# Regulatory Updates from Health Sciences Authority Singapore

January 2021

# Overview

- ❑ Facilitating the submission of Change Notification applications arising from the EU MDR and IVDR related changes
- ❑ Plans for phased implementation of Unique Device Identifier (UDI) system in Singapore
- ❑ New Digital Health Webpage
- ❑ New Medical Device Grouping Tool
- ❑ Online platforms to facilitate submissions and reporting
- ❑ Regulatory Guidelines on Software MDs – A lifecycle approach
- ❑ Key initiatives related to COVID-19

# Facilitating the submission of Change Notification applications arising from the EU MDR and IVDR related changes

- EU's transition to the Medical Device Regulation (MDR) and In-vitro Diagnostic Regulation (IVDR) requires some changes to be made, particularly to the Instructions for use (IFU) and labels of the devices

- Some of the locally registered MDs will require Change Notification (CN) applications to be submitted for these changes

- Focus group discussion with members from the SMF MTIG was held in Jul 2020 to seek feedback on the proposed approach

- Final document was published in Oct 2020, incorporating feedback from the industry
  - It provides clarity on different scenarios that would require/not require the submission of a CN application, as well as the changes that could be bundled in a single submission

# Plans for phased implementation of Unique Device Identifier (UDI) system in Singapore

- UDI provides "standardized identification codes" for MDs to:
  - **Improve the traceability of MDs and identification** by regulators, hospital users and industry, including manufacturers and distributors
  - **Enhance patients' health and safety** with more efficient identification of specific MDs impacted by recalls, device failures or serious adverse events

- Implementation of UDI in Singapore will be:
  - **Aligned to internationally harmonised principles** outlined in the UDI guidance published by the International Medical Device Regulators Forum (IMDRF)
  - **Leveraging the existing UDI barcodes** that manufacturers applied on their devices for US and/or EU markets
    - No Singapore specific UDI will be required
  - **Risk calibrated**, starting with three types of high risk implantable MDs* in 2022

- A webinar was held on 19 Oct 2020 to engage stakeholders early regarding this initiative

*Three types of high risk implantable MDs are: Coronary stents, orthopaedic joint replacement implants & Intraocular lens

# New Digital Health Webpage

- This webpage serves as a one stop reference for stakeholders interested in understanding the regulatory controls for digital health medical devices in Singapore
- It includes information on digital health products that are regulated as medical devices, the relevant regulatory controls and information on various guidelines relevant to these medical devices
- The new webpage can be accessed online at:

https://www.hsa.gov.sg/medical-devices/digital-health


## Digital Health

UNDERSTANDING DIGITAL HEALTH PRODUCTS AND THE REGULATIONS

### What is Digital Health

Digital health includes diverse categories of products comprising telehealth and telemedicine, mobile health, wearable devices, health information technologies and personalised medicine.

It refers to the usage of connected devices, wearables, software including mobile applications (apps) and artificial intelligence (AI) to address various health needs via information and communications technologies.

Digital health has opened up the medical device space to an array of providers such as software or mobile app developers and IT solution providers.

### Supporting Digital Health Product Innovation

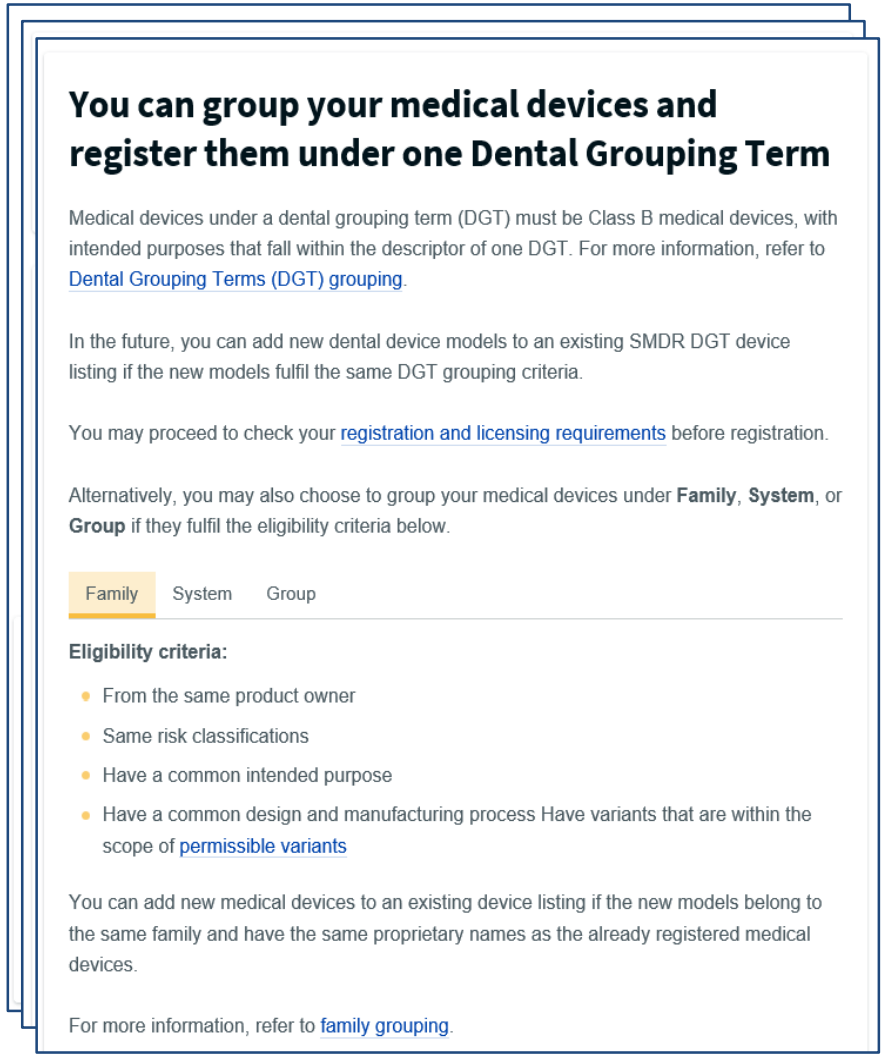
**1. Regulatory Guidelines for Telehealth Products**

This guideline was developed in 2017 to help manufacturers, developers or importers of a digital health device or tool i) to determine if their device, software or app are regulated medical devices under HSA and ii) understand the relevant regulatory requirements.

**2. Immediate Registration Pathway for Standalone Software and Mobile Applications**

# New Medical Device Grouping Tool

- ❑ To guide users in determining typical grouping options for the MD registration applications
- ❑ Key features:
  - Interactive Q&A format
  - Provides guides and info if unsure
  - Final answer card provides info on next steps, future amendments and alternative grouping options for consideration
  - Users are able to print the outcome with their device's name
- ❑ Targeted for launch by end Jan 2021

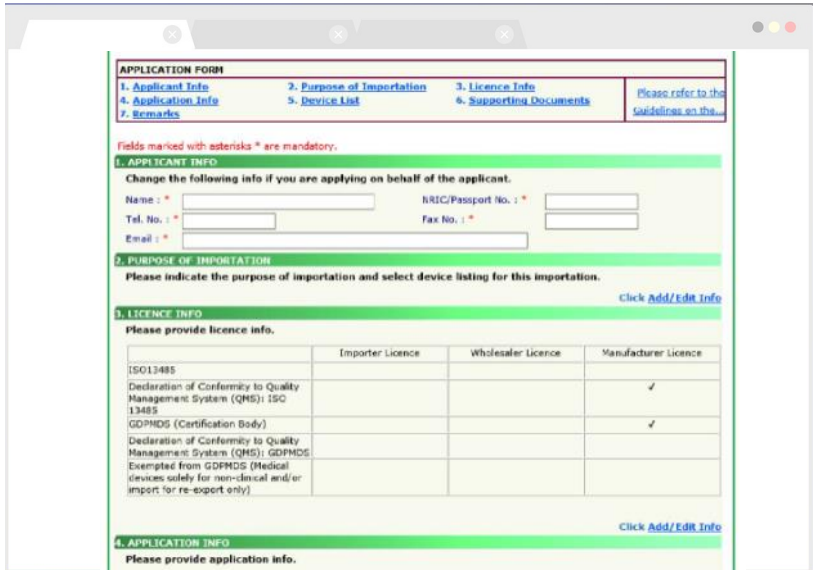


# Online platforms to facilitate submissions and reporting

(1 of 2)

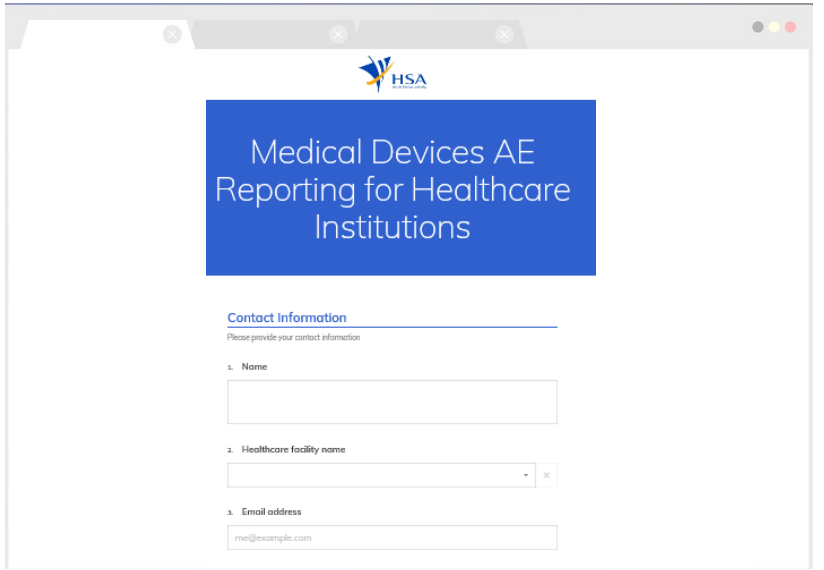
**a) New module in MEDICS for Special Access Route (SAR) applications**

Submission and tracking of these applications can done under one centralised platform in MEDICS




**b) Online form for the submission of medical devices adverse events by Healthcare Professionals**

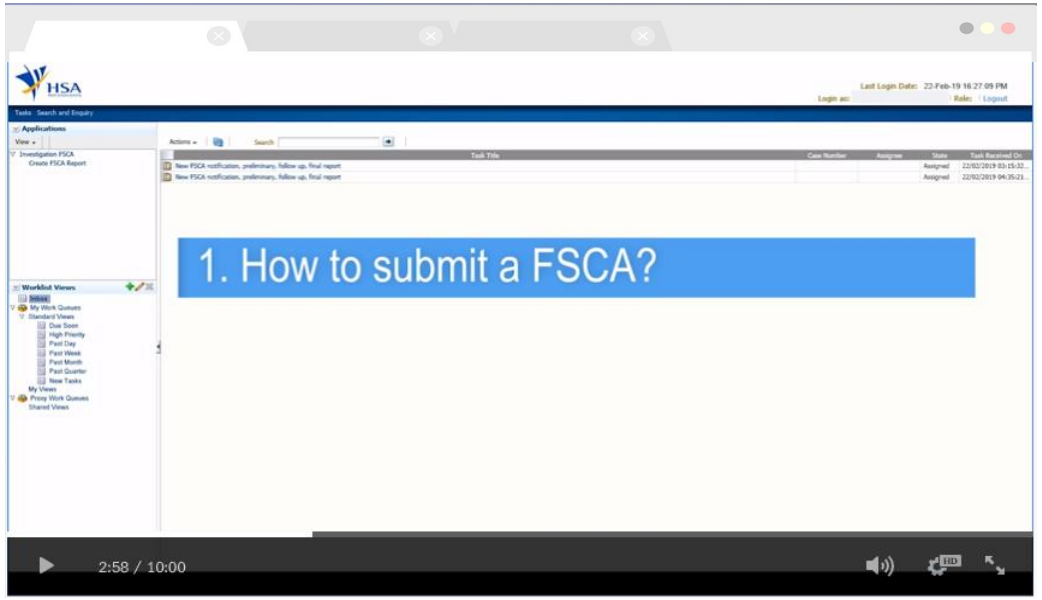
This mobile compatible and user-friendly online form will provide greater convenience to facilitate reporting



# Online platforms to facilitate submissions and reporting
(2 of 2)

## c) Online system for Field Safety Corrective Action (FSCA)

- This system was launched in Jan 2020 to enhance the ease of reporting and facilitate tracking of past FSCA submissions as well as the identification of “open” cases that requires follow-up
- There are plans for the system to be extended to cover AE reporting in 2021 to enable more effective data mining and trending analysis, which will enhance signal detection and response
- Relevant guidance and training videos on how to access the platform are available online



# Development of guidance document to enhance clarity of regulatory controls

- **Regulatory Guidelines on Software MDs – A lifecycle approach**
  - This guidance document covers the regulatory considerations and requirements applicable throughout the lifecycle of the software medical device
  - Final document, which incorporated the comments received from online consultation and focus group discussions with industry groups, was published in Apr 2020

# Key initiatives related to COVID-19

## Supporting product innovation

**Consultations**
conducted to provide early scientific and regulatory advice for COVID-19 medical devices

## Expediting market access


**Provisional Authorisation applications approved**
*which consists of*

**- diagnostic tests**

**- ventilators**

**- decontamination devices**

## Facilitating local manufacturing

**New local medical masks manufacturers licensed**
facilitating an overall manufacturing capacity

## Enhancing clarity of requirements

**Guidances**
published on medical devices used in the diagnosis and management of COVID-19

## Partnerships & collaborations

Contributing our regulatory & scientific expertise in local & international working groups on COVID-19 topics

# COVID19 Related Guidances published

- COVID10 related information is available at:

https://www.hsa.gov.sg/covid-19-information-and-advisories

  - Guidance on the expedited approval of COVID-19 diagnostic tests
  - Guidance on the import of surgical masks, hand sanitisers, respirators, thermometers and protective gear
  - Guidance on the supply of respiratory devices
  - Guidance on 3-D printing of essential medical devices and accessories for use in COVID-19 situation
  - Guidance on medical devices for decontamination of single use respirators during the COVID-19 situation
  - Guide to masks and respirators

# Thank you