31.10.2019

Therapeutic Goods Administration
Medical Devices Reform Unit
Medical Devices Branch
Medical Devices and Product Quality Division
Health Products Regulation Group
Australian Government Department of Health

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

We would like to thank the TGA for allowing Sage Medical Pty. Ltd. (Sage) the opportunity to provide feedback on proposed changes to the current regulatory requirements applied to system and procedure packs (SOPPs).

Sage has been manufacturing sterile surgical procedure packs for over 25 years and has a long history with the healthcare sector in Australia. As an Australian manufacture we are conformity assessed by the TGA, in addition to conformity assessment by an EU NB.

As per our quality policy, we continually strive to provide surgical procedure packs both medicated and non-medicated that are fit for their intended purpose, aid the end user and are safe and effective for the patient.

Our responses to the questions in the consultation paper are outlined below;

1[a] Sage Medical **supports in principle** the inclusion of specific definitions for -system, procedure pack, and compatibility.

Where possible, alignment of regulations in a global harmonisation approach generally benefits both medical device manufacturers and the end user/patient.

However, as detailed on pp 6 & 7 of the consultation paper, first aid kits for consumers and first aid kits for professionals are quite different and could be differentiated. A first aid kit for consumers is essentially a "kit" of useful items used in simple emergency situations, while a first aid kit for professionals is a "procedure pack", where invasive devices are supplied to the professional to undertake a procedure.

Therefore professional first aid kits would still fall under the definition of "procedure pack", and be called a procedure pack, while a consumer first aid kit would be defined as a "kit". Subsequently, should a "kit" be considered as a SOPP or should this type of generally lower risk medical device have its own specific category?

1[b] Sage Medical **supports in principle** the proposed changes to the special conformity assessment procedure set out in Regulation 3.10 and Clause 7.5, Schedule 3, of the AU MD Regulations.

As manufacturers are utilising the Notified Body pathway for conformity assessment to supply product into Australia, then this approach makes sense.

However, should consideration be applied for further clarification or sub category into the definition of a Manufacturer - for example, during the workshop on "Systems and Procedure packs" held at the TGA, Symonston earlier this year, some groups identified the possible need to differentiate between a Manufacturer and an Assembler.

A Manufacturer would hold conformity assessment by the TGA or comparable overseas regulator, because they either modify original equipment manufacturer device(s), or undertake sterilisation of the system or procedure pack, and have the supporting validation evidence, and/ or agreements from the original equipment manufacturer(s) to support these processes.

While an Assembler is an legal entity whom assembles, for example, first aid kits for the consumer market where no sterilisation of the finished kit or modification to the included items has been undertaken, and would be required to make a Declaration of Conformity in relation to the items that make up the kit and that the items have been individually conformity assessed if above class I classification.

1[c] Sage Medical **supports** consideration into whether the required retention period of 5 years is adequate.

The record retention period required by manufacturer's for a type of medical devices is based on the device risk classification. For example, and implantable class III medical device will have a longer record retention period than a non-invasive class Is device. The same record retention period should apply to the type of medical device and risk classification of the SOPP.

2. Sage Medical **supports in principle** the changes proposed with further suggestions in answers 1[a] and 1[b] above.

3. Impacts that may be come from these amendments for industry may include;

- Original equipment manufacturers not willing to draw up specific agreements with SOPP manufacturers on validated processes due to confidentiality or IP issues. This in turn could impact the supply of a SOPP that has been supplied to market without issue prior to this change in requirement.
- Original equipment manufacturers may not be aware their devices are being used in SOPP's currently manufactured by a third party, as basic components of a pack can be purchased via suppliers, including online suppliers.
- SOPP manufacturers not able to obtain conformity assessment certificates from the original equipment manufacturer.

In view of these points above, small backyard enterprises will be 'weeded out' of the medical device industry, and in-turn reducing the risk to the end user/patient, which is considered a positive outcome.

4. As mentioned in 1[a] and 1[b] above, should consideration be given into whether a first aid kit which is supplied for consumer use, be considered as a procedure pack and where the legal entity is a manufacturer.

5. i) In referring to p15 of the consultation paper, the last sentence in paragraph two states, "This means that goods supplied sterile, with the original labelling stating that the good should not be re-sterilised, cannot be included in a SOPP that is using the *medical devices used for a special purpose* pathway." –

What is the result of this requirement if the goods' manufacturer has not indicated this with the original device labelling?

For example, ARGMD Essential Principle 13 (EP 13) requires manufacturers to indicate on the labelling of the device whether the device is supplied sterile with the word 'STERILE' and information about the method used. EP 13 also requires manufacturers to indicate on the labelling whether the medical device is single use only. While Clause 7.5 of the ARGMD addresses pre-sterilised components in sterile SOPPs, EP 13 does not clearly address re-sterilisation statements on device labelling. Single use only does not imply do not re-sterilise. Single use is implied around contamination control, to be used on one patient

only. Additionally in ISO 15223-1 there are specific symbols to differentiate between single use and do not re-sterilise. Experience has shown that not all manufacturers who supply sterile devices indicate on the labelling, either a statement or symbol stating the device cannot be re-sterilised.

With this in mind, should further clarification of the interpretation by the TGA be applied to the above sentence on p15 of the consultation paper?

ii) Would the TGA consider under an MoU with the EU the possibility to issue MDR EC certificates for SOPP manufacturers in Australia?

6. Sage Medical **supports in principle** the transitional arrangements as these align with the EU MDD to MDR transition timeframes for existing SOPP manufactures currently holding ARTG certificates.

However we believe caution should be made to the applied regulations in practice that the EU MDR signifies. While the evolution of the medical device regulations in any jurisdiction is a natural progression, the true implications and impacts of those changes are generally not realised for some time.