3DMEDiTech™
Customised healthcare solutions

PROPOSED REFINEMENTS TO THE REGULATION OF PERSONALISED MEDICAL DEVICES

3DMEDiTech submission in respect of Therapeutic Goods Administration consultation paper dated June 2021

CONTENTS

Overview

3DMEDiTech welcomes the opportunity to respond to the TGA's consultation paper *Proposed refinements to the regulation of personalised medical devices* and looks forward to continuing our engagement with the TGA in relation to the issues contained therein.

3DMEDiTech supports the aims of the consultation and the goal of ensuring that the regulatory regime for Patient-Matched Medical Devices is clear and maintains its currency in a rapidly changing technological environment. Given also that compliance with both the previous and the current regulatory system is variable, 3DMEDiTech is keen to ensure that regulatory certainty, effective compliance and strong enforcement are present as the key elements necessary to deliver patient safety and clinical efficacy within the Australian medical supply chain.

The consultation paper notes that, during the implementation phase of the new regulatory framework, numerous sectors advised the following:

- that previous changes were a duplication of existing regulation already provided by professional accrediting bodies or other regulatory bodies;
- that the classification of certain requirements for some devices were excessive compared with the actual risk posed by the device; and/or
- the regulatory burden associated with compliance is unreasonable.

The current regulatory environment for Patient-Matched Medical Devices has been subject to rigorous public consultations:

- 2017 - *Proposed Regulatory Changes Related to Personalised and 3D Printed Medical Devices*;
- 2018 - *3D Printing workshop*;
- 2019 - *Proposed Regulatory Scheme for Personalised Medical Devices, Including 3D-Printed Medical Devices*; and
- 2020 - *Regulatory Changes for Personalised Medical Devices, Including 3D-Printed Medical Devices.*

3DMEDiTech welcomed the opportunity to provide comments to each of these consultations and has been supportive of the new regulatory regime at each step of the consultative process.

The Australian Government's own Regulation Impact Statement dated December 2019 titled "Proposed regulatory scheme for personalised medical devices, including 3D-printed device" clearly and concisely outlined the benefits, costs and risks associated with the both the previous and the current regulatory regime. The Regulation Impact Statement gave three key reasons that the current regime be introduced:

- the rapid emergence of new technologies and rapid uptake of personalised medical devices;
- the continued need for international alignment; and
- no other suitable mechanisms to manage issues with personalised medical devices.

The proposed refinements are entirely inconsistent with the recommendations of that Regulation Impact Statement.

The "refinements" contained in the consultation paper outline three key mechanisms to reduce TGA oversight of certain Medical Devices:

- Medical Devices proposed to be deregulated - "excluded" from TGA oversight completely;
- Medical Devices proposed to be less regulated - "exempted" from ARTG inclusion; and
- Medical Devices proposed to be self-regulated - "Alternative conformity assessment procedure."

A number of key elements outlined in the consultation paper are welcome and should be maintained and applauded as the regulatory environment changes and evolves. 3DMEDiTech acknowledges the changing nature of the Patient-Matched Medical Device space as it moves from being comprised purely of small scale individual artisanal producers to increasingly incorporating customised production at scale and the risks inherent to patients and the public that this creates. Ensuring that devices manufactured at scale in this manner are registered with the Australian Register of Therapeutic Goods (ARTG) is important and 3DMEDiTech welcomes the intent to achieve this.

In addition to this, 3DMEDiTech believes that there is a need to recognise, honour and uphold the history and artisanal nature of customised device manufacturing in some areas of health care and to protect those individuals who continue to create medical devices using the methods and materials in which they were originally trained and continue to use. Whilst production at scale is becoming more common and it is essential that the regulatory environment recognises this, the smaller scale producers who continue to pursue traditional artisanal manufacturing methods should not be crowded out of the market by regulatory change that fails to support their ongoing activity.

Respectfully, this consultation misses the mark on protecting and upholding patient and community safety within this evolving environment. Exemption from regulations such as the Essential Principles should not be based on which trade association a manufacturer is a member of, but rather on the safety of the device. Where a device is made in low volume using traditional artisanal techniques and materials in place for decades, an exemption would be entirely reasonable. However, where the manufacturer is making a relatively new device with novel designs, materials and manufacturing processes, an exemption from regulatory oversight makes no sense whatsoever and represents a potential risk to patients and the community.

These concerns, on which more detail is provided within the body of this response, are informed by 3DMEDiTech's own experience in developing and manufacturing custom products and the requirement for multi-disciplinary expertise, such as software and material engineering as well as clinical oversight, in advanced manufacturing; and our deeply held concern for patients and understanding of the potential risks to them of insufficient regulatory protection.

3DMEDiTech is an outstanding example of the scale manufacturing of customised 3D printed devices that the TGA appears to be trying to enable in recent regulatory changes. From our perspective, those changes could be weakened significantly if the currently proposed "refinements" are adopted in their current format.

Without proper management of these risks and regulatory oversight over such devices, the Australian market would be severely impacted. It would damage regulatory stability, lose an internationally competitive edge and undermine safety for patients.

According to Statista Research Department's analysis, the worldwide 3D printing materials market is set to grow 12 percent annually to nearly USD$4 billion by 2026,[1] while Mordor Intelligence research finds the 3D printing market will be worth USD $63.46 billion in 2026.[2] Medical devices will play a part of that growth and research shows that the 3D printing medical devices is projected to reach USD $5.1 billion by 2026, growing at compound annual growth rate of 16.3%.[3]

As the Australian Government's own Regulatory Impact Statement found, the current measures are appropriate and necessary in order to manage the risks that these devices (and potential new devices) will pose. Refinements to these measures need to be very carefully calibrated.

[1] Statista, *3D Printing Industry – worldwide market size 2020-2026,* June 2021.
[2] Morder Intelligence, *3D Printing Market - Growth, Trends, COVID-19 Impact , and Forecasts (2021 - 2026),* February 2021.
[3] Markets and Markets, *Global 3D Printing Medical Devices Market,* May 2021.

About 3DMEDiTech

3DMEDiTech is a Melbourne-based company which aims to deliver world class personalised devices and manufacturing services utilising 3D printing and other advanced manufacturing technologies at scale to the health sector across the Asia Pacific region.

Each medical device developed in preparation for mass personalisation requires significant research and development. This includes mapping and interpreting the clinical needs and the development and application of novel algorithms, as well as finding solutions to material and engineering problems.

Founded in 2016, 3DMEDiTech has strong experience in 3D manufacturing technology and has a practice of extensive multidisciplinary collaboration of clinicians, engineers and technicians necessary to delivering excellence throughout both research and development, and product development.

The company has already completed product development of a number of devices and has spun out stand-alone subsidiaries to support and invest in their focused go-to-market.

While our current devices – Serkel and SmileStyler – are Class I and IIa, respectively, our research and development function has begun work on significantly more advanced devices. 3DMEDiTech's clinical and research partners include Melbourne University, St Vincent's Health Australia, Orthokids and the Australian Research Council Training Centre for Medical Implant Technologies (ARC CMIT).

These devices are manufactured using state-of the-art advanced manufacturing processes, including 3D printing, to produce unique devices.

While a portion of 3DMEDiTech's research and development function has been in Israel, all of its end-use manufacturing occurs in a custom-built clean room environment in Melbourne. SmileStyler has *ISO 13485:2016 Medical Devices – Quality Management Systems* certification.

3DMEDiTech's workflow is completely digital, working only with clinicians that have in place the latest digital scanning technology, thereby enabling the fastest and most accurate design and delivery of precision customised devices to the patient.

3DMEDiTech aligns research and development expertise and experience with customised advanced manufacture at scale. It has strong IP understanding and linkages, and its founders comprise industry veterans committed to ongoing growth and delivering strong outcomes for patients' health and wellbeing.

Responses to proposals for change

Exclusions

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

   3DMEDiTech disagrees with the rationale for proposed exclusion.

   In the event that a product currently does not meet the definition of a medical device under the current regime, then self-evidently it does not need to be excluded.

   In the event that a product already meets the definition of a medical device under the current regime, then it ought not be excluded.

   We note that the TGA do not have oversight over products which are not defined as medical devices. An exclusion would mean that Essential Principles will not apply, including requirements for clinical efficacy, patient safety and conformity assessment. Further, TGA's strict adverse event reporting and recall frameworks will not apply.

   Confusingly for both clinicians and patients, the TGA would continue to regulate adaptable and non-personalised versions of these same medical devices.

   Any clear-eyed assessment of risk would likely find that by their very nature Patient-Matched Medical Devices carry more inherent risk than adaptable and non-personalised versions of those medical devices.

   There is also significantly more complexity in assessing clinical efficacy for Patient-Matched Medical Devices compared to the non-personalised versions of these medical devices.

   Products which meet the current definitions for medical device in section 41BD of the Act should continue to be regulated as a medical device.

   There does not appear to be any coherent reason why certain devices should be excluded. To deregulate only certain medical devices based solely on the desire of some small-scale manufacturers to be less regulated creates a confusing environment for both clinicians and patients as well as an uncertain environment for industry and investors.

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.***

   No suggestions or proposals to date demonstrate how the risks of the devices would be adequately managed.

   With technology developing and advancing at a rapid rate, Patient-Matched Medical Devices do require specialised, expert regulation such as the TGA's. Every day, new design techniques, new materials and new fabrication technologies are being released to the market and used in the creation of medical devices.

   We would respectfully suggest that neither the Australian Competition and Consumer Commission (ACCC) nor the state or territory consumer protection agencies are currently equipped to take over regulation of any medical devices, let alone ones as complex and subject to rapid disruption and technological change as Patient-Matched Medical Devices.

The number of products that are Patient-Matched Medical Devices is rapidly growing. Devices such as spectacle frames, mouthguards and eyeball prostheses all have the capacity to be harmful or to fail and therefore should be covered by the Essential Principles and safety reporting.

Indeed, it is difficult to see how such exclusions would benefit patients or any element of the medical supply chain.

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

Please provide an explanation for why:

- ***the product represents no, or insignificant levels, of risk; or***
- ***the product does not meet the definition of a medical device.***

The current definition of Medical Device in section 41BD of the Act is appropriate and that there is no need to arbitrarily remove some medical devices which meet that definition from the operation of the Act or oversight by the TGA.

We acknowledge that many items which never met the current definition of Medical Device in section 41BD of the Act have been improperly entered into the ARTG for various reasons. This problem affects both patient-matched and non-patient-matched items, and the proposed refinements will have little impact on resolving that problem.

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?***

Health professionals exercise clinical judgement when prescribing a medical device but they do not determine the variables of the design envelope of patient-matched devices. Further, they do not have the appropriate expertise in conformity assessment standards, manufacturing standards, material properties or patient safety of novel designs, materials or manufacturing processes.

It is therefore inappropriate to ascribe all such related device risks to prescribing health professionals. These risks should remain the responsibility of the device sponsors who do have expertise over such matters and a legislated mechanism to give patients and clinicians surety as to legal liability.

The design and manufacturing aspects of such devices and the risks associated should be monitored and regulated to ensure full safety, compliance and proper market surveillance. The proposed exemption and the rationale for it is inadequate for the above reasons.

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.***

Without the oversight and monitoring resulting from ARTG inclusion, the risks of such devices would not be adequately managed. Further, Australia would go from a market-leading, safe and transparent jurisdiction to one with less regulatory oversight than many comparable countries throughout the world.

The risk would be transferred to clinicians and, in a *de facto* way, to the nominated oversight bodies including AHPRA, NDISQSC, ASCQHC, AOPA, and AHPA none of which have expertise over safety compliance standards, manufacturing standards, registration, reviews or clinical performance. This is particularly the case for mass manufactured medical devices utilising novel designs, materials and manufacturing processes.

The sponsors of such devices have the expertise and capability to monitor and assess compliance, so it naturally follows that they should retain the liability. This is best done through inclusion in the ARTG.

It should also be noted that patient-matched medical devices pose more risk than non-personalised device counterparts and that such risks, while often low, are not insignificant. Again, as technological and complex capabilities of such devices advance, the risks also have a potential to grow.

For example, the proposed exemptions for plagiocephaly helmets outlined in this consultation would omit or leave such assessment and regulation of the proposed devices solely to clinicians, with some level of oversight from one or more of AHPRA, NDISQSC, ASCQHC, AOPA, and AHPA. These are largely oversight and regulatory bodies for clinical professions. Neither they nor clinicians have the technical capability or expertise necessary to assess the safety, efficacy and conformity of medical devices and products like plagiocephaly helmets. Nor would they be able to continuously regulate and monitor their use in the Australian market.

The increasing complexity and technology involved in producing these devices is placing further limits on the capability of health professionals in this regard. While health professionals continue to be best placed to identify the specific clinical requirements for their individual patients, regulating the devices should remain the express responsibility of the TGA. Including and retaining these devices on the ARTG with primary legal liability resting with the Device Sponsor is the single best way to ensure the safety and efficacy of Patient-Matched Medical Devices such as plagiocephaly helmets.

It is also important to note that, as the technological and complex capabilities of such devices advance, the gap between clinicians' and manufacturers' expertise and capability will continue to grow. This means that the issues and risks identified above will intensify over time rather than be ameliorated in any way.

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.

For reasons expressed above, Class I devices do and will continue to pose risks which cannot be adequately managed in the case of exemption from the ARTG.

Example – Plagiocephaly helmets

Plagiocephaly helmets or cranial orthoses are one of the medical devices nominated in the consultation as being so low risk that they ought be exempted from inclusion on the ARTG.

The terms "plagiocephaly" and "brachycephaly" are sometimes referred to as "flat head syndrome." Largely because of (very successful) SIDS guidance the incidence of plagiocephaly has increased significantly. Nearly one in two infants today (47%) are somewhat affected, with experts recommending that one in every ten babies be evaluated for treatment. Helmet therapy is most effective if treatment starts between six and eight months of age and is completed before 12 months, as this is the time of rapid growth of the skull.

Part of the reason that we decided to develop the Serkel helmet Patient-Matched Medical Device was in fact because of the high level of clinical complications. Accordingly, our significant R&D expenditure was focused on finding customisation, design, material and fabrication solutions to solve a series of inherent and common clinical problems resulting from traditional helmet design and fabrication.

There has been one study that specifically addressed clinical complications associated with cranial orthoses (see Wilbrand JF, Wilbrand M, Malik CY, Howaldt HP, Streckbein P, Schaaf H, et al: *Complications in helmet therapy*. Journal of Cranio-Maxillofacial Surgery 40:341–346, 2012).

A retrospective analysis of 410 patients undergoing helmet therapy for positional plagiocephaly was undertaken specifically to examine the complication rate. This study found a significantly higher rate of complications than had been previously described. Observed complications included:

- 43 pressure sores;
- 26 cases of ethanol erythema (their protocol for cleaning the inside of the helmet included ethanol wipes);
- 5 cases of skin infection;
- 1 case of bacterial abscess requiring local incision and drainage;
- 25 cases of poor fitting helmet.
- 5 cases of unsatisfactory cosmetic results.

Other clinical complications known to arise from plagiocephaly helmets include contact dermatitis, hypertrophy gap from poorly designed closure systems and pain from poorly fitted helmets (see van Wijk R M, van Vlimmeren L A, Groothuis-Oudshoorn C G M, Van der Ploeg C P B, IJzerman M J, Boere-Boonekamp M M et al. *Helmet therapy in infants with positional skull deformation: randomised controlled trial BMJ* 2014; 348 :g2741 doi:10.1136/bmj.g2741)

Example – Orthodontic Aligners

Another example of how this consultation is out of step with global regulatory trajectory relates to orthodontic aligners. Orthodontic aligners, are a Patient-Matched Medical Device used in the oral cavity ~22 hours a day for up to 24 months.

Tooth movement occurs as a result of safely and precisely applied pressure over time and is achieved by prescribing a series of aligners that are changed every 10 – 14 days, each with a target Orthodontic Teeth Movement (OTM) of ~0.25mm.

The treatment planning process for major suppliers working with Orthodontists requires an X-ray. X-rays show the hidden anatomy of the teeth (roots, restorations, etc.) which have an impact on the safe movement of the teeth. The x-ray will indicate the health of the root of the teeth.

One of the possible adverse effects of orthodontic movement is root absorption, which results in tooth loss. If the root is not healthy, no movement should be planned for that tooth. The primary risk from sub-standard treatment planning or poor device quality is permanent tooth loss, and this does regularly happen with low quality aligners which do not both use x-rays and strong clinical oversight for their treatment planning.[4]

This consultation presupposes that aligners are Risk Class I, which would make Australia a global outlier in terms of its approach to managing patient risks associated with this device category.

The U.S. Code of Federal Regulations 21CFR872.5470 mandates orthodontic clear aligners as "Device Class II." The bulk of premium orthodontic aligner device companies are already regulated under this ruling.

In the event that Australia decides to apply a substantially lower risk classification than comparable jurisdictions, the only substantive affect would be to open up the Australian market to lower quality providers unable to meet the Class II and variant requirements in other OECD countries.

Serious adverse clinical events can and do occur from the use of orthodontic clear aligners[5] and poor treatment-planning can even result in tooth loss.[6] For this reason, orthodontic clear aligners are consistently given a Risk Classification of Class II (or equivalent) in other IMDRF-aligned jurisdictions.

The prescribed course of treatment is typically 12 months and often up to 18 or even 24 months, with the prescription nearly always to wear them whenever not eating and "for at least 22 hours a day." The delivered course of treatment is typically longer than the initially prescribed one for most aligner systems because of "corrections."

In Australia the classification level revolves around interpretation of the term "short-term use" for the purposes of Classification Rule 3.1(2)(b)(ii). A consistent application of this rule in Australia would clearly place orthodontic aligners squarely with Risk Class IIa.

[4] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5430001/
[5] https://www.ajodo.org/article/S0889-5406(17)30603-0/pdf
[6] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5430001/

Inclusion in ARTG using alternative conformity assessment procedures

7. ***Do you agree with the rationale for the proposed alternative conformity assessment procedures for Class IIa patient-matched devices when produced under the circumstances listed in this consultation paper? If not, why not?***

The rationale for the proposed alternative conformity assessment procedures is not clearly laid out in the Consultation paper.

While it explains why regulation is required, considering the risks that Class IIa devices pose, it fails to articulate the need for alternative procedures. In fact, the proposal outlines a far more convoluted and complex structure of regulation which in itself is likely to cause problems for both clinicians and patients.

That is because, with so many different assessment pathways, the proposed refinements eliminate the involvement of one streamlined, efficient regulatory body and instead introduce a mixture of different organisations including AHPRA, NDISQSC, ASCQHC, AOPA, and AHPA which have no oversight of the other organisations. Risks that this change may generate include regulatory arbitrages, loopholes or areas which do not receive proper regulatory coverage.

Indeed, no case or rationale was provided for why having one, dedicated specialist regulator is unsatisfactory or insufficient. Instead, the proposed changes complicate and further exacerbate regulatory confusion.

By placing membership of particular nominated commercial peak bodies as the key factor in accessing those alternative conformity assessment procedures, the proposed refinements effectively place those commercial peak bodies in the place of Designated Conformity Assessment Bodies. To do this at a time when Patient-Matched Medical Devices are going through such rapid technological change with novel materials, designs and technologies seems counter-intuitive.

At a minimum, we would propose that the relevant peak bodies which wish to provide an alternative conformity assessment pathway for their members ought be required to make a successful application for an Australian Conformity Assessment Body Determination.

Australia's Designated Conformity Assessment Bodies are not only essential to safety and efficacy in our medical supply chain but represent critical economic infrastructure with specific roles to play pursuant to our international obligations under various free trade agreements. As a nation, Australia facilitates trade through a series of robust standards and conformance infrastructure and mutual recognition agreements (MRAs), each of which prescribes certain standards required of Designated Conformity Assessment Bodies.

The interaction of the proposed inclusion of patient-matched medical devices in the ARTG using an alternative conformity assessment procedure with the ability to import and export medical devices pursuant to these international agreements is at best unclear and, at worst, places at risk Australia's position as a leader in the manufacture and export of Patient-Matched Medical Devices.

For example, *The Mutual Recognition Agreement on Conformity Assessment Between the Government of Australia and the Government of the Republic of Singapore* stipulates that "... designated Conformity Assessment Bodies shall be impartial. Any other services offered by the Conformity Assessment Body shall be provided in a manner that does not compromise the objectivity of its conformity assessment activities and decisions."

The current proposals do not meet this requirement given the other responsibilities and focus of organisations such as AHPRA, NDISQSC, ASCQHC, AOPA, and AHPA.

8. ***Do you agree that the risks associated with the proposed Class IIa patient-matched devices when produced under the circumstances listed in this consultation paper could be adequately managed through the proposed alternative conformity assessment procedure? Please explain your response, including by providing examples that illustrate and/or support your position.***

While the proposed recognising or approving bodies to access the alternate pathways are commercial peak bodies, there is no indication that they have particular regulatory or risk management expertise.

Therefore, while they may have clinical and technical knowledge that would be relevant to the various devices, there is no indication that they are the suitable or most effective governing bodies to deal with alternative conformity assessment of such increasingly complex devices.

Further, with so many avenues of assessment, this creates considerable confusion for patients seeking accountability. Patients and clinicians deserve a clear line of sight to the responsible entities for devices they use. This is currently achieved with the existing regulations but the proposed changes would confuse and convolute matters.

Further, where devices are increasingly complex and technologically advanced, the regulatory requirements and challenges in fact increase. This will extend the peak bodies' inability to effectively govern the conformity assessment pathways of these devices and risk patient and community safety as well as potentially undermining confidence in the sector overall.

9. ***Are there further circumstances where an alternative conformity assessment procedure for Class IIa patient-matched devices would be appropriate? If so, what measures are in place to manage the risks associated with the devices?***

As outlined above, no. Alternative conformity assessment procedures adds unnecessary complexity and lack of clarity for the medical supply chain.

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

No devices should be subject to alternative conformity assessment procedures for the reasons outlined above.

General question

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

No other alternative mechanisms are necessary where the current regime is properly administered and implemented.

The regulatory burden is not significantly higher for Class IIa patient-matched devices than was previously the case for custom-made devices. The only marked difference between the current regime as it was conceived and implemented is that it is actually enforceable.

Risk-based approach

3MEDiTech considers that the risk here is not one solely relating to the clinical indication of the devices supplied or the classification of those devices but to the broader manufacturing framework and that this should be reflected.

At present, underpinning the suggested regulatory carve-outs, the risk-based framework remains the same i.e., Class I to Class III with their variations. As a risk-based approach, this is fundamentally flawed for a number of reasons, including varying compliance and evolving practice of manufacture.

Devices that are and have always been manufactured by qualified personnel, such as orthotic prosthetists, dental orthotists or podiatrists who manufacture a device according to their industry's traditional practice, are correctly identified within the framework as low risk. Many of the devices produced by these individuals use traditional methods, often creating hand crafted devices with longstanding materials in which their producers have been extensively trained.

This is extremely different from the mass manufacture utilising different and non-traditional designs, materials and techniques.

The risk factor here may not be low, a factor inherently acknowledged in the consultation paper, and highlighted by the examples above.

Different regulations and definitions are required to capture this situation. Appropriate protection is needed to enable those professionals who manufacture their devices in line with traditional and best industry practice to continue to do so. This is in both the interests of those individuals and the patients they treat and, in addition, these individuals have not behaved in any way for which they should be penalised. Further, they should not face any additional regulatory burden in terms of paperwork or compliance than they do at present.

3DMEDiTech is aware that the low cost barriers to entry level 3D printers and materials have encouraged a number of clinicians and companies within the broader medical sector to attempt the creation of medical devices utilising advanced manufacturing techniques but with little or no expertise on how to manage the inherent risks of these new technologies. 3DMEDiTech and its clinical partners have been alarmed by some of the designs, procedures and materials utilised by these clinicians, with some deploying high profile marketing campaigns for these devices to highly vulnerable Australians. These refinements would hand these rogue clinicians and companies a long term regulatory holiday at precisely the wrong time.

Additional regulatory requirements for those manufacturing at scale would seem appropriate given the greater risk associated with their activities – regardless of which peak body they are a member of.

Example – Essential Principle 8—Infection and microbial contamination

A worker infected by a virus such as Avian Influenza who works in a traditional artisanal customised device manufacturing environment will not spread the disease particularly widely, simply due to the number of devices being produced.

In contrast, a worker with the same virus in a manufacturing environment producing Patient-Matched Medical Devices at scale has the capacity to cause harm to a significantly higher number of people and this is without reference to the actual device itself.

The change in manufacturing technology and the evolution of large scale manufacturing of customised devices demands that the Essential Principles be rethought in a broader context. The proposed refinements do not take this into consideration and treat traditional artisanal producers the same as mass manufacturers as long as they are a member of a particularly narrow class of peak bodies.

Without addressing the duality of this issue, which is at the heart of the evolving Patient-Matched Medical Device industry, groups will continue to make devices without appropriate clinical oversight and/or without appropriate mechanical knowledge and manufacturing properties.

This would represent a failure of appropriate protection and oversight and a lack of quality control which ultimately risks patient wellbeing.

Recommended approach

To address this issue, 3DMEDiTech would seek a resolution that supports the ongoing work of those professionals who are producing devices that are made in a traditional or 'artisanal' manner and enables them to continue to operate in a light touch environment. This could be achieved by grandfathering existing professionals either by qualification, craft group membership or by some other mechanism suggested by the TGA. This would not necessitate the craft group or qualifying body accrediting individual professionals as such but instead would simply acknowledge that these groups' membership requirements reflect a level of training and experience that is acceptable for the manufacture of the type of devices being produced when made in a traditional manner with traditional materials.

At the same time, regulations are required that will ensure that other manufacturers who are producing at scale, utilising non-traditional design and other technologies, are captured within a more rigorous regime and their products evaluated by the TGA and added to the ARTG.

This would require further clarification of the current categories and the introduction of regulations that recognise the manner by which devices are created, not simply the type of device being produced. This begins to be captured by the notion of a medical device production system but both additional expansion and further refinement of the proposed definitions are necessary.

Conclusion

3DMEDiTech appreciates the opportunity to provide input to the TGA's consultation. We would welcome ongoing dialogue and interaction with the TGA regarding our recommendations.

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