30th March 2019

Therapeutic Goods Administration
Department of Health
PO Box 100
Wooden ACT 2606

Reference:

Consultation - Proposed regulatory scheme for personalised medical devices, including 3D-printed devices

Thank you for the opportunity to provide feedback.

ATSA in principle supports the proposed changes as it is consistent with ATSA's policy for international alignment of all Australian regulation for AT.

The only reservations on this proposal is the need for additional clarity so that the balance between level of risk and regulation is achieved. In addition, the regulation does not unintentionally increase the cost of compliance to the detriment of the supply of these very important devices.

Below ATSA has responded to the series of questions posed by the consultation paper;

1. ***Do you support the proposal to change the way personalised medical devices are regulated? Why or why not? If you do not support the proposal, do you have any suggestions for an alternative that would be acceptable to you?***

   ATSA is in principle supportive of the proposed changes as it will better align Australia to the common international approach in the regulation of medical devices.

   However, there are several concerns that may greatly impact the supply of Class 1 custom made/ patient matched device i.e. custom personal AT devices. The proposed changes as they stand may create barriers to supply especially for low cost solutions that utilise everyday materials that are lifechanging for the patient due to over regulation. The intentions of the proposed changes are supported but a balance is needed to be applied to ensure the intent is achieved, which does not create a high level of complexity and "minimising unnecessary regulatory burden".

Concerns

1. The proposed regulatory requirements for Class1 custom personal AT devices, as indicated would result in a significant administrative and financial burden for these low risk devices.
2. The cost to register has not been indicated however if the current Class 1 cost of $530 is applied, this would create a prohibitive cost for the supply of these types of devices.
3. There appears to be an approach to apply the same set of standards on all Classes of medical devices. If this is the case, ATSA questions how encompassing Class 1 devices without distinction can be described as "minimising unnecessary regulatory burden". In addition, how would the approach reduce public health risks if Class 1 devices are deemed as low risk.

   E.g. the level of compliance for an implantable device on the type of material used compared to a customised joy stick for a person with a hand control need. For the implant it is imperative (allergies, infection etc.) whereas the type of material for the joystick, is based on function (mechanical demands).
4. The quantity of Class 1 devices made annually would create an extreme level of documentation and demands for record keeping, based on the proposed approach.
5. The typical life expectancy of a Class 1 AT device is 5 years, therefore is record keeping for 15 years necessary?
6. The use of technology that profiles the patient's body for the development of AT items such as "shaped seating", the proposed rules are not clear. Depending on the approach adopted by the TGA there maybe unintended complexities introduced in the regulatory model, i.e. a mould taken of patient may be either adopted as the final shape of the product, alternatively it maybe the basis to a designed solution to aid the person's seating and medical needs. Clarity is required to determine if this is an issue or not.
7. If the understanding from the proposed regulation, Class 1 devices such as a manufactured(bespoke) lateral support using PVC and some foam from Dunlop, neither PVC nor the foam are registered materials on the ARTG. This would place the onus on the manufacturer of the custom personal AT devices to register with ARTG which is currently $530 per device. In addition, there are many operations across Australia who make custom devices using foam, plastics, metal etc. and this will have a substantial impact. The current requirements for custom made Class 1 devices is to have proper documentation in place but there is no requirement for registering them with TGA and we believe this should

continue as the risk associated with Class 1 custom made devices is very low.

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Possible Solution

Considerations to when an AT custom made/patient matched device is to fall under the Class 1 definitions, to reduce/limit what is necessary under the proposed reporting, in turn reduce the burden. This should be based on the risk profile of the AT device.

Considerations to a tiered approach for Class 1 low risk devices that are external to the body.

Consideration to register/licence the provider of Class 1 custom made/patient matched devices rather than the device.

Consideration that Class 1 AT devices should be exempt from using the MDPS and the current custom-made devices regulatory requirement. This will reduce the administrative burden on both TGA as well as the providers.

Further definitions of the elements of the proposal is required to assist in the identification of issues in this complex need

2. ***What do you consider to be the benefits and disadvantages of particular proposals for change?***

ATSA re iterates that alignment with international convention will benefit Australia plus assist in the universal approach with the supply of AT in Australia.

However, regulation should not be introduced beyond what is necessary for the safety of the user. The most important approach is to have proportionate regulation to match the risk profile of the device that is to be supplied regardless if it is one off, bespoke or mass produced.

The key to the success of this appropriate planned change, is to ensure the approach to the definitions of the categories of devices in relation to the Class of medical device, is balanced to when, where and how the device is used.

3. ***Do you believe there will be any unintended consequences arising from the proposed changes?***

Unfortunately, in the structured outline that has been presented there are several unintended consequences possible, the definitions will need to be carefully considered as this will have significant impact and may remove some if not all unintended consequences;

1. Due to the volume of AT custom made/patient matched devices made each year the cost to provide the level of records and reporting to the TGA will be high, therefore so will the cost of compliance will be high.
2. Length of holding the records from 5 to 15 years for Class 1 AT custom made/patient matched device in the context that most of these have a typical life of 5 years. This is due to changing needs, ware and tear, new technology that makes the device obsolete.
3. The viability of the supply for small low-cost items, may no longer be feasible. This is of great concern as often simple cost-effective solutions that are currently "doable" may no longer be "legal" within the context of this proposal. This is a result of the new compliance cost to the manufacture of the Class 1 device. The new supply cost will go beyond the material and labour as it needs to also cover the new compliance costs, i.e. the solution is no longer cost effective or affordable for the client. This will encourage "backyard" fixes as the client finds a person who is willing to provide the solution at a price they can afford.
4. The use of common materials that are not registered as a Class 1 device, i.e. the proposal in its current form would require nearly every known material to be registered on the ARTG or every AT custom made/patient matched device would have to be registered.

   E.g. foam that is used in every chair or couch, is also used for custom seating solutions in a wheelchair to manage the clinical needs of the user, Therefore, do you register the foam or the one-off seating solution? This also comes into play if a specialized joystick is crafted, from PVC, stainless steel. One could go on, but it is a real practical issue in the context of the proposal as it stands.

4. What changes would you need to make (if any) to meet the new arrangements? If not, what are the impediments?

ATSA is an industry body therefore the following comments are based on feedback that it has received from its members and associates;

Some of the changes that a business would potentially need to make would be:

- A process and procedure review that may result in the purchase of suitable software to manage the additional data
- Possible employment of additional staff to manage the level of compliance paperwork and records

- Identify additional resources to complete the data entry of all low risk Class 1 custom made devices into to the ARTG
- Make changes in the business databases to generate reports to TGA
- Educate relevant customer base of anticipated delays due to added paperwork and steps to meet the compliance requirements
- Increase the cost of supply to off-set the additional administration to supply Class 1 devices custom made/patient matched devices

5. ***What financial impact (both costs and savings) would implementing the proposed amendments have for you? If possible please provide a breakdown of the impacts. This information will be used to quantify the financial impact to all affected stakeholders.***

ATSA is an industry body therefore the following comments are based on feedback that it has received from its members and associates. The information provided is based on the Consultation paper. Dependant on additional clarification of the definitions these figures would likely change;

Most business estimate that for every bespoke device under the proposal as presented, it would add between 1 to 3 hours of work, based an estimate of an $55 average hourly rate, would add between $55 to $165 per device plus the cost to register, assuming the current Class 1 Fee of $530, then a cost impact range of $585 to $695 per device.

If you combine this to an average business who turn out around 2000 units per year, the resulting cost would be between $1.17Mill and $1.39Mill per business in compliance costs that would have to be recovered through the increase of charges to the client or funder.

This does not take in to consideration of any purchase new software or business process changes and required training.

6. ***What period would be needed for your organisation to implement the proposed changes? This information will be used to inform any transitional arrangements.***

The feedback ATSA received indicated that it would be greater than18 months. This timing reflects the need to rollout an education programme across the industry of the changes. Once the businesses that are affected fully understand the new requirements, it is likely that either changes to current computer systems would be applied, or new computers systems would need to be installed.

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