3DMEDiTech™
Customised healthcare solutions

PRODUCTS USED FOR AND BY PEOPLE WITH DISABILITIES

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

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Overview

3DMEDiTech welcomes the opportunity to respond to the TGA's consultation paper *Products used for and by people with disabilities* and looks forward to continuing our engagement with the TGA in relation to the issues contained therein.

3DMEDiTech has provided submissions to a number of TGA consultations regarding the regulation of medical devices and welcomes the current consultation paper. Given 3DMEDiTech's portfolio, our comments to the current consultation are limited and relate solely to the regulation of prosthetic and orthotic devices.

It is important in this consultation, as with the earlier consultations to which 3DMEDiTech has responded that the proposed regulatory scheme delivers the regulatory control necessary to deliver patient safety and supporting a business environment that will encourage innovation and investment. The changes in technology for digital scanning, 3D printing and the rapid development of machine learning and complex proprietary algorithms have rapidly altered the realities of the prosthetic and orthotic market.

To maintain an effective system for patient safety during this period of rapid technology-led change, it is more important than ever that prosthetic and orthotic devices should be recognised as "medical devices" and regulated as such. This aligns with proposals outlined by the TGA in their 2017 consultation paper *Proposed regulatory changes related to personalised and 3D printed medical devices* and changes to the regulation of products used for and by people with disabilities should not inadvertently undermine the intent and direction of the earlier consultation.

About 3DMEDiTech

3DMEDiTech is a Melbourne-based company which aims to deliver world class Personalised Medical Devices utilising 3D printing and manufacturing services 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 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.

Response to the consultation paper

Purpose

3DMEDiTech supports the ongoing work that the Therapeutic Goods Administration (TGA) is undertaking in reforming and strengthening the regulation of medicines and medical devices in Australia and providing clarification where regulations and definitions require it. Certainly, unless necessary for patient or public safety, products should not be subject to regulation and, in addition, any regulation should be appropriate to the risk posed by particular products. The overarching aim should be an effective and clear regulatory system.

To this end, the consultation about which products might be better regulated by systems other than the TGA's and the reclassification of products where there is little or no risk to consumers where products malfunction or not perform as specified is a logical next step of this reform work.

Clarifying the definitions

Given this, 3DMEDiTech welcomes the work being undertaken to improve clarity in relation to products intended for use by people with disabilities and redefining "household aids, or furniture or utensils, for people with disabilities" as "assistive technology" where these items, products and equipment are used to help people with disabilities in their daily living.

At the same time, 3DMEDiTech notes, as does the consultation paper, that this does not entirely clarify which of these items and equipment need regulatory oversight and therefore specifying this is necessary. This is particularly the case where safety is involved.

Prosthetic and orthotic devices

At present, prosthetic and orthotic devices are mentioned in the consultation paper as potentially being captured with the definition of "household and personal aids, or furniture and utensils for people with disabilities" and thus potentially could be excluded goods for the purposes of the *Therapeutic Goods Act.*

At the same time however, other changes recommended by the TGA, including in the 2017 consultation paper *Proposed regulatory changes related to personalised and 3D printed medical devices* mean that custom made devices, including prosthetic and orthotic devices, will in future require pre-approval by the TGA and be included in the ARTG. This level of regulation is appropriate and should be welcomed by the sector.

In addition to clarifying the status of custom made prosthetic and orthotic devices, the changes proposed by the TGA to the definitions for personalised and 3D printed devices will also bring some of the lower quality or lower scale activity within the value chain within a more meaningful and appropriate regulatory regime and uphold the TGA's essential principles of medical safety, efficacy, quality control and so forth.

3DMEDiTech is aware that the low-cost barriers to entry level 3D printers and materials have encouraged a number of individuals and/or companies within the "maker movement" to attempt the creation of prosthetic and orthotic devices, 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.

It is important that the changes that are made in relation to products used for and by people with disabilities do not inadvertently change or undermine the other advances that the TGA are making in relation to their proposed regulatory changes to personalised and 3D printed medical devices.

As such, and in light of activity such as that outlined in the case study below, 3DMEDiTech urges that both customised and personalised prosthetic and orthotic devices be regulated as medical devices. This is also in line with the definitions on page 8 of the consultation paper where regulated medical devices are defined as those used for:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease;
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability; or
- Investigation, replacement or modification of the anatomy or of a physiological process.

Further, ensuring that these devices are regulated, and where appropriate registered, as medical devices reflects the intent of other TGA consultations and documents that clearly aim to ensure that personalised medical devices are registered on the ARTG. Given this, developing an appropriate pathway from the customised device environment to that of the ARTG is also critical and should be a priority.

This means that we are strongly recommending against the inclusion of prosthetic and orthotic devices as being suitable for inclusion in any amendment to the *Therapeutic Goods (Excluded Goods) Determination* 2018.

Case Study One - Re:Purpose for Good

One example of concern is Re:Purpose for Good. This organisation is aiming to manufacture low cost robotic prostheses from single use plastics and e-waste and is currently working on a prosthetic leg for someone who lost theirs to a rare cancer; a finger for a woman working in the army; and a hand for a child who was born without one. To begin making their products more widely available to the Australian public, they recently raised $10,000 on a crowd-funding website.

The company reports that the prosthetic is designed using 3D modelling for the mould, automation, programming and electronics. Waste plastic, like ABS and PET, is collected with examples indicated for ABS as being keyboards and Lego and for PET as water bottles and peanut butter jars. The materials are then shredded, washed and extruded into filament that is then used in the 3D printer.

Whilst no clinical input or oversight is mentioned, the company has already made a number of claims vigorously refuted by the Australian Orthotic Prosthetic Association (AOPA). These include that the currently available prostheses in Australia are impractical, expensive and can be painful. Further Re:Purpose for Good have also claimed that design in Australia is a 'one size fits all' approach and that 'more invasive surgery is required to make the prosthetics fit the person, instead of customising for their specific needs'.

These claims, and the processes described, strongly suggest that this manufacturing is in breach of both the current and proposed regulatory regime. This is of deep concern given patient vulnerability, the need to promote their safety above all else and the profile that is being taken by the organisation. Further, it raises serious questions about the enforcement of the current regulations which is not something, given the TGA's international reputation and the reliance that the Australia public has on them for their safety, that should continue. Enforcing regulations is as critical as writing them effectively.

Source: https://chuffed.org/project/repurposeforgood Accessed 28 November 2017

Case Study Two – Recycling shampoo bottles and bottle caps into prosthetic hands

Recently attention has been generated by organisations recycling shampoo bottles and plastic bottle caps to make prosthetic hands and limbs.

A trial in south east Queensland involving 38 salons in Gympie and on the Sunshine Coast sees one group picking up plastic bottles from hairdressers "and other types of plastic". It is then taken to a warehouse, sorted it and shredded. Bernie Craven, a retired hairdresser, then comments that they then "put it through the extruder and turn it into 3D filament, and then we print prosthetics with it".

These prosthetics, currently in trial phase, are being provided to children who have missing limbs and one recipient comments that he wants his in "Red and yellow, like the Broncos".

Envision Hands, another organisation, is on a mission "to create 100 bespoke aids out of bottle caps, with 3D printers, which we will then donate to children in in need". After "considerable experimentation", they have managed to take plastic from bottle caps and extruded it to create functioning filament for 3D printers. Once they have the filament, they 3D print the components to make up the hand.

Yet another organisation, led by retired engineer, Mat Bowtell, sees devices manufactured in his "man cave" on Phillip Island. With help from crowdfunding, he has 12 3D printers in his workshop and, earlier this month, was reported as being close to "fitting their first version of a $60,000 bionic hand that they have made with $50 of materials".

Sarah Anderson, Director of Academic Partnerships and Head of Prosthetics and Orthotics at La Trobe University's School of Allied Health Human Service and Sport, notes a number of problems with the approaches taken by these types of organisations. Highlighting some of the processes, she identies that some of the 3D printed hands "use a single web page to provides prescription advice about what sort of hand you should chose…similar to choosing a pair of shoes over the internet. You wouldn't send a one size fits all pair of shoes to the other side of the world expecting them to fit and work, so why are we sending a generic product that needs to be so specialised in the guise of helping".

She also highlights that people who get a prosthetic hand usually get it as part of a broader prosthetic limb – "they don't just get a hand and get sent off". Scans are taken of the remainder of their limb, a prosthetist then individually designs a socket which is fitted to that individual and it is that socket that the hand or other components are attached to in order to return function. This socket is critical and needs to be able to support hundreds of movements a day.

Limbs that don't fit properly or are poorly suspended are amongst the key reasons people stop using prosthetic limbs together with a lack of training in use and a lack of locally available repairs. This means that "these 3D printed hands…just won't do the job".

Finally she notes, whilst helping people feel like they are being useful in collecting bottle tops, chances are that, within a month to a year, the prosthetic hands will be broken or not worn because they don't deliver the functional outcomes needed. At worst, they will cause injury.

Sources: https://www.abc.net.au/news/2019-04-22/recycled-plastic-made-into-prosthetic-limbs/10992038; https://envision.org.au/envision-hands/; https://www.abc.net.au/news/2018-10-23/retrenched-engineer-makes-3d-prosthetic-limbs-for-free/10418050; www.Free3DHands.org; https://www.linkedin.com/pulse/bottle-top-hands-prosthetic-limbs-sarah-anderson/

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 this consultation paper is trying to achieve and the fact that it lists the type of products used by or for people with disabilities.

As orthoses and prostheses are defined as assistive technology, under option 1A or 1B of the consultation paper they would be excluded from TGA oversight and the requirement to meet the Essential Principles.

We believe that the risks arising from providing orthoses and prostheses without meeting minimum standards for device quality, safety and efficacy are significantly greater than the likely benefits. Without the regulatory safeguards relating to minimum standards specific to therapeutic devices there is increased likelihood of injury as a result of a device being poorly fitted, performing ineffectually or experiencing critical failure.

The changing nature of the devices industry, particularly the growing use and emergence of 3D printed devices and products, means that clarifying definitions and the regulatory regime is critical in order to protect patients and maintain public safety. Ensuring the closure of loopholes in regulations that enable the existence of 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, is vital. To do this, regulating the availability of customised and personalised prosthetic and orthotic devices is necessary.

We look forward to working with the TGA to achieve effective regulatory oversight.

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