Australian Government
Department of Health
Therapeutic Goods Administration

Current public consultations
Medical Devices Reforms

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TGA Health Safety Regulation

Current Public Consultations

Medical Devices Reforms

The Medical Devices Branch of the TGA currently has 5 open consultations which are related to our ongoing reforms work:

- Review of Therapeutic Goods Order 54 - Standards for Disinfectants; and associated guidance
- Medical device cyber security
- Proposal to introduce a Unique Device Identification (UDI) system for medical devices in Australia
- Potential reclassification of active medical devices for diagnosis and patient therapy
- Changes to a number of definitions and the scope of the medical device regulatory framework in Australia

Consultation: Disinfectants Standard –TGO 54

What is the TGA proposing?

- Hard surface disinfectants are regulated by the TGA through a Therapeutic Goods Order (TGO 54).
- TGO 54 is a standard that sets the requirements for performance, packaging and labelling. The Order will expire on 1 April 2019.
- A new Order is being made. There are no material changes other than a new requirement to ensure disinfectants cannot be presented in a way that implies use on the skin (skin disinfectants are regulated as medicines).
- For industry the new Order clarifies existing requirements for these products.
- For consumers there will be no substantial change to the way these products are regulated.

Consultation: Disinfectants Standard (cont.)

Why might it be important to consumers?

- Given their wide use (hospitals, healthcare, homes), it is important the TGA is aware of any consumer concerns regarding disinfectants.
- While the Order has a strong focus on technical requirements, consumer feedback on any issues, including packaging and labelling (label clarity and mandatory information), or concerns around clarity of product efficacy will be useful to the TGA.
- This consultation closes: 12 February 2019

Consultation: Guidance on Medical Device Cybersecurity

What is the TGA proposing?

- The fast increase of products with software or digital components has resulted in increased cyber security concerns for consumers, government and industry.
- Consequences of cyber security breaches could include anything from a release of personal information to failure of a life supporting device (e.g. a pacemaker)
- The TGA has partnered with the CSIRO (See: https://www.tga.gov.au/research-software-medical-device-and-cyber-security-medical-devices) to develop some guidance for consumers. The guidance will increase understanding of emerging cyber security concerns.

Consultation: Guidance on Medical Device Cybersecurity (cont.)

Why might it be important to consumers?

- Cyber security concerns may involve many ‘connected’ devices commonly used by consumers (i.e. Apps, internet linked medical devices or devices with a software component).
- As consumers are a core target audience of the guidance, it is important for the TGA to understand any consumer concerns and to have feedback on the overall content, clarity, level of information, and knowledge gaps in the guidance.
- Direct consumer feedback on the consumer fact sheet included in the guidance is vital.
- This consultation closes: 14 February 2019

Consultation: Introduction of a Unique Device Identification System

What is the TGA proposing?

Is a UDI system feasible in Australia?

- UDI System consists of:
  - globally harmonised standards;
  - requirements for manufacturers to create and place a Unique Device Identifier (e.g. alphanumeric code) on a device, its labelling and packaging; and
  - requirements to enter certain information into a central database.
- Benefits include:
  - Being able to track and trace medical devices throughout the supply chain;
  - A consistent way to identify the same device around the world.

Consultation: Introduction of a Unique Device Identification System (cont.)

Why might it be important to consumers?

- Whether the UDI requirements should apply to all devices (i.e. including ‘low risk’), or should the proposal exempt some devices
- Whether the TGA or another entity should manage the proposed database
- What impacts may be anticipated for consumers
- This consultation closes: 18 February 2019

Consultation: Reclassification of 'active medical devices'

What is the TGA proposing?

- To reclassify some categories of medical devices from medium risk to higher risk classifications. This will mean higher levels of clinical evidence assessment and scrutiny will occur.
- *Active medical devices - devices with a diagnostic function that changes a patient's therapy* (i.e. an automated external defibrillator (AED) or artificial pancreas).
- More stringent assessment of the manufacturer and the device, mandatory audits by the TGA and improved traceability in ARTG.

Consultation: Reclassification of active medical devices (cont.)

Why might it be important to consumers?

- These devices are often used in acute patient care, as such, patient concerns may be considerable.
- Feedback from affected consumers on the appropriateness of more stringent regulation of these products and proposed implementation timeframes would be highly valuable.
- Feedback as to whether other active medical devices from this category (e.g. CPAP devices, hyperthermia systems, etc.) should be classified as Class III, is also being sought.
- This consultation closes: 18 February 2019

Consultation: Changes to medical device definitions and scope of regulatory framework

What is the TGA proposing?

Changes are being considered to some of the definitions relating to medical devices and the scope of the products regulated as medical devices including:

- Clarifying the definition of what constitutes a medical device, accessory and other related definitions
- Proposing changes to the regulation of some products that do not have an ‘intended medical purpose’ (e.g. cosmetic facial injections, laser hair/tattoo removal equipment, decorative contact lenses)

Consultation: Changes to medical device definitions and scope of regulatory framework (cont.)

Why might it be important to consumers?

- Regulation of a product as a medical device means manufacturers are required to implement appropriate quality management and control over the design of the device.
- In addition, suppliers in Australia are required to have written evidence demonstrating that their products comply with safety and performance requirements and post-market requirements (i.e. recall procedures and advertising laws)
- Consumer feedback is important as to where perceived benefits or disadvantages may result from the proposed changes.
- Consultation closes: 18 February 2019

Watch this space:

Further consultations are proposed for 1st Quarter 2019:

- Personalised Devices (including 3D Printing)
- Reclassification of certain devices including: devices containing nanomaterials, spinal implants, IVF/Human tissue, central circulatory (i.e. heart) devices
- Software as a medical device (e.g. Apps, patient diagnostic software)

Where to find information on the consultation documents

- Visit the TGA webpage to view the current consultations and make a submission, https://www.tga.gov.au/open-consultations
- Instructions on how to submit is available on the page
- Submissions to the consultations will be published on the website
- To know more about TGA's consultation in general see https://www.tga.gov.au/about-consultations

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