Australian Government
Department of Health
Therapeutic Goods Administration

Potential reforms for the regulation of system and procedure pack medical devices

Stakeholder Workshop

Dr. Tania Ahmed
Devices Conformity Assessment Section
Medical Devices Branch
Medical Devices & Product Quality Division

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TGA Health Safety Regulation

Presentation overview

- Purpose of the workshop
- Background – Current legislative provisions for systems and procedure packs
- International approaches
- Common findings impacting patient health and safety
- Factors impacting adequacy of the current legislative provisions for systems and procedure packs
- Conclusion

Purpose of this workshop

- To discuss with our key stakeholders the current Australian regulatory framework for ensuring the safety and performance of systems or procedure packs.
- To gather feedback that will be used to inform a consultation on potential reforms to the current regulatory requirements for systems and procedure packs.
- To gather other feedback that be relevant to the broader reform program for the medical device regulatory framework.

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Current legislative provisions for systems and procedure packs

The Therapeutic Goods Act 1989

- **Section 41BG** – definition of "manufacturer"
- **Section 41BF** – definition of "system or procedure packs"
- **Section 41FD(f)** – applicant for ARTG inclusion must certify that appropriate conformity assessment procedures or requirements, comparable to the conformity assessment procedures, have been applied to devices of that kind

The Therapeutic Goods (Medical Devices) Regulations 2002

- **Division 3.2, Regulation 3.10** – outlines requirements for systems and procedure packs as medical devices used for a special purpose (paragraphs (1) (d) and (e), (2), (3), and (4))
- **Schedule 3, Part 7, clause 7.5** – provides requirements for manufacturer's declaration of conformity

Definition:

Section 41BF of the Act - System or procedure packs

(1) A package and therapeutic goods in the package are a ***system or procedure pack*** if:

(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

(b) the package contains at least one medical device; and

(c) the package and the therapeutic goods do not constitute a composite pack.

(2) To avoid doubt, a system or procedure pack is a medical device.

Options for supply of systems and procedure packs in AU

Two options for supply of systems and procedure packs

- obtain *conformity assessment document* covering the entire system or procedure pack
- use the special conformity assessment procedures outlined in Reg. 3.10 and Clause 7.5 of Schedule 3 of the Regulations for systems and procedure packs

Regulation 3.10 Medical devices used for a special purpose

(1) This regulation applies to … **medical devices used for a special purpose** […]

(d) a **system or procedure pack** to which subregulation (3) applies

(e) a **system or procedure pack** that contains at least 1 medical device, that is not an IVD medical device, and at least 1 IVD medical device

(2) The **conformity assessment procedures applied to a medical device used for a special purpose**

(3) This **subregulation applies to a system or procedure pack**:

(a) that contains one or more of the following:

(i) **medical device/devices**, to which the **relevant conformity assessment procedures have been applied**;

(ii) **medicine or medicines, a biological or biologicals, or other therapeutic goods**, that are entered **on the Register** […]

(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

(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**.

(4) If **a system or procedure pack is intended** by the manufacturer **to be supplied in a sterile state**, the production quality assurance procedures […] 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.

The Regulations - Clause 7.5 Systems and procedure packs

Schedule 3, Part 7, Clause 7.5 of the Therapeutic Goods (Medical Devices) Regulations 2002:

7.5 System or procedure packs

(1) The manufacturer of a system or procedure pack must make a declaration of conformity in relation to the system or procedure pack.

(2) The declaration must:

(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 [...]

(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.

(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: [...]

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International approaches – the EU

Regulation (EU) 2017/745, Article 22 (OJ L 117/33, 5.5.2017):

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**; [...]

2. In the statement made pursuant to paragraph 1, **the natural or legal person concerned shall declare that**: [...]

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. [...]

International approaches - the EU (cont.)

Regulation (EU) 2017/745, Article 22 (OJ L 117/33, 5.5.2017):

Article 22 Systems and procedure packs

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.

International approaches – the FDA

'Convenience Kits Interim Regulatory Guidance', U.S Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, May 20, 1997:

- Use of the term **'convenience kits': comprised of legally marketed devices** that are simply assembled in kit form for the "convenience" of the purchaser or user

- Separate terms for **'assembler'** and 'manufacturer' of kit

- Convenience kits […] include components that are either:
  (1) legally marketed preamendments devices,
  (2) exempt from premarket notification, or
  (3) have been found to be substantially equivalent through the premarket notification process.

- **The components should be purchased in finished form, i.e., they should be packaged, labeled, etc., consistent with their legal marketing authorization.**

International approaches – the FDA (cont.)

'Convenience Kits Interim Regulatory Guidance', U.S Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, May 20, 1997:

- Processing […] **It is the responsibility of each kit assembler/manufacturer to carefully consider the impact that any processing may have on the kit's components.**
- […] kit assemblers should carefully consider the impact of the sterilization process on individual kit components. If the kit's components may be sensitive to further processing, e.g., surgical sutures, the assemblers/manufacturers **should take measures necessary to ensure that the components are not adversely affected by the reprocessing procedures**.
- […] where the assembler/manufacturer is able to reasonably conclude that any further processing of **the kit and its components does not significantly affect the safety or effectiveness of any of its components**

- **Documentation to support each of these determinations should be maintained** in the assembler's/manufacturer's files in accordance with the Quality System regulation (21 CFR 820) and should be available for FDA review if needed.

- It should be noted that while FDA intends to exercise enforcement discretion with respect to premarket notification requirements, **assemblers/manufacturers of convenience kits are still required to comply with other general controls** including registration, listing, prohibition against misbranding, **and good manufacturing practices**.

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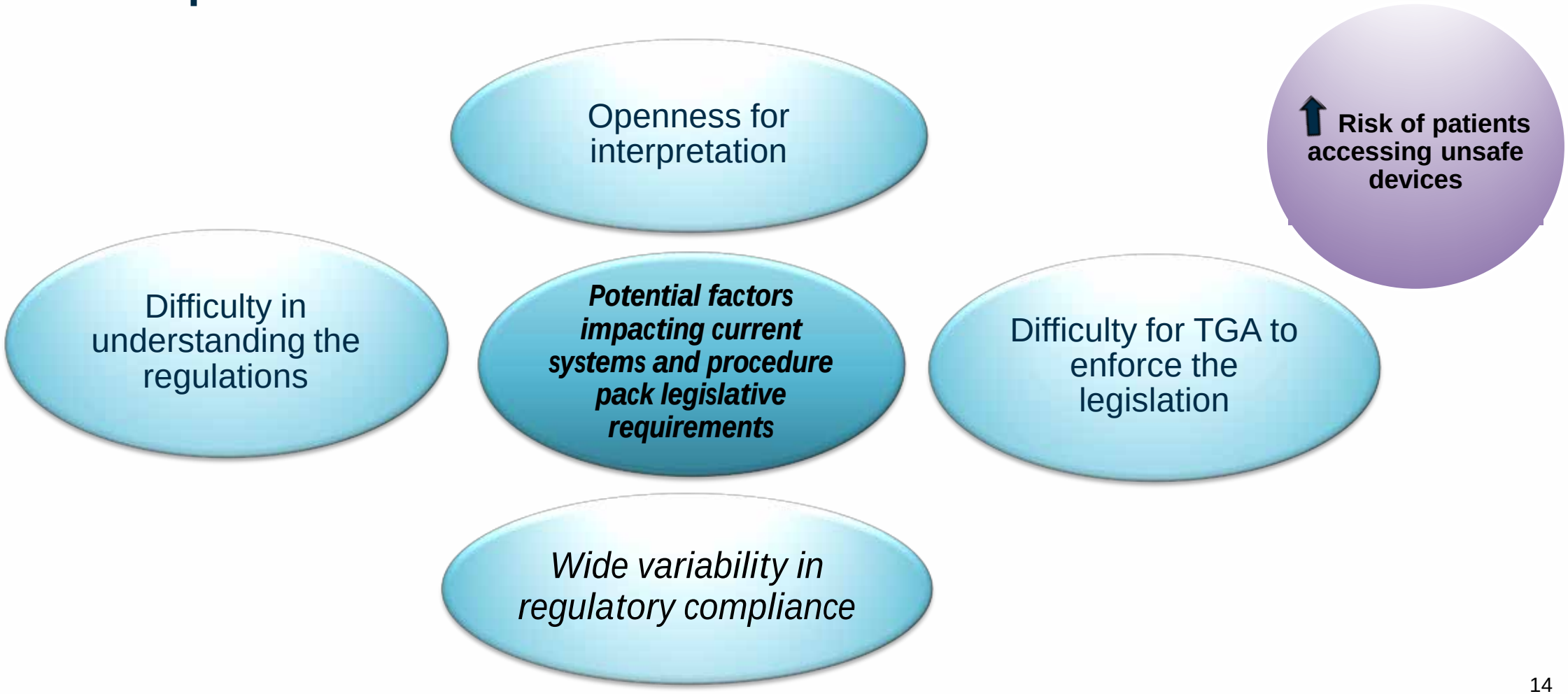
Factors impacting adequacy of the current legislative provisions for systems and procedure packs



Common findings impacting patient health and safety

- inclusion of component devices in the system or the pack where appropriate CA procedures have not been applied to those devices:
  - finished medical devices in the system or procedure pack that are subjected to additional steps of manufacture, such as re-sterilisation, contrary to the original manufacturer's instructions
  - 'unfinished' component devices included in the packs where the component manufacturer has not applied complete CA procedures to those devices
- **The individual that is supplying the pack has become the 'manufacturer of device' without meeting the quality management system requirements**

Common findings impacting patient health and safety

- Lack of identification and traceability:
  - Supply of ‘assembled’ packs where information has been removed from the original packaging of the of the device component
  - Information, such as component manufacturer’s details, is not provided with the device component supplied in the pack
  - **Component devices in the pack must meet the essential principles (EP)**
  - **The procedure pack as a medical device, also must meet the essential principles, including EP 13**

Common findings impacting patient health and safety

- Insufficient evidence to demonstrate that appropriate sterilisation validation processes are in place during the manufacturing process – where the device component or the entire procedure pack is supplied sterile
- Supplying systems or procedure packs where device components were not tested for the presence of endotoxin contamination which is particularly important for moderate to high risk medical devices or those used in the ocular environment
- Manufacturing procedure packs (rather than simply ‘assembling’ under the special conformity assessment procedure) without adequate supplier control, such as quality agreements
- Including insufficient safety and performance evidence from the component suppliers to demonstrate compliance with the essential principles of the Regulations, for the components in the pack.

Common findings impacting patient health and safety

- Information such as instructions for use provided by the device component manufacturer in order to use device safely and as intended has been omitted from the pack
- Instructions for use supplied by the device component manufacturer has been replaced with the procedure pack manufacturer's own or changes to the original intended purpose without evidence that they are the manufacturer of the device
- Device components included in the system or pack where the components where mutual compatibility of the each device has not been verified in the pack

Key factors associated with the current regulatory framework – that influence the patient safety concerns with the systems and procedure packs

No clear distinction between the terms ‘system’ and ‘procedure pack’

Table 1: Comparison of definitions for system or procedure pack in Australia and EU.

Australia	EU
System or Procedure Pack: (1) A package and therapeutic goods in the package are a system or procedure pack if: (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 (b) the package contains at least one medical device; and (c) the package and the therapeutic goods do not constitute a composite pack. (2) To avoid doubt, a system or procedure pack is a medical device. Therapeutic Goods Act, section 41 BF (System or procedure packs, p. 364)	***‘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. ***‘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. Regulation (EU) 2017/745, Article 2(4) (OJ L 117, 5.5.2017, p. 16)

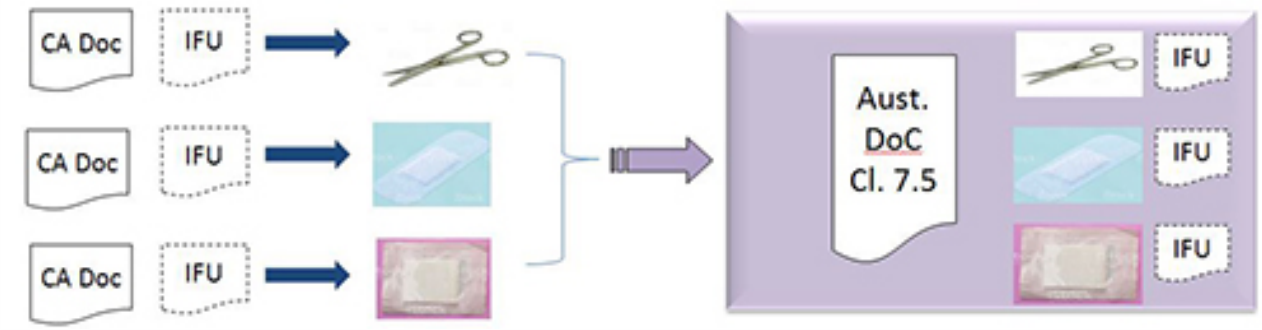
Clarity and consistency within and across jurisdictions

No clear distinction between the ‘manufacturer’ and ‘assembler’ of a system or pack

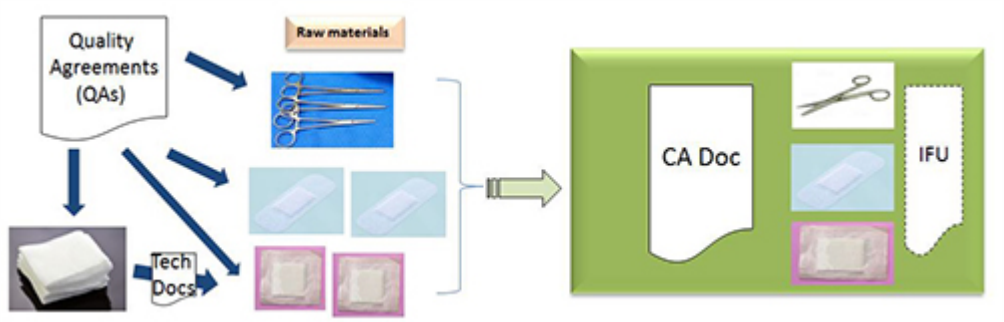
- *Therapeutic Goods Act 1989*, section 41 BG refer to “Manufacturers” of medical devices
- Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Clause 7.5 System or procedure packs refer to “‘manufacturer’ of a system or procedure pack”
- The activities undertaken by individuals who assemble the system or procedure pack using ready-made products are more accurately described as those of an ‘**assembler**’ rather than ‘manufacturer’ of a system or procedure pack
- Lack of clarity in the current legislation on the differences between an ‘assembler’ and a ‘manufacturer’ of the system or procedure pack has sometimes led to procedure pack ‘assemblers’ undertaking activities as ‘manufacturers’ without the required and appropriate conformity assessment evidence.

Clarity of the differences between the two entities and their responsibilities

- Assembler of system or procedure pack



- Manufacturer of system or procedure pack



No explicit requirement for each device in the system or procedure pack to be covered by conformity assessment documents when using the 'assembly' pathway

- For system or procedure packs supplied using clause 7.5:
  - current requirements do not clearly specify that each medical device in the system or the pack must be covered by an appropriate conformity assessment document from the TGA or a comparable overseas regulator or assessment body
  - The EU MD Regulation are more clear on this matter – devices in the system or procedure pack are each required to have CE marking (which means conformity assessment certification)

Clarity of the current requirements and mitigates risks for patients receiving these devices

No definition of the term ‘compatibility’

- When devices in a procedure pack are intended to be used with other components in the pack, they must be mutually compatible.

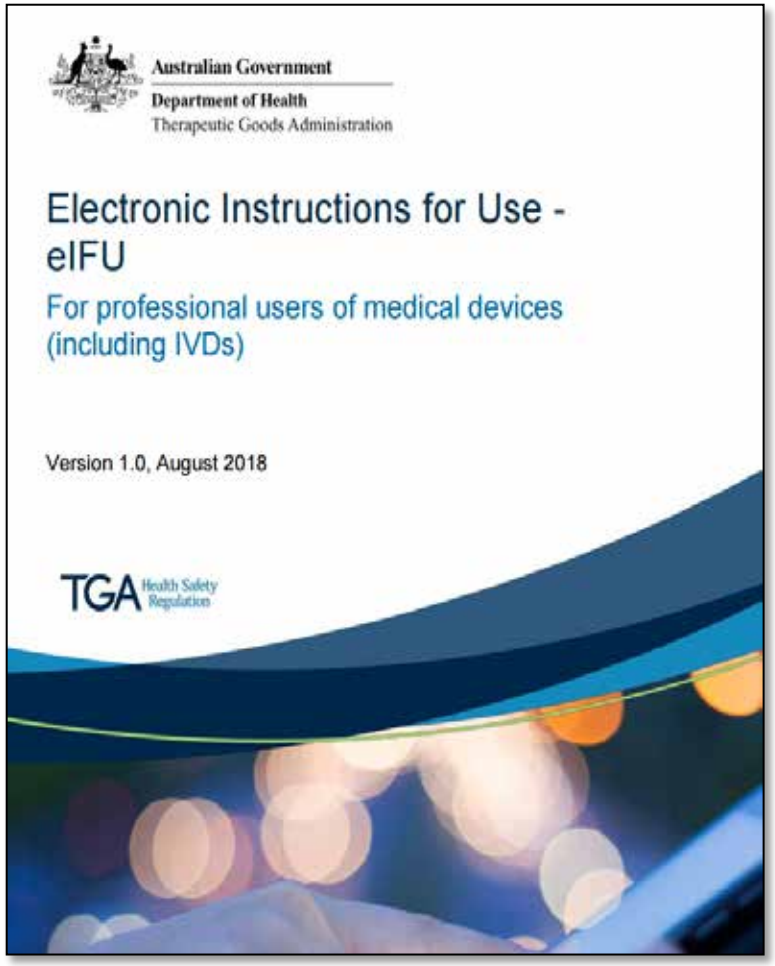
Table 2: Comparison of definition for compatibility in Australia and EU.

Australia	EU
No equivalent definition	*‘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 adaption of any part of the combined devices, and /or (c) Be used together without conflict/interference or adverse reaction. Regulation (EU) 2017/745, Article2(4) (OJ L 117,5.5.2017,p.17)

Clarity & understanding of ‘mutual compatibility’

Acceptance of Instructions for use in electronic or online format – professional users only

- No clear option for electronic instructions for use with the systems or procedure packs intended for use by professional users
- Potentially mitigate risk of omitting instructions for use provided by the device component manufacturer (for systems and procedure packs used by professional usere).



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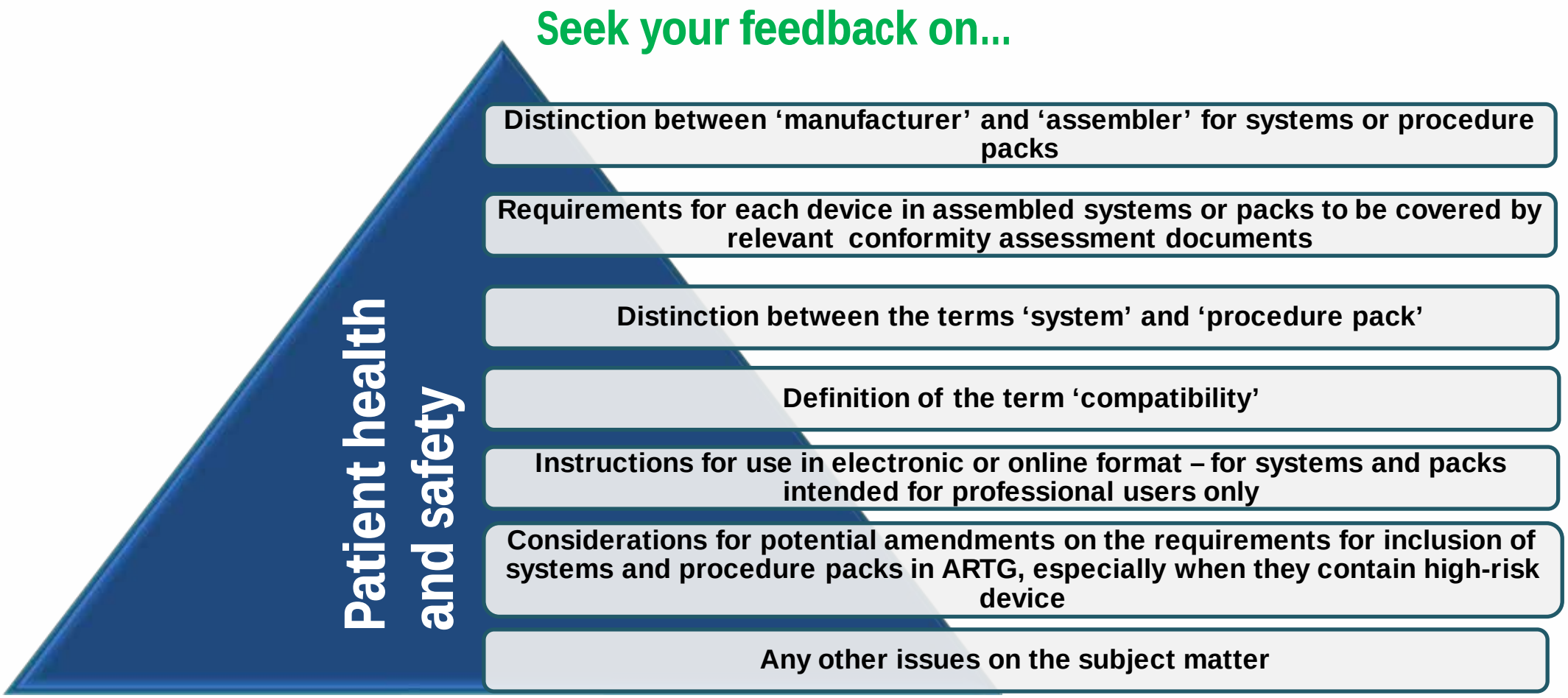
Conclusion - What do we intend to achieve?



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