IMDRF International Medical Device Regulators Forum

Regulatory Updates
Health Sciences Authority
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UDI Implementation - Updates

- HSA will be implementing UDI for medical devices (MDs) supplied in Singapore in phases starting from 2022 and the proposed approach is:
  - **Aligned to internationally harmonised principles** outlined in the UDI guidance published by IMDRF
  - **Capturing UDI information on our current medical device database –** Singapore Medical Device Register (SMDR) is an existing database where companies currently submit essential information on their registered medical devices including model information
  - **Leveraging the existing UDI barcodes** that manufacturers have applied on their MDs for US and/or EU markets
    - No Singapore specific UDI will be required for MDs with existing US or EU UDI
  - **Risk calibrated**, Only medium to high risk MDs will require UDI label; For low risk MDs (Class A), UDI will not be mandatory.
    - May be implemented on a voluntary basis e.g. UDI labelled in country of origin
  - **Phased approach**, In phase 1 (2022) only three types of high risk implantable MDs will be required to be labelled with UDI
    - Coronary stents, orthopaedic joint replacement implants & IOLs
    - The 3 subsequent phases of implementation will start 2 years after each phase for Class D, Class C and then Class B respectively

UDI Implementation - Updates

- HSA published the UDI guidance for consultation – “Guidance on the medical device Unique Device Identification system”
  - Online consultation completed on 30 June 2021
  - Focus group discussion sessions with stakeholders completed in July & August 2021
  - Review of comments/feedback received completed and the finalised guidance published in August 2021 https://www.hsa.gov.sg/medical-devices/guidance-documents
- Our current online medical device application system (MEDICS) and our online database (SMDR) have been enhanced to be able to accept and include UDI related information
- Local medical device companies who have registered or who are registering medical devices (Class B, C and D) in Singapore may start submitting UDI information on a voluntary basis

Guidance Documents – Update

- **Regulatory Guidelines for 3D Printed Medical Devices**
- This document presents HSA's current thinking and policy on regulating 3D printed medical devices
  - Approach to differentiate custom-made and mass manufactured medical devices that are 3D printed
  - Regulatory controls applicable to these categories of 3D printed medical devices
  - Key design, manufacturing and validation considerations applicable for all 3D printed medical devices in demonstrating compliance with essential safety and performance requirements
- This document completed consultation and the finalised document and the FAQ can be accessed online at:

  https://www.hsa.gov.sg/medical-devices/guidance-documents

Guidance Documents – NEW

- **Regulatory Guidelines on Software as Medical Device (SaMD)**
- HSA published a regulatory guideline for consultation in July 2021. This document covers our current thinking and approach for:
  - Risk Classification of Software as Medical Device (Standalone medical mobile applications and software)
  - Qualification of Clinical Decision Support Software (CDSS)
- The principles and approach presented in this document are aligned with the relevant IMDRF documents from the SaMD working group
- Consultation period for this document ended on 19 August 2021 and review of the feedback/comments received is in progress
- The finalised version of this document will be published by Q4 2021 or Q1 2022.

Thank you!