6th February, 2018

[redacted]
Business Improvement and Support Section
Medical Devices and Product Quality Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Re: TGA Consultation: Proposed regulatory changes related to personalised and 3D printed medical devices

In review of the TGA's Consultation paper on the "*Proposed regulatory changes related to personalised and 3D printed medical devices*" Stryker welcomes TGA's commitment to amend the current medical device regulations to ensure Australia has adequate controls in place to support the supply of safe and effective medical devices.

Stryker is also in support of the TGA's commitment to align the current Australian Medical device regulations with Europe to ensure that a consistent approach and framework can be applied to reduce the associated regulatory burden.

Below we have provided feedback to the proposal included in the TGA's consultation document.

Proposal 1: New definitions for personalised devices

Stryker is in support of the inclusion of the proposed terms and recommends further clarity in their definitions to provide a consistent interpretation across the industry.

Patient-specific medical devices:

As a patient-specific medical device may not always be based on a standard device template, we support the expansion of the definition to include "a predetermined design range".
i.e. *"a medical device based on either a standard device template or a predetermined design range…."*
We recommend guidance be issued regarding how to determine whether a process is capable of being validated. The proposed definition is ambiguous and may result in different determinations even though the device was manufactured via a similar process; for example, one manufacturer may have a validated process and supply the item as a "patient-specific medical device", whilst another manufacturer may not deem the process able to be validated, thus classifying the device not as a "patient-specific medical device' and therefore claim it as a "custom made medical device".

Mass produced medical devices:

There is insufficient detail in the proposed definition. This opens up the possibility that a single product run/batch producing a specific medical device in one day could perhaps be repeated for 10 days, thus manufacturing 10 units of the same specific device, yet claiming that the device is not mass produced and hence custom made. The TGA's intention is to exclude the above scenario from the custom made definition and it is therefore recommended to either redefine the term or amend the custom made definition to add an exclusion, which could also include reference to a mass produced customised medical device e.g. *"Medical devices that have previously been supplied /manufactured, regardless if they have been customised or are able to be customised shall not be considered to be custom made medical devices".*

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Stryker does not believe there is a need to introduce a limit to the number of custom made medical devices a manufacturer can supply in any given period. The custom made pathway is intended to reduce the regulatory burden for supply of medical devices intended to be used under limited circumstances. Adding a limit will only prevent patient access and potentially introduce a selection criteria that is not based on need.

Stryker also does not support the introduction of an application process for custom made medical devices as it unnecessarily increases the regulatory burden. If the TGA require additional controls we recommend adding additional detail/documentation to the notification process. If further controls are warranted the TGA could introduce an approval process for manufacturers of custom made medical device.

Proposal 2: Changes to the custom made conformity assessment procedure

In principle Stryker is in overall support of the TGA's recommended changes to the Conformity Assessment procedure for custom made medical devices. It is recommended that additional guidance be issued to define the scope of any audit and for this audit criteria to be aligned with the Medical Device Single Audit Program.

Proposal 3: Changes to the definition of manufacturer

Stryker supports the need to define a customised medical device and the need to update the current legislative definition of a manufacturer of medical devices. Stryker disagrees with the inclusion of 3b as this excludes a representative from the legal manufacturer or sponsor from providing the service of customising a medical device.

The proposal to create a new category of medical device under "medical device production system" has the potential to create confusion between manufacturing and a marketed product. Further clarity is required regarding this concept, especially in the assessment of the manufacturing quality requirements.

Proposal 4: New classification for anatomical models and digital 3D print files

The TGA's proposed changes to rule 5.4 will affect current medical devices that are intended to capture/ record general diagnostic images, which are currently class I in Australia (Part 4.1) and Europe (Rule 12).

If the intent is to capture these types of devices then it is recommended that a transition period be supportive of this change as the TGA is moving away from the European classification which would then require the current manufacturer/sponsor to obtain an Australian Conformity Assessment Certificate to continue to support the existing range of medical devices.

Proposal 5: New arrangements for devices with human material

We agree with the TGA's proposal to regulate devices containing material of human origin, both viable and non-viable, as Class III medical devices, in alignment with other jurisdictions.

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