DENTAL LABORATORY REGULATORY REQUIREMENTS IN SINGAPORE

MEDICAL DEVICES CLUSTER

MAY 2022

OVERVIEW OF

MEDICAL DEVICE REGULATORY CONTROLS

MD Regulatory Controls

Pre-market

Post-market

Product Controls

- Medical devices (MDs), except Class A devices, are generally required to be registered with HSA before import and supply in Singapore
- Exceptions to registration include custom-made MDs
  - Custom-made MDs have unique design, attributes and/or specifications to fit an individual patient
  - Examples of custom-made dental MDs by risk classification*:

Class A *(lowest risk)*	Class B	Class C	Class D *(highest risk)*
• Dental aligners • Dentures	• Dental crowns • Dental bridges • Retainers • Inlays	• Dental implants intended for long term use	None

  - Dealers are required to notify HSA of the list of custom-made MDs that they deal with

* *See page 12 for more details on risk classification of dental implant components*

Dealers Controls

Dealer's Licensing

Local companies who **manufacture**^, import or supply MDs by wholesale are required to be licensed by HSA

Types of Dealer License – based on company's activities

Local manufacturing^	Importing	Wholesale (including export)
Manufacturer's License	Importer's License	Wholesaler's License

^ "***manufacture***", *in relation to a health product, means to make, fabricate, produce or process the health product and includes*
(a) any process carried out in the course of so making, fabricating, producing or processing the health product; and
(b) the packaging and labelling of the health product before it is supplied

Dealers Controls

- Dental laboratories that manufacture^ dental MDs, including custom-made MDs, are considered manufacturers

- Current requirements for a Manufacturer's License:
  - ISO 13485^^ certificate (Class B and above)

  OR

  - Declaration of conformity to a Quality Management System (Class A only)

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*^^**ISO 13485**: Medical devices — Quality management systems — Requirements for regulatory purposes*

STANDALONE:

Operating outside PHMC^ licensed healthcare institutions and dental clinics, not licensed by MOH under the PHMCA^

UPCOMING REGULATORY APPROACH FOR

LOCAL STANDALONE DENTAL LABORATORIES

*^**Private Hospitals and Medical Clinics Act (PHMCA)** or **PHMC** Act covers the control, licensing and inspection of private hospitals, medical clinics, clinical laboratories and healthcare establishments in Singapore.*

Considerations

- Local dental laboratories have experience with manufacturing custom-made dental MDs

- Locally manufactured custom-made dental MDs
  - have had no serious safety incidents reported so far
  - are typically of lower risk class (risk class A and B)
  - are manufactured based on a prescription and fitted by registered dentists

Risk-calibrated regulatory approach
for local standalone dental laboratories manufacturing
Class A and/or Class B dental custom-made devices

Calibrated Regulatory Approach

1. Dealers Control (Manufacturing Activity)

Calibrated Approach For local standalone dental laboratories manufacturing **only** Class A and/or Class B dental custom-made MDs	**Standard Approach** For registrable MDs
Implementation of a Quality Management System • No certification required **One-time notification to HSA** • Local manufacturing site • Scope of manufacturing activities **No fees required**	**ISO 13485 certification** **Manufacturer's License application and annual renewal** **Licence fees apply**

- Standalone dental laboratories manufacturing higher risk MDs (Class C and/or Class D) will be subject to standard regulatory requirements

Calibrated Regulatory Approach

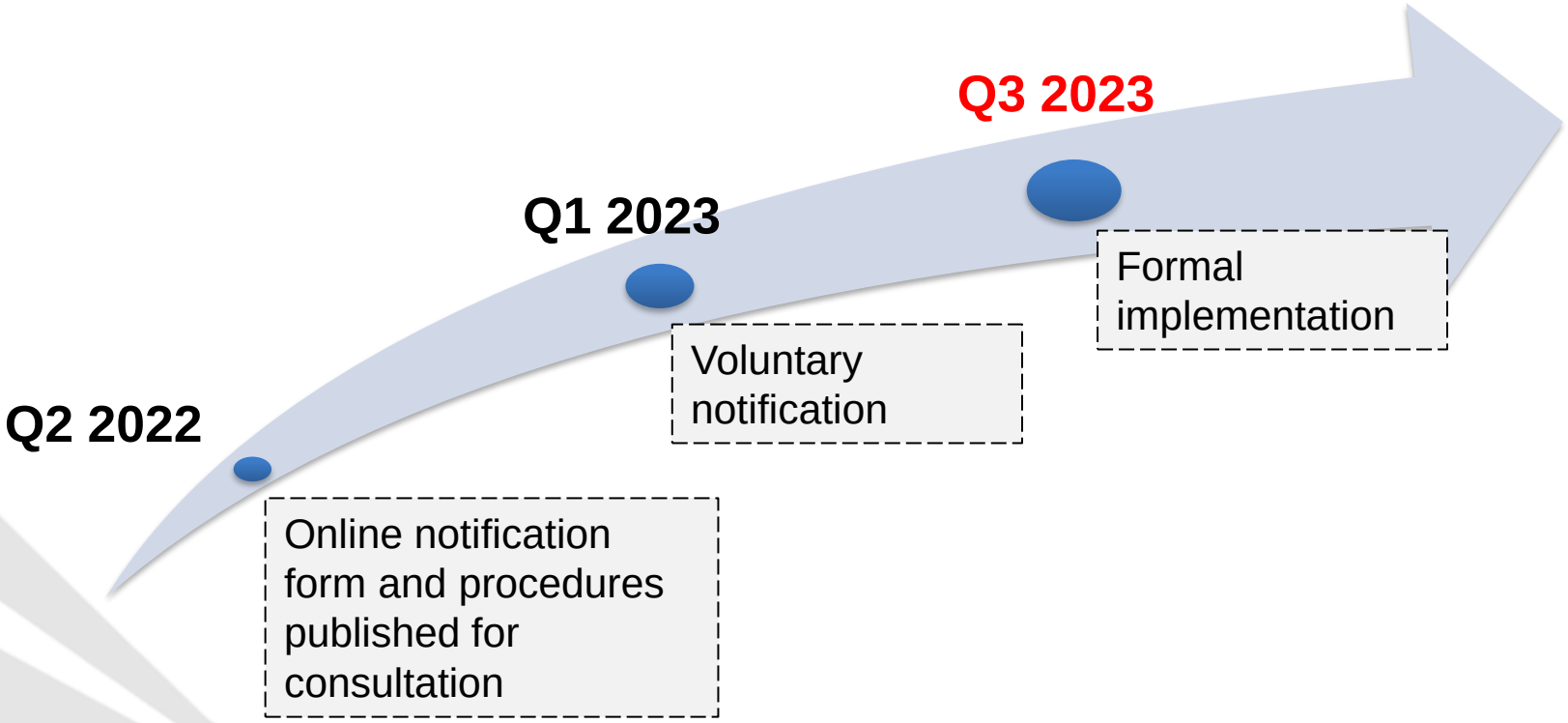
2. Product Control

Calibrated Approach For local standalone dental laboratories manufacturing **only** Class A and/or Class B dental custom-made MDs	**Standard Approach** For registrable MDs
Product notification of dental MD type (e.g. aligners, bridges) prior to supply **No fees required**	**Product registration prior to supply** **Registration fees apply**

3. Post-market Control

- All post-market obligations will apply, e.g.
  - Mandatory reporting of field safety corrective actions and adverse events
  - Maintenance of distribution records and complaints

Proposed Implementation Plan



Risk Classification of Dental Implant Components

Dental implant components are risk classified based on their

- degree of invasiveness, and
- duration of contact with the patient.

1. **Surgically-invasive, long-term**

   → Class C, Rule 8

   e.g. implant body, abutment

2. **Not surgically invasive, long-term (in oral cavity)**

   → Class B, Rule 5

   e.g. fixed dental prostheses: crowns, bridges, overdentures

For more information on risk classification rules, their definitions and examples, please refer to *GN-13 Guidance on the Risk Classification of General Medical Devices* available at https://www.hsa.gov.sg/medical-devices/guidance-documents

Useful Links

Controls on custom-made medical devices:

https://www.hsa.gov.sg/medical-devices/registration/special-access-routes/custom-made-devices

Medical Device Guidance Documents:

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

- GN-13 Guidance on the Risk Classification of General Medical Devices
- Regulatory Guideline For 3D-Printed Medical Devices
  (*Product registration → Product Specific Regulatory guidelines*)
- GN-07 Guidance on Complaint Handling of Medical Devices
- GN-05 Guidance on Reporting of Adverse Events for Medical Devices
- GN-10 Guidance on Medical Device Field Safety Corrective Action
  (Safety Monitoring)

Queries

For clarifications regarding
dental laboratory requirements,
please email **HSA_MD_Info@hsa.gov.sg** with the
email subject "**Dental Laboratory**".