IMDRF International Medical Device Regulators Forum

Regulatory Updates
Health Sciences Authority, Singapore

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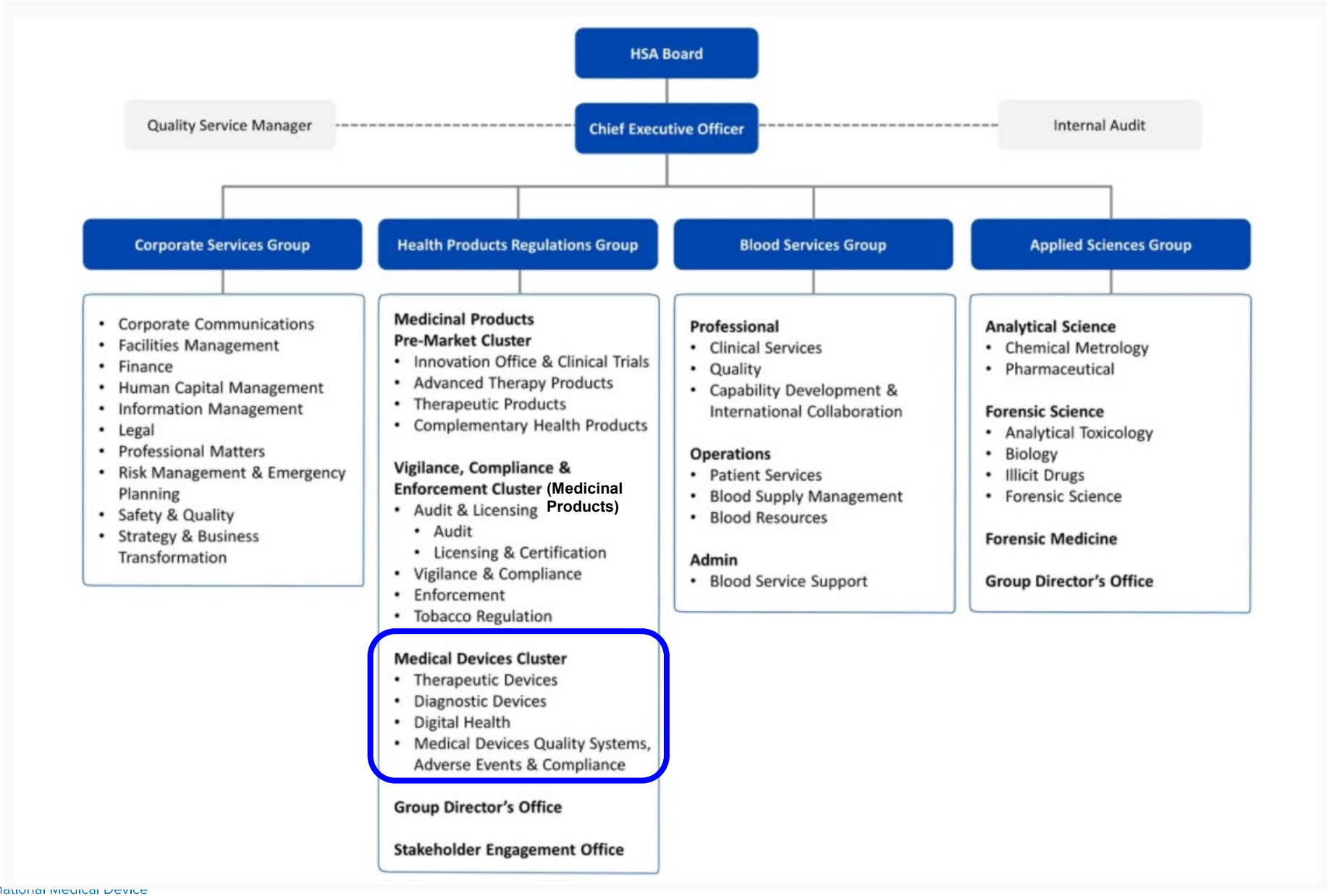
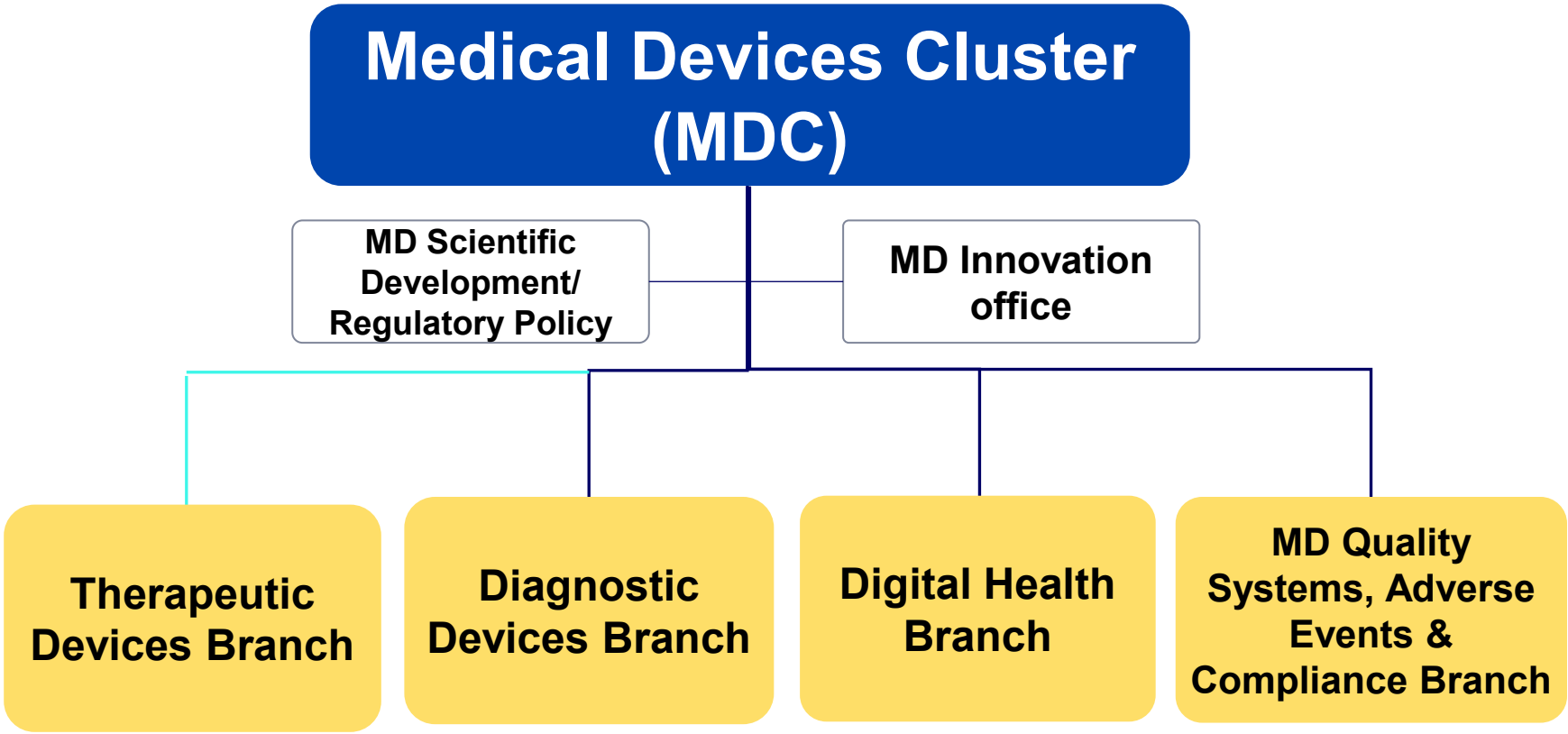
HSA Organisational Chart



Medical Devices Cluster – New Structure (effective Jan 2022)



Guidance Documents – Update

Guidelines on Risk Classification of SaMD* and Qualification of CDSS#

- ❑ This guideline explains the approach for determining the risk classification of SaMD drawing reference from the IMDRF's framework for risk classification for SaMD and the current classification based on the existing rule based approach
- ❑ Provides clarity on the qualification of CDSS as regulated medical device or otherwise and presents the current regulatory requirements for such software medical devices
- ❑ The guideline was published for consultation in 2021 and the finalised version incorporating stakeholders' feedback and comments has been published in April 2022
- ❑ This document can be accessed online at:

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

**SaMD – Software as Medical Device (also referred as Standalone Medical Mobile applications in Regulations in Singapore*
#CDSS – Clinical Decision Support Software

Guidance Documents – Update

Medical Devices Product Classification Guide

- This guide presents the classification (medical device or non-medical device) of certain products/ product categories that are commonly misclassified by stakeholders and the rationale for the classification, where relevant
- A product classified and regulated as a medical device in one jurisdiction may not necessarily be classified similarly in Singapore
- As part of our continual efforts to support stakeholders' needs, the guide was developed to aid stakeholders in determining whether their products are classified as medical devices
- The finalised version of the guide has been published online in November 2021 after incorporating the feedback and comments received during stakeholders consultation
- This document can be accessed online at:

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

Guidance Documents – Update

Regulatory Guidelines for Laboratory Developed Tests (LDTs)

- This guideline describes a fit for purpose regulatory approach for laboratory developed tests (LDTs) developed and used within licensed clinical laboratories
- The regulatory approach has been developed in consultation with the Ministry of Health (MOH) and takes into consideration the existing regulatory requirements applicable to clinical laboratories under the Healthcare Services Act (HCSA) administered by MOH
- The guideline provides an overview of the scope of LDTs and the regulatory requirements applicable, which includes Product controls, Manufacturing Quality controls and Post-market controls.
- Consultation period for the document ended in August 2022. Review of feedback and comments in progress and the finalised version to be published in Q3 2022

Facilitating Regulatory Reliance and Recognition

❑ HSA, Singapore has been working together with the ASEAN Medical Device Regulators under the ASEAN Medical Device Committee (AMDC) in harmonising the medical device technical regulatory requirements under the ASEAN Medical Device Directive (AMDD)

❑ Confidence building efforts - HSA has shared our medical device regulatory process and requirements in various knowledge sharing sessions including workshops, one-to-one sharing, trainings sessions, seminars etc.

❑ Medical devices evaluated and approved by HSA, Singapore are now eligible for expedited pathways in certain ASEAN markets

- ✓ **Thailand** – High-risk medical devices approved by HSA are eligible for expedited evaluation by the Thailand Food and Drug Administration (Thai FDA); HSA shares our evaluation reports for these medical devices with Thai FDA to support their regulatory process
- ✓ **Philippines** – Class B, C or D medical devices approved by HSA using the ASEAN Common Submission Dossier Template (CSDT) are eligible for Philippines Food and Drug Administration's abridged registration process.

❑ HSA continues to work with the regional regulators and the industry associations to facilitate these efforts

HSA Singapore Achieves Highest Maturity Level in WHO Classification

https://www.who.int/news

Singapore medicines regulator world's first to achieve highest maturity level in WHO classification

27 February 2022 | Departmental news | Geneva/Manila | Reading time: 2 min (569 words)

Out of 28 countries formally assessed by WHO, Singapore is the first to have achieved the highest maturity level (ML 4) in WHO's classification of regulatory authorities for medical products. Achieving ML 4 brings Singapore closer to becoming a WHO listed authority, a new scheme that will be operational later this year and will list the world's regulators of reference.

- Singapore is the first WHO member state to achieve the highest level, or Maturity Level (ML) 4, for operating an advanced medicines regulatory system
- Involved a rigorous and comprehensive assessment by a team comprising 19 international assessors and WHO officials using the WHO Global Benchmarking Tool (GBT)
- HSA Press Release:

  HSA Singapore the First National Regulatory Authority Awarded the Highest Recognition for an Advanced Medicines Regulatory System by the World Health Organization

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Thank you/Questions

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