Response ID ANON-3NHQ-DDKD-H

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-07-14 08:40:14

Introduction

1 What is your name?

Name:
Masako Dunn

2 What is your work title?

Work title:
Head and Neck Cancer Research and Innovation Manager (Craniomaxillofacial Prosthetic and Advanced Reconstructive Translational Surgery

3 What is your email address?

Email:
[redacted]

4 What is your company/organisation?

Organisation:
Craniomaxillofacial Prosthetic and Advanced Reconstructive Translational Surgery @ Chris O'Brien Lifehouse

5 What is your company/organisation address?

Please provide the business address of your company or organisation.:

[redacted]

6 Which industry do you work in, or represent?

Please state the industry that you work in, or are representing in your submission.:
Healthcare Professionals: Craniomaxillofacial Prosthetic and Advanced Reconstructive Translational Surgery

7 Are you responding:

On behalf of an organisation

Exclusion

8 Do you agree with the rationale for the proposed exclusion of products?

Yes

If you answered 'no' to the above question, why do you disagree with the rationale for the proposed exclusion of the products listed?:

9 Are the risks posed by the products adequately managed if they are excluded from regulation by the TGA?

Yes

Please explain your response, including by providing examples that illustrate and/or support your position.:

We agree with TGA's rationale regards to the proposed exclusion of products (from the regulation) for devices that do not fall into the definition of medical device or that are accessory to medical devices. We agree with TGA's risk assessment that those products pose a minimum risk and likelihood of harm is negligent.

We believe that risks products pose will be adequately managed through ACCC and appropriate consumer protection laws as those products do not possess any therapeutic benefits.

10 Are there further products that meet the principles proposed for exclusion? What are they and why should they be excluded?

Ensure your answer directly addresses (1) why the products pose no, or insignificant, levels of risk or (2) why the product does not meet the definition of a medical device. :

(1)
We have listed below further products where we believe they would meet the principles proposed for exclusion as they meet the definition of a medical device, or an accessory to a medical device, but the level of risk posed by the devices is considered to be very low.

Silicon Craniofacial prosthesis
• Spectacle retained
• Adhesive retained
• Anatomical models (physical or virtual) to create these
• Software used in the process of manufacturing these products

Above products are manufactured by the qualified health professionals (prosthetic subspecialities such as Anaplastologist) work in healthcare facilities. The above patient-matched medical device poses negligible risks. Regulating them will increase cost to manufacture these negligible prosthetics and be significant disincentive to incorporate digital pathways which assist in improving the workflow.

Exemption

11 Do you agree with the rationale for the proposed exemption of Class I non-sterile, non-measuring patient-matched devices when produced under the circumstances listed in the consultation paper?

Yes

If you answered 'no' to the above question, please explain why it is that you disagree with the rationale for the proposed exemption of Class I non-sterile, non-measuring patient-matched medical devices?:

12 Can the risks posed by Class I non-sterile, non-measuring patient-matched medical devices when produced under the circumstances listed in the consultation paper be adequately managed if they are exempted from inclusion in the ARTG?

Yes

Please explain your response, including by providing examples that illustrate and/or support your position.:

We welcome TGA's proposed the regulation exemption of Class I non-sterile, non-measuring patient-matched devices manufactured in the accredited healthcare facility or by a provider who has been registered with the National Disability Insurance Scheme as this proposal will significantly reduce unnecessary burden on healthcare professionals. We agree with the TGA's suggestion that in the healthcare facility, these medical devices will be "prescribed" by a registered health professional and are manufactured by a qualified or accredited professional according to the specifications provided by the healthcare practitioner, thus risks can be adequately mitigated by the safety measure already in place at healthcare facility. Furthermore, medical devices "post-market" surveillance and adverse event reporting will be monitored as part of standard of care by the healthcare practitioner further mitigating the risk.

Example – Patient-matched 3D printed denture

Manufacture:
• a healthcare manufacture in healthcare facility accredited against NSQHS standards by ASCQHC.
• healthcare professionals who are AHPRA registered
• support healthcare professionals who are recognised under relevant Australian qualification framework
• The devices produced are intended to be used by a patient of healthcare facility

John is a qualified prosthodontist who works with Sam a registered dental assistant in the dento-facial clinic within the ASCQHC accredited hospital. John consults patient A in the dento-facial clinic and prescribes a patient-matched 3D printed denture to patient A.

The hospital has a dedicated 3D printing medical device manufacturing facility. This facility has all the necessary records and documentation of manufacturing patient-matched 3D printed denture pertaining; meeting Essentials Principles, a documented evidence of conformity assessment, labelling and instruction for use and reporting adverse events. Patient A undergo optical scanning of intra-oral cavity and Orthopantomogram. Sam creates virtual anatomical model based on patient's scanned image. Sam, as a dental technician, follows the "prescription" specified by John to design the denture virtually and manufactures the denture for patient A with 3D printer. John and Sam will be able to provide a patient-matched 3D printed denture manufactured in this facility without its being included in the ARTG. John provides the denture to patient A with the appropriate labelling and instruction of use in the package as per documentations at his clinic. John has follow-up appointments with patient A for continuous clinical care and will record any adverse events which will be registered by Sam in the manufacturing facility.

Risk associated with manufacturing of patient-matched 3D printed denture is mitigated by:
• The device Classification itself (low risk)
• State or Territory law for their qualification and registration
• Healthcare facility's risk reporting system for safety and adverse event
• Prescribing healthcare professionals providing an ongoing and continuity of care
• Documentations kept at the manufacturing facility in the healthcare facility

13 Are there further circumstances where Class I non-sterile, non-measuring patient-matched devices could be exempt? If so, what measures are in place to manage the risks associated with the devices?

Ensure your answer directly addresses the specific circumstances that are in place (such as qualifications, accreditation, certification, etc) to ensure that the risks associated with the manufacture of the devices have been managed and the Australian regulatory requirements for medical devices have been met before they are supplied.:

TGA lists health professional and support health professionals to deliver healthcare services in the document "Personalised medical devices V3.0 June 2021" as below:
The Regulations (TGA) defines a health professional as:
• A medical practitioner, a dentist or any other kind of health care worker registered under a law of a State or Territory; or
• A biomedical engineer, chiropractor, optometrist, orthodontist, osetopath, pharmacist, physiotherapist, podiatrist or rehabilitation engineer.

Support health professionals includes, but is not limited to:
• allied health assistants;
• speech pathologists
• medical physicists;
• clinical scientists;
• orthotists;
• occupational therapists;
• medical and dental laboratory technicians or technical officers;
• prosthetic subspecialities (e.g. ocularists, anaplastologists); and
• dental technicians

We would like to propose further circumstances below where Class I non-sterile, non-measuring patient-matched devices could be exempt.

1. Profession: Anaplastologist
Devices:
• Facial prostheses: also known as epitheses* or extra-oral maxillofacial prosthetics, include auricular, nasal, mid-facial, orbital (including ocular), upper facial, hemi-facial, partial facial, nasal septal and other areas of the head and neck, but exclude intra-oral prostheses (Reference: Association IA. Clinical Anaplastology Guidelines 2000). * International nomenclature for extraoral facial prostheses

These are removable prostheses that are usually highly realistic in appearance, and may be attached to the body via spectacles, adhesive, or bone anchored implants.

• Somatic prostheses: include fingers, thumbs, partial hands, hands, breasts, toes,
cosmetic partial feet and other areas of the body, but exclude prosthetic devices for weight-bearing anatomy. These are removable prostheses that are usually highly realistic in appearance, and may be attached via passive vacuum (suction retained), adhesive, or bone anchored implants.

• Anatomical models (Virtual and Physical) to produce above prostheses
• Software used in the process of manufacturing these products

An Anaplastologist is an allied health care professional educated and trained in the design, fabrication and management of prosthetics that include custom-made facial, ocular (eye), and/ or somatic (body) prostheses, surgical templates/guides and other specialised devices based on clinical assessment and, when necessary, a healthcare provider referral and/or a physician's order. Anaplastology is a niche field that cross collaborates with ocularists, dental and surgical specialists, and P&O clinicians for the effective and safe provision of custom extra-oral, non-weightbearing prostheses. These prostheses have been manufactured and supplied in Australia since the 1960's, however like the profession of ocularistry, anaplastology is currently self-regulated in this country, and there are no anaplastology-specific Australian Qualified Framework Educational Pathways. Clinicians were traditionally trained on the job following a dental technician qualification, however recently in order to keep up with rapid technological advancements and world standard clinical practices, there has been a shift towards seeking profession-specific post-grad qualifications from overseas education providers. There is precedent of these qualifications being sought and accepted at various tertiary and quaternary care hospital departments in Australia, and for an Anaplstologist to be accepted as a registered NDIS provider for the custom prosthetics registration group.

Example:
Custom made nasal prosthesis
- Required as a result of nasal amputation to treat invasive cancer
- Prescribed by treating physician
- Manufactured by an anaplastologist on site at a hospital (as per dental example above)
- OR Manufactured by an anaplastologist who is registered with the National Disability Insurance Scheme for the custom prosthetic registration group

2. Profession: Dental prosthetists
Devices:
• Interim Dental Prostheses
o Tissue stent
o Interim prosthesis
o Anatomical models (Virtual and Physical) to produce above prosthesesSoftware used in the process of manufacturing these products

• Impression Tray
o Anatomical models (Virtual and Physical) to produce tray
o Software used in the process of manufacturing these products

• Aligners

o Orthodontic aligner
o Occlusal aligner
o Osteotomy aligner
o Anatomical models (Virtual and Physical) to produce aligners
o Software used in the process of manufacturing these products

Profession of dental prosthetists fall under the below qualification already outlines in the proposal:
• By a dental laboratory accredited by the Oral Health Professional Association and The devices they produce are intended to be used by a patient of a healthcare facility, registered provider or AHPRA-registered health professional.

Alternative conformity assessment procedures

14 Do you agree with the rationale for the proposed alternative conformity assessment procedures for Class IIa patient-matched medical devices when produced under the circumstances listed in the consultation paper?

Yes

If you answered 'no' to the above question, please explain why you disagree with the rationale for the proposed alternative conformity assessment procedures for Class IIa patient-matched medical devices?:

15 Do you agree that the risks associated with the Class IIa patient-matched medical devices when produced under the circumstances listed in the consultation paper could be adequately managed through the proposed alternative conformity assessment procedure?

Yes

Please explain your response, including by providing examples that illustrate and/or support your position.:

We welcome TGA's proposal to introduce alternative conformity assessment procedures for Class IIa patient-matched devices manufactured by a trained, accredited professional or the third-party mechanisms of oversight in place for inclusion in the ARTG. We especially welcome the provision of self-assessment template to comply with the Essential Principles by TGA and removal of the requirement to obtain certification for quality management system from the TGA (or another body). This will significantly reduce both time and financial burdens on healthcare professionals where an alternative mechanism of oversight is already in place to manage the risk posed by Class IIa patient-matched devices. As stated above in Class I non-sterile, non-measuring patient-matched devices, we agree with the TGA's suggestion that in the healthcare facility, Class IIa patient-matched devices will be "prescribed" by a registered health professional and are manufactured by a qualified or accredited professional according to the specifications provided by the healthcare practitioner, thus risks can be adequately mitigated by the safety measure already in place at healthcare facility. Furthermore, medical devices post-market surveillance and adverse event reporting will be monitored as part of standard of care by the healthcare practitioner further mitigating the risk.

Example 1 – Class IIa patient-matched 3D printed anatomical models and surgical guides

Manufacture:
• a healthcare manufacture in healthcare facility accredited against NSQHS standards by ASCQHC.
• healthcare professionals who are AHPRA registered
• support healthcare professionals (a biomedical engineer, prosthetist or rehabilitation engineer)
• The devices produced are intended to be used by a patient of healthcare facility

Ethan is a AHPRA registered surgeon works in ASCQHC accredited hospital. He works with Tom who is a biomedical engineer (support healthcare professional) in the hospital. Ethan consults patient B who is requiring a jaw reconstruction surgery. Ethan prescribes a patient-matched 3D printed anatomical models and surgical guides to be used in the surgery.
The hospital has a dedicated 3D printing medical device manufacturing facility. This facility has all the necessary records and technical documentation of manufacturing patient-matched 3D printed anatomical models and surgical guides pertaining; meeting Essentials Principles, a documented evidence of conformity assessment, labelling and instruction for use, reporting adverse events and post-market monitoring, reporting and corrective action system. Ethan and Tom have already submitted TGA self-assessment template for evidence of the compliance to the Essential Principles and applied for ARTG listings for anatomical models and surgical guides. ARTG listings for anatomical models and surgical guides have been approved and accepted for Ethan and Tom to supply those devices regally at this healthcare facility.

Patient B undergoes CT scan and optical scan prescribed by Ethan. Tom uses patient's scanned images to create virtual anatomical models. Tom, as a biomedical engineer, then follows the "prescription" specified by Ethan and designs and manufactures the anatomical models and surgical guides for patient B following the technical documentation using 3D printer. Tom provides anatomical models and surgical guides to surgeon Ethan with the appropriate labelling and instruction of use in the package to be used in the surgery. Ethan uses anatomical models and surgical guides in the jaw reconstruction surgery and continues to have follow-up appointments with patient B for clinical management. He will record any adverse events during the follow-up appointments which will be registered by Tom in the manufacturing facility to keep an up-to-date post-market documentation.

Example 2 - Class IIa patient-matched 3D printed anatomical models

Manufacture:
• a healthcare manufacture in healthcare facility accredited against NSQHS standards by ASCQHC.
• healthcare professionals who are AHPRA registered
• support healthcare professionals (a biomedical engineer, prosthetist or rehabilitation engineer)

• The devices produced are intended to be used by a patient of healthcare facility

Deborah is an AHPRA registered surgeon works in ASCQHC accredited hospital. She also works with Tom who is a biomedical engineer (support healthcare professional) in the hospital. Deborah consults patient C who needs ear surgery for an implantable hearing device already on the prosthetic list. Patient C has unusual ear anatomy and Deborah "prescribes" a 3D model of Patient C's ear from Tom to allow her to visualise which implantable hearing device would best be suitable in Patient C's case. Deborah will use the model for mock surgery to assess of a range of devices, which may be the most suitable to use in this case. This will prevent opening and wasting devices in theatre which will be required if Deborah did not have access to 3D models. The model will not make contact with the patient (non sterile) or have measurements and is being used for the surgeon's preoperative preparation work prior to a case. It will not be used during the surgery.
Tom manufactures the 3D printed device in the hospital's dedicated manufacturing facility. Deborah will record any adverse events of the 3D models which will be registered by Tom in the manufacturing facility to keep an up-to-date post-market documentation.

Risk associated with manufacturing of Class IIa patient-matched 3D printed anatomical models and surgical guides in both examples is mitigated by:
• The device Classification itself (low - medium risk)
• State or Territory law for their qualification and registration
• Healthcare facility's risk reporting system for safety and adverse event
• Prescribing healthcare professionals providing an ongoing and continuity of care
• Documentations of manufacturing facility in the healthcare facility

16 Are there further circumstances where an alternative conformity assessment procedure for Class IIa patient-matched devices would be appropriate?

Please ensure that your answer directly addresses what measures are in place to manage the risks associated with the devices.:

Profession: Health professional (Surgeon) and Support Health Professional (Biomedical engineer)

Devices:
Biomodels – Surgical and Virtual
• Virtual Anatomical model
• Physical Surgical Anatomical model
• Preoperative model
• Planning model
Surgical Guides
• Cutting guide
• Drilling guide
• Contouring guide (to assist anatomical contour of target site)

For above devices, qualifications, accreditation, or certification listed below are in place and suggested alternative conformity assessment procedures will ensure that the risks associated with the manufacture of the devices have been managed and the Australian regulatory requirements for medical devices have been met before they are supplied.

• Within a healthcare facility accredited against the National Safety and Quality Health Service (NSQHS) Standards by a body recognised by the Australian Commission on Safety and Quality in Health Care (ASCQHC); or
• By a health professional registered with the Australian Health Practitioner Regulation Agency (AHPRA) under the Health Practitioner Regulation National Law Act 2009, and whose scope of practice encompasses production of the patient-matched medical devices that they are producing; and
The devices they produce are intended to be used by a patient of the healthcare facility, registered provider or AHPRA-registered health professional.

17 Are there any Class IIa patient-matched medical devices that should not be subject to an alternative conformity assessment procedure? What are they, and why not?

Please outline your reasoning.:

We would like to propose that Class IIa patient-matched devices Anatomical models (virtual and physical) should not be subjected to an alternative conformity assessment procedure. Anatomical models (virtual and physical) should be Patient-matched medical devices that could potentially be exempt from inclusion in the ARTG and detailed justification is outlined below.

Rationale:
TGA proposed refinement lists examples of devices that could potentially be excluded or exempt from the Regulation as a medical device, or an accessory to a medical device, but the level of risk posed by the devices is considered to be very low, or Class I non-sterile, non-measuring patient-matched medical device such as dentures, occlusal splints, aligners, respectively. In most of circumstances, these low risk and Class I devices are manufactured using the patient virtual anatomical model which is classified as Class IIa medical devices from the images that are acquired through a method that relies on energy outside of the visible spectrum.

1. This new classification of Anatomical models (physical or virtual) as Class IIa medical devices negates the aim of this refinement to reduce unnecessary regulatory burden.

Healthcare professionals who manufacture the Regulation Exclusion or Exempt low risk or Class I non-sterile, non-measuring patient-matched medical device will still need to apply for ARTG listing of Anatomical models (physical or virtual) Class IIa medical devices separately through alternative conformity assessment procedures.

Furthermore, the use of Anatomical models (physical or virtual) in the manufacture of Class I non-sterile non-measuring devices such as facial prosthetics is simply replacing "physical impressions of a patient's anatomy and models cast from these" which TGA is proposing to be exempt from the Regulation. Thus, classifying Anatomical models (physical or virtual) as Class IIa medical devices will add unnecessary regulatory burden to healthcare professionals who produces those devices.

2. Use of Anatomical models (physical or virtual) increase the safety and minimised the risk which aligns with not regulating products where there is no risk to safety (a no-harm principle).

The intention of healthcare professionals for the usage of Anatomical models (physical or virtual) is to increase the accuracy therefore patient health and safety. Medical devices manufactured using Anatomical models (physical or virtual) produce more accurate design compared to the 'free-hand" approach which minimise the risk. Unnecessary regulatory burden will increase cost and drive away healthcare professionals from using digital anatomical models which may potentially increase risk to patients. Instead of regulating all anatomical models, anatomical models used in moderate to high risk devices should be selectively regulated, so there is compliance with the end intention of the manufactured device. Anatomical models for high risk devices such as 3D printed titanium hip or spinal implants need an extremely high degree of regulation. However, visualising a patient's disease using augmented reality or virtual reality by a surgeon, which assist in preoperative preparation is unnecessary to regulate in the same way.

Alternative approaches we should consider

18 Are there alternative mechanisms for minimising the regulatory burden for patient-matched medical devices without compromising patient health and safety that you would like to propose?

If applicable, please write your response in the text box below.:

1. Proposal for re-classification of Class IIa patient-matched Anatomical models (physical or virtual).

Further to the proposal made in Point 10, we would like to propose a refinement of classification or provision of alternative regulation for diagnostic images and anatomical models used by healthcare professionals in healthcare facility.
TGA documentation of Personalized medical devices V3.0 June 2021 outlines
1) If:
(a) a medical device is intended by the manufacturer to be used to record patient images that are to be used for either or both of the following:
(i) the diagnosis or monitoring of a disease, injury or disability;
(ii) the investigation of the anatomy or of a physiological process; and
(b) the images are to be acquired through a method that relies on energy outside the visible spectrum;
the device is classified as Class IIa.
(2) A medical device that is an anatomical model (whether physical or virtual) that is intended by the manufacturer to be used for either or both of the following:
(a) the diagnosis or monitoring of a disease, injury or disability;
(b) the investigation of the anatomy or of a physiological process;
is classified as Class IIa.
(3) A programmed or programmable medical device, or software that is a medical device, that is intended by the manufacturer to be used to generate a virtual anatomical model that is to be used for either or both of the following:
(a) the diagnosis or monitoring of a disease, injury or disability;
(b) the investigation of the anatomy or of a physiological process;
is classified as Class IIa.

Background:
Advance in technologies in recent years have enabled many of healthcare professionals to utilise recording of patient images to manufacture personalized medical devices at healthcare facilities. The usage of diagnostic images and anatomical models medical devices range from production of Class I non-sterile, non-measuring medical device to Class III implantable medical device.
Healthcare professional's active involvement in the design-manufacture process of medical devices has revolutionalised the precision and accuracy of care provided to patients. Healthcare professionals use diagnostic images in day-to-day practices and are the only professions qualified to use them safely and accurately.

Consequences of new classification:
"a medical device is intended by the manufacturer to be used to record patient images and a programmed or programmable medical device, or software intended by the manufacturer to be used to generate a virtual anatomical model" to be Class IIa patient-matched medical devices means that they will be regulated and listed on ARTG. Consequently, the financial cost to comply to the regulation and listings on ARTG for each of these devices will need to be added on to the cost of devices themselves. Ultimately, the higher cost devices such as 3D optical scanners and the software will pose significant financially burden to the end users, who are healthcare professionals. In some cases, this will mean that healthcare professionals will need to revert back to "free-hand" and "guessing" approach to treat patients due to the prohibitive cost of accessing imaging devices and software compromising patient health and safety and increasing risks. Un-intended implications of unnecessary regulation include inequity in access to standard of care especially by rural and remote areas if only high volume hospitals can afford the infrastructure even to support very low risk applications. In addition, the process of getting approval for funding from the hospital on a case by case basis, will also cause delay for low risk application, which may further impair patient's outcome, especially in the setting of cancer.

Proposal:
When healthcare practitioner "prescribes" a medical device, the end intention of the product must match the regulation on the workflow. For instance, is the intention is to produce a Class 1 medical device such as an adhesive retained ear silicon prosthesis, the software and digital models created during the process of developing the device should be regulated accordingly. In addition, the use of these devices should be restricted to "prescription" by

qualified health care practitioners who are directly involved in the care of the patient.

2. Proposal for patient-matched medical devices alternative conformity assessment procedures appropriate for its class for health professionals.

Background:
As we have stated above, we welcome the TGA's proposal in the refinement to introduce "Exclusion" and "Exemption" for devices as it reduces the regulatory burden for patient-match medical devices. However, we believe that there is a better way to regulate patient-matched medical devices with more patient-focused approach.

Patient-matched medical devices provide the patient-centred health service embracing advances made in new technologies. Because they are tailored to patients, we believe they increase the safety and accuracy and also patients' quality of life compared to generalized medical devices.

Consequences of Exclusion and Exemption:
We appreciate that the scope of this refinement proposal focuses on patient health and safety and not necessarily on the financial implication. However, the financial implications should not be ignored, and we believe it has a significant effect on patient health and safety.

The regulatory burden will be reduced by having Exclusion and Exemption for patient-matched medical devices, but the downside of this is that those devices will not to be included in ARTG to provide pathways for patient's reimbursement through Prosthesis List/MBS.

This is an issue for healthcare professionals as the cost will inhibit the acceptability and sustainability of patient-matched medical devices that can improve patients' health and safety.

Proposal:
Patient-matched medical devices that are intended to be "prescribed" by a qualified healthcare practitioner for a patient in an accredited healthcare facility should have alternative conformity assessment procedures appropriate for its Class, similarly to what has been proposed for Class IIa devices. We propose that TGA provide the self-assessment templates according to the Class of devices to comply with the Essential Principles in order for them be included in ARTG listings.

Required final step - Publishing my response

19 Do you consent to the Department collecting the information requested in Citizen Space about you, including any sensitive information, for the purposes of this consultation?

I consent

20 I consent to the submission made by me being published on the Department's website, and accessible to the public, including persons overseas, in accordance with the following preference:

Publish response, including both my name and organisation's name

21 If there are specific answers you have provided that you do not wish to be published, please indicate these below.

Please state below any specific questions that you do not wish to have your answers to published.:
None

22 May we contact you for further information or to seek feedback about how the consultation was undertaken?

Yes

23 By making a submission, I acknowledge that:

I acknowledge the above