IMDRF International Medical Device Regulators Forum

Regulatory Updates
Health Sciences Authority
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UDI - Phased Implementation Plan

- 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
  - **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 - Phased Implementation Plan

- The UDI information will be captured and published on the Singapore Medical Device Register (SMDR), our current online database for registered medical devices which is available to the public.
  - SMDR already captures most of the essential data such as intended use, model information, manufacturer information etc. for registered MDs
  - SMDR is fit-for-purpose to serve as the database for UDI related information – No new database is required
  - Minimum necessary additional UDI related data fields will be incorporated into our current SMDR database

- A webinar was held on 19 Oct 2020 to engage stakeholders early regarding this initiative and presentation can be accessed online at:
  https://www.hsa.gov.sg/docs/default-source/announcements/regulatory-updates/udi-implementation-for-singapore_19oct20.pdf?sfvrsn=ce7c866c_0

Guidance Documents – Updates

- An interim guideline “Change Notification applications arising from the EU MDR/IVDR related changes to registered medical devices” has been finalised and published in October 2020
  - A significant percentage of the registered medical devices distributed in Singapore are from Europe. With the MDR and IVDR implementation, many of these registered medical devices are impacted by the new or updated requirements
  - Changes to the registered medical devices here could include simple labelling updates to more complex changes
  - The document provides clarity on different changes that would require/not require the submission of a CN application, as well as the changes that could be bundled in a single submission
  - The document can be accessed online at:

https://www.hsa.gov.sg/docs/default-source/hprg-mdb/change-notifications-arising-from-the-eu-mdrivdr-related-changes-(oct---pub).pdf?sfvrsn=9ccfdc77_0

Guidance Documents – Updates

- **Regulatory Guidelines for 3D Printed Medical Devices**
  - Currently published for consultation until 28 February 2021.
- 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 can be accessed online at:

https://www.hsa.gov.sg/announcements/regulatory-updates/consultation-on-regulatory-guidelines-for-3d-printed-medical-devices

Thank you!