely, this remains a business decision and is not dictated by the regulatory framework and is therefore not included in the regulatory costing. It is also possible, particularly in relation to dental (general and specialist) practices, that they are already using MDPS in the manner specified in the changes to the regulatory framework and would need to contact the respective manufacturer during the regulatory transition period to encourage the manufacturer to list the system on the ARTG (and hence avoid taking on the regulatory responsibilities of a manufacturer themselves).

It is considered most MDPS, given the advanced manufacturing techniques and capital requirements for market entry, coupled with the size of the Australian domestic market, will be imported. It is also considered that any likely sponsor for the MDPS would have already registered for TGA Business Services and is familiar with the regulatory requirements for an ARTG listing. However, as Australia is pioneering the regulation of MDPS, a conformity assessment is not likely to have been performed on the MDPS by a European notified body and hence a truncated regulatory pathway (i.e. via an application audit) will not be open to the manufacturer/sponsor. The tables below provide a breakdown of the regulatory activities and associated time to complete

the Market Authorisation and Post-Market regulatory processes. The figures in these tables have previously been validated by TGA via consultation with industry.[29]

Table 7. Regulatory activities (and associated cost) for listing on the ARTG

Task	Subtask	Application (A) Ongoing (O) Both (B)	Subtask – Time (minutes)	Remarks
Create eBS Account	Become familiar with EBS Manual	A	0	As existing sponsor already have an eBS Account
	Client Details Form	A	0	
	eBS AccessForm	A	0	
	Wait for account creation	A	0	
Determine - Class of device	Review classification rules	A	240	
	Review Device	A	60	
	Delegate Approval	A	60	
Decide procedures to demonstrate Essential Principles	Review Essential Principles	B	240	
	Review Device and operations	A	120	
	Obtain documentation	A	60	
	File/manage documentation	B	60	
Gain Conformity Assessment Certification	See alternate process for detail (Table 8)	A	0	
Declaration of Conformity	Review Requirements	A	120	
	Complete Essential Principles checklist	A	240	
	Locate supporting information	A	240	
	Prepare declaration	A	60	
	Delegate approval	A	60	
Manufacturer Evidence	Form relationship with Manufacturer	A	60	
	Request information from Manufacturer	A	30	
	Review information	A	240	
	Upload information to eBS	A	60	
	Update changes	O	60	
	Review/correct	B	30	

[29] Excel workbook titled '[D17-655509] Regulatory compliance – industry timeframes' provided on 7 August 2017 for a previous regulatory costing activity.

Task	Subtask	Application (A) Ongoing (O) Both (B)	Subtask – Time (minutes)	Remarks
Application for inclusion	Review instructions	A	120	
	Complete form	A	240	
	Checked/approved by delegate	A	60	
Application selected for Audit	See alternate process for detail	A	0	Not applicable
Fees	Receive invoice	A	5	
	Check invoice	A	20	
	Process invoice	A	5	
ARTG Issued	Log-in/download certificate	A	10	
	Review certificate	A	30	
	Delegate review	A	60	
	File/distribute certificate	A	30	
Ongoing Monitoring	Maintain relationship with manufacturer	O	30	
	Allow entry	O	30	
	Deliver samples on request	O	30	
	Ensure information is available	O	30	
	Meet labelling/ advertising requirements	O	30	
	Report incidents	O	30	
	Assist in investigations	O	30	
	Take corrective action	O	30	
	Maintain distribution records	O	520	
	Adhere to conditions of inclusion	O	30	
	Post market surveillance	O	120	
	3 consecutive annual reports	O	360	
		Total (minutes) for application (full process)	2560	
		Total (hours) for application (full process)	42.67	
		Cost application (full process)	$3,706.45	
		Total (minutes) for ongoing (full process)	1660	
		Total (hours) for ongoing (full process)	27.67	
		Cost ongoing (full process)	$2,403.40	

Task	Subtask	Application (A) Ongoing (O) Both (B)	Subtask – Time (minutes)	Remarks
		Total (minutes) (full process)	4220	
		Total (hours) (full process)	70.33	
		Cost (full process)	$3,776.79	

Table 8. Regulatory activities (and associated cost) for undertaking a conformity assessment

Task	Sub-task	Application (A) Ongoing (O) Both (B)	Subtask – Time (minutes)	Remarks
Determine - is a medical device	Review Regulations	A	240	
	Review Product	A	60	
Determine - requires conformity assessment	Review Regulations	A	240	
	Review Product	A	60	
	Delegate Approval	A	60	
Pre-meeting with TGA	Negotiate/manage diaries	A	30	
	Travel	A	180	
	Meet	A	60	
Create eBS Account	Client Details Form	A	0	Assumed existing sponsor
	eBS AccessForm	A	0	
	Wait for account creation	A	0	
Compliance with Essential Principles	Review 15 principles, consider relevance	A	480	
	product(tion) changes / ongoing relevance	O	480	
Part 1- Full quality assurance procedure	Review Regulations	A	300	
	Consider that QMS meets requirements	A	480	
	Maintain QMS	O	960	
	Document QMS	A	480	
	Surveillance audits	B	480	
	Consider that Post market surveillance system meets requirements	A	480	
	Maintain Post market surveillance system	O	960	

Task	Sub-task	Application (A) Ongoing (O) Both (B)	Subtask – Time (minutes)	Remarks
	Document Post market surveillance system	A	480	
	Develop summary technical documentation	A	1440	
	Consider that summary technical documentation meets requirements	A	480	
	Delegate approval of Summary technical documentation	A	480	
	Maintain Summary technical documentation	O	480	
Clause 1.6 Examination of Design	Develop Design Dossier- Device Design	A	11250	
	Develop Design Dossier- Clinical	A	11250	
	Format/edit doc ument to TGA requirements	A	2500	
	Delegate Approval	A	2500	
	Maintain Design Dossier	O	240	
Application form	Review Instructions	B	120	
	1. General Details	B	30	
	2. Application Scope - New	A	40	
	2. Application Scope - Change	O	40	
	2. Application Scope - Recertification	O	20	
	3. Manufacturers Details	B	40	
	4. Critical Supplier Details	B	40	
	5. Device Details	B	60	
	A1. New Certificate Checklist	A	960	
	A2. Substantial Change checklist	B	60	
	A3. Recertification Checklist	O	60	
	Checked/approved by delegate	B	60	
	Print and post	B	60	
Application/recertification fee	Receive invoice	B	5	
	Check invoice	B	20	
	Process invoice	B	5	

Task	Sub-task	Application (A) Ongoing (O) Both (B)	Subtask – Time (minutes)	Remarks
41JAA Additional Information	Retrieve and Provide Design Dossier	A	60	
	Retrieve and Provide QMS information	A	60	
	Retrieve and Provide Clinical Data	A	60	
	Retrieve and Provide Post market system documentation	A	60	
	Print and post	A	60	
Pre-assessment	Review Pre-assessment information	A	60	
	Receive invoice	A	5	
	Check invoice	A	20	
	Process invoice	A	5	
Certification	Receive	A	30	
	Check	A	30	
	Delegate Acceptance	A	60	
	File	A	20	
	Ongoing management / Recall	O	60	
Total (minutes) for application (full process)			**36,040**	
Total (hours) for application (full process)			**600.67**	
Cost application (full process)			**$52,179.91**	
Total (minutes) for ongoing (full process)			**4,280**	
Total (hours) for ongoing (full process)			**71.33**	
Cost ongoing (full process)			**$6,196.73**	
Total (minutes) (full process)			**40,320**	
Total (hours) (full process)			**672**	
Cost (full process)			**$58,376.64**	

While the proposed regulatory framework for MDPS will not introduce any new regulatory processes, the regulatory impact of this change principally arises from the fact that it is applying existing regulatory requirement to patient-matched medical devices. In the absence of this regulatory change, such medical deviceswould have fallen under the custom-made medical device exclusion and hence a much lighter regulatory touch.

As this is a new regulatory requirement focussed on emerging technology (such 3D dental printers) not previously captured in the ARTG, we need to look elsewhere than the current ARTG to inform population estimates.

A desktop analysis of current worldwide manufacturers of 3D dental printers revealed that the majority of manufacturers are concentrated in the United States (39%) and Europe (29%), though 43% of the examined companies have an Australia distributor/ reseller and one company (Asiga) is based in Australia.

If we assume 50% of worldwide dental printer manufacturers would seek to list a MDPS on the ARTG (likely via an Australian sponsor), this equates to 14 listings.

Table 9. Analysis of 3D dental printer manufacturers (worldwide)

Country/Region	No. of 3D dental printer manufacturers	No. of Australian distributors/resellers
Australia	1	
China	2	2
Europe	8	2
Japan	2	2
Korea	1	1
Singapore	1	
United States	11	4
Canada	2	1
Total	**28**	**12**

In the course of its research into 3D dental printers, Noetic also came across some companies that marketed 3D printer s for the making of prosthetics and implants using non-human origin material and one company using a 3D printer to make ophthalmic lens. The technological pathway seems to be moving towards bioprinting for implants (though this will be some years off), though orthotics and prosthetics will likely continue to be produced using non-human origin materials. Given that the number of certified Australian orthotic/ prosthetic practices is much smaller than the number of Australian dental practi ces, we havetaken a figure of 5 listings (approximately a third of the projected MDPS ARTG listings for 3D dental printers).

It has been noted that 3D dental printers (as well as orthotic/ prosthetic/ophthalmic 3D printers) will likely be Class IIa (based on the initial TGA assessment of the application of this regulatory change).

Private sector hospitals (noting the impact of regulatory changes on the public sector is specifically excluded from a regulatory costing) have traditionally manufactured custom-made medical devices and this activity 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. It is assumed that some private hospital biomedical engineering labs will wish to maintain the design flexibility of creating patient -matched medical devices without using a MDPS. Such a decision might arise due to an affiliation with a university so as to provide manufacturing options for research purposes.

As the concept of a patient-matched medical device has recently emerged, there is very little empirical data on which to base any assumptions regarding sponsor/manufacturer behaviour in this area. Noetic notes that the Department has reached out to the sector for comment but their commercial and regulatory strategies are still evolving in this area. It is therefore difficult to predict whether private sector 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 MDPS (the latter two options negating the need for certification). For those private hospitals that choose to go down the certification rather than MDPS regulatory pathway, they could also seek to leverage the effort in achieving certification by having more than one ARTG entry (therefore being able to manufacture a range of medical devices).

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.

Regulatory costing

Key assumptions

- Given the degree of uncertainty around the population calculation (number of private hospitals who will seek certification and the number of ARTG entries per hospital), Noetic has modelled six scenarios incorporating 33% and 10% of all in-scope private hospitals (299) for Year 1 (2020-21) choosing to pursue certification and each hospital having 1, 3 or 5 ARTG listings.
- The majority of dental and orthotic/prosthetic practices will likely not seek certification to manufacture patient-matched medical devices (noting they can still produce custom-made medical devices without certification).
- The current population for 3D printers (dental and other) represents the total population over the ten-year regulatory period and not the population for Year 1.
- The number of hospital biomedical engineering labs in private sector hospitals will grow at the rate detailed earlier in the report (i.e. 2%).

Inputs

- Number of businesses (current): (14 - 3D dental printer manufacturers + 5 other 3D printer manufacturers + 99 private hospital biomedical engineering labs (33% scenario) = 118
- Number of businesses (current): (14 - 3D dental printer manufacturers + 5 other 3D printer manufacturers + 30 private hospital biomedical engineering labs (10% scenario) = 49
- Number of businesses (future – 33% scenario): private hospital biomedical engineering labs = 19
- Number of businesses (future – 10% scenario): private hospital biomedical engineering labs = 6

§ Time required to complete Market Authorisation activities: 2,560 + 36,040 minutes = 38,600

Given the complexity of the calculation, a model was built in Excel. An example calculation output is provided below:

Table 10. Extract from Excel model to calculate regulatory costs for certification pathway

Scenario A - 33% of in scope Private Hospital Population - Current (1 ARTG listing)		
Field Description	*Field*	*Value*
Input	Time ARTG listings plus conformity assessment	38,600
Input	Population 3D Dental Printers Manufacturers	14
Input	Population Non-Dental 3D Printers Manufacturers	5
Input	In scope Private Hospitals Scenario A	99
Input	Number of ARTG for Private Hospitals	1
Calculation	Adjusted pop for Private Hospitals	99
Calculation	Population	118
Calculation	Time Minutes	4,554 ,800
Calculation	Time in hours	75,913
Input	Hourly rate	$86.97
Calculation	**Total regulatory burden**	**$6,602,182.60**

Scenario A - 33% of in scope Private Hospital Population - Future (1 ARTG listing)		
Field Description	*Field*	*Value*
Input	Time ARTG listings plus conformity assessment	38,600
Input	In scope Private Hospitals Scenario A	19
Input	Number of ARTG for Private Hospitals	1
Calculation	Adjusted pop for Private Hospitals	19
Calculation	Time Minutes	733,400
Calculation	Time in hours	12223
Input	Hourly rate	$86.97
Calculation	**Total regulatory burden**	**$1,063,063.30**

Total (Current and future)	**$7,665,245.90**
Average over 10 years	**$766,524.59**

The results from the six scenarios are shown in the table below:

Table 11. Results from scenario modelling

	Average over ten years		
Scenario	1 ARTG	3 ARTG	5 ARTG
Scenario A 33%	$766,524.59	$2,086,961.11	$3,407,397.63
Scenario B 10%	$307,728.85	$710,573.89	$1,113,418.93

The average (mean) of the six scenarios was $1,398,768 with the median being $939,972. Note this figure is for both existing and future populations averaged over ten years. The median was assessed to be the more appropriate measure of central tendency and was taken forward into the overall regulatory costing.

Change 4 – Update the Classification Rule for Medical Devices that Record Diagnostic Images

Need for regulatory change

Currently, there is a special classification rule that states: '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.'[30] Recent technological changes for patient imaging, including the advent of 3D printing of patient-specific anatomical models for consideration by a specialist in diagnosing a condition or planning a surgery, have increased the range of diagnostic images. Software that records patient diagnostic images, either for on-screen diagnosis or for production of 3D printed anatomical models, is another factor to be considered when assessing the consistency of the current regulatory framework across a range of medical devices.

The TGA commented in its 2019 consultation paper for proposed change to the regulatory scheme for personalised medical devices that: 'It is reasonable to think that these anatomical models should require the same regulatory oversight as X-rays, to mitigate the risk of inaccuracy and to ensure they are a true representation of the patient's anatomy of sufficient quality for their diagnostic purpose. Software that records patient diagnostic images should also be captured by this rule.'[31]

Proposed change

The existing rule classifying X-ray film as Class IIa should be changed to the following:

[30] Schedule 2, Item 5.4.

[31] Therapeutic Goods Administration, 'Consultation: Proposed regulatory scheme for personalised medical devices, included 3D-printed devices', February 2019, p.9.

5.4 Medical devices intended to record diagnostic images

A medical device that is intended by the manufacturer to be used to record diagnostic images is classified as Class IIa. This includes software and anatomical models intended for diagnosis or investigation of the anatomy.

Regulatory impact

Manufacturers of anatomical models used for diagnosis or investigation of the anatomy for the purpose of planning surgery and/or treatment (but not intended purely for training or education purposes), would be required to hold appropriate conformity assessment evidence for a Class IIa medical device. The requirement for conformity assessment evidence would not apply to healthcare providers if they used a MDPS included in the ARTG to produce the anatomical models.

Manufacturers of software that is intended to be used to record patient imaging for diagnosis or investigation of the anatomy will be required to hold appropriate conformity assessment evidence for a Class IIa device. Australian manufacturers of medical devices intended to record diagnostic images (and sponsors for imported devices) will also be required to include their medical devices in the ARTG (if not already included) and to comply with the requirements for maintaining the inclusion.

There is a degree of cross-over between the regulatory requirement to undergo a conformity assessment for patient-matched medical devices, the regulatory requirements for manufacturers of MDPS and this requirement (diagnostic images) as the same type of medical device (i.e. a bioprinter) may be used.

A search of the ARTG revealed the following:

- searching on 'anatomical models' returned 1record (Class IIa) relating to software to provide computer-aided manufacturing of patient-specific custom-made devices (e.g. orthopaedic implants) - hence is already classified at the correct level; and
- searching on PACS (picture archiving and communication system) and DICOM (Digital Imaging and Communications in Medicine – international standard related to the exchange, storage and communication of digital medical images and other related medical data) returned 29 Class IIa and 11Class IIb records (therefore at the required class or higher – noting some of these records relate to the imaging system not just the software). Of greater interest is that it returned 46 Class I (many of which are software programs) and 6 Class Im records (mostly software programs/picture archiving system). These will need to undergo a Class IIa conformity assessment.

The Department undertook a line-by-line analysis[32] of ARTG inclusions with 'software' and 'image' in the title to determine each manufacturer and whether they were likely to have previously obtained conformity assessment certification via a European notified

[32] Excel workbook titled 'Software entries in the ARTG 2019-02-04 (002) – Software manufacturers already 3rd-party certified', provided to Noetic on 21 October 2019.

body (to accord to EU medical devices requirements). This analysis revealed that for approximately 1/3 of in-scope ARTG entries they are already likely to have undergone a conformity assessment by a third party and therefore are required to complete only the inclusion on the ARTG regulatory process. In addition, Class Im medical devices (unlike Class I medical devices which are self-certified) require a third-party conformity assessment and therefore will not undergo the full conformity assessment though they may be selected for a non-mandatory audit (note this has not been factored into the regulatory costing due to the small number of ARTG entries involved).

In relation to the growth in the population of in-scope ARTG entries over the ten-year period of the regulatory costing, the requirement to undertake an ARTG application is an existing regulatory burden and therefore excluded from this regulatory costing. It has been assessed that the majority, if not all, new Medical Devices that Record Diagnostic Images will already have undergone a third-party conformity assessment (likely in the EU) and therefore be required to only complete the ARTG application process which, as noted above, is an existing regulatory requirement.

Regulatory costing

Key assumption

- The current population who need to modify their existing ARTG entry represents the total population impacted by this regulatory change over the ten-year period of the regulatory costing.

Inputs

- Number of ARTG listings for Class I = 46
- Number of Class I ARTG entries adjusted for existing third-party conformity assessment = 31
- Number of Class I ARTG entries who complete ARTG listing only = 15
- Number of ARTG entries for Class Im = 6
- Time required to complete full Market Authorisation activities: 2,560 + 36,040 minutes = 38,600 (this applies to the 31 Class I ARTG entries only that do not have an existing third-party conformity assessment)
- Time required to complete ARTG listing only: 2,560 minutes = (this applies to the 15 Class I ARTG entries do have an existing third-party conformity assessment as well as the 6 Class Im ARTG entries – therefore 21)

Current population (note no future population in -scope for regulatory costing)

Step 1 Calculate total time in minutes to fulfil regulatory requirement: 31x 38,600 = 1,196,600 minutes + 21x 2,560 = 53,760 so in total = 1,250,360 minutes

Step 2. Calculate total time in hours to fulfil regulatory requirement: 1,250,360/60 = 20,839 hours

Step 3. Apply the hourly rate to determine overall regulatory compliance cost): 20,839 x 86.97 = **$1,812,396.82**

Change 5 – Regulate medical devices with a human origin component

Need for regulatory change

Some comparator overseas regulators, including those of Canada, Europe and the USA, regulate medical devices with human origin material as medical devices. In contrast, the *Therapeutic Goods Act 1989* specifies that any product that comprises, contains or is derived from human cells or human tissues is a biological[33] and is thus regulated through the biologicals framework. TGA noted in its 2019 consultation paper for proposed change to the regulatory scheme for personalised medical devices that this regulatory 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 and, which are regulated as medical devices.[34] This jurisdictional divergence in regulatory approaches potentially creates confusion and additional regulatory burden for manufacturers with a multi-national client base.

Proposed change

TGA has proposed that medical devices that contain as a component, but that are not wholly comprised of, human origin material would not be regulated solely as biologicals; rather, they would be Class III medical devices with a biological component (thereby more closely aligning the Australia regulatory framework with those of comparator overseas regulators). The biological component would continue to be regulated in accordance with the existing regulatory framework. The intersection between the two regulatory frameworks is the assessment of the biological component during the design examination step of the conformity assessment.

Regulatory impact

There are no proposed changes to the regulation of the human origin component of medical devices, which will be regulated in accordance with the existing framework, including Therapeutic Goods Orders for controlling infectious disease transmission. Rather, the overall medical device would proceed down the relatively simpler regulatory pathway for medical devices.

Regulatory costing

There are anticipated to be some regulatory simplifications arising from the harmonisation of the regulatory treatment of medical devices with a human origin component by the TGA with the treatment of such devices by comparable overseas

[33] Therapeutic Goods Act 1989, s.32A.

[34] Therapeutic Goods Administration, 'Consultation: Proposed regulatory scheme for personalised medical devices, included 3D-printed devices', February 2019, p.10.

regulators. However, the reduction in the existing regulatory burden from this proposed measure is difficult to quantify and unlikely to be material to the overall regulatory costing for the proposed changes to regulation of personalised medical devices.

Change 6 – Clarify regulatory arrangements for any changes to a personalised medical device

Need for regulatory change

Under the current definition of 'manufacturer', a person is not the manufacturer of a medical device if the person *assembles* or *adapts* the device for an individual patient [35]; the device has already been supplied by another person; and, the assembly or adaptation does not change the purpose intended for the device. 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 the manufacturer will have tested the performance of samples of its device when adapted or assembled according to its instructions. Any modifications or adaptations outside of what has been specified by the original manufacturer, however, may impact on the device's compliance with the essential principles, therefore increasing patient risk. Projected increases in the use of 3D-printed medical devices increases the need to clarify this matter 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. The complexity of the process magnifies the importance of complying with each element of the original manufacturer's validated instruction to ensure compliance with the essential principles.

Proposed change

Additional text will be added to the regulatory framework to make clear that a person will *not* be considered a manufacturer in circumstances where a medical device has been assembled or adapted for an individual patient in accordance with validated instructions provided by the original manufacturer of the relevant device. However, if a heath care provider or another party modifies or adapts a medical device in such a way that compliance with the essential principles may be affected, that person shall be considered the manufacturer from a regulatory framework perspective. As the manufacturer, they assume the obligations incumbent on manufacturers and will be subject to the compliance and enforcement regime on that basis. The need for the provision of validated instructions by the original manufacturer will also be reinforced by the proposed change.

[35] Therapeutic Goods Act 1989, s.41BG(3)(a).

The practical effect of these changes will be to clarify the circumstances in which an entity holds responsibilities as a medical device manufacturer. The proposed definition for an 'adaptable medical device' is relevant here. The new definition is:

> 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.[36]

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) according to the classification of their medical devices because these types of devices are mass-produced.

Regulatory impact

The sought regulatory impact from this change will be to reinforce to healthcare providers/manufacturers who supply and/or fit patient-matched medical devices (produced using an MDPS) and adaptable medical devices the regulatory risk of variating from the original manufacturer's validated instructions. Healthcare providers and other parties who chose to depart from these instructions should do so with the full knowledge of the regulatory requirements that such an action would impose (such as submitting the device for the appropriate conformity assessment procedure).

Noting the expected increased reliance on MDPS for the manufacturing of patient-matched medical devices, few healthcare providers will likely take on and fulfil the regulatory burden of a conformity assessment for an ARTG listing (and being subject to the related ongoing compliance and enforcement regime) by varying medical devices in such a way that compliance with the essential principles may be affected.

The new requirements will 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 will be an express confirmation of the existing arrangements and therefore will not produce any new regulatory requirements. Australian manufacturers of adaptable medical devices (and sponsors of imported adaptable medical devices) will 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.

The regulatory burden of this proposed change will therefore be limited to:

§ the time taken by sponsors/manufacturers to become aware of definition changes – as changes are minimal and the key message is that nothing much has changed, so no regulatory impact has been costed; and

[36] IMDRF PMD WG/N49 FINAL: 2018.

§ the time take by healthcare providers involved with the supply and fitting of patient-matched medical devices and adaptable medical devices to become aware of the changes to the regulatory framework to clarify the 'tipping' point as to when they are considered a 'manufacturer' from a regulatory viewpoint (and therefore need to fulfil the associated regulatory requirements). Note this awareness of the changes has been rolled into the regulatory costing for Changes 1 and 2.

Conclusion

The table below consolidates the regulatory costing for each of the specific regulatory changes.

Table 12. Summary of regulatory costing

		Column 1	Column 2	Column 3
Row	Summary Sheet	Cost for Current Population	Cost for Future Population	Average cost over 10-year period
A	*Changes 1 and 2 (Custom-made Medical Devices)*			
B	Annual Report on custom-made medical devices	**$881,593.15**	**$439,372.44**	
C	Manufacturers Statement provided to patient			**$5,158.13**
D	Annual inspection			**$7,392.45**
E	*Change 3 (Medical Device Production Systems)*			$**939,971.76**
F	*Change 4 (Medical Devices that Record Diagnostic Images)*	**$1,812,396.82**	No additional regulatory burden	
G	*Change 5 (Medical Devices with Human Origin Component)*	No additional regulatory burden		
H	*Change 6 (Clarify regulatory changes)*	Costed under Changes 1 and 2		
I	*Total cost for current and future populations*	**$2,693,989.97**	**$439,372.44**	
J	*Total combined cost for current and future populations (Columns 1 and 2)*	$3,133,362.41		
K	*Average over ten years of combined cost for current and future populations*	$313,336.24		
L	*Total cost for average cost over the ten-year period (Column 3)*			$952,522.34
M	**Total cost (rows K + L)**	**$1,265,858.58**		

As per OBPR guidance, regulatory costs are projected over a 10-year period and then averaged to arrive at an average annual regulatory cost. The table below provides the average estimated savings in regulatory compliance costs.

Table 13: Summary of estimated regulatory compliance costs

Average annual regulatory costs (from business as usual) ($million)				
Change in costs	Business$	Community Organisation$	Individual$	**Total change in costs**
Option A				
Status quo: Current Regulatory framework is appropriate - no change is required				
Option B				
Amended the regulatory framework for personalised medical devices in accordance with the 6 proposed regulatory changes	$1.261		$0.005	**$1.266**

Annex A – Acronyms and Abbreviations

ABS	Australian Bureau of Statistics
ACHI	Australian Classification of Health Interventions
AIHW	Australian Institute of Health and Welfare
ANZSIC	Australian and New Zealand Standard Industrial Classification
ARTG	Australian Register of Therapeutic Goods
DICOM	Digital Imaging and Communications in Medicine
GMDN	Global Medical Device Nomenclature
IMDRF	International Medical Device Regulators Forum
MDPS	Medical Device Production System
OBPR	Office of Best Practice Regulation
PACS	Picture Archiving and Communication System
RIS	Regulation Impact Statement
TGA	Therapeutic Goods Administration

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