Proposed refinements to the regulation of personalised medical devices

Submission by OSTEOPATHY AUSTRALIA to:

The THERAPEUTIC GOODS ADMINISTRATION (TGA)

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Contact

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Recommendations

Osteopathy Australia thanks the TGA for the opportunity to lodge a submission on the *Proposed refinements to the regulation of therapeutic goods.* Our recommendations are as follows:

Recommendation 1: the TGA should require plagiocephaly helmets be subject to inclusion on the ARTG as a medium risk medical device for redirecting the growth of a baby, infant or young child's skull.

Recommendation 2: the TGA should exclude clinical foot orthoses from ARTG registration and ARTG registration exemption applications, just as it is considering for 'orthoses like' goods masquerading as 'cosmetic products'

Recommendation 3: should the TGA require osteopaths and other allied health professionals to lodge ARTG exemption applications for designed or modified foot orthoses, it should act similarly for prefabricated foot orthoses masquerading as 'cosmetic products' or 'extensions to orthoses' from non-clinical businesses or persons

Recommendation 4: should the TGA intend on treating foot orthoses masquerading as 'cosmetic products' differently, it must:

- Define precisely what a 'cosmetic extension to foot orthoses' might be in comparison to orthoses proper
- Outline the detailed circumstances where a 'cosmetic extension' could influence the function of orthoses and thus be classified as part of the orthoses for ARTG purposes
- Offer a framework to monitor and assess compliance across the spectrum of the orthoses industry, both 'cosmetic' and clinical to assure devices are being classified, ARTG exempted or excluded appropriately.

Recommendation 5: the TGA should declassify and release any internally held consumer feedback about orthoses in deidentified reports.

About osteopathy and ‘medical devices’ related to it

Osteopaths in Australia are government (AHPRA) regulated allied health professionals having inbound and outbound referral relationships with other health professionals.

Osteopaths complete a dual Bachelor or Bachelor/ Masters qualification covering functional anatomy, biomechanics, human movement, the musculoskeletal and neurological systems, functional/clinical assessment, and neuromusculoskeletal clinical intervention approaches.

Significant commonalities exist between the health science units undertaken by osteopaths and those undertaken by peers of other allied health professions, including physiotherapy. As a defining characteristic, the osteopathic profession emphasises the neuromusculoskeletal system as integral to a client’s function and uses biopsychosocial and client-centred approaches in managing functional limitations. The Capabilities for Osteopathic Practice (2019) outline the required capabilities for professional skill, knowledge, and attributes; osteopaths are required to possess many interdisciplinary professional skills common across allied health and health professions.[i] In addition to broad primary health care competencies, osteopaths offer enhanced skillsets in neuromusculoskeletal care, including with manual therapy, clinical exercise programs, therapeutic needling, clinical lasers, and other very low risk medical devices such as orthotics.

A minority of osteopaths measure, customise and create clinical orthotics for individual patients following a rigorous clinical and biomechanical assessment; while some osteopaths who work with babies, infants and young children will refer to accredited Australian businesses and clinics that do measure and fit individualised plagiocephaly helmets under the direction of qualified medical/health professionals. Osteopaths are not involved in creating these helmets, but can be involved in facilitating access to an appropriately created product. We found this following consultation with members of Osteopathy Australia; given the profession’s interface with these devices, we focus our submission on these and offer specific recommendations for TGA action in relation to each.

About Osteopathy Australia

Osteopathy Australia is the national peak body representing the interests of osteopaths, osteopathy as a profession, and consumer's rights to access osteopathic services. We promote standards of professional behaviour over and above the

requirements of AHPRA registration. A vast majority of registered osteopaths are members of Osteopathy Australia.

Our core work is liaising with state and federal government, and all other statutory agencies, professional bodies, and private industry regarding professional, educational, legislative, and regulatory issues. As such, we have close working relationships with the Osteopathy Board of Australia (the national registration board), the Australian Health Practitioner Regulation Agency (AHPRA), the Australasian Osteopathic Accreditation Council (the university accreditor and assessor of overseas osteopaths), the Therapeutic Goods Administration (TGA)- to which we address this submission, and other professional health bodies through our collaborative work with Allied Health Professions Australia (AHPA). In our representative capacity, we welcome the opportunity to give feedback to the TGA's consultation on *Proposed refinements to the regulation of personalised medical devices.*

Plagiocephaly helmets

We hold concerns that plagiocephaly helmets could be reclassified as either devices excluded from regulation by the TGA or devices exempt from inclusion on the Australian Registry of Therapeutic Goods (ARTG) following a rigorous assessment of safety and quality.

There is risk the TGA's definition of medical devices to be excluded from the ARTG could encompass these helmets given the agency is considering excluding 'physical impressions of a patient's anatomy and models cast from these' (p.11 *Proposed refinements to the regulation of personalised medical devices)*. Unfortunately, our fears about this risk have been reinforced by reputable TGA vetted manufacturers of plagiocephaly helmets: Orthokids, 3DMEDiTech and Serkel.

As a device which redirects the growth of a baby, infant or young child's delicate and growing skull, we would propose that current safeguards be continued, including review, manufacturing, safety checks and inclusion on the ARTG. As a professional association abiding to high quality standards, we advise our members to refer parents, caregivers and their children to manufacturers with products vetted by the TGA with heightened regulatory oversight. Where a member is unsure of the appropriateness of a preapproved device, our advice is always to refer onward for appropriate medical and paediatrician assessment input.

Any TGA failure to appropriately regulate plagiocephaly helmet products could lead to the entry of dubious market entrants in no way qualified to be shaping the skulls of vulnerable Australian babies.

Should this scenario come to pass, the risks of assuring full product compliance would fall to osteopaths as the delegated 'sponsor' under the TGA reform proposal; given the heightened risks of plagiocephaly helmet fitting, modification and use, we do not believe this device presents an appropriately low level of risk to be individualised to allied health professional responsibility for quality control.

Recommendation 1: the TGA should require plagiocephaly helmets be subject to inclusion on the ARTG as a medium risk medical device for redirecting the growth of a baby, infant or young child's skull.

Foot orthoses

Foot orthotics may be prescribed by an osteopath in clinical care when an appropriate differential diagnosis indicates need. Some osteopaths may make or modify orthotics for individual patient use applying appropriate measures and technologies, as suitable.

Sadly, the TGA's proposed reform makes the regulation of orthotics inconsistent and dubious, failing to provide consistency.

The reform framework differentiates between devices with a 'cosmetic intention', allowing for these to be excluded from the ARTG altogether, versus lower risk 'patient matched medical devices' subject to an ARTG exemption application; we understand clinical orthotics currently fall into this second category as opposed to 'cosmetic extensions' to orthoses which would fall into the first (pp. 10-11 *Proposed refinements to the regulation of personalised medical devices)*. Without a very concrete definition of what these extensions are and are not, this could see foot orthotic products masquerading as cosmetics created by companies without any health or allied health professional oversight excluded from national device regulation. We do not support the TGA's differential treatment of what would be similar devices based only upon their advertised 'intended use'.

Should regulatory requirements proceed as outlined, osteopaths and other suitably trained allied health professionals could face delays in providing indicated clinical care to patients using foot orthoses. Exemption application approvals would no doubt rely upon TGA bureaucratic timelines and any variations to these timelines; we would not want to see patients prescribed less appropriate generic 'cosmetic' orthotic products unsuited to their assessed health care needs simply because these might be excluded from the ARTG and offer a timely approach.

Foot orthoses overall constitute quite low risk devices, whether custom made or generalised in design, and irrespective of whether full length, complete soles, or heel inserts. [ii] [iii] Indeed, the primary question pertaining to foot orthoses in the clinical literature is of their efficacy for improving lower limb movement and force direction, rather than one of explicit clinical risk of harm or worsening injury/movement. While orthotics can alter lower limb biomechanical function and/or foot movement, there are limited iatrogenic responses in the peer reviewed prospective trial literature.

Whether such a low level of quantified experimental risk would warrant the TGA to exercise regulatory oversight with all the operational and administrative burdens this brings to the exclusion of 'cosmetic products' masquerading as orthotics, is an important question needing TGA consideration. The TGA may have clinical orthotics related internal anecdotal data that is relevant to the matter from consumer complaints and feedback processes, and if possessed, we would kindly request the data be transparently reported on.

In addition to a paucity of observations concerning risk of harm in the clinical orthoses literature, the TGA should consider the following points in determining a compliance regime for clinical orthoses:

- That allied health professionals designing or modifying orthoses (one category of which is osteopaths, but including others like physiotherapists) possess extensive knowledge of biomechanics generally, and of the individualised biomechanics of the patient to whom they are being designed, modified or fitted. This is a first-line check and balance based on educational competencies and capabilities

- That the course of patient clinical management by a practitioner with regulated duty of care is a second-line check and balance over clinical orthoses risks (while device risk can not be assumed altogether absent, it is quite limited in the experimental literature, once more). Clinical management inherently involves practitioner to patient assessment, intervention, reassessment and change if required; these feedback loops help govern these devices and their application

- That as government regulated allied health professionals, osteopaths are required to have professional indemnity insurance coverage with run-off cover appropriate to scope of practice. We would consider this to be a third-line check and balance.

We are unaware of any professional indemnity claims regarding foot orthoses lodged with the endorsed professional indemnity insurer, Guild Insurance, within the last 10 years. Guild insures the professional practice of most osteopaths in Australia.

Recommendation 2: the TGA should exclude clinical foot orthoses from ARTG registration and ARTG registration exemption application requirements, just as it is considering for orthoses masquerading as 'cosmetic products'

Recommendation 3: should the TGA require osteopaths and other allied health professionals to lodge ARTG exemption applications for foot orthoses, it should act similarly for prefabricated foot orthoses masquerading as cosmetic products or 'extensions to orthoses' made by non-clinical businesses or persons

Recommendation 4: should the TGA intend on treating foot orthoses masquerading as 'cosmetic products' differently, it must:

- Define precisely what a 'cosmetic extension to foot orthoses' might be in comparison to orthoses proper
- Outline the detailed circumstances where a 'cosmetic extension' could influence the function of orthoses and thus be classified as part of the orthoses for ARTG purposes
- Offer a framework to monitor and assess compliance across the spectrum of the orthoses industry, both 'cosmetic' and clinical to assure devices are being classified, ARTG exempted or excluded appropriately.

Recommendation 5: the TGA should declassify and release any internally held consumer feedback about orthoses in deidentified reports.

Endnotes

[i] Osteopathy Board of Australia (2019), *Capabilities for Osteopathic Practice* [online];

[ii] Bonanno et al, 'Effectiveness of foot orthoses and shock-absorbing insoles for the prevention of injury: a systematic review and meta-analysis', *BJSM,* 51 (2), 2017

[iii] McMillan & Payne, 'Effect of foot orthoses on lower extremity kinetics during running: a systematic literature review', *Journal of Foot and Ankle Research*, 1 (13), 2008