



Australian Government
Department of Health
Therapeutic Goods Administration

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

V1.1 October 2019

TGA Health Safety
Regulation

Copyright

© Commonwealth of Australia 2019

This work is copyright. You may reproduce the whole or part of this work in unaltered form for your own personal use or, if you are part of an organisation, for internal use within your organisation, but only if you or your organisation do not use the reproduction for any commercial purpose and retain this copyright notice and all disclaimer notices as part of that reproduction. Apart from rights to use as permitted by the *Copyright Act 1968* or allowed by this copyright notice, all other rights are reserved and you are not allowed to reproduce the whole or any part of this work in any way (electronic or otherwise) without first being given specific written permission from the Commonwealth to do so. Requests and inquiries concerning reproduction and rights are to be sent to the TGA Copyright Officer, Therapeutic Goods Administration, PO Box 100, Woden ACT 2606 or emailed to <tga.copyright@tga.gov.au>.

Confidentiality

All submissions received will be placed on the TGA's Internet site, unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked "IN CONFIDENCE". Reasons for a claim to confidentiality must be included in the space provided on the TGA submission form. For submission made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA's Internet site. In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission form.

Contents

Introduction	5
Background	5
Prior consultation	5
What are systems and procedure packs?	6
Systems	6
Implantable ventricular circulatory assist system	6
Blood glucose monitoring system (IVD medical device)	6
Procedure packs	6
First aid kits	6
Sterile surgical procedure packs	7
Current regulatory requirements	8
Current SOPP requirements in Europe	8
Current SOPP requirements in Australia	10
SOPPs as medical devices	10
SOPPs as ‘medical devices used for a special purpose’	11
Why change the regulations?	12
Examples of risks and issues associated with specific categories of devices	12
Issues with procedure packs such as first aid kits intended for consumers	12
Issues with sterile procedure packs including those containing medium or high-risk devices	13
Proposed amendments	14
1. Add new definitions	14
Proposed amendments	14
2. Clarify the requirements for SOPPs that are medical devices used for a special purpose	15
Regulation 3.10 - <i>medical devices used for a special purpose</i>	15
Declaration of conformity - clause 7.5	17
Benefits	18
Impact	18
What will change for manufacturers	18

What will change for sponsors _____	19
Transitional arrangements _____	19
Fees and charges _____	19
Engagement _____	19
Feedback notes _____	20
What we invite you to do _____	20
Questions _____	20
How to submit _____	21
Enquiries _____	21
Appendix – Comparison analysis of EU Regulations, Australian MD Regulations and the proposed changes	22
Definitions related to systems and procedure packs _____	22
Conformity assessment applied to SOPPs that are medical devices used for a special purpose _____	24

Introduction

The Australian Government endorsed a significant program of reform to further strengthen the regulation of medicines and medical devices in Australia. As part of the Australian Government Department of Health, the Therapeutic Goods Administration (TGA) regulates these products, and is responsible for implementing the Government's reforms.

In 2015, the Report of the *Expert Panel Review of Medicines and Medical Devices Regulation* (MMDR) made 58 recommendations for reform of the regulatory framework for medicines and medical devices in Australia. The [Australian Government Response to the Review of Medicines and Medical Devices Regulation](#) was released in September 2016. The Government accepted 56 MMDR recommendations including Recommendation Twenty¹ which addressed matters within the remit of the TGA. This Recommendation provided that the regulation of medical devices, wherever possible and appropriate, align with the European Union (EU) framework.

The focus of this paper is to obtain feedback on proposed changes to the current regulatory requirements applied to systems and procedure packs. The proposed changes in this consultation apply to medical devices, including IVD medical devices in Australia.

On page 20 there is a [list of questions](#) to help you address the proposal in your feedback.

Please refer to page 20 on [How to submit your feedback to the TGA](#).

This consultation paper considers the EU regulatory framework as an input into the review and reform of the Australian regulatory requirements for systems and procedure packs medical devices including IVD Medical devices.

Background

Medical devices are regulated in Australia having regard to the risks (to the individual or public health) considered in the context of the device's intended use. All devices carry some level of potential risk, and the TGA applies scientific and clinical expertise to ensure our assessments and decisions are made based on the balance between the benefits and the risks.

Regulatory requirements are periodically reviewed to ensure they continue to be appropriate. When undertaking such reviews, the TGA has regard to, among other things, the international best regulatory practices and any emerging issues.

This will ensure sustainability of the Australian regulatory system for medical devices, appropriateness and robustness of assessments and timeliness of access to medical devices.

Prior consultation

On 8 February 2019, the TGA held a stakeholder workshop to discuss a range of known issues related to systems and procedure packs. The participants included representatives from industry, clinicians, health organisations, emergency services, state and territory government purchasing organisations and consumer advocacy groups. The participants discussed different viewpoints relating to manufacturing, supply and use of systems and procedure packs, and potential reforms to the regulation of these medical devices. The outcomes from that workshop have been used to inform the preparation of this consultation paper.

¹ Sansom L, Delaat W, Horvath J. Review of Medicines and Medical Devices Regulation: Recommendations to the Minister for Health on the Regulatory Frameworks for Medicines, Medical Devices, Complementary Medicines and Advertising of Therapeutic Goods, July 2015, p. 10.

What are systems and procedure packs?

A *system or procedure pack (SOPP)* is a package containing therapeutic goods, at least one of which is a medical device or IVD medical device. The goods are put together for use as a unit either in combination as a system or for use in a medical or surgical procedure².

There are many different types/categories of SOPPs currently available on the market. These devices can be marketed under different names, such as 'system', 'kit', 'pack', 'tray', etc.



Please note

Under the *Therapeutic Goods Act 1989* a 'system' or 'procedure pack' is defined to be a medical device and is regulated as a medical device.

Examples of SOPPs are provided below.

Systems

Implantable ventricular circulatory assist system

A portable assembly of devices intended to provide mechanical assistance to a heart ventricle, typically by pumping blood from the left ventricle to the aorta through an extra-cardiac circuit. It includes an implantable pump, implantable connecting cannula and or grafts, a percutaneous electrical lead, and external electronic components (e.g., battery pack, controller). It is typically intended to be used as a bridge to heart transplantation.

Blood glucose monitoring system (IVD medical device)

A non-continuous blood glucose monitoring system is a medical device intended to be used for monitoring blood glucose levels in patients with diabetes. A blood glucose monitoring system may consist of a blood glucose meter that connects to a smart phone, a software app, blood glucose test strips, blood glucose controls, and lancets.

Procedure packs

First aid kits

First aid kits are medical devices that are put together as a unit and contain a collection of equipment and materials intended to be used in an emergency for the rapid, initial treatment of an injury. These devices are intended for use by:

- Emergency medical service officers,
- First aid officers in different institutions or in schools,
- Consumers at home, in motor vehicles or in other public settings.

² *Therapeutic Goods Act 1989*, s.41BF

A first aid kit for consumers may contain (but is not limited to): bandages, tweezers, pain-relief tablets, adhesive strips, and swabs, while a professional kit may include invasive devices such as intravenous access catheters.

Sterile surgical procedure packs

Sterile surgical procedure packs are medical devices intended for use in hospitals by healthcare professionals. These packs are put together as a unit and contain some or all of the necessary materials to perform a surgical procedure. As these packs are to be used in sterile surgical settings, it is essential that the sterility of the entire pack and its components are maintained. Sterile surgical procedure packs may contain (but are not limited to) the following contents: clamps, drapes, sutures, needles, forceps, scalpels, gauze and dressings.

Please note



Manufacturers sometimes describe a set of different devices under the common name of a '*system*', even when they are referring to multiple optional components that may or may not be used together, rather than a defined set of items that must be used together to achieve their intended purpose. For example, joint replacement medical devices are often marketed as a '*system*'. However, device components of such a '*system*' are not intended to always be used together. Instead, the '*system*' provides a surgeon with a choice of optional devices that are compatible and are selected to suit a particular patient.

For the purpose of the therapeutic goods legislation, such products are not considered systems or procedure packs and are not considered in this consultation paper. However, each individual component is a medical device and therefore must meet all relevant regulatory requirements.

Current regulatory requirements

Current SOPP requirements in Europe

The [EU Regulation on medical devices 2017/745](#) (EU MD Regulation) specifies the requirements that govern the regulation of SOPPs. The EU regulation on IVD medical devices 2017/746 (EU IVD Regulation) does not include a definition of system or procedure pack.

Article 2 Definitions

(10) Procedure pack means a combination of products packaged together and placed on the market with the purpose of being used for a specific medical purpose.

(11) System means a combination of products, either packaged together or not, which are intended to be interconnected or combined to achieve a specific medical purpose.

Article 22 Systems and procedure packs

1. Natural or legal persons shall draw up a statement if they combine devices bearing a CE marking with the following other devices or products, in a manner that is compatible with the intended purpose of the devices or other products and within the limits of use specified by their manufacturers, in order to place them on the market as a system or procedure pack:
 - (a) other devices bearing the CE marking;
 - (b) *in vitro* diagnostic medical devices bearing the CE marking in conformity with Regulation (EU) 2017/746;
 - (c) other products which are in conformity with legislation that applies to those products only where they are used within a medical procedure or their presence in the system or procedure pack is otherwise justified.
2. In the statement made pursuant to paragraph 1, the natural or legal person concerned shall declare that:
 - (a) they verified the mutual compatibility of the devices and, if applicable other products, in accordance with the manufacturers' instructions and have carried out their activities in accordance with those instructions;
 - (b) they packaged the system or procedure pack and supplied relevant information to users incorporating the information to be supplied by the manufacturers of the devices or other products which have been put together;
 - (c) the activity of combining devices and, if applicable, other products as a system or procedure pack was subject to appropriate methods of internal monitoring, verification and validation.
3. Any natural or legal person who sterilises systems or procedure packs referred to in paragraph 1 for the purpose of placing them on the market shall, at their choice, apply one of the procedures set out in Annex IX or the procedure set out in Part A of Annex XI. The application of those procedures and the involvement

of the notified body shall be limited to the aspects of the procedure relating to ensuring sterility until the sterile packaging is opened or damaged. The natural or legal person shall draw up a statement declaring that sterilisation has been carried out in accordance with the manufacturer's instructions.

4. Where the system or procedure pack incorporates devices which do not bear the CE marking or where the chosen combination of devices is not compatible in view of their original intended purpose, or where the sterilisation has not been carried out in accordance with the manufacturer's instructions, the system or procedure pack shall be treated as a device in its own right and shall be subject to the relevant conformity assessment procedure pursuant to Article 52. The natural or legal person shall assume the obligations incumbent on manufacturers.
5. The systems or procedure packs referred to in paragraph 1 of this Article shall not themselves bear an additional CE marking but they shall bear the name, registered trade name or registered trade mark of the person referred to in paragraphs 1 and 3 of this Article as well as the address at which that person can be contacted, so that the person's location can be established. Systems or procedure packs shall be accompanied by the information referred to in Section 23 of Annex I [...]

The requirement for each medical device in a pack to have a CE mark means that the manufacturers of each of the individual medical devices in the pack assume responsibility for the safety of the medical devices and their compliance with the medical device legislation³.

When a procedure pack contains medical devices without a CE mark, or if the compliance guaranteed by the original manufacturer of a CE marked device has been compromised by actions such as removing original packaging, not providing original instructions for use, or sterilising devices without instructions from their original manufacturers, then the procedure pack itself must be CE marked. This means the manufacturer of the procedure pack takes responsibility for the safety of the entire pack as a medical device, and for its compliance with the medical device legislation.

Please note



This consultation paper **does not consider requirements related to placement of Unique Device Identifiers (UDI) on systems and procedure packs.**

TGA consulted separately on the requirements related to the UDI System.⁴

³ https://ec.europa.eu/growth/single-market/ce-marking/manufacturers_en

⁴ Consultation: Proposal to introduce a Unique Device Identification (UDI) system for medical devices in Australia, Closed 18 February 2019, <https://www.tga.gov.au/consultation/consultation-proposal-introduce-unique-device-identification-udi-system-medical-devices-australia>

Current SOPP requirements in Australia

The definitions and regulatory requirements for SOPPs in Australia are provided in the [Therapeutic Goods Act 1989](#) (TG Act) and the [Therapeutic Goods \(Medical Devices\) Regulations 2002](#) (Australian MD Regulations). The terms 'system' and 'procedure pack' are currently not defined separately and are used interchangeably in the TG Act and Australian MD Regulations.

Section 41BF of the TG Act defines SOPPs, and the Australian MD Regulations provide regulatory requirements for certain special SOPPs in Regulation 3.10 and Part 7, Clause 7.5 and 7.6 of Schedule 3. These requirements are provided in the [Appendix](#).

SOPPs as medical devices

SOPPs are defined to be medical devices in the TG Act and are subject to the same requirements as other medical devices. The goods, including medical devices, contained in a SOPP are supplied together as one product, and sponsors, seeking pre-market authorisation, apply for inclusion of a SOPP in the Australian Register of Therapeutic Goods (ARTG) as a kind of medical device or IVD medical device.⁵ In certain situations, IVD components that are part of a system are supplied separately (for example, components with different storage temperature requirements) and may or may not require separate ARTG entries based on the GMDN code and kind of device. In general, consumable components of a SOPP require separate ARTG entries.

Any medical device supplied in Australia must have the appropriate conformity assessment procedures, or procedures comparable to conformity assessment⁶, applied to the device by its manufacturer. The conformity assessment procedures are specified in Parts 1 – 6 of Schedule 3 of the Australian MD Regulations. Conformity assessment procedures depend on the classification of a medical device⁷ unless it is a so-called '*medical device used for a special purpose*'. Some SOPPs may meet the definition of a *medical device used for a special purpose*.⁸

Manufacturers of medical devices must have appropriate technical documentation demonstrating compliance of their devices with the relevant essential principles. Further, manufacturers of medical devices (except Class I medical devices, Class 1 IVD medical devices and *medical devices used for a special purpose*) must be assessed by the TGA or an acceptable independent assessment body/overseas regulator, and have a *conformity assessment document* issued by that assessment body/regulator demonstrating that the manufacturer has applied appropriate conformity assessment procedures, or requirements comparable to the Australian conformity assessment procedures, to the device. This conformity assessment document is required for making an application to include a SOPP that is a medical device in the ARTG.



Manufacturers of Class I medical devices, Class 1 IVD medical devices and *medical devices used for a special purpose*, **self-declare compliance**, i.e. are not required to be assessed by an independent assessment body or a regulator.

⁵ *Therapeutic Goods Act 1989*, s.41BE and *Therapeutic Goods (Medical Devices) Regulations 2002*, Reg. 1.6 and 1.7

⁶ The concept of 'procedures comparable to conformity assessment' was introduced to allow recognition of approvals made by comparable overseas regulators.

⁷ *Therapeutic Goods (Medical Devices) Regulations 2002*, Div.3.2 - Conformity assessment procedures

⁸ *Ibid*, Dictionary (reg.1.3)

SOPPs as ‘medical devices used for a special purpose’

Some SOPPs may fit the criteria of a *medical device used for a special purpose* as per Regulation 3.10 in the Australian MD Regulations. In order for a SOPP to be a *medical device used for a special purpose* it must meet the following requirements:

- the package contains one or more of the following:
 - medical device(s), including IVD medical device(s) to which relevant conformity assessment procedures have been applied;
 - medicine(s), biological(s) or other therapeutic goods entered on the ARTG;
 - any other item(s) that are not therapeutic goods; **and**
- the package has been put together in accordance with the intended purpose⁹/approved indications for each good included in the pack; **and**
- the contents of the package are compatible having regard to the intended purpose/approved indications for the use of each good, and the intended purpose of the system or procedure pack.¹⁰

If a SOPP as a *medical device used for a special purpose* is intended **to be supplied sterile**, at a minimum, the production quality assurance procedures must also be applied to the SOPP in relation to the aspects of the manufacturing process that relate to ensuring that the SOPP is supplied and maintained in a sterile state.¹¹

SOPPs that meet the criteria for *medical devices used for a special purpose* must comply with the conformity assessment procedure set out in Part 7 of Schedule 3 of the Australian MD Regulations. This Part requires a **manufacturer of a SOPP to make a declaration of conformity** under clause 7.5.

This declaration requires the manufacturer, among other things, to identify each item in the package, state that: the manufacturer has evidence that the relevant conformity assessment procedures have been applied to each medical device in the package; each medical device in the package complies with the applicable provisions of the essential principles and is intended to be used for its original intended purpose, and each medicine, biological or other therapeutic goods in the package is intended to be used within the approved indications for use specified by the manufacturers of those items; state that the mutual compatibility of each medical device, medicine, biological or other therapeutic goods, and any other goods, in the package has been verified in accordance with any instructions for use provided by the manufacturer of each item or the approved indications for use of each item; and that the information supplied with the system or procedure pack includes instructions for use provided by the manufacturer of each item in the package.

⁹ *Therapeutic Goods (Medical Devices) Regulations 2002*, Dictionary (reg.1.3)

¹⁰ *Ibid*, reg. 3.10(1)(d), 3.10(3)

¹¹ *Therapeutic Goods (Medical Devices) Regulations 2002*, reg.3.10(4)

Why change the regulations?

There is a broad variety of SOPPs available on the Australian market with an even broader range of devices and other therapeutic goods that are included in the SOPPs. Consequently, the risks to individuals and the public arising from the use of these devices vary in nature and level from lowest to the highest.

The intent of the special conformity assessment procedure (self-declaration) for ***medical devices used for a special purpose*** is to enable supply of multiple products — that all individually comply with relevant regulatory requirements — as a single product for a medical purpose or procedure. This means that only one ARTG entry is needed for the SOPP, rather than an ARTG entry for each medical device included in the SOPP.

This special conformity assessment procedure recognises that risk mitigation has been applied to all individual products included in the pack by their original manufacturers, and that the individual components are intended to be included in the pack in their original, market-ready, finished state, as if they were being supplied under their own individual ARTG entries. The special conformity assessment procedure respectively reflects the expected low-risk associated with the production process required for assembling the final product (SOPP) under these conditions.

However, manufacturers of SOPPs that do not comply with the requirements of the special conformity assessment procedure, are required to apply the conformity assessment procedures appropriate to the classification of the SOPP (which, as explained earlier in this paper, includes an independent assessment and certification/approval of the manufacturer by an assessment body/overseas regulator for any devices higher than Class I). These SOPPs are still able to be supplied under a single ARTG entry, rather than an entry for every medical device in the pack, but the evidence for including the pack in the ARTG is an official conformity assessment document, rather than a self-declaration.

The current requirements are not sufficiently clear regarding the criteria for, and application of, the special conformity assessment procedure for SOPPs that are *medical devices used for a special purpose*. Therefore, the proposed amendments are intended to improve the clarity and understanding of the existing regulatory requirements for medical devices that are SOPPs, to facilitate better regulatory compliance and consequently to improve the safety and performance of these medical devices.

Examples of risks and issues associated with specific categories of devices

Issues with procedure packs such as first aid kits intended for consumers

First aid kits are often used by a general public, including by consumers at home, in the event of an emergency. Consequently, it is important that the information provided with the first aid kit, including on the labelling, packaging and instructions for use, where applicable, is clear, comprehensive and relevant to each product included in the kit. It must include all required information and this information should be clearly displayed so that it can be easily seen by the user. The expiry date stated on the kit should be the shortest expiry date of any product included in the kit, and must be easily visible on the packaging. If any information is not accurate or not properly provided on the packaging it may increase the risk of consumers using products incorrectly and/or after the expiry date. Using expired devices or other therapeutic goods can potentially impact on the performance and effectiveness, and thereby increase the risks to the user.

Issues with sterile procedure packs including those containing medium or high-risk devices

Sterile procedure packs are often supplied to hospitals or other healthcare facilities. They are intended to provide quick convenient access to sterile products intended to be used in a certain medical procedure and aim to reduce the preparation time required for the procedure. Very often these procedure packs are designed having regard to the needs specified by the end-user, and include devices and other therapeutic goods required by that user.

Manufacturers of sterile procedure packs that are *medical devices used for a special purpose* are required to implement the minimum production quality assurance conformity assessment procedures in relation to the aspects of the manufacturing process that relate to ensuring that the system or procedure pack is supplied and maintained in a sterile state.¹² This requirement aims to ensure that appropriate sterilisation validation processes are in place and applied appropriately in relation to all products included in the procedure pack, as well as the pack itself. Manufacturers of procedure packs are required to have regard to the instructions for use provided by the manufacturers of each therapeutic good included in the pack, especially when these goods are sterilised as part of the procedure pack.

Some sterile procedure packs that use the special conformity assessment procedure may contain medical devices (including medium and high-risk sterile single use devices) and other therapeutic goods that have been removed from their original packaging prior to being placed in the procedure pack. Concerns have been raised regarding re-sterilisation of medical devices that are not designed or not intended to be re-sterilised. There are also other concerns, including the potential for using a method of sterilisation that may be inconsistent with the original manufacturer's instructions, or breaking/damaging the device as a result of removing it from its original packaging. These issues may significantly increase the risks of these devices not performing as intended.

Further, if ethylene oxide was originally used to sterilise the individual devices in the pack and ethylene oxide is also used for sterilisation of the procedure pack, this may increase the exposure of patients to ethylene oxide residuals above the allowable limit, which creates a significant risk to the patient given that the ethylene oxide residuals are considered as carcinogenic¹³ to humans.

Moreover, re-sterilisation of these devices may affect the materials that make up the device and cause new or altered physicochemical properties due to their inability to withstand the re-sterilisation conditions. This can impact device performance which may lead to patient harm.

Additionally, if the sterile device is removed from its original packaging contrary to the manufacturer's instructions, the exposure to uncontrolled conditions of the handling environment may result in the device being contaminated with microorganisms, resulting in a non-sterile device. If this non-sterile device is included in the procedure pack and then exposed to another sterilisation process, there is potential that this process may not be suitable or adequate to sterilise the contents of the package, including the device that was originally supplied in a sterile state. Therefore, the contents within the package including the device that was originally supplied in a sterile state, may not have an appropriate level of sterility assurance, which could lead to patient infections.

¹² *Therapeutic Goods (Medical Devices) Regulations 2002*, reg. 3.10(4)

¹³ Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals, Second edition 2008-10-15

Proposed amendments

It is proposed that the current provisions applied to systems and procedure packs in the Therapeutic Goods Act and the Australian MD Regulations be changed to ensure the regulatory requirements relating to SOPPs are clear.

Having regard to the broad range of applications and risks for SOPPs, it is important to ensure that the level of assessment and regulatory oversight are appropriate and adequate, aiming to minimise any real or potential risks and verify that systems and procedure packs supplied in Australia are suitable and fit for purpose.



Please note

The paper **does not cover the conformity assessment procedures applied to any other medical devices**. TGA is consulting separately on those procedures.¹⁴

There are two proposals, as follows:

1. Add new definitions

The EU MD Regulation provides separate definitions for: **system** and **procedure pack**, compared with the TG Act and Australian MD Regulations which currently provides one definition covering both and uses these terms interchangeably. While usually referring to systems and procedure packs as one broad category of medical devices may be acceptable, in some cases it may create misunderstanding, especially when referring to issues and risks associated with the use of systems and procedure packs. For example, some issues raised in this consultation are relevant to procedure packs but not necessarily to devices supplied as systems.

Therefore, defining *systems* and *procedure packs* separately may address such ambiguity and misunderstandings.

Further the EU MD Regulation defines the term '**compatibility**', which is also not currently defined in the Australian legislation, although it is referred to as one of requirements for *medical devices used for a special purpose*.¹⁵

Proposed amendments

It is proposed to introduce the definitions of system, procedure pack, and compatibility.

Procedure pack means a combination of products at least one of which is a medical device or IVD medical device packaged together and placed on the market with the purpose of being used in a medical procedure.

System means a specified combination of products, either packaged together or not, which are intended to be interconnected, combined or used together to achieve a specific medical purpose.

¹⁴ Therapeutic Goods (Medical Devices) Regulations 2002, Parts 1 – 6, Schedule 3

¹⁵ Therapeutic Goods (Medical Devices) Regulations 2002, Reg.3.10(3)(c)

Compatibility is the ability of a device, including software, when used together with one or more other devices in accordance with its intended purpose, to:

- (a) perform without losing or compromising the ability to perform as intended, and/or
- (b) integrate and/or operate without the need for modification or adaptation of any part of the combined devices, and/or
- (c) be used together without conflict/interference or adverse reaction.

The [Appendix](#) provides a comparison of the definitions relevant to systems and procedure packs in the Australian MD Regulations and the EU MD Regulation.

2. Clarify the requirements for SOPPs that are medical devices used for a special purpose

Regulation 3.10 - *medical devices used for a special purpose*

The EU MDR includes a requirement for individual medical devices in a SOPP to be CE marked, in order to use the self-declaration pathway for supplying a SOPP. This means that each device requires a current conformity assessment certificate (if above Class I), and is in a market-ready, finished state. It is proposed to align with this requirement and require that manufacturers of SOPPs as *medical devices used for a special purpose* obtain evidence, in the form of a **conformity assessment document**, from the manufacturers of each medical device they put into the SOPP and present each good in the SOPP in its original market-ready, finished state.

Where SOPPs that are *medical devices used for a special purpose* are intended to be supplied sterile, the manufacturer of the SOPP will be required to apply the minimum conformity assessment procedure appropriate for ensuring the sterility of their system or procedure pack. As per the European requirement, this will be clarified to ensure that sterilisation of the SOPP has been carried out in accordance with the written instructions from the original manufacturers of all goods put into the SOPP. 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.

In cases when the manufacturer of a SOPP intends to open or modify (including opening and resealing) the individual packaging of any goods put into the SOPP, especially those supplied sterile, the manufacturer will be required to have a written agreement with the original manufacturers of the respective goods they unpackage. This agreement will allow verification that such a production step (i.e. unpackaging and sterilisation or re-sterilisation of the goods) has been performed in accordance with the original manufacturers' instructions and does not impact on the performance of the goods.

The proposed changes are intended to provide assurance that the necessary steps have been taken by the manufacturer of procedure packs to verify that the safety and performance of the goods supplied in the procedure pack has not been adversely affected when compared with the safety and performance verified by the goods' manufacturers.

This should mitigate the risks associated with the use of SOPPs that are *medical devices used for a special purpose*.

In cases, where a person produces and supplies SOPPs other than *medical devices used for a special purpose*, they must apply the conformity assessment procedures appropriate to the classification of their systems or procedure packs.

These proposed amendments are consistent with the intent provided in Article 22, EU MD Regulation.¹⁶

Proposed amendments

It is proposed to more clearly define requirements for systems and procedure packs that are *medical devices used for a special purpose*.

These changes would include:

- Clarification of the existing requirements such as:
 - Subregulation 3.10 (3) applies to systems and procedure packs that must include at least one therapeutic good which is a medical device or IVD medical device.
- Additional requirements relating to:
 - the requirement that the manufacturer of a SOPP must obtain evidence, in the form of a *conformity assessment document from the TGA, a comparable overseas regulator or assessment body*, from the manufacturers of each medical device (other than Class I medical device or Class 1 IVD medical device, not supplied sterile and not having a measuring function) they put into the SOPP,
 - where SOPPs are intended to be supplied sterile, the manufacturer of the SOPP must apply the minimum conformity assessment procedure appropriate for ensuring the sterility, and must ensure that sterilisation of the SOPP has been carried out in accordance with the instructions from all manufacturers of all goods put into the SOPP,
 - if the manufacturer of a SOPP intends to open or modify the packaging of any goods when these goods are put into the SOPP, the manufacturer of the SOPP must have a written agreement, with the manufacturers of the respective goods they unpackage, that will allow validation that such a production step does not impact on the performance of the goods.
- Clarification that systems and procedure packs should be subject to relevant conformity assessment procedure outlined in Division 3.2 of the Regulations (ie – not the special procedure for *medical devices used for a special purpose*) if:
 - the SOPP contains a medical device or IVD medical device (other than Class 1 medical device or Class 1 IVD medical device) that is **not** covered by a current conformity assessment document, or
 - the chosen combination of devices is **not** compatible in view of their original intended purpose, or
 - the sterilisation has **not** been carried out in accordance with the manufacturer's instructions.

¹⁶ The Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, Article 22, (OJ L 117, 5.5.2017, p. 33)

Declaration of conformity - clause 7.5

The existing regulatory provisions for *medical devices used for a special purpose* require a SOPP manufacturer to self-declare compliance through a *declaration of conformity under clause 7.5*, Schedule 3.

Proposed amendments

It is proposed to respectively change Clause 7.5, Schedule 3 in the Australian MD Regulations, and to consider whether change is necessary for Clause 7.6.

These changes will include (Clause 7.5):

- Clarification of the matters currently certified in the declaration such as the instructions for use can be provided in an electronic or online format when SOPPs are intended for professional users; and
- Addition of the new matters that the manufacturer of a SOPP must certify, including that
 - the manufacturer of a SOPP holds evidence in the form of a *conformity assessment document from the TGA, a comparable overseas regulator or assessment body* for each medical device they put into the SOPP, obtained from the manufacturers of those devices
 - where SOPPs are intended to be supplied sterile, the manufacturer of the SOPP has applied the minimum conformity assessment procedure appropriate for ensuring the sterility and has ensured that sterilisation of the SOPP has been carried out in accordance with the instructions from all manufacturers of all goods put into the SOPP
 - if the manufacturer of a SOPP intends to open or modify the packaging of any goods when these goods are put into the SOPP, the manufacturer of the SOPP has ensured that they have a written agreement, with the manufacturers of the respective goods they unpackage, that will allow verification that such a production step has been performed in accordance with the manufacturers' instructions and does not impact on the performance of the goods.

In addition, it is proposed to consider whether the required retention period of 5 years for the self-declaration statement, and other requirements for SOPP records, are adequate (Clause 7.6).



Please note

The **closing date of this consultation has been extended from 17 October 2019 to 31 October 2019.**

Before providing feedback, it is important to read the explanatory material that follows.

Benefits

The proposed regulatory changes will allow a greater international alignment and offer significant benefits such as:

- improved clarity and transparency regarding the requirements for SOPPs
- minimising public health and safety risks;
- increased confidence in safety and performance of devices used in SOPPs
- consistency as far as possible with the international requirements in other jurisdictions
- minimising regulatory burden

The proposed changes are expected to provide benefits to regulated industry sector because the requirements will be clearer and will provide additional detail and precision, facilitating better regulatory compliance, thus improving and enhancing product safety.

The consistency with the global approach of our requirements will increase consumer confidence in safety and performance of these devices, minimising patient health and safety risks.

Additionally, by moving Australia's regulation towards international harmonisation the proposed changes are expected to decrease the overall cost of regulatory compliance, promote global convergence, and improve timely access to safe, high quality medical devices that perform as intended.

Impact

What will change for manufacturers

Manufacturers of SOPPs that are *medical devices used for a special purpose* using the self-declaration pathway will be required to comply with the following requirements:

- hold a current conformity assessment document *from the TGA, a comparable overseas regulator or assessment body* for each medical device they put into the SOPP, obtained from the original manufacturers of those devices.
- for SOPPs intended to be supplied sterile, ensure that the minimum conformity assessment procedure appropriate for ensuring the sterility has been applied, and ensure that sterilisation of the SOPP has been carried out in accordance with the instructions from all original manufacturers of all goods put into the SOPP.
- where the packaging of any goods is opened or modified when these goods are put into the SOPP, ensure that a written agreement is in place, with the manufacturers of the respective goods that are unpackaged, that will allow verification that such a production step has been performed in accordance with the manufacturers' instructions and does not impact on the performance of the goods.

Manufacturers of SOPPs that do not meet the above requirements will be required to obtain conformity assessment certification, or an equivalent conformity assessment document from a comparable overseas regulator, for the SOPP as a whole.

What will change for sponsors

Sponsors of any SOPPs that are *medical devices used for a special purpose*, will be required to obtain current *conformity assessment documents* (i.e. conformity assessment document *from the TGA, a comparable overseas regulator or assessment body*) from the manufacturer of the SOPP for each medical device included in the SOPP, and provide such documents to the TGA if requested. This is to demonstrate that procedures appropriate for their devices have been applied for inclusion of a medical device in the ARTG, and to demonstrate ongoing compliance with the conditions applying automatically on inclusion of a medical device in ARTG.¹⁷

There will be no change for sponsors of SOPPs that are not *medical devices used for a special purpose*. These SOPPs will still require a valid conformity assessment document for inclusion in, and to demonstrate ongoing compliance for, the ARTG.

Transitional arrangements

In Europe, under the transitional arrangements, medical devices lawfully placed on the market prior to 27 May 2020 that have pre-market authorisation in the form of a valid EC Certificate¹⁸ can remain on the market until the expiry date of that EC Certificate or until 27 May 2024 (when these certificates become void), whichever is the earliest. Devices lawfully placed on the market may continue to be made available on the market or put into service until 27 May 2025.

It is proposed that the clarified requirements for systems and procedure packs for **new medical devices in Australia**—that is, a device included in the ARTG following successful completion of an application submitted to the TGA on or after the commencement date of the amended regulations—would start from August 2020.

If the application for ARTG inclusion for a medical device is **submitted to the TGA before the date the proposed amendment takes effect**, it is proposed that **the device will be subject to the transitional arrangements** and will have four (4) years to transition (i.e. until August 2024).

Fees and charges

The changes proposed in this consultation will not impact on fees or charges.

Engagement

Wherever practicable, the TGA will:

- liaise with the healthcare sector, patient associations and industry peak bodies to inform and raise awareness about this proposal,
- provide relevant material on the TGA website.

¹⁷ *Therapeutic Goods Act 1989*, par.41FN(3)(b)

¹⁸ EC certificates issued in accordance with EU Directive 93/42/EEC and which comply with the requirements in para. (2) of Article 120 of the EU MD Regulation.

Feedback notes

It is important to note that while the European medical device framework and broader international regulatory practice will be taken into account, the Australian legislative instruments are structured differently and there is variation in the legal terminology acceptable in each jurisdiction. Legislation cannot always be successfully replicated across jurisdictions. Therefore, your views on the impacts of the proposed regulatory changes related to systems and procedure packs are very important.

When considering the proposed measures, assume that the EU MD Regulation provisions apply to medical devices in the context of the TG Act and Australian MD Regulations.

What we invite you to do

In your submission, please consider the questions below and provide comments related to any other matter outlined in this consultation paper.

Questions

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

How to submit

Complete the [online consultation submission form](#) to upload your submission in either pdf or word format.

You can also submit your feedback directly to the TGA by email at: devicereforms@tga.gov.au. If you do so, **please ensure your submission is accompanied by a coversheet.**

This consultation closes on 31 October 2019.

Enquiries

If you have any questions relating to submissions please direct them to: devicereforms@tga.gov.au.

Appendix – Comparison analysis of EU Regulations, Australian MD Regulations and the proposed changes

Definitions related to systems and procedure packs

EU MD Regulation	TG Act and Australian MD Regulations	Proposed amendments
<p>CHAPTER I SCOPE AND DEFINITIONS</p> <p><i>Article 2 Definitions</i></p> <p>(10) Procedure pack means a combination of products packaged together and placed on the market with the purpose of being used for a specific medical purpose.</p> <p>(11) System means a combination of products, either packaged together or not, which are intended to be interconnected or combined to achieve a specific medical purpose.</p>	<p>s. 41BF System or procedure packs, TG Act</p> <p>(1) A package and therapeutic goods in the package are a <i>system or procedure pack</i> if:</p> <p>(a) the package and the therapeutic goods are for use as a unit, either in combination as a system or in a medical or surgical procedure; and</p> <p>(b) the package contains at least one medical device; and</p> <p>(c) the package and the therapeutic goods do not constitute a composite pack.</p> <p>(2) To avoid doubt, a system or procedure pack is a medical device.</p>	<p>Inclusion of separate definitions for <i>system</i> or <i>procedure pack</i> provides a clear distinction between the two terms. More specially, unlike a procedure pack where a combination of products with unique intended purposes are packaged together with the collective purpose of being used in the same procedure, a system is a specific combination of products either packed together or not which are intended to be interconnected or combined to achieve the intended medical purpose.</p> <p>The incorporation of separate definitions for the terms <i>system</i> or <i>procedure pack</i> would not only highlight the differences between the two but also harmonise the Australian legislation with the EU MD Regulation to improve clarity and consistency across the different jurisdictions.</p> <p>The proposed definitions are:</p> <p><i>Procedure pack</i> means a combination of products at least one of which is a medical device or IVD medical device packaged together and placed on the market with the purpose of being used in a medical procedure.</p> <p><i>System</i> means a specified combination of products, either packaged together or not, which are</p>

EU MD Regulation	TG Act and Australian MD Regulations	Proposed amendments
		intended to be interconnected, combined or used together to achieve a specific medical purpose.
<p>Article 2 Definitions</p> <p>(25) Compatibility is the ability of a device, including software, when used together with one or more other devices in accordance with its intended purpose, to:</p> <p>(d) perform without losing or compromising the ability to perform as intended, and/or integrate and/or operate without the need for modification or adaption of any part of the combined devices, and/or</p> <p>(e) be used together without conflict/interference or adverse reaction.</p>	<p>Compatibility is not defined in the TG Act or the Australian MD Regulations</p>	<p>The inclusion of a definition of ‘compatibility’ should alleviate any confusion in the interpretation of the term ‘mutual compatibility’ referenced in Clause 7.5 of Schedule 3 of the Australian MD Regulations for systems and procedure packs.</p> <p>The clarity of the requirements is intended to facilitate better regulatory compliance.</p> <p>It is proposed to align with the EU definition.</p>

Conformity assessment applied to SOPPs that are medical devices used for a special purpose

Conformity assessment procedures applied to systems and procedure packs are provided in Regulation 3.10 and Part 7 of Schedule 3 of the Australian MD Regulations.

Table 1: Regulation 3.10 - medical devices used for a special purpose

EU MD Regulation	Australian MD Regulations	Proposed amendments
<p>Article 22 Systems and procedure packs</p> <p>1. Natural or legal persons shall draw up a statement if they combine devices bearing a CE marking with the following other devices or products, in a manner that is compatible with the intended purpose of the devices or other products and within the limits of use specified by their manufacturers, in order to place them on the market as a system or procedure pack:</p> <p>(a) other devices bearing the CE marking;</p> <p>(b) <i>in vitro</i> diagnostic medical devices bearing the CE marking in conformity with Regulation (EU) 2017/746;</p> <p>(c) other products which are in conformity with legislation that applies to those products only where they are used within a medical procedure or their presence in the system or procedure pack is otherwise justified.</p>	<p>3.10 Medical devices used for a special purpose</p> <p>(1) This regulation applies to the following kinds of medical devices (<i>medical devices used for a special purpose</i>):</p> <p>[...]</p> <p>(d) a system or procedure pack to which subregulation (3) applies;</p> <p>[...]</p> <p>(2) The conformity assessment procedures that must be applied to a medical device used for a special purpose are the procedures for medical devices used for a special purpose.</p> <p>(3) This subregulation applies to a system or procedure pack:</p> <p>(a) that contains only one or more of the following:</p> <p>(i) a medical device, or devices, to which the relevant conformity assessment procedures have been applied;</p> <p>(ii) a medicine or medicines, a biological or biologicals, or other therapeutic goods, that are entered on the Register;</p>	<p>The following proposed amendments are intended to provide clarity of the requirements under regulation 3.10 (3) (a) (iii) of the system or procedure pack. It is proposed that the regulation 3.10 states that the subregulation 3.10 (3) applies to systems or procedure packs that must include at least one therapeutic good which is a medical device or IVD medical device.</p>

EU MD Regulation	Australian MD Regulations	Proposed amendments
	<p>(iii) any other item or items that are not therapeutic goods when in the package; and</p> <p>(b) that has been put together in accordance with the intended purpose of each medical device and the approved indications for use of each medicine, biological and other therapeutic goods; and</p> <p>(c) the contents of which are compatible, having regard to the intended purpose of each medical device, the approved indications for use of each medicine, biological or other therapeutic goods, and the intended purpose of the system or procedure pack.</p>	
<p>3. Any natural or legal person who sterilises systems or procedure packs referred to in paragraph 1 for the purpose of placing them on the market shall, at their choice, apply one of the procedures set out in Annex IX or the procedure set out in Part A of Annex XI. The application of those procedures and the involvement of the notified body shall be limited to the aspects of the procedure relating to ensuring sterility until the sterile packaging is opened or damaged. The natural or legal person shall draw up a statement declaring that sterilisation has been carried out in accordance with the manufacturer's instructions</p>	<p>(4) If a system or procedure pack is intended by the manufacturer to be supplied in a sterile state, the production quality assurance procedures (other than clause 4.7) must also be applied to the system or procedure pack in relation to the aspects of the manufacturing process that relate to ensuring that the system or procedure pack is supplied and maintained in a sterile state.</p> <p>Note: If the package contains a medicine, the manufacturer of the system or procedure pack must ensure that the method to be used for sterilisation or re-sterilisation is appropriate or is in accordance with the approved indications for use of the medicine.</p>	<p>In principle, the Australian MD Regulations are consistent with the requirements of the EU MD Regulation relating to sterility aspects of the SOPPs. However, amendments are proposed to clarify the existing requirements.</p> <ul style="list-style-type: none"> • Where SOPPs are intended to be supplied sterile, the manufacturer must apply the minimum conformity assessment procedure appropriate for ensuring the sterility and must ensure that sterilisation of the SOPP has been carried out in accordance with the instructions from all manufacturers of all goods put into the SOPP. • If the manufacturer intends to open or modify the packaging of any goods when these goods are put into the SOPP, the manufacturer must have written agreements with the manufacturers of the respective goods they unpackage, that will allow verification that

EU MD Regulation	Australian MD Regulations	Proposed amendments
		<p>such a production step has been performed in accordance with the manufacturers' instructions and does not impact on the performance of the goods.</p> <p>Note: The EU MD Regulation requires that the statement must declare that sterilisation has been carried out in accordance with the manufacturer's instructions. This is addressed below in Table B.2: Part 7 – declaration of conformity.</p>
<p>4. Where the system or procedure pack incorporates devices which do not bear the CE marking or where the chosen combination of devices is not compatible in view of their original intended purpose, or where the sterilisation has not been carried out in accordance with the manufacturer's instructions, the system or procedure pack shall be treated as a device in its own right and shall be subject to the relevant conformity assessment procedure pursuant to Article 52. The natural or legal person shall assume the obligations incumbent on manufacturers.</p>	<p>3.10 Medical devices used for a special purpose</p> <p>(1) This regulation applies to the following kinds of medical devices (<i>medical devices used for a special purpose</i>):</p> <p>[...]</p> <p>(d) a system or procedure pack to which subregulation (3) applies;</p> <p>[...]</p> <p>Note for paragraph (d): A system or procedure pack is treated as a single medical device. If [...] subregulation (3) does not apply to a system or procedure pack:</p> <p>(a) the system or procedure pack is classified in accordance with Division 3.1 and either Schedule 2 or Schedule 2A; and</p> <p>(b) the conformity assessment procedures that must be applied to the system or procedure pack are the procedures that apply to the relevant classification.</p>	<p>The following proposed amendments are intended to provide clarity of the requirements and obligations of the manufacturer of the system or procedure pack:</p> <p>The SOPP should be subject to the relevant conformity assessment procedures outlined in Division 3.2 of the Medical Device Regulations (i.e. – not the special procedure for <i>medical devices used for a special purpose</i>) if:</p> <ul style="list-style-type: none"> the SOPP contains a medical device that is not covered by a current conformity assessment document, or the chosen combination of devices is not compatible in view of their original intended purpose, or the sterilisation has not been carried out in accordance with the instructions of the manufacturers of goods included in the SOPP
<p>5. The systems or procedure packs referred to in paragraph 1 of this Article shall not themselves bear an additional CE marking but they shall bear the name, registered trade name or registered</p>	<p>Part 7.6, Schedule 3 – Records</p> <p>(1) The manufacturer must keep the statement and documentation required under the relevant clause of this Schedule in relation to a medical device to</p>	<p>Clarify that SOPPs shall be accompanied by the required information specified in the Essential Principles (currently EP 13) except where parts of this information, such as the instructions for use,</p>

EU MD Regulation	Australian MD Regulations	Proposed amendments
<p>trade mark of the person referred to in paragraphs 1 and 3 of this Article as well as the address at which that person can be contacted, so that the person's location can be established. Systems or procedure packs shall be accompanied by the information referred to in Section 23 of Annex I. The statement referred to in paragraph 2 of this Article shall be kept at the disposal of the competent authorities, after the system or procedure pack has been put together, for the period that is applicable under Article 10(8) to the devices that have been combined. Where those periods differ, the longest period shall apply.</p>	<p>which the conformity assessment procedures in this Part have been applied.</p> <p>(2) The manufacturer must keep the statement and documentation for at least 5 years after the manufacture of the last medical device to which the statement and documentation relates.</p> <p>(3) On request from the Secretary, the manufacturer must make the statement and documentation available to the Secretary.</p>	<p>are allowed to be provided in electronic form where the SOPP is intended for professional users.</p> <p>Consider whether the record retention period for SOPPs using the special conformity assessment procedure is adequate.</p>

Table 2: Part 7 – Declaration of conformity

EU MD Regulation	Australian MD Regulations	Proposed amendments
<p>Article 22 Systems and procedure packs</p> <p>2. In the statement made pursuant to paragraph 1, the natural or legal person concerned shall declare that:</p> <p>(a) they verified the mutual compatibility of the devices and, if applicable other products, in accordance with the manufacturers' instructions and have carried out their activities in accordance with those instructions;</p> <p>(b) they packaged the system or procedure pack and supplied relevant information to users incorporating the information to be supplied by the manufacturers of the devices or other products which have been put together;</p> <p>(c) the activity of combining devices and, if applicable, other products as a system or procedure pack was subject to appropriate methods of internal monitoring, verification and validation.</p>	<p>Part 7.5, Schedule 3 – Conformity Assessment Procedure for System or Procedure Pack Medical devices used for a special purpose</p> <p>(1) The manufacturer of a system or procedure pack must make a declaration of conformity in relation to the system or procedure pack.</p> <p>(2) The declaration must:</p> <p>(a) state that the declaration is a declaration of conformity made under clause 7.5 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002; and</p> <p>(b) state the name and business address of the manufacturer of the system or procedure pack; and</p> <p>(c) state sufficient information to enable the user to identify the system or procedure pack or, if relevant, the contents of packaging; and</p> <p>(d) identify each item in the package; and</p> <p>(e) state that the manufacturer has evidence:</p> <p>(i) that the relevant conformity assessment procedures have been applied to each medical device in the package; and</p> <p>(ii) that each medical device in the package complies with the applicable provisions of the essential principles; and</p> <p>(f) state the registration or listing number for each medicine or other therapeutic goods, or the biological number for each biological, in the package; and</p> <p>(g) state that each medical device in the package is intended to be used for its original</p>	<p>The Australian MD Regulations provides more detailed requirements than the EU MD Regulation for the information that must be declared in the declaration of conformity. Therefore, it is not proposed to reduce the requirements specified in the Australian MD Regulations, but rather provide amendments to clarify the existing requirements.</p> <p>The following proposed amendments are intended to provide clarity of the requirements and obligations of the manufacturer of SOPPs:</p> <ul style="list-style-type: none"> clarify that the manufacturer of a SOPP must hold evidence in the form of a current conformity assessment document from the TGA, a comparable overseas regulator or assessment body for each medical device they put into the SOPP, obtained from the manufacturers of those devices. clarify that where SOPPs are intended to be supplied sterile, the manufacturer of procedure packs has applied the minimum conformity assessment procedure appropriate for ensuring the sterility and ensured that sterilisation of the SOPP has been carried out in accordance with the instructions from all original manufacturers of all goods put into the SOPP. clarify that if the manufacturer of procedure packs intends to open or modify the packaging of any goods when these goods are put into the system or procedure pack, the manufacturer of procedure packs has ensured that they have a

EU MD Regulation	Australian MD Regulations	Proposed amendments
	<p>intended purpose, and each medicine, biological or other therapeutic goods in the package is intended to be used within the approved indications for use specified by the manufacturers of those items; and</p> <p>(h) state:</p> <p>(i) that the mutual compatibility of each medical device, medicine, biological or other therapeutic goods, and any other goods, in the package has been verified in accordance with any instructions for use provided by the manufacturer of each item or the approved indications for use of each item; and</p> <p>(ii) that the manufacturer has manufactured the system or procedure pack in accordance with those instructions (if any) or indications; and</p> <p>(i) state that the information supplied with the system or procedure pack for the use of the system or procedure pack includes instructions for use provided by the manufacturer of each item in the package; and</p> <p>(j) state that the process of manufacturing the system or procedure pack, and the verification and packaging of the system or procedure pack, has been subjected to a documented method of internal control and inspection that ensures the safety, quality, performance and effectiveness of each item in the package; and</p> <p>(k) if the system or procedure pack is intended by the manufacturer to be supplied in a sterile state—state that the production quality assurance procedures (other than clause 4.7)</p>	<p>procedures in place, including a written agreement, with the manufacturers of the respective goods they unpackaged, that will allow verification that such production step has been performed in accordance with the manufacturers' instructions and does not impact on the performance of the goods.</p>

EU MD Regulation	Australian MD Regulations	Proposed amendments
	<p>have been applied to the system or procedure pack in accordance with the manufacturer's instructions for use, or the approved indications for use, of each item in the package; and</p> <p>(l) be signed by a person authorised by the manufacturer; and</p> <p>(m) set out the name and position of the person signing the declaration; and</p> <p>(n) state the date when the declaration is signed.</p>	
<p>Article 10 General obligations of manufacturers</p> <p>10.Manufacturers of devices shall implement and keep up to date the post-market surveillance system in accordance with Article 83.</p>	<p>(3) The manufacturer of a system or procedure pack must establish, and keep up-to-date, a post-marketing system that complies with subclause (4) for use in relation to the system or procedure pack.</p>	<p>No change is proposed.</p>
<p>Article 83 Post-market surveillance system of the manufacturer</p> <p>1. For each device, manufacturers shall plan, establish, document, implement, maintain and update a post-market surveillance system in a manner that is proportionate to the risk class and appropriate for the type of device. That system shall be an integral part of the manufacturer's quality management system referred to in Article 10(9).</p> <p>2. The post-market surveillance system shall be suited to actively and systematically gathering, recording and analysing relevant data on the quality, performance and safety of a device throughout its entire lifetime, and to drawing the necessary conclusions and to determining,</p>	<p>(4) A post-marketing system complies with this subclause in relation to a system or procedure pack if the post-marketing system requires the manufacturer of the system or procedure pack:</p> <p>(a) to systematically review experience gained in the post-production phase in relation to the system or procedure pack; and</p> <p>(b) to implement appropriate means to apply any necessary corrective action in relation to the production of the system or procedure pack; and</p> <p>(c) to notify the Secretary as soon as practicable after becoming aware of:</p> <p>(i) information relating to:</p>	<p>No change is proposed.</p>

EU MD Regulation	Australian MD Regulations	Proposed amendments
<p>implementing and monitoring any preventive and corrective actions.</p> <p>3. Data gathered by the manufacturer's post-market surveillance system shall in particular be used: (a) to update the benefit-risk determination and to improve the risk management as referred to in Chapter I of Annex I; (b) to update the design and manufacturing information, the instructions for use and the labelling; (c) to update the clinical evaluation; (d) to update the summary of safety and clinical performance referred to in Article 32; (e) for the identification of needs for preventive, corrective or field safety corrective action; (f) for the identification of options to improve the usability, performance and safety of the device; (g) when relevant, to contribute to the post-market surveillance of other devices; and (h) to detect and report trends in accordance with Article 88. The technical documentation shall be updated accordingly.</p> <p>4. If, in the course of the post-market surveillance, a need for preventive or corrective action or both is identified, the manufacturer shall implement the appropriate measures and inform the competent authorities concerned and, where applicable, the notified body. Where a serious incident is identified or a field safety corrective action is implemented, it shall be reported in accordance with Article 87.</p>	<p>(A) any malfunction or deterioration in the characteristics or performance of the system or procedure pack; or</p> <p>(B) any inadequacy in the production, labelling, instructions for use or advertising materials of the system or procedure pack; or</p> <p>(C) any use in accordance with, or contrary to, the use intended by the manufacturer of the system or procedure pack;</p> <p>that might lead, or might have led, to the death of a patient or a user of the system or procedure pack, or to a serious deterioration in his or her state of health; or</p> <p>(ii) information relating to any technical or medical reason for a malfunction or deterioration of a kind mentioned in subparagraph (i) that has led the manufacturer to take steps to recall system or procedure packs of that kind that have been distributed.</p>	

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Therapeutic Goods Administration, Medical Devices Branch	September 2019
V1.1	The closing date of this consultation has been extended from 17 October 2019 to 31 October 2019.	Therapeutic Goods Administration, Medical Devices Branch	October 2019

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
<https://www.tga.gov.au>

Reference/Publication #