3DMEDiTech™
Customised healthcare solutions

PROPOSED REGULATORY SCHEME FOR PERSONALISED MEDICAL DEVICES, INCLUDING 3D-PRINTED MEDICAL DEVICES

3DMEDiTech submission in respect of Therapeutic Goods Administration consultation paper dated February 2019

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Overview

3DMEDiTech welcomes the opportunity to respond to the TGA's consultation paper *Proposed regulatory scheme for personalised medical devices, including 3D-printed medical devices,* and looks forward to continuing our engagement with the TGA in relation to the issues contained therein.

Having supported the aims of the November 2017 consultation paper regarding proposed regulatory changes, 3DMEDiTech welcomes the current consultation paper and notes that its effectiveness in moving towards achieving the aims of the original consultation paper. The proposed regulatory scheme strikes an effective balance between delivering the regulatory control necessary to deliver patient safety and supporting a business environment that will encourage innovation and investment whilst facilitating Australian businesses to export their devices. Further, it recognises the changes in the technology in 3D printing and the realities of how this has changed the market for 3D-printed medical devices.

Critically, the proposed scheme acknowledges the changed risk profile that technological shifts have created and the importance of adjusting the regulatory scheme to manage that profile and the potential risks it presents for patients.

A number of elements that 3DMEDiTech noted in the original consultation paper have been maintained and accentuated in this current paper. These include, as noted, the acknowledgement of the changing nature of the 3D medical device printing industry as it moves from being comprised principally of small scale individual producers to increasingly incorporating customised production at scale and the risks inherent to patients and the public in this; the need to ensure that devices manufactured at scale in this manner are registered with the Australian Register of Therapeutic Goods (ARTG); and the need to protect patient and community safety within this evolving environment.

The paper also recognises the history and artisan nature of customised device manufacturing in some areas of health care and protects 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 increasingly common, the smaller scale producers who continue to pursue traditional manufacturing methods should not be crowded out of the market by regulatory change.

3DMEDiTech also welcomes the increased clarity regarding definitions within the current consultation paper and its clear focus on compliance.

The harmonisation of definitions with the IMDRF is extremely important for Australian businesses. Harmonisation facilitates access to export markets for companies, such as 3DMEDiTech, that are actively seeking to broaden the markets to which we can supply our products. It also supports innovation by giving greater confidence that our products will reach sufficient markets to support the investment needed to develop them and our manufacturing facilities even further.

Australia has been a leader in both the development of precision or personalised medicine and the systematic digitisation of the health supply chain. These two trends have the capacity to deliver not just better clinical outcomes for patients, but more efficient financial outcomes for payers in the health system. The introduction of a personalised medical device category in Australia (as well as the other 34 countries which are members of the IMDRF) is a logical next step to facilitate further research and development, investment and scaling of these important advances.

3DMEDiTech is an archetypal example of a scale manufacturer of personalised 3D-printed devices that the proposed regulatory scheme will support. From our perspective, the consultation paper effectively delivers the framework, safeguards and clarity required so that we can confidently grow our business knowing that patient and consumer confidence will be upheld via the Australian regulatory system. Given past experience, it is important to ensure that the regulatory scheme proposed is effectively enforced and this paper makes it clear that the intent is there to achieve that.

About 3DMEDiTech

3DMEDiTech is a Melbourne-based company which aims to deliver world class customised 3D printed devices and manufacturing services at scale to the health sector across the Asia Pacific region.

Each medical device developed in preparation for mass customisation requires significant research and development. This includes mapping and interpreting the full spectrum of the clinical problem and the development and application of novel algorithms, as well as finding solutions to significant design, 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.

SmileStyler® is the first fully digital staged orthodontic clear aligner system, which has used digitisation, machine learning and advanced manufacturing to solve the single biggest clinical problem in the rapidly growing clear aligner category of Class IIa devices.

Serkel® creates precision-personalised orthoses for prescription by orthotist/prosthetists, such as plagiocephaly helmets and ankle foot orthotics. In the case of Serkel® plagiocephaly helmets, we are not just solving a significant market shortage of the traditionally manufactured device, but are seeing significant quantitative gains in clinical outcomes.

While our current devices are Class I and IIa, our Research and Development function has begun early work on significantly more advanced devices. 3DMEDiTech's clinical and research partners include Melbourne University, St Vincent's Health Australia, Orthokids and Ivoclar Vivodent.

While a portion of 3DMEDiTech's Research and Development function is based in Israel, all of its end-use manufacturing occurs in a custom built clean room environment in Melbourne. 3DMEDiTech is currently working towards *ISO 13485:2016 Medical Devices – Quality Management Systems* certification, which should be complete this calendar year.

3DMEDiTech's workflow is completely digital, as we only work 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 end user.

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

Proposal 1: New definition for personalised devices

Definitions

3DMEDiTech notes the new definitions proposed by the TGA, particularly the fact that these are aligned with those recently published by the International Medical Device Regulators Forum (IMDRF). 3DMEDiTech welcomes this harmonisation with the IMDRF definitions as they align strongly with the clarity and changes we sought during the original consultation. Having greater clarity about definitions is essential to making sure that the new regulatory scheme works effectively and with minimal confusion.

Harmonisation with the IMDRF also supports Australian companies seeking to export their devices globally as 3DMEDiTech is. Harmonised definitions can support shared regulatory approvals and hopefully abridged assessments over time and enable faster access to global markets. This speed and ease of access supports Australian companies seeking to innovate and the competitiveness of the sector as a whole.

The changes recommended to the definitions will also result in custom made devices requiring pre-approval by the TGA and being included in the ARTG. The sector should welcome this as an appropriate outcome that supports high quality activity within the value chain and protects investment through a more meaningful and appropriate regulatory regime.

As indicated in our submission to the initial consultation paper in 2017, 3DMEDiTech has observed the impact that low cost barriers to entry level 3D printers and materials have had in encouraging a number of individuals and/or companies within the "maker movement" to attempt the creation of prosthetics and orthotics, including some with embedded electronics. 3DMEDiTech and its clinical partners have been alarmed by some of the procedures, materials and lack of clinical oversight utilised by those deploying high profile marketing campaigns for these devices to highly vulnerable Australians and is comforted by the fact that the proposed regulatory scheme, coupled with an effective compliance framework, should eradicate this risky behaviour.

Proposal 2: Changes to requirements for supplying custom-made medical devices

Manufacturer's statement re devices provided to patients

3DMEDiTech welcomes the intent to introduce the requirement that manufacturers provide to patients a statement regarding the custom-made device they are receiving. This aligns with other areas of healthcare in Australia, such as the provision of Consumer Medical Information (CMI) leaflets to patients receiving pharmaceutical medicines, and represents best practice in consumer care.

The provision of this type of information also promotes and supports an appropriate level of transparency within the sector and support informed decision making and consent on behalf of the patient. 3DMEDiTech entirely supports this approach and the company already provides this information to patients receiving SmileStyle® aligners.

TGA entry and inspection rights to manufacturing sites

Again, 3DMEDiTech supports this proposed change bringing the practice in relation to 3D-printed medical devices in line with a variety of other jurisdictions for which the TGA has responsibility, such as manufacturing sites for pharmaceuticals and complementary medicines. In aligning these requirements, the TGA is recognising the significance of the 3D-printed devices industry and the importance of monitoring its quality, safety and performance. Without entry and inspection rights, the TGA would be hamstrung in performing

these roles and in ensuring the effective and safe performance of the sector. 3DMEDiTech is of the opinion that these rights support the industry and should be welcomed by all legitimate manufacturers.

Annual reports to the TGA for custom-made devices

This proposed change represents appropriate oversight by the TGA over custom-made devices, an oversight which to date has not been able to be delivered. Annual reports to the TGA should not represent a significant burden to any legitimate manufacturer as the type of information to be submitted should be maintained as part of company records as a matter of good practice.

Supplying that material to the TGA however supports transparency, delivers appropriate oversight and supervisory powers to the TGA and, critically, acts to protects patient safety and enhance consumer confidence. 3DMEDiTech supports this proposed change.

Holding documentation for implantable devices for 15 years

Whilst 3DMEDiTech does not at the current time manufacture implantable custom-made devices, the proposal to retain documentation regarding these devices for fifteen years is appropriate and recognises the changing nature of the risk posed by the changes in the device market.

Proposal 3: Framework for regulating medical device production systems

The introduction of a definition for a *medical device production system* (MDPS) is a critical element in clarifying the regulatory system. Making it clear that these systems themselves are considered to be medical devices and will be incorporated in the ARTG delivers confidence to manufacturers about the treatment of these systems and their appropriate classification. 3DMEDiTech supported treating MDPS in a more holistic manner in our submission to the original consultation and welcomes its inclusion in the proposed regulatory system in the manner outlined.

This is because, where a self-contained system that has been approved by the TGA and included in the ARTG is being used as specified and with the materials specified, i.e., as a 'closed' system, the manufacturer of the system should retain the responsibility as the manufacturer of the finished product.

However, where any changes to either the software, materials utilised or the printer itself are undertaken, the production system at that point should cease to hold TGA approval or be registered on the ARTG as proposed. At that point, responsibility for the finished product should rightly be that of the individual or organisation who made the changes and the manufacturer of the MDPS released from culpability with the modified device.

3DMEDiTech supports this proposed change.

Proposal 4: Medical device classification to include all diagnostic image recordings

As highlighted in our previous submission, 3DMEDiTech supports medical devices intended by the manufacturer to record diagnostic images being classified as Class IIa. This proposed change to Rule 5.4 aligns with the current rule for X-ray film and would hold manufacturers to an appropriately high standard.

A lack of scanners within the clinical environment is one of the key barriers to the uptake of personalised medical devices within the Australian healthcare system. Creating regulated certainty of scanner quality is a necessary precondition to facilitate the investment in the mass digitalisation of many clinical settings in Australia.

At the present time, 3DMEDiTech is anecdotally aware of various scan data sets used to create anatomical models and digital 3D print files that do not conform with this level of standards.

To ensure that this situation does not continue, 3DMEDiTech would seek further clarification by the TGA as to the status of digital scanners. Whilst the consultation paper clearly suggests that digital scanners would be classified as Class IIa, some of the supporting paragraphs in the document are less clear.

Given that the specialised and complex functions of these devices lies with the specialist manufacturer of the scanner, it is important that purchasers of such devices can rely on them as being accurate and approved and that personalised device manufacturers can rely on the data from many different scanners in clinical environments across Australia in order to accurately customise each patient's device. This would seem in line with proposal three and is important given that almost every personalised medical device (and increasingly many custom devices) relies on a scan.

At a macro public policy level, Australia has been a world leader in respect of recognising the immense benefits for patients, clinicians and the taxpayer of digitising as much as possible of the clinical environment. Digitalising the capture of diagnostic images in clinical environments across the Australian health value chain will rely on the knowledge that each scanner covered by the TGA and that the manufacturer of the scanner, rather than its user, is responsible for its listing on the ARTG and in ensuring its accuracy and compliance with appropriate regulatory frameworks.

As the discussion paper rightly points out, inclusion of personalised medical devices in the ARTG is a necessary first step to facilitate reimbursement processes for some devices. Retention of accurate diagnostic scans of patients before, during and after treatment will be critical to device manufacturers seeking to make the case for reimbursement.

Recommendation: 3DMEDiTech recommends that the TGA clarifies their intent in relation to digital scanners and that it be made clear that such devices will be classified as Class IIa.

Proposal 5: Regulation of medical devices with a human origin element

Whilst medical devices with a human origin element are neither 3DMEDiTech's focus nor expertise, the proposal to align the regulation of devices incorporating such elements but not wholly compromised of them with the European and Canadian classifications is one which we support. Harmonisation with other jurisdictions supports Australian companies' capacity to export and build the markets necessary both for growth and to support innovation.

3DMEDiTech also notes with interest the section in proposal five that indicate that the abridged assessments could be undertaken. 3DMEDiTech strongly supports this concept and considers that it should not be limited to medical devices with a human origin component but rather utilised across the entire breadth of medical devices as suggested in our comments in relation to proposal one. This would both utilise the TGA's expertise to its full extent and support Australian manufacturers in accessing markets in a timely manner.

Proposal 6: Modifications or adaptations must be intended by the original manufacturer

3DMEDiTech's personalised medical devices are designed, customised and manufactured so as to avoid the requirement for later alteration by a clinician. 3DMEDiTech supports the notion that any modifications or adaptations to personalise a medical device that has already been supplied must be in line with the intent of the original manufacturer. This is necessary to ensure that the device performs in the manner intended, giving certainty and confidence to patients but also to those manufacturers whose products may be modified and who should not be held responsible for any adaptation or modification of their product beyond that for which they planned.

This change will need to be carefully worded to ensure that it is clear precisely how this will operate and when the exclusion from being considered a manufacturer and taking on the responsibilities of a manufacturer will occur. This is particularly so given, as the consultation paper notes, the multifactorial process now in place for many of these devices. Without this clarity, however, both the original manufacturer and the individual or organisation adapting the device are at risk and questions about responsibility would be unresolved.

Recommendation: *3DMEDiTech would recommend wording this proposed change carefully to ensure that there is clarity about responsibility and when responsibility for a device moves from the original manufacturer to the individual or organisation who has modified or adapted it.*

A series of case studies such as that incorporated in the consultation paper may assist with this.

Benefits of the proposed changes

The proposed regulatory changes confer the certainty and consistency necessary for the 3D-printed medical device industry in Australia to move forward with confidence knowing that issues of risk, patient safety and overarching responsibility are well managed and well regulated.

Harmonising our regulations with other jurisdictions also enables companies to further progress and expand export plans and supports the capacity for the Australian industry to innovate and compete internationally.

Confidence in any regulatory system is critical to achieving these goals and 3DMEDiTech commends the TGA on their approach to these issues.

Regulatory impact

3DMEDiTech has long supported rigorous regulation of the 3D-printed medical device industry in order to support patient safety and industry growth. Given this, none of the proposed changes in the consultation paper are overly challenging in terms of compliance or other costs. 3DMEDiTech welcome the more stringent requirements being proposed and trusts that they will come into being shortly.

These regulatory changes will be positive for the industry and for patients and companies and organisations manufacturing 3D-printed medical devices should be able to comply reasonably readily. Those who cannot comply readily should be viewed with suspicion as the requirements outlined in the consultation paper are not onerous nor unreasonable considering the use to which the devices in question are put.

That said, there are some observations that should be made regarding how the proposed changes will impact manufacturers such as 3DMEDiTech. These include:

- Conformity Assessment Evidence

  It is important that mutual recognition is established with other jurisdictions in relation to Conformity Assessment Evidence and processes. Clarification about how this will work during the transition period from the current state to the environment in which the proposed changes are in operation is also important given the fact that many products that will be subject to these regulations are already on the market.

  It is also critical that the concept informing the idea of abridged assessments whereby jurisdictions share information and shorten time to market is not limited purely to those devices with a human origin element. Supporting mutual recognition and facilitating timely access for patients is a goal that should be held across all forms of 3D-printed medical devices and 3DMEDiTech looks forward to working with the TGA to ensure that goal can be achieved.

- ARTG status

  Clarification would also be useful in relation to the timing of submissions for inclusion on the ARTG and likely timeframes for approvals. Identifying and communicating a pre-application process is also essential, particularly during the transition period when these products will continue to be sold and supplied to patients.

- New processes required for compliance with the new regulations

  Given the extent of the proposed changes, there will undoubtedly need to be new processes designed and implemented to ensure that the new regulations are clearly understood and that companies are able to comply with them. The importance of these regulatory changes, both to support patient

safety and the 3D-printed medical device industry, means that these processes should be identified and rolled-out as soon as possible.

- Administration costs

  As highlighted above, whilst there are undoubtedly administration costs associated, both for government and industry, in introducing these regulatory changes and implementing them, these are not prohibitive and are in fact essential to the safe and effective operation of the sector in Australia. Companies overly concerned with compliance and administration costs of these regulations needed to be considered carefully as it suggests that they may be behaving in a manner that questions their license to operate.

- Timeliness of implementation

  Given the work being done in relation to 3D-printing globally and the regulatory changes being introduced elsewhere, it is critical that Australia acts now to introduce an appropriate regulatory framework for 3D-printed medical devices.

  By doing so, patient safety will be enhanced and Australia has the opportunity to firmly establish a clear environment that gives businesses certainty about the future of their operation and enables them to maximise their export potential whilst assuring the ongoing viability of the industry in Australia.

Time to implement

3DMEDiTech has long aligned itself with the strong regulatory approaches adopted elsewhere. As a result, while some changes will be needed to comply with new reporting requirements and conformity assessments, this will not take significant time to implement once there is clarity and agreement about the information required and the processes established.

It is critical however and as outlined above that implementation of these initiatives begins immediately. Establishment of a new regime by the end of this calendar year would be ideal with full implementation no more than six months later.

Conclusion

As always, 3DMEDiTech appreciates the opportunity to provide input to the TGA's consultations and welcomes greatly the approach the TGA has taken on this critical issue. We appreciate the additional clarity that has been provided within this consultation paper and support this as it recognises the changing nature of the industry, protects patients and public safety and hopefully will eliminate rogue operators who undermine the credibility and viability of this industry, putting at risk the benefits it can generate for patients and the Australian economy.

3DMEDiTech commends the TGA on recognising the significant changes to 3D printing industry and supporting regulatory change that will provide ongoing protection to patients and the public. We look forward to ongoing dialogue and interaction with the TGA as the proposed regulatory changes are introduced and implemented.

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