Response ID ANON-3NHQ-DDS3-8

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-07-14 17:03:25

Introduction

1 What is your name?

Name:
[redacted]

2 What is your work title?

Work title:
[redacted]

3 What is your email address?

Email:
[redacted]

4 What is your company/organisation?

Organisation:
[redacted]

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.:
Health

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.:

The proposed rationale for exclusion of certain medical devices recognises their low risk nature and that they do not present a risk of harm to consumers. The proposed exclusions are logical from a risk/benefit perspective.

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. :

No comment

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.:

The proposal recognises that health professionals are qualified to prescribe and manufacture such medical devices within their scope of practice. There are few and only minor risks to the patients with these devices and therefore a low regulatory burden is preferential.

Health professionals whose scope of practice includes prescribing and manufacturing medical devices complete accredited programs of study. The accreditation standards for health professions (both those regulated under the National Registration and Accreditation Scheme (NRAS) i.e. Dentistry, Dental Prosthetics; Occupational Therapy, Physiotherapy and Podiatry; and self-regulated professions i.e. Prosthetics and Orthotics, Audiology) include the competencies relating to the prescription and manufacture of medical devices relevant to the particular profession.
Universities are required to demonstrate that their programs meet these accreditation standards for students to graduate from an accredited program of study and be eligible to practice their profession in Australia. Oversees trained health professionals are required to demonstrate that they have completed an equivalent program of study before they can practice in Australia. This applies to both health professions regulated under NRAS and self-regulated allied health professions.

Following graduation from an accredited program of study, health professionals are required to maintain professional competencies and undertake continuing professional development. Under the NRAS, this is enforced through registration standards, codes and guidelines, including recency of practice, professional development and professional capabilities. The Health Practitioner Regulation National Law 2009 (as in force in each State and Territory) requires that the Australian Health Practitioner Regulation Agency (Ahpra) and National Boards regulate individual health professionals under the regulatory framework articulated through the National Law. Ahpra and the National Boards are responsible for investigating complaints about individual practitioners and can place conditions on an individual's registration or de-register health professionals who are not fit to practice i.e. if they present a risk of harm to consumers. These powers could be applied in the circumstances that a health professional has manufactured a medical device that has caused injury to a patient and a complaint was made to Ahpra. Employers also have obligations to report health professional employees to Ahpra if there are concerns regarding their safety to practice, including competence to prescribe and manufacture medical devices.

Self-regulated allied health professions, such as Prosthetics and Orthotics, have similar requirement articulated through their Code of Conduct; Competency Standards; Scope of Practice and Continuing Professional Development Standard. AOPA members who meet these standards are certified by AOPA. Similar arrangements exist for other self-regulated professions, such as audiology. Self-regulation bodies like AOPA and Audiology Australia are also responsible to investigating complaints made against their members. Consumers are also empowered to make complaints to Health Complaints Commissioners.

The National Code of Conduct for Healthcare Workers (the Code) was agreed by Health Ministers in 2015. This Code augments the regulation arrangements for self-regulated allied health professions and other healthcare workers, as well as health professionals regulated under the NRAS but who provide health services not related to their registration. The Code requires (among other things) health care workers to provide services in a safe and ethical manner (including maintaining competence in his or her field of practice; not providing health services that are his or her experience or training); obtain informed consent; take appropriate action in response to adverse events (including notifying relevant authority); and keep appropriate records. Health Complaints Commissioners can investigate complaints made under the Code and have powers to issue interim prohibition orders and prohibition orders in circumstances where a healthcare workers continued practice presents a serious risk to public health and safety.

The health professionals that prescribe and manufacture medical devices and are employed in a public hospital or health service are also regulated under national standards including the National Safety and Quality Health Service (NSQHS) Standards. This is mandatory for public and private hospitals, day procedure centres and public dental services. The Australian Commission on Safety and Quality in Healthcare is currently developing national standards for primary care. At the current time, it is understood that accreditation against the primary care standards will initially be voluntary. The NSQHS Standards, in particular, Standard 1 - Clinical Governance; Standard 2 – Partnering with Consumers; Standard 5 – Comprehensive Care and Standard 6 – Communicating for Safety, support the regulatory requirements for medical devices exempt from inclusion in the Australian Register of Therapeutic Goods (ARTG).

While the regulatory environment for allied health and dental services in private practice is somewhat different, professional regulation is enforced through other means. For example, to be eligible to claim Medicare benefits, allied health and dental practitioners are required to meet qualification requirements relevant to the respective profession as articulated through the Health Insurance (Allied Health Services) Determination 2007 or the Health Insurance (Dental Services) Determination 2007 and be registered with Ahpra or a respective board or organisation, such as Audiology Australia. Alternatively, allied health professionals working in private practice may be registered providers under the National Disability Insurance Scheme, which requires the same qualifications and registration or membership with professional associations such as AOPA and Audiology Australia.

Health professionals responsible for prescribing and manufacturing medical devices will work in manufacturing environments, such as orthotic/prosthetic labs and dental labs. These labs include various machines, such as ovens, vacuum presses, milling machines and grinders. Employers and employees must be cognisant of the Work Health and Safety law and regulations, including that employees are adequately trained to use equipment and machinery safely and competently to manufacture medical devices that are fit for purpose.

Health professionals and/or the organisations they work in can also have their manufacturing procedures certified against other standards and/or demonstrate compliance with internationally agreed ISO Standards, including but not limited to ISO 13485:2016 – Quality Management for Medical

Devices; ISO 20417:2021 Medical Devices – Information to be supplied by the manufacturer; ISO 14971:2019 Medical Devices – Application of risk management to medical devices.

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.:

In regards to orthoses prescribed by podiatrists and orthoses and prostheses prescribed by orthotists and prosthetists, manufacturing may occur by technicians according to the prescription and under supervision from health professionals. As such, the qualifications and certification described for podiatry and prosthetics and orthotics applies (as outlined in response to question 12 above).

Audiology is a self-regulated allied health profession, the regulatory model mirrors that of other self-regulated allied health professions, such as prosthetics and orthotics. Audiologists must complete accredited programs of study or demonstrate completion of an equivalent overseas qualification before being eligible to practice in Australia. Audiologists must meet the professional regulatory requirements set by their peak body, Audiology Australia, including complying with the code of conduct, professional development standards, professional competencies and their complaints process. The scope of practice of audiologists can include manufacturing certain class 1 (non-sterile, non-measuring) medical devices. While it is noted that audiologists working in public or private hospitals or day procedure centres accredited against the National Safety and Quality Health Service Standards and audiologists operating as NDIS providers would be able to manufacture class 1 (non-sterile, non-measuring) medical devices exempt from inclusion in the ARTG, there is a cohort of audiologists that would not be covered by these two categories, namely audiologists working in private practice who are not registered as NDIS providers and who operate their business model based on revenue from full fee paying clients, MBS rebates and private health insurance revenue. As such, it is recommended that audiology is added as a profession, in a similar way as prosthetics and orthotics are included on page 12 of the consultation paper i.e. 'By an audiologist who is a full member of Audiology Australia.

The National Alliance of Self-Regulating Health Professions (NASRHP) is an alliance representing the peak bodies for self-regulated allied health professions in Australia. NASRHP member organisations, such as Audiology Australia, Australian Orthotic and Prosthetic Association, Speech Pathology Australia, must meet benchmark standards for regulation and accreditation of practitioners. NASHRHP standards have been closely modelled on Ahpra standards and include
1. Scope (Areas) of Practice
2. Code of Ethics/Practice and/or Professional Conduct
3. Complaints Procedure
4. Competency Standards
5. Course Accreditation
6. Continuing Professional Development
7. English Language Requirements
8. Mandatory Declarations
9. Professional Indemnity Insurance
10. Practitioner Certification Requirements
11. Recency and Resumption of Practice Requirements

NASRHP standards facilitate national consistency in quality and support for self-regulating allied health professions and satisfies national and jurisdictional regulatory requirements, including the National Code of Conduct for Healthcare workers. This provides assurance to patients that they are receiving quality health care from a certified health professional.

The scope of practice of allied health professionals is evolving and influenced by advances in assistive technology. It is foreseeable that the scope of practice of other self-regulated allied health professions may evolve to include prescription and manufacture of class 1 (non-sterile, non-measuring) medical devices. In order to future proof the regulatory framework for medical devices, it is recommended that the TGA consider adding another category to the classes of health professionals able to manufacture medical devices exempt from inclusion on the ARTG, by including 'By a health professional who is a full member of a peak body that is a member of the National Alliance of Self-Regulating Health Professions'.

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.:

Yes. As outlined in response to Question 12 and 13 above, there are numerous regulatory mechanisms in place to regulate the practice of health professionals, whether regulated under the NRAS or self-regulated, and whether employed in public hospitals and health services or private practice. The recommended additions outlined in response to question 12 and 13 would also be relevant for the alternative conformity assessment requirements.

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.:

No comment

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.:

No comment

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.:

No comment

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 without my name or my organisation's name (anonymously)

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.:
N/A

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