Conformity Assessment Evidence
A Regulator’s Perspective

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Presentation Overview

Definition & Important Concepts

The Evidence

Change is Coming
What is Conformity Assessment?

**Conformity Assessment:** The systematic examination of evidence generated and procedures undertaken by the manufacturer, under requirements established by the Regulatory Authority, to determine that a medical device is safe and performs as intended by the manufacturer and, therefore, conforms to the *Essential Principles of Safety and Performance for Medical Devices.* - GHTF
What is Conformity Assessment?

- All Devices, unless exempt, Must Undergo Conformity Assessment according to their risk classification.

- All Devices must comply with the applicable essential principles.
Important Concept 1

“Begin at the beginning,” the King said, very gravely, “and go on till you come to the end, then stop.”

- Lewis Carroll
Important Concept 1 (continued)

DEVICE LIFECYCLE

Conformity Assessment Evidence
Important Concept 2
The Evidence
The Essential Principles

• Schedule 1 – Medical Devices Regulations

• Set out requirements relating to the safety and performance of the medical device
Essential principles for safety and performance

General principles

1. Use of medical devices not to compromise health and safety
2. Design and construction of medical devices to conform to safety principles
3. Medical devices to be suitable for intended purpose
Essential principles for safety and performance

General principles

4. Long-term safety

5. Medical devices not to be adversely affected by transport or storage

6. Benefits of medical devices to outweigh any side effects
Essential principles for safety and performance

Principles about design and construction

7. Chemical, physical and biological properties
8. Infection and microbial contamination
9. Construction and environmental properties
10. Medical devices with a measuring function
11. Protection against radiation
Essential principles for safety and performance

Principles about design and construction

12. Medical devices connected to or equipped with an energy source
13. Information to be provided with medical devices
14. Clinical evidence
15. Principles applying to IVD medical devices only
Demonstrating Compliance

Harmonised Standards

A harmonised standard is a European standard developed by a recognised European Standards Organisation: CEN, CENELEC, or ETSI. It is created following a request from the European Commission to one of these organisations. Manufacturers, other economic operators, or conformity assessment bodies can use harmonised standards to demonstrate that products, services, or processes comply with relevant EU legislation.

The references of harmonised standards must be published in the Official Journal of the European Union. The purpose of this website is to provide access to the latest lists of references of harmonised standards and other European standards published in the Official Journal of the European Union (OJEU).
Demonstrating Compliance

Clinical evidence guidelines
Medical devices

Version 1.0, February 2017

Format

• Should be easy to understand/find where information is located!
• Documents should be searchable
• Guidance on structuring a submission
  – The IMDRF Table of Contents documents (on TGA website)
Changes are on the way
The new Regulations on medical devices

On 5 April 2017, 2 new Regulations on medical devices were adopted. These replace the existing Directives.


The new rules will only apply after a transitional period. Namely, 3 years after entry into force for the Regulation on medical devices (spring 2020) and 5 years after entry into force (spring 2022) for the Regulation on in vitro diagnostic medical devices.
The Expert Panel Review of Medicines and Medical Devices regulation

- Two reports on **medicines and devices** and **complementary medicines and advertising** released during 2015
- **Review process** included discussion papers, submissions and interviews with key stakeholders. Followed by **stakeholder workshops and other meetings** to get feedback
- **Department considered** stakeholder feedback and advised Minister, who took her preferred position to Cabinet
- **Government intent** released in May 2016 budget, and full response released on 15 September 2016
Recommendation 20 – Continue to Align with the EU

• Australian regulation of medical devices is, wherever possible, aligned with the European framework,

• Where there are Australian specific requirements, there must be a clear rationale for this
  − Classification, EPs, CA Procedures, Definitions, etc.
Implementation and Governance

• A broad plan for implementation over 2-3 years agreed by Government

• We will also consult closely with stakeholders in developing the finer detail on implementation, including assessment of regulatory impacts and fees and charges

• TGA has been empowered to work out much of the detail on how specific changes could be implemented
  – But we will need to go back to government for approval, in particular where changes to the TGA Act or Regulations are needed
Aligning the EPs and GSPRs

- Annex 1 of the new **EU** regulations
- Includes 23 ‘General Safety and Performance Requirements’ (GSPR) replacing ‘Essential Requirements’
- Based on the GHTF Essential Principles 2012
GSPR Chapter I

General Requirements – GSPRs 1 - 9

• Key changes:
  − Major changes regarding risk management (GSPRs 2 – 5)
    • Closely aligned with ISO: 14971;
    • GSPR 3 – Continuous Risk Management processes;
    • GSPR 4 – Sequence of risk control procedures;
    • GSPR 5 – Risk regarding usability – ergonomics, training, intended user.
  − GSPR 9: Minimise risks for non-therapeutic devices (aesthetic, etc.)
GSPR 10 **Substances**:  
- Justification for CMR or endocrine-disrupting substances, when present > 0.1% (w/w);  
- Guidelines on phthalates;  
- Labelling requirement on devices and packaging for above substances.  

- Reduce risks linked to the size and properties of particles released into patient’s or use’s body, particularly **nanomaterials**.
GSPR Chapter II

Requirements Regarding Design and Manufacture – GSPR 10 - 22

- **GSPR 11 – Infection and microbial contamination**
  - Reduce risks from unintended cuts and pricks;
  - Design to facilitate safe cleaning, disinfection and/or re-sterilisation;

- **GSPR 12 – Devices incorporating a substance considered to be a medicinal product** and devices that are composed of substances or of combination of substance that are absorbed by or locally dispersed in the human body
  - Verified with the specified requirements laid down in Directive 2001/83/EC;
  - Evaluation of ADME profile, local tolerance, toxicity, interaction with other devices.
Chapter II
Requirements Regarding Design and Manufacture – GSPR 10 - 22

- GSPR 14 – **Construction of Devices and Interaction with Environment**
  - designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively.
  - be designed and manufactured in such a way as to facilitate their safe disposal and the safe disposal of related waste substances by the user, patient or other person.
  - manufacturers shall identify and test procedures and measures as a result of which their devices can be safely disposed after use. Such procedures shall be described in the instructions for use.
GSPR Chapter II
Requirements Regarding Design and Manufacture – GSPR 10 - 22

• GSPR 17 - **Software**
  – Key changes:
    ▪ software shall be developed and manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation.
    ▪ requirements for software and **mobile computing platforms** – considerations for size and contrast ratio of screen, level of light and noise in environment.
    ▪ minimum hardware requirements, IT network characteristics, IT security measures.
GSPR Chapter II

Requirements Regarding Design and Manufacture – GSPR 10 - 22

- GSPR 18 - **Active devices and devices connected to them**
  - Key improvements:
    - Immunity to electromagnetic interference;
    - (EP 12.5 – only minimise electromagnetic field generation)
    - Protect, as far as possible, against unauthorised access that could hamper the device from functioning as intended
GSPR Chapter II
Requirements Regarding Design and Manufacture – GSPR 10 - 22

• GSPR 19 - **Particular requirements for active implantable devices**
  - minimise risks connected with medical treatment, in particular those resulting from the use of defibrillators or high-frequency surgical equipment.
  - minimise risks which may arise where maintenance and calibration are impossible, including:
    - excessive increase of leakage currents,
    - ageing of the materials used,
    - excess heat generated by the device,
    - decreased accuracy of any measuring or control mechanism.
GSPR Chapter II
Requirements Regarding Design and Manufacture – GSPR 10 - 22

• GSPR 22 – Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons (no requirement in current EPs)
  - Important for home use devices,
  - Safety, performance, design and manufacture considering the skills and means available to the lay person, easy to understand information.
GSPR Chapter III
Requirements Regarding Information Supplied with the Device – GSPR 23

• GSPR 23 – **Information supplied by the manufacturer**
  – Numerous Changes, Including
  – a requirement for UDI
  – in the case of implantable devices, the overall qualitative and quantitative information on the materials and substances to which patients can be exposed;
  – a notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established;
  – Implant card and information/warnings for patients
Work has already begun…

Consultation: Alignment with European medical device regulatory framework

Up-classification of surgical mesh & Patient implant cards

28 July 2017

This consultation closes on 25 August 2017.

Question time…