Cook Medical Australia's comments to the Consultation Paper:

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

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Cook Medical Australia

Cook Medical, based in Bloomington, Indiana, USA, is one of the world's largest privately owned medical device companies. Throughout its 53 year history, Cook Medical has pioneered many of the medical devices currently used to perform minimally invasive medical procedures. The company has grown to now serve 13 specialties with over 16,000 products.

Cook Medical's Australian business, Cook Medical Australia, is based in Brisbane and employs more than 500 people in manufacturing, R&D, operational and sales capacities. The Brisbane facility is also Cook Medical's Asia Pacific (APAC) headquarters and provides support for the more than 1,000 staff across the APAC region. As a manufacturer, Cook is one of only a few medical device companies that continue to utilise Australia as a manufacturing base. From this facility, Cook Medical exports Australian made products to over 135 countries around the world. Through our R&D function, Cook Medical Australia has grown to become a centre of excellence for the design, development and manufacture of endovascular aortic devices and products designed for use in reproductive health.

Background

As a manufacturer and supplier of custom-made devices, Cook Medical welcomes the opportunity to comment on the consultation paper: *Proposed regulatory scheme for personalised medical devices, including 3D printed devices***.** Cook Medical manufactures a range of endovascular grafts to treat aneurismal disease of the aorta. Standard registered off-the-shelf products are only able to treat patients who fit the anatomical criteria for which the devices were designed. Consequently, Cook Medical manufactures custom-made endovascular grafts for patients whose anatomy or disease progression precludes treatment with standard off-the-shelf grafts. When a doctor prescribes a custom-made graft for their patient, the doctor's requirements and the patient's CT scans are provided to Cook Medical's Brisbane facility where these grafts are planned and manufactured (not utilising 3D printing). It is assumed that these custom-made endovascular grafts will continue to be considered custom-made devices under the TGA's proposed new definition.

Responses to applicable questions

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?
The proposed change to the way personalised medical devices are regulated is clear and is supported by Cook Medical. The following additional requirements for custom-made devices are applicable to the devices manufactured by Cook Medical and therefore the focus of this response: • *that the manufacturer's statement about a custom-made device is provided to the patient receiving the device* • *that the TGA be allowed to enter and inspect custom-made device manufacturing sites, in accordance with the authority it has to inspect all other medical device manufacturers* • *that a manufacturer in Australia, or a sponsor of an overseas-manufactured custom-made device, provides an annual report to the TGA of the custom-made devices it has supplied, and* • *that documentation about an implantable custom-made device is retained for a minimum period of fifteen (15) years; as the current specification of a five (5)-year retention period is considered inadequate.*

2. What do you consider to be the benefits and disadvantages of particular proposals for change?
Cook Acknowledges the benefits of the proposed regulatory changes, particularly as the changes align with international regulatory requirements, and specifically with the European MDR. The audit, record retention and reporting requirements align with MDR requirements for a conformity assessment based on quality system for custom-made devices. The benefit of these requirements, particularly in the case of high risk, implantable devices is improved patient safety, particularly for manufacturers not already under scrutiny as non-exempt medical device manufacturers.
3. Do you believe there will be any unintended consequences arising from the proposed changes?
While there will be some additional workload for manufacturers and sponsors, Cook Medical does not believe there will be any unintended consequences arising from the proposed changes.
4. What changes would you need to make (if any) to meet the new arrangement? If not, what are the impediments?
Manufacturers will need to implement the system for annual reporting and document retention. For manufacturers who are currently manufacturing high risk non-exempt devices, the changes required will be minimal.
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.
For a manufacturer currently supplying custom-made devices under the existing framework, and where those devices will remain as custom-made devices, the financial impact will include costs associated with annual reporting, hosting audit and record retention for 15 years for implantable devices where not already applied.

6. What period would be needed for your organisation to implement the proposed changes? This information will be used to inform any transitional changes.
The implementation timeline for the additional requirements for custom-made devices should align with the implementation of the European MDR. For custom-made devices under the EU MDR, compliance is required by May 2020.