Australian Government
Department of Health
Therapeutic Goods Administration

Regulation of Personalised, including 3D Printed, Medical Devices

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ARCS

TGA Health Safety Regulation

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Australian Context

Personalised devices currently regulated as custom-made devices

> ***custom-made medical device*** means a medical device that:
> (a) is made specifically in accordance with a request by a health professional specifying the design characteristics or construction of the medical device; and
> (b) is intended:
> (i) to be used only in relation to a particular individual; or
> (ii) to be used by the health professional to meet special needs arising in the course of his or her practice.

In Australia, custom-made devices

- Are exempt from Inclusion in the Australian Register of Therapeutic Goods
- Are not subject to third party oversight of manufacturing or evidence of compliance with the Essential Principles
- Are required to be notified to the TGA and have post market surveillance and reporting requirements in place

Are consumers protected under these requirements?

- Custom-made implants are **not currently subject to third party pre-market review of safety, quality and performance**
- Historically, custom-made medical devices were **considered to comprise low risk products, or be very limited in number**
- **High risk devices** e.g. implants, that are manufactured conventionally are subject to rigorous regulatory oversight of design and manufacture
- **There are some novice players with limited awareness of QMS and regulatory requirements** involved in 3D printed device development

So TGA consulted on options for regulatory requirements to address risks posed by those higher risk medical devices which are custom-made

Some international approaches to regulation

US - Most 3D printed patient-specific devices subject to normal pre-market requirements

- Custom-made devices must only be for treating a "**sufficiently rare condition, such that conducting clinical investigations on such a device would be impractical**"
- Production of the device must be "**limited to no more than five units per year** "
- Manufacturer is required to submit an annual report

EU – Certification for manufacturers of high risk custom-made devices

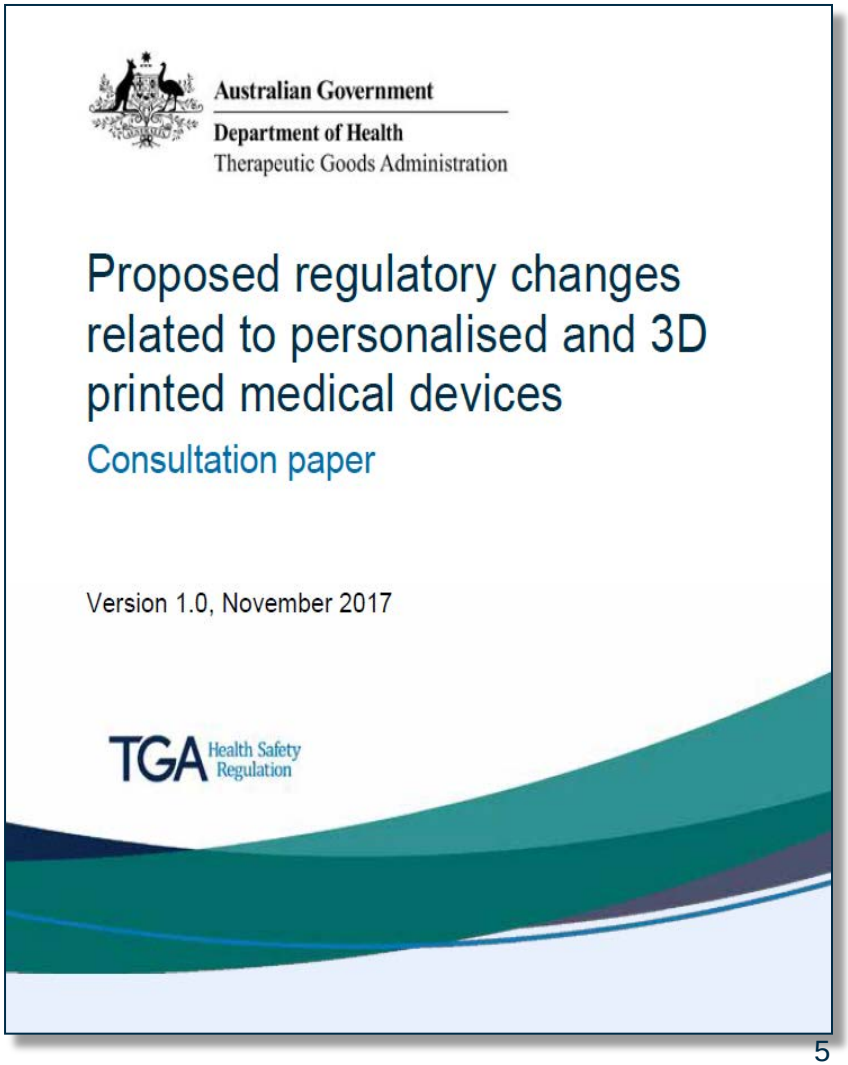
- The new 2017 EU Medical Devices Regulation requires that manufacturers of high risk custom-made devices will now require notified body certification

Canada - has an application process for the use of custom-made devices.

IMDRF – is currently developing recommendations for a harmonised approach to defining medical devices manufactured for particular individual/s

TGA's activities

- Stakeholder workshop August 2017
- Numerous meetings with Australian stakeholders and international regulators Sep 2017 - June 2018
- Public consultation in Nov - Dec 2017
- In May 2018, the submissions and a summary of the response were published on TGA website
- Stakeholder workshop July 2018



Proposals for regulatory change

Proposal 1: New definitions for personalised devices

- **customised / adaptable medical device**
  - a mass-produced device that must be adapted or assembled at the point of care, to suit an individual patient's anatomy
- **patient-specific medical device**
  - manufactured based on a standard device template model, or specified design envelope that is matched to a patient's anatomy
- **custom-made medical device**
  - intended for the sole use of a particular individual; made on request of the healthcare professional and intended to address the specific anatomy or pathological condition of the patient

Application or Number limits for custom-made devices?

Responses to proposal 1:

- A range of responses regarding the proposed definitions – also need to consider international regulator views and potential for alignment
- Suggestions to include examples aligned to each definition
- Most submissions not in favour of a limitation in the number of custom-made devices to be produced by one manufacturer per year (as per the USA)
- Few submissions commented on the proposed application and approval process for custom-made devices (as per Canada).

Proposal 2: Changes to the custom made device conformity assessment procedure

- The manufacturer's statement about a custom made device is provided to the patient (as per in the EU)
- TGA be allowed to enter and inspect custom made device manufacturing sites
- An Australian manufacturer or sponsor of custom made devices to provide an annual report to the TGA
- Documentation about an implantable custom made device to be maintained for at least 15 years

Reponses to proposal 2 were positive throughout

- Some comments on added cost and administrative burden from annual reporting and requirement to store device-related data for a longer period
- No objections to allowing the TGA to enter and inspect custom-made medical device manufacturing sites

Proposal 3: Changes to the definition of manufacturer

- To clarify when someone, who modifies a supplied device for an individual, does not meet the regulatory requirements of a manufacturer
- To address new paradigm of point-of-care manufacturing for health care facilities and practitioners - introduction of ‘medical device production system’

Only half of the submissions commented on proposal 3

- Of those, half agreed with the TGA's proposal while the other half raised issues such as need for further clarification on “medical device production system”
- Proposed exemptions for health care practitioners/hospitals not fully supported
- Uncertainty about what exactly should be considered a medical device production system and request for examples
- Comments on potential added cost and administrative burden

Proposal 4: New classification for anatomical models and digital 3D files

- Up-classification of software and anatomical models intended for diagnosis or investigation of the anatomy to class IIa
- This would not apply to hospitals or healthcare practitioners that use a medical device production system to produce the anatomical models for treating their patients, and the medical device production system was included in the ARTG

General support for Proposal 4

- Some concerns about the potential additional cost and administrative burden that would arise from reclassification
- Concerns as to which anatomical models would be captured under the new provision (e.g. anatomical models used for education ?)
- Some submissions debated whether the reclassification would be enforceable

Proposal 5: New arrangements for devices with human material

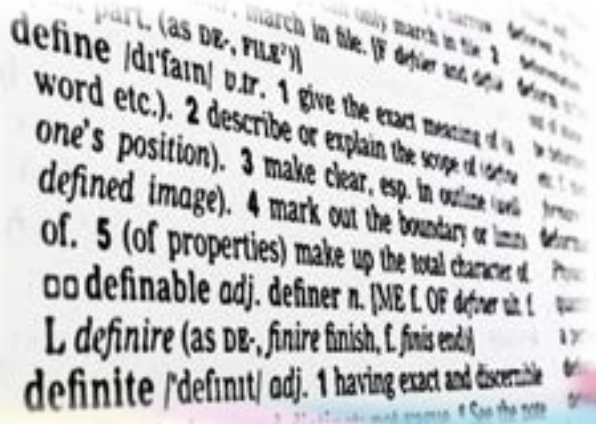
- **Devices containing human material to not be regulated as** biologicals (cell and tissue products) but as Class III devices

Responses to proposal 5 were positive

- Welcomed the plan to align with other regulators for these types of products
- One submission requested clarification on devices that are made wholly from substantially altered human material (e.g. fixation pin made from human bone)
- A suggestion to differentiate between products with different cell types

The International Perspective:
IMDRF Personalized Medical Devices Working Group
Chair: Australia

NWIP Purpose:
Harmonised Definitions
Aligns with IMDRF Strategic Priorities



Progress

- Established Working Group membership – all member jurisdictions represented, also two Affiliate Organization members.
- Reviewed GHTF foundation documents for references to custom-made devices.
- Conducted Working Group member survey for definitions in own country regulations or guidance that address personalized medical devices.
- Developed draft document proposing relevant definitions.
- Conducted public consultation and revised draft
- Submitted revised draft to IMDRF MC for September meeting

WG Member Survey - Summary

Jurisdiction	Regulatory definition for custom-made	Regulatory definition for other personalized devices	Any guidance material related to personalized devices
AHWP	N/A	N/A	✔
Australia	✔		
Brazil			
Canada	✔		
China			✔
Europe	✔		
Japan			
Korea			✔
Russia			
Singapore	✔		
United States	✔		✔

OPPORTUNITY FOR HARMONISATION

IMDRF Draft Document

IMDRF International Medical Device Regulators Forum

PROPOSED DOCUMENT

International Medical Device Regulators Forum

Title:	Definitions for Personalized Medical Devices
Authoring Group:	IMDRF Personalized Medical Devices
Date:	XX XXXXXX 2018

Proposed Definitions in Draft Document

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's specific anatomo-physiologic features prior to use.

DRAFT

Proposed Definitions in Draft Document

patient-matched medical device – a medical device that meets the following requirements:

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

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Proposed Definitions in Draft Document

patient-matched medical device (continued)

Note 1: A written request from an authorized healthcare professional is not mandatory.

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

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

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Proposed Definitions in Draft Document

custom-made medical device – a medical device that, at a minimum, meets the following requirements:

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

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Proposed Definitions in Draft Document

custom-made medical device (continued)

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

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

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Proposed Definitions in Draft Document

- **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-specific, or adaptable medical device.

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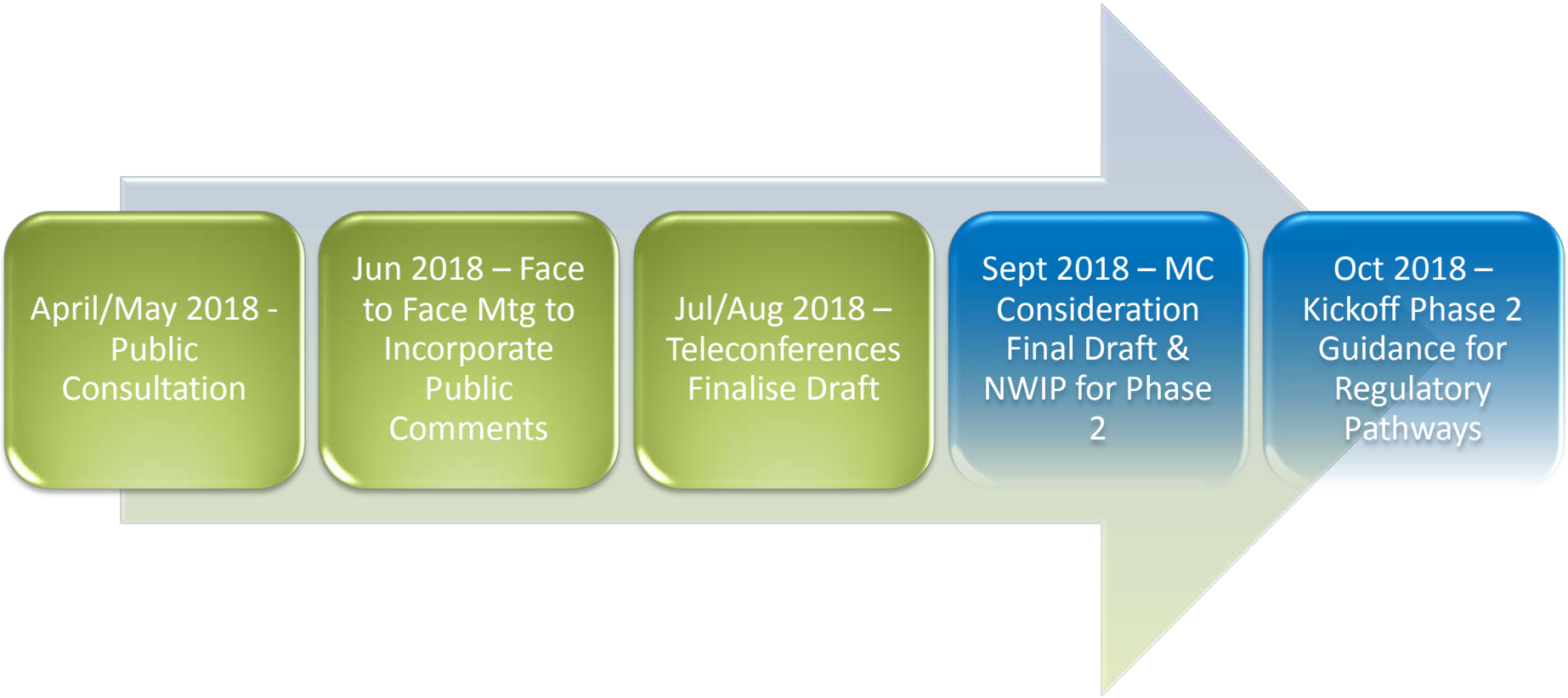
Working Group Timeline



Conclusion

- Further clarification and consultation is required
- For medium to high risk devices, **both patient-matched and mass-produced devices need reasonable regulatory oversight**
  - current custom-made device regulation is no longer fit for purpose
- Next Steps:
  - Continue IMDRF Work
  - October 2018 - Conduct 2nd consultation in Australia for regulatory reform
  - November/December 2018 – Analyse consultation responses, prepare policy recommendation
  - December 2018 - Seek policy approval to amend regulations

Thank You
Questions?

Australian Government

Department of Health

Therapeutic Goods Administration