Allied Health Professions Australia

Submission in response to TGA Consultation: Proposed Refinements to the Regulation of Personalised Medical Devices (Version 1.0, June 2021)

July 2021

This submission has been developed in consultation with AHPA's allied health association members.

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About AHPA and the allied health sector

AHPA is the recognised national peak association representing Australia's allied health professions. AHPA's membership collectively represents some 130,000 allied health professionals and AHPA works on behalf of all Australian allied health practitioners, including the largest rural and remote allied health workforce numbering some 14,000 professionals. AHPA is the only organisation with representation across all disciplines and settings.

With over 200,000 allied health professionals, allied health is Australia's second largest health workforce. Allied health professionals work across a diverse range of settings and sectors, providing services including diagnostic and first-contact services, preventive and maintenance-focused interventions for people with chronic and complex physical and mental illnesses, supporting pre- and post-surgical rehabilitation, and enabling participation and independence for people experiencing temporary or long-term functional limitations. Allied health also provides an essential bridge between the medical sector and social support systems such as aged care and disability, where it can represent the key formal health support in a person's life.

AHPA provides representation for the allied health sector and supports all Australian governments in the development of policies and programs relating to allied health. AHPA works with a wide range of working groups and experts across the individual allied health professions to consult, gather knowledge and expertise, and to support the implementation of key government initiatives.

Introduction

AHPA welcomes the opportunity to respond to the proposed refinements, and thanks the TGA for the extension of time granted to enable consultation with our members.

Current personalised medical devices relevant to allied health include hand splints, orthoses and prostheses, therapeutic insoles, cervical spine collars, moulds used to anchor hearing aids, and compression garments. Due to the diversity of allied health professions, it is important to consider that devices relevant to this consultation are often quite specific to individual allied health disciplines.

Accordingly, our submission should be considered alongside individual submissions from our member associations, including Osteopathy Australia, Audiology Australia, Occupational Therapy Australia, Australian Physiotherapy Association, Australian Hand Therapy Association, Speech Pathology Australia and Australian Orthotic Prosthetic Association. Noting that some of the comments in these individual submissions concern misrepresentations in the consultation paper pertaining to individual devices and professions, AHPA strongly recommends that our individual members be consulted before any specific lists of devices are included in primary legislation or regulations.

Almost all allied health devices do not penetrate the skin or the body, are not required to be sterile, do not involve measuring, and are for long-term use. These devices are presently described as 'patient-matched' devices and classified as Class I. They are therefore at the lowest end of the spectrum of risk, particularly when they are used in treatment by trained professionals.

Allied health professionals want to ensure that patients and clinicians are protected, but without duplicating the time and effort already spent on existing quality assurance processes. In AHPA's

view, the consultation paper recognises these issues by proposing that most of the Class I patient-matched devices relevant to us should be either made exempt or excluded from TGA regulation.

Exclusions

1. Do you agree with the rationale for the proposed exclusion of products? If not, why not?

Yes, AHPA agrees with the proposed exclusion rationale.

2. Are the risks posed by the products adequately managed if they are excluded from regulation by the TGA? Please explain your response, including by providing examples that illustrate and/or support your position.

For most products proposed to be excluded, we consider that the risks would be adequately managed, but we also refer the TGA to our response to Question 5. With regard to the potential risk and proposed exclusion of specific devices, we defer to our members' submissions.

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

AHPA defers to our members' submissions.

Exemptions

4. 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 this consultation paper? If not, why not?

Yes, AHPA agrees with the rationale for the proposed exemption. We appreciate that elements of the Framework which took effect in February 2021 were developed in response to the proliferation of devices enabled by new technologies and to the rise of new, not necessarily trained manufacturers. However, given that almost all devices used or manufactured by allied health practitioners are at the lowest end of the risk continuum, our members are dismayed that the Framework currently requires registration on the Australian Register of Therapeutic Goods (ARTG) of those devices that were previously exempt.

Allied health professionals have been concerned about the new requirement for registration, because despite previous consultations with the TGA, it is not always clear to practitioners when an allied health professional is deemed to be a manufacturer; nor to what extent each potentially relevant device (or group of devices) should be regarded as sufficiently distinct to require registration. Lastly, when weighed against the comparatively low risk of an adverse event when the device is used in treatment by an allied health professional who is already subject to various forms of regulation and quality assurance, a registration requirement appears to be legislative overkill.

5. Can the risks posed by the Class I non-sterile, non-measuring patient-matched medical devices when produced under the circumstances listed in this consultation paper be adequately managed if they are exempted from inclusion in the ARTG? Please explain your response, including by providing examples that illustrate and/or support your position.

Risk assessment and management is of necessity concerned not with absolute measures but rather with the probability and consequences of adverse events, weighed against the direct and indirect impacts of compliance. AHPA contends that an appropriate balance is struck by the exemption

proposal, because although an exempt device would not be required to be registered, qualifying for exemption depends on there being several types of adequate processes to manage the risks associated with device manufacture and use.

The first set of processes are those associated with TGA requirements regardless of registration, such as self-certification that the device is consistent with the Essential Principles of safety and performance, and obligation on the manufacturer to report to the TGA any adverse events associated with the device. In contrast to exemption, in our view exclusion does not strike the right balance for most Class I devices, because it removes them from medical device regulation altogether.

A second important set of safeguards is that the exemption is proposed to be subject to conditions in the Regulations. We consider that the conditions proposed address the concerns underpinning the development of the new Framework, at least as they pertain to Class I devices. We further submit that these conditions should be slightly extended – see our response to Question 6.

Finally, it is critical that appropriate risk allocation and lines of accountability are built into any modified regulatory system. Where allied health practitioners are manufacturers of medical devices, in order to uphold the Essential Principles they should be able to have confidence in the chain of supply of materials used in manufacture. Regardless of whether these materials are themselves medical devices, they must be both appropriately regulated and traceable.

Product recall and accountability to patients where an adverse event is suspected is particularly important if the allied health practitioner has produced a device within a specified design envelope (and is therefore not the manufacturer), or, as the manufacturer, has transformed raw materials according to a standardised process that can be validated, verified and reproduced. If it is the material that is suspected to be faulty and that material is excluded from TGA regulation, consumer protection mechanisms must be able to 'talk to' the TGA system. One possible example where this communication process might feasibly be required concerns the consultation paper's proposed exclusion of polymers and resins used in the manufacture of a medical device (p11).

6. 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?
Please provide details (describe 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.)

Yes. Many of Australia's allied health professionals are registered under the National Registration and Accreditation Scheme (NRAS) for health practitioners, maintained by the Australian Health Practitioner Regulation Authority (AHPRA). However, some allied health professions are not covered by the NRAS, due to national registration through AHPRA being currently limited to those health professions that were already registered or partially registered prior to 1 July 2010.

Some of these non-registered allied health professions are recognised as self-regulating health professions and are represented by the National Alliance of Self-Regulating Health Professions (NASRHP). For each of these professions, the accreditation process is managed by the relevant

professional peak body. These professional associations provide similar functions to AHPRA, including certifying qualifications and overseeing professional development. Member professions must also meet the NASRHP practice standards, which are closely modelled on AHPRA standards.

This ensures consistent regulation and accreditation of practitioners across self-regulating professions, and compliance with national and jurisdictional regulatory requirements, including the National Code of Conduct of health care workers.

AHPA therefore submits that the proposed requirement for exemption from inclusion in the ARTG of some Class I patient-matched medical devices – where it can be demonstrated that the risks associated with the manufacture and use of the device can be adequately managed – are also met where the qualified allied health professional is accredited through membership of a self-regulating profession.

Accordingly, we propose two additions to the conditions for exemption along the following lines (the proposed additions are shaded):

'Examples where Class I (low-risk) patient-matched medical devices could be exempted are where they are being manufactured:
• 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 provider who has been registered with the National Disability Insurance Scheme Quality and Safeguards Commission (NDISQSC), and the scope of their registration encompasses the patient-matched medical devices that they are producing; **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;
or
• By a health professional certified by a self-regulating profession that is a member of the National Alliance of Self-Regulating Health Professions (NASRHP), and whose scope of practice encompasses production of the patient-matched medical devices that they are producing;
or
• By a fully qualified pedorthist who is a member of the Pedorthic Association of Australia

and
The devices they produce are intended to be used by a patient of the healthcare facility, registered provider, or a health professional regulated as described above.'

Inclusion in ARTG using alternative conformity assessment procedures (Questions 7-10) and General question (alternative mechanisms, Question 11)

AHPA provides no comment on Questions 7-11.