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Submission to TGA Consultation:

Proposed clarification of the regulatory requirements for medical device systems and procedure packs

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About Device Technologies

Since 1992, Device Technologies has been dedicated to improving patients' lives through leading edge technology and services.

Successfully supplying hospitals and healthcare professionals with the finest medical solutions for their patients, Device Technologies continues to grow, with over 200 trusted brands and 850 highly skilled staff Australia and New Zealand-wide.

Leading the way in the medical technology field, Device Technologies provides the highest calibre of medical supplies – with innovation and client care at the core of its values. All products distributed by Device Technologies are compliant with quality and regulatory requirements, with in-servicing and ongoing support provided as part of the trusted partnership between Device Technologies staff and healthcare professionals.

Our Values

Here at Device Technologies, our values are linked to four key areas of our business: Innovation, Collaboration, Ownership, and Good Business.

Foremost, we support innovation and ingenuity, and we believe that by collaborating with the best in the business, we can deliver the finest technologies and results. We believe that good business relies on intuition and precision, and we back every decision with 100% ownership and support.

Submission Information

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Introduction

The Australian Government is undertaking a significant program of reform to the regulation of therapeutic goods in Australia. As part of the Australian Government Department of Health, the TGA regulates therapeutic goods, and is responsible for implementing the Government's reforms. The Therapeutic Goods Administration (TGA) has issued the consultation paper "Proposed clarification of the regulatory requirements for medical device systems and procedure packs" as part of the Government's reform program.

This Consultation

The TGA is considering the EU regulatory framework as an input into review and reform of the Australian regulatory requirements for systems and procedure packs medical devices including IVD medical devices. Furthermore, the consultation paper distinguishes the risk benefit profile of system and procedure packs.

The TGA is seeking feedback on:

Do you support the proposals for change in this document, why or why not?

In particular:

(a) the proposed definitions -system, procedure pack, and compatibility

(b) the proposed changes to the special conformity assessment procedure set out in Regulation 3.10 and Clause 7.5, Schedule 3, of the Australian MD Regulations

(c) the adequacy of the requirements for Records specified in Clause 7.6, Schedule 3, of the Australian MD Regulations, for SOPPs using the special self-declared conformity assessment procedure,

2. *If you do not support the proposed changes, do you have any suggestions for an alternative way to improve regulation of these medical devices?*

3. *If the proposed amendments take effect, what impacts—including any that we may not have anticipated and are therefore unintended—do you anticipate the requirements may have for yourself and other stakeholders (such as consumers, healthcare professionals, health organisations, industry etc.)?*

4. *Are there any groups/categories of systems or procedure packs (e.g. - IVD systems, orthopaedic loan kits) that should be given particular consideration?*

5. *Are there any further issues and questions we should consider when implementing these changes (including areas that can/should be clarified in our guidance)?*

Do you have any comments regarding the transitional arrangements proposed in this paper?

Device Technologies' Response

Device Technologies is submitting this response in order to emphasise some aspects and provide nuances that may be worth clarifying for better understanding and implementation by the industry.

1. Do you support the proposals for change in this document, why or why not?

In particular:

(a) the proposed definitions -system, procedure pack, and compatibility

Device Technologies supports the proposed definitions of system, procedure pack, and compatibility, as they align with the EU MDR. These definitions provide clarity on the terms and help in harmonisation with European requirements.

However, it is noted that the TGA has not considered alignment of definitions with other jurisdictions such as the FDA and Health Canada. Since the TGA now accepts comparable overseas regulators (CORs) such as the US FDA, Health Canada and Japan's Ministry of Health and given the differences in requirements for SOPP in these jurisdictions it would be beneficial for the industry if the TGA provides further guidance on the their expectation with other comparable overseas regulatory systems, not only Europe.

(b) the proposed changes to the special conformity assessment procedure set out in Regulation 3.10 and Clause 7.5, Schedule 3, of the Australian MD Regulations

We agree with the proposed change to clarify the existing and introduce additional requirements Regulation 3.10(3) and Clause 7.5, Schedule 3, of the Australian MD Regulations.

However, further clarity and guidance is required to ensure manufacturers understand and can reliably implement the new requirements in terms of what constitutes a "conformity assessment document from a comparable overseas regulator". For example, in scenarios where the SOPP manufacturer has medical device components approved by different jurisdiction e.g. MDSAP certificate in combination with FDA 510k or Health Canada license instead of or as well as CE mark.

(c) the adequacy of the requirements for Records specified in Clause 7.6, Schedule 3, of the Australian MD Regulations, for SOPPs using the special self-declared conformity assessment procedure,

We recommend that the proposed requirements for Records specified in Clause 7.6, Schedule 3, of the Australian MD Regulations, for SOPPs using the special self-declared conformity assessment procedure should be reviewed further to be aligned with comparable overseas regulators.

2. If you do not support the proposed changes, do you have any suggestions for an alternative way to improve regulation of these medical devices?

We agree with the proposed changes in context of alignment with the EU MDR however, we are concerned that there is lack of harmonisation with other CORs such as the FDA, Health Canada and Japan's Ministry of Health.

We suggest that the TGA specifically clarifies what will be expected for SOPPs containing components which have been assessed, by the FDA, Health Canada and Japan's Ministry of Health.

3. If the proposed amendments take effect, what impacts—including any that we may not have anticipated and are therefore unintended—do you anticipate the requirements may have for yourself and other stakeholders (such as consumers, healthcare professionals, health organisations, industry etc.)?

Depending on how they are implemented, the proposed amendments to Regulation 3.10 may restrict manufacturers of SOPP who have components supported by different conformity assessment documents. This would be common for local manufacturers, and is expected to increase now that the TGA does accept evidence of conformity from comparable overseas regulators.

For example:

- 'SOPP' is Class IIb and contains:
    - 1 implantable device CE marked, manufactured by Company A
    - 1 instrument with MDSAP certification and FDA 510K approval, manufactured by Company B
    - 1 instrument with MDSAP and Health Canada Medical Device Licence, manufactured by Company C.
- Manufacturer B and C do not supply in Europe, so there is no CE mark for the instruments.
- Will the SOPP manufacturer be able to use these overseas conformity assessment documents to declare compliance with the TGA Clause 7.5?

4. Are there any groups/categories of systems or procedure packs (e.g. - IVD systems, orthopaedic loan kits) that should be given particular consideration?

Orthopaedic, as well as other surgical loan kits (i.e. as described on page 7 of the consultation paper, also referred to as 'sterile surgical procedure packs') should be excluded from the requirements of Regulation 3.10(3) and Clause 7.5, Schedule 3, of the Australian MD Regulations. As described on page 7, these loan kits contain 'multiple optional components that may or may not be used together' and are supplied as individual medical devices.

5. Are there any further issues and questions we should consider when implementing these changes (including areas that can/should be clarified in our guidance)?

Although the consultation paper refers to comparable overseas regulators (CORs), there is lack of harmonisation with other jurisdiction such as the FDA, Health Canada and Japan's Ministry of Health.

- The FDA still uses the term "convenience kits". According to FDA 21 CFR 801.3 "convenience kit means two or more different medical devices packaged together for the convenience of the user." This is a bit like a procedure pack, although the definition of a procedure pack does not specify whether the packaging together of the medical devices is for convenience or not. The devices packaged together in a convenience kit are not necessarily (all) used for a single medical purpose. In

addition, according to the proposed TGA definition (aligned with EU MDR) procedure pack is a combination of products with at least one medical device whereas FDA's states two or more different medical devices.

- Again, there is a lack of alignment with Health Canada. According to Health Canada Guidance Document, SOPPs are registered as a "medical device group" or "system". A medical device group - means a medical device group is comprised of a collection of medical devices, such as a procedure pack or tray, which is sold under a single name. Examples include: a denture repair kit, a declotting tray, a parenteral administration kit or disposable circumcision tray. A system is a medical device comprising a number of components or parts intended to be used together to fulfil some or all of the device's intended functions, and that is sold under a single name and are manufactured by the same manufacturer. Examples include hip prostheses, knee prostheses or an ultrasonic imaging system.

We recommend that the TGA specifically clarifies what will be expected in Australia for SOPPs, which have been assessed, by the FDA, Health Canada and Japan's Ministry of Health.

6. Do you have any comments regarding the transitional arrangements proposed in this paper?

We acknowledge and support the transitional arrangement proposed in this paper, which aligns with the implementation of EU MDR.

Device Technologies appreciates the ongoing engagement and opportunity for input into the TGA's proposal for clarification of regulatory requirements for medical device systems and procedure packs. Should you have any questions regarding our consultation feedback, we welcome the opportunity to discuss further.