IMDRF
International Medical Device Regulators Forum

EU2023
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Regulatory Updates from IMDRF Management Committee and Official Observers

IMDRF International Medical Device Regulators Forum

EU2023 EUROPEAN UNION Chair

08:40 – 08:55

Australia

Tracey Duffy

First Secretary, Medical Devices and Product Quality Division, Therapeutic Goods Administration (TGA)

European Commission | European Union

IMDRF International Medical Device Regulators Forum

Regulatory Update - Australia

Ms Tracey Duffy
First Assistant Secretary
Medical Devices and Product Quality Division
Therapeutic Goods Administration (TGA)
28 March 2023

Overview

- An Action Plan for Medical Devices
  - Reforms since June 2021 (snapshot only)
- EU MDR Impact
- COVID-19
- TGA Strategic Activities
- TGA Transformation Program - Purpose
- IMDRF Participation

An Action Plan for Medical Devices

Continues to guide medical device reforms that:

- strengthen our regulatory system
- remains patient focused
- provides greater transparency: and
- increases public confidence in Australia's medical device regulatory system.

Also takes account of international harmonisation efforts.

The three strategies in the Action Plan are:

1. Pre-market medical device reforms - improve how new devices get on the market
2. Post-market medical device reforms - strengthen monitoring and follow-up of devices already in use (focus for 2022-2024)
3. Consumer focused reforms - provide more information to patients about the devices they use

An Action Plan for Medical Devices | Therapeutic Goods Administration (TGA)

Action Plan for Medical Devices - Progress Report Card: December 2022

Strategy 1: Pre-market medical device reforms

- **15 public consultations undertaken; 25 guidances published**

- **Personalised medical devices (PMD)**
  - New framework commenced in 2021, impacts more than 10,000 stakeholders previously manufacturing custom-made devices. Focus has now shifted to point-of-care manufacturing

- **Software-based medical devices**
  - Clarification, refinements and “carve outs” commenced in 2021, focus on an adaptive approach to regulation
  - Specialist unit established to increase capacity in assessing and monitoring

- **Reclassification of certain devices**
  - Eg: mesh, spinal devices, devices that come into contact with the central nervous system – devices not able to transition are cancelled from the Australian Register of Therapeutic Goods (ARTG)

- **Australian conformity assessment bodies (Australian CABs)**
  - Australian corporations can apply to become an Australian CAB for medical devices

- **Nanomaterials**
  - Regulatory amendments define nanomaterials and make explicit the requirement to minimise risks associated with nanomaterials, but (unlike the EU MDR) do not add nanomaterials characteristics to the classification rules.

Strategy 1: Pre-market medical device reforms (Cont.)

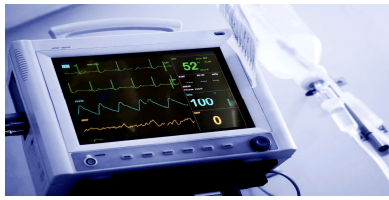
- **Streamlining processes and timeframes**
  - Global benchmarking of conformity assessment timeframes
  - Development of new risk based application audit/review approach rather than mandatory approach
  - Recognition of other regulators and mutual recognition agreements

- **Clinical trials**
  - Proposed involvement by TGA for very high risk devices

- **Changes to the Medical Device Regulations**
  - Changes to the Therapeutic Goods (Medical Devices) Regulations

Strategy 2: Post-market medical device reforms

- **Undertaken 4 public consultations; will be our focus until 2024-25**
- **Review of adverse event reporting arrangements**
  - Improvements to reporting forms, processes and internal TGA analysis processes
  - Changes to existing exemptions
  - Mandatory reporting by hospitals – required change to primary legislation and partnership with other governments and agencies to implement in coming 3 years
  - Introduction of a pilot vigilance program including self-assessment tool, desk top review and onsite inspection
- **Review of recall processes**
  - Including greater transparency of supply chains; simplified terminology; ability to share information quicker
- **Targeted reviews of specific kinds of devices**
  - Established dedicated team, examples include spinal cord stimulators, metal backed patella, RATs
- **Implementation of Unique Device Identification system**
  - Australian UDI “test” database (AusUDID) with 400 users including manufacturers, healthcare stakeholders; established Technical Working Group; webinar program; regulatory changes currently being finalised, including voluntary and mandatory compliance dates
  - Two “Early Adopter” projects to assess adoption and benefits of UDI in healthcare (hospital) settings



Strategy 3: Consumer focused reforms

❖ **Five working groups with consumer representation have been established**

Eg: Medical Device Consumer Working Group

- 21 health consumer organisations engaged to progress the Action Plan for Medical Devices reforms
- Developed a range of consumer-focused products about medical devices eg: Five things to ask your health professional before you get a medical implant
- Review of website materials and processes for consumer engagement, including co-development of fact sheets (eg: software fact sheets) and adverse event reporting forms and processes
- Feedback on electronic IFUs for consumer facing medical devices
- Feedback on selected Patient Information Leaflets

Eg: Women's Health Products Working Group

- Advice to the Minister and the TGA on the regulation of health products that relate to women's health

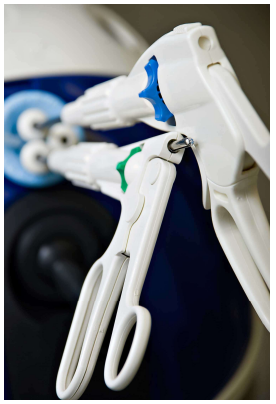
❖ **Patient information Leaflets (PILs) and Patient Implant Cards (PICs)**

- In place since 2021 for implantable medical devices – building a repository on TGA website. Some implementation challenges at hospitals distributing/providing to patients.

Impact of European Union Medical Device Regulations (EU MDR)

Significant impacts as most marketing approvals (above class I) in Australia is based on EU certification:

- **EU MDR Transition:** The TGA has implemented streamlined arrangements to manage the transition for devices supplied in Australia.
- **Transition extension:** Australian transitions are generally 6 months after the EU – need to seek Government approval to account for recent extension arrangements
- **Reclassifications:** medical devices subjected to reclassification may not meet transitional timeframes in Australia due to the EU MDR transition extension. Extending transitional timeframes requires Australian Government approval. A streamlined process for managing the change is being explored.
- **Unique Device Identifier (UDI):** Australia implementing and seeking alignment with both EU and USA
- **Mutual Recognition Agreement:** TGA unable to issue MRA certification until MRA updated (subject to negotiation with EU)
- **In Vitro Diagnostic Regulations (IVDR):** EU IVD certification is also recognised in Australia. We are updating our streamlined arrangements to account for the IVDR transition in the EU and looking at options for further alignment.



COVID-19 update

❖ **COVID-19 rapid antigen tests**

- November 2021, legislation amendment to enable supply of COVID-19 self tests (111 approved)
- Validation laboratory testing of 94 approved tests – results published on website for wildtype, delta and omicron variants
- Focus is combination Rapid Antigen Tests that detect Flu and COVID (7 approved)

❖ **Disinfectant products making COVID-19 claims or residual activity**

- Legislative instruments to clarify the regulation of borderline products and published guidance
- Regulations amended to include specific test requirements that must be used to support claims of residual activity

❖ **COVID-19 Lessons and Changes**

- Class I inclusion process revised to require upfront submission of evidence for devices that are integral to COVID-19 response

- Emphasised life cycle approach to approval and ongoing monitoring of emerging risks in pre-market and post-market
- Stronger emphasis on communication with Stakeholders:
  - Industry

    - publishing new and targeted guidance/checklists and webinars for preparing applications, collecting evidence and meeting ongoing obligations

    - targeted guidance and webinars to aid in promoting sovereign manufacturing
  - State and Territory, government, international regulators – instigated regular meetings and channels for sharing information

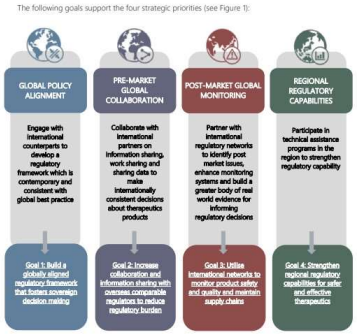
  - Consumers and general public – increased reach and interaction through traditional and social media

TGA Strategic Activities

❖ **Strategic priorities – set out in our International Engagement Strategy**

Focus on four strategic priorities to foster international partnerships:

- Global policy alignment
- Pre-market global collaboration
- Post-market global monitoring
- Regional regulatory capabilities



❖ **Mechanisms to facilitate international engagement**

- Mutual Recognition Agreements and Memoranda of Understanding
- Free Trade Agreements and International treaties

TGA Transformation Program - Purpose

- reduce regulatory burden by making it easier and simpler to do business with the TGA
- modernised and streamlined websites to access regulatory information
- a new single portal for regulatory and reimbursement applications
- improved data quality in databases and better search facilities for the Australian Register of Therapeutic Goods (ARTG), recalls and adverse events databases

IMDRF Participation

IMDRF Member since 2012 ; IMDRF Chair and Secretariat in 2022

Participating in the following IMDRF Working Groups

- Adverse Event Terminology
- Artificial Intelligence Medical Devices
- Good Regulatory Review Practices
- Medical Device Cybersecurity Guide
- Personalized Medical Devices (WG Chair)
- Regulated Product Submission
- Software as a Medical Device
- Medical Devices Single Review Program


Thank you/Questions

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08:55 – 09:10

Brazil

Augusto Bencke Geyer

General Manager, General Management of Health Product Technology, Brazilian Health Regulatory Agency (ANVISA)

European Commission | European Union

IMDRF International Medical Device Regulators Forum

Regulatory Updates – Brazil

Augusto Bencke Geyer, Office of Medical Devices

ANVISA – Brazilian Health Regulatory Agency

28 March 2023 – Brussels

Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices

- Public Consultation took place between 15 September and 14 November 2022
- Anvisa received 29 contributions with 631 comments/suggestions
- All comments will be shared with NRAs from Mercosur jurisdictions for consolidation in April 2023
- Based on IMDRF documents:
  - Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices (IMDRF/GRRP WG/N47FINAL:2018)

Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices

- Main objectives:
  - The purpose is to update safety and performance requirements of MD and IVDMD and to restructure the previous regulation in line with the Good Regulatory Practices
  - Inclusion of specific requirements for new technologies
  - Harmonization of requirements for all Mercosur jurisdictions

Clinical Investigations Requirements Revision

- Public Consultation took place between 27 October and 27 December 2022
- Anvisa received 8 contributions with 124 comments/suggestions
- Expected to be published until June 2023
- Main objectives:
  - Decrease regulatory cost
  - Adoption of definitions converging with ISO 14155:2020
  - Clarification about clinical investigations that must be submitted to Anvisa for approval before the start of study activities

Requirements for Pre-Market Authorization of Medical Devices

- Resolution RDC 751/2022
- Definitions and classification rules updated considering new technologies
  - Software as Medical Device (IMDRF/SaMD WG/N12FINAL:2014)
  - Nanomaterials
  - Manufacturers (legal manufacturer and manufacturing sites)
  - Notification (low risk products)
  - Regulatory assessment revision

Requirements for Pre-Market Authorization of Medical Devices

- Consolidation with other regulations – MD changes; e-IFU
- Simplification of required administrative documents
- Adoption of the Table of Contents Structure
- Good Regulatory Practices and Regulatory Convergence
- Effective since 1st of March 2023

Requirements for Pre-Market Authorization of In Vitro Diagnostic Medical Devices

- Completion of the consolidation of contributions from the public consultation
- Submission of the final text for deliberation by the collegiate board of Anvisa
- Definitions and classification rules updated according to IMDRF/IVD WG/N64 FINAL:2021 – Principles of In Vitro Diagnostic (IVD) Medical Devices Classification

Requirements for Pre-Market Authorization of In Vitro Diagnostic Medical Devices

- Consolidation with other regulations – MD changes; e-IFU
- Simplification of required administrative documents
- Adoption of the Table of Contents Structure
- Good Regulatory Practices and Regulatory Convergence
- Expect to publish the RDC in the 1st semester 2023
- Effective date will be 180 days after publication

Use of MDSAP Reports by ANVISA

Number of GMP Certificates Issued Based on MDSAP Reports by ANVISA per Year

Year	# GMP Certificates Issued Based on MDSAP Reports (% of total)
2017	38 (4.7%)
2018	107 (19,3%)
2019	374 (48,7%)
2020	544 (49,1%)
2021	529 (51,4%)
2022	621 (59,7%)
2023	103 (69,1%) – Until 28 February

Thank you/Questions

Office of Medical Devices
Email ggtps@anvisa.gov.br

IMDRF International Medical Device Regulators Forum

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09:10 – 09:25

Canada

David Boudreau

Director General, Medical Devices Directorate,
Health Canada

European Commission

European Union

IMDRF International Medical Device Regulators Forum

Regulatory and Policy Updates Health Canada

David Boudreau

Director General, Medical Devices Directorate

March 28, 2023

Overview

- Continuing to Enable Access to COVID-19 Devices
- Expanding Device Terms and Conditions
- New Guidance on Clinical Evidence Requirements
- Launch of Interactive Submission Tool: eSTAR
- Upcoming Public Consultations

Continuing to Enable Access to COVID-19 Devices

- Health Canada used temporary measures (Interim Orders No. 1, 2, 3) to expedite the review of, and access to, COVID-19 medical devices in Canada.
- On February 22, 2023, Health Canada introduced *Regulations Amending the Medical Devices Regulations (Interim Order No. 3)* to:
  - Enable COVID-19 medical devices to continue to be imported and sold after the expiry of Interim Order No. 3 on February 21, 2023.
  - Maintain most authorization flexibilities for authorizations where an urgent public health continues to exist.
  - Provide an expedited authorization pathway for new COVID-19 medical devices that are on the **List of Medical Devices for an Urgent Public Health Need in Relation to COVID-19** (UPHN list).

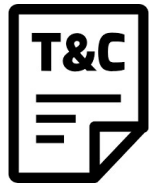
Continuing to Enable Access to COVID-19 Devices

- Edits to the UPHN list can be made by the Minister of Health and do not require regulatory amendments. This provides agility to address public health needs as they emerge.

Part 2. Categories of medical devices that have a UPHN related to COVID-19

Category of medical devices
testing devices that offer a multiplex feature for detecting COVID-19 and other respiratory pathogens (for example, influenza A, B and respiratory syncytial virus)
molecular or antigen tests that offer saliva sample types
testing devices that offer other unique sample types
testing devices that offer a unique feature that meets a clinical or accessibility need
testing devices that offer environmentally sustainable features
medical devices that do not belong to any other category of medical devices set out in Part 2 of the List for which an application for an authorization was submitted to the Minister under Interim Order No. 3 [1] before the day on which Part 1.1 of the MDR came into force, and in respect of that application: • no decision had been made under the Interim Order before that day, • no decision has been made under Part 1.1 of the Regulations, and • the applicant has not withdrawn the application.

Expanding Device Terms and Conditions



- As part of the **Agile Licensing** initiative, Health Canada is proposing expanded Terms and Conditions (T&Cs) regulations to support the life cycle approach for regulating medical devices.

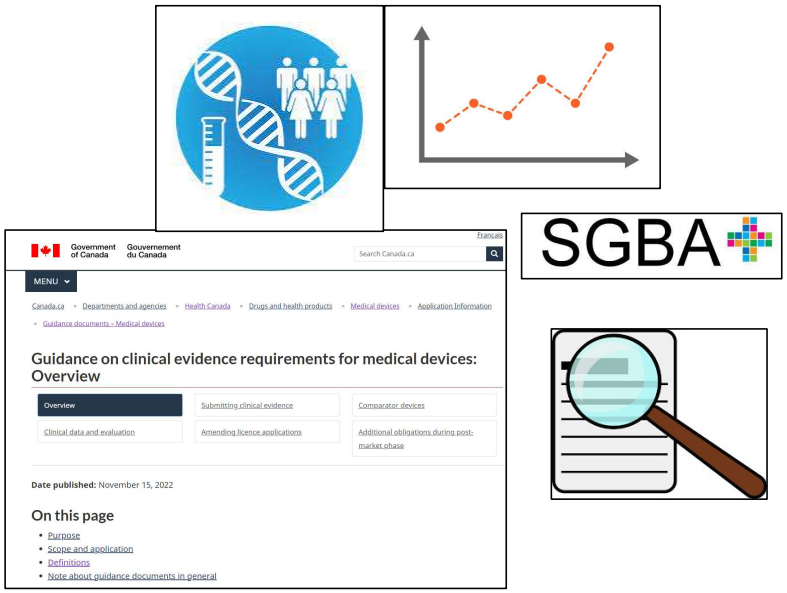
- These proposed regulations provide us with authorities to:
    - expand the scope of use of T&Cs and;
    - impose or amend T&Cs at any time during the medical device's life

- The consultation on the proposed regulations and corresponding guidance document is open until the end of April.

- Health Canada also plans to publish information about the T&Cs that have been imposed on medical device licences, to increase transparency and communicate risks.

New Guidance on Clinical Evidence Requirements

- Guidance on Clinical Evidence Requirements for medical devices was published in November 2022.



- Guidance includes information on:
  - when clinical data/evidence is required
  - the common methods to generate clinical data
  - how to compare devices appropriately
  - sex, gender, and population considerations

Launch of Interactive Submission Tool: eSTAR

eSTAR is an interactive PDF form that guides applicants through the process of preparing a comprehensive medical device submission.

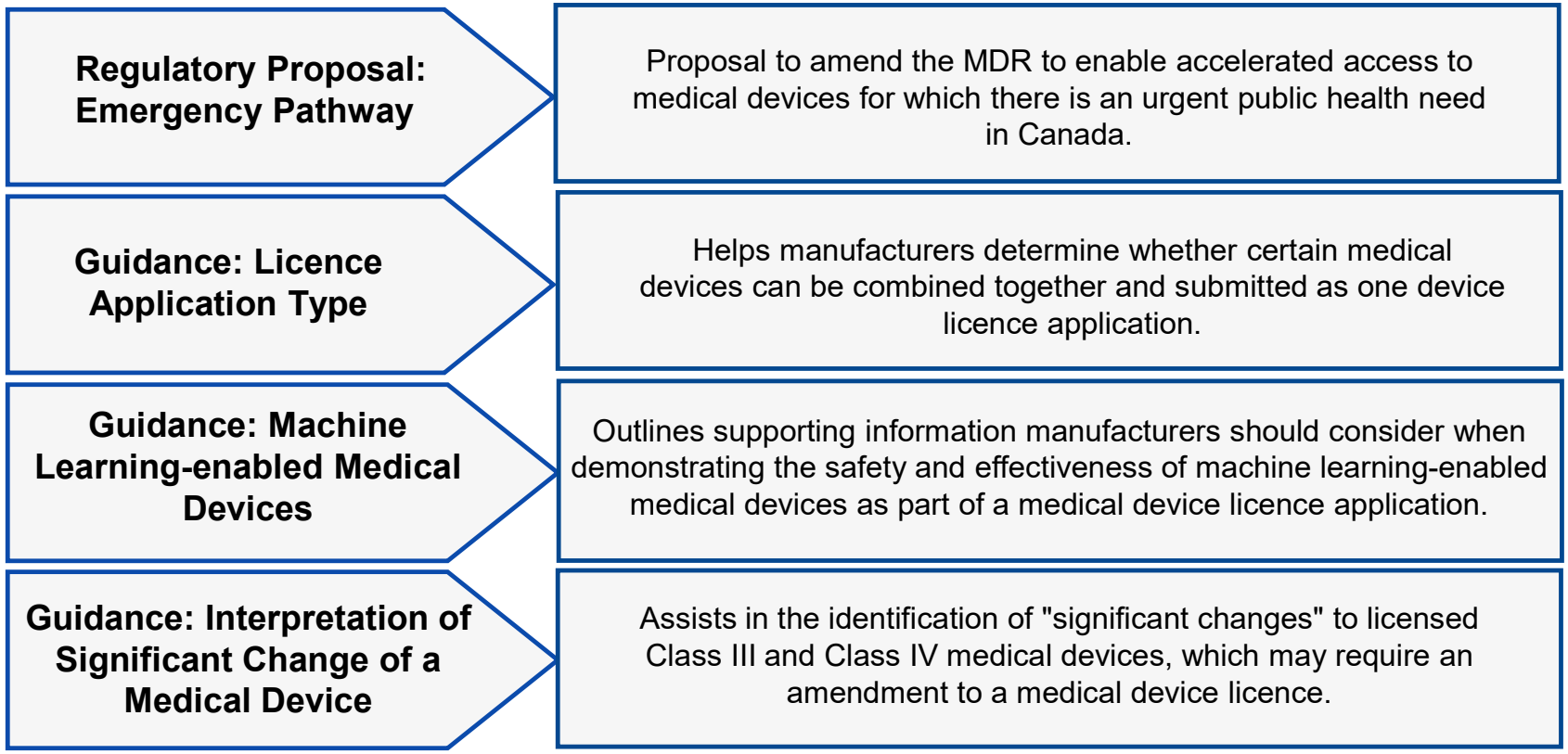
- Features in this template include the integration of multiple resources, automatic verification and guided construction for each submission section.

On January 10th, 2023, Health Canada launched two eSTAR pilots:

- Joint Health Canada and U.S. Food and Drug Administration pilot:
  - Enables manufacturers to submit an application to both jurisdictions using a common submission building tool (eSTAR). While the content will be dictated by each jurisdiction's requirements, a common format will be used (IMDRF's Table of Contents structure).
  - The joint pilot is now full, having reached its total of 9 participants.

- Health Canada-only pilot program:
  - Provides opportunity for manufacturers to apply to Health Canada using the eSTAR tool.
  - Pilot is still accepting participants.

Upcoming Health Canada Public Consultations



IMDRF International Medical Device Regulators Forum

Thank you/Questions

Email david.boudreau@hc-sc.gc.ca

IMDRF International Medical Device Regulators Forum | EU2023 EUROPEAN UNION Chair

09:25– 09:40

China

Yuan Peng

Division Director, Department of Medical Device Registration, National Medical Products Administration (NMPA)

European Commission | European Union

IMDRF International Medical Device Regulators Forum

Update on China Regulatory

Yuan Peng
NMPA

Work achievements in recent years

- First, to improve the system of regulation and standard. Regulations on Supervision and Administration of Medical Devices was revised for the third time. China has established the MAH system, and reconstructed the clinical evaluation system. Today China has improved the regulatory system by centering on the Regulation as the core and 13 Provisions as the support. At present, there are nearly 2,000 national standards for medical devices in China, reaching over 90% consistency with international standards. There are 534 technical guidances for evaluation, which guide the R&D and evaluation of medical devices.

- Second, to deepen the reform of review & approval system. Up to now, 192 innovative medical devices including surgical robots and 131 products for clinically urgent needs have been approved.

- Third, to strengthen the full life cycle regulation. Focusing on certain products with high risks, NMPA carried out in-depth investigations and special programs to address potential risks. NMPA issued documents on tiered regulation of medical device, enhanced active surveillance on adverse events. NMPA also promotes the vigilance project, and conducts international exchanges of safety information within NCAR.

- Fourth, to carry out international cooperation in regulation. NMPA actively participated in IMDRF, and took the lead in setting up medical device clinical evaluation working group and issued related guidelines, and made timely application to China's regulatory practice. In GHWP, NMPA is also deeply involved, including serving as Vice Chair and leading 2 working groups, enhancing the strategic framework of GHWP.

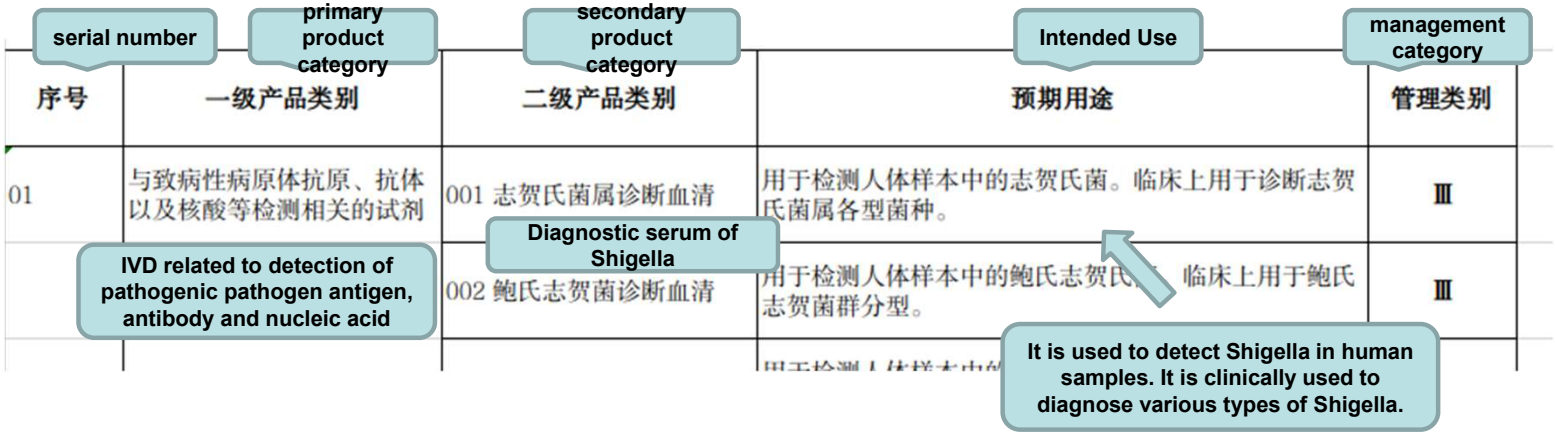
Classification of IVD

2023.3.8 The revised IVD classification catalogue is open for comments on NMPA website, till to the 2023.4.12

Background: In the past decade, the IVD industry has rapid growth, with new technologies, new methods and new targets emerging. The old version of catalogue can't fully meet the regulatory and industrial requirements, and some IVD calssification are not completely consistent with the Classification Rules for IVD, which was issued in October 2021.

Main change: New revision catalogue absorb and adopt the achievements of the IMDRF IVD classification working group, especially the corresponding guidance. Compared with the old version, The structure of the new catalogue is adjusted into five parts: "serial number, primary product category, secondary product category, intended use, and management category", iclude 25 primary product category, 2023 secondary product category.

The content of "intended use" includes the tested object and its main clinical use. Its purpose is to determine the management category of the product.



Promote the implementation of Medical Device standards

IEC 60601/GB 9706 serials standards

➢In order to better integrate with the international standards, further improve the level of China's medical device industry, 2020.4.9 the GB 9706.1-2020 (Medical electrical equipment—Part 1:General requirements for basic safety and essential performance (IEC 60601-1;2012,MOD))had been published, as the mandatory national standards and will implement on 2023.5.1

➢Parallel standards and special standards of GB 9706.1 are being issued in succession

➢the medical device should comply with the general standards requirements after 2023.5.1, but if the medical device has the applicable special standards, it can comply with the general standards after the applicable special standards

- According to the National Standardization Law, manufacturer should ensure that the products produced and sold after the implementation of the standards meet the requirements of the standards.

But, For the registred medical electrical equipment , the registrant shall apply for registration alternation in time and complete within 3 years from the date of implementation(2023.5.1 or applicalbe special standards implementation date) . Corresponding measures will ensure the smooth transition of the implementation of relevant standardsensure a smooth transition.

Announcement of the NMPA on the implementation of GB 9706.1-2020 and parallel standards and special standards can find on NMPA website.

Continue to promote UDI implementation

UDI recent years in China

Establish a complete system

- Incorporated into the Regulations on the Supervision and Administration of Medical Devices and supporting regulations
- Rules for UDI system of medical devices
- published 4 industry standards, for example: YY/T 1630-2018 Basic requirements for UDI of medical devices
- Established Medical device UDI database

Gradually promote comprehensive implementation

- The first batch of implementation: 2021.1.1, 69 varieties in 9 categories
- the second batch of Implementation of : 2022.6.1, except for the first batch of 69 types of Class III medical devices (including IVD)

2023.2.17 the third batch of implementation 103 class II varieties in 15 categories, for these medical devices:

- produced from June 1, 2024 shall have the UDI of medical devices;

- Applying for registration from June 1, 2024, the registration applicant shall submit the product UDI information of the minimum sales unit of its product in the registration management system;

- manufactured from June 1, 2024, Before the products are put on the market, the registrant shall upload the product UDI and relevant data of the minimum sales unit and higher level packaging to the UDI database of medical devices according to the relevant standards or specifications.

International Cooperation

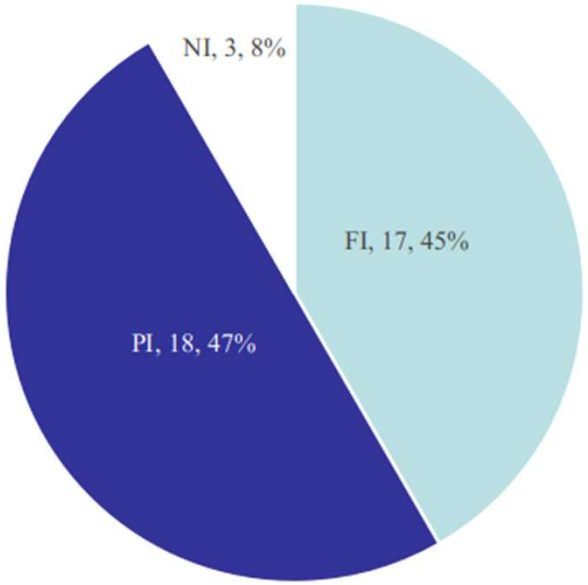
Ø From February 13 to 16, 2023, the 26th Technical Committee Meeting and Annual Meeting of the GHWP was held in Riyadh, Saudi Arabia. Xu Jinghe, Deputy Director of the State Drug Administration.

Ø The GHWP technical committee meeting includes closed meeting and open meeting. The nine GHWP working groups introduced the latest progress of their work and discussed the focus and development direction of the next step. The meeting elected Xu Jinghe, Deputy Director of the State Drug Administration, as the chairman , representatives of NMPA participated in the election of the Vice-Chairman of the Technical Committee, the Chairman of Working Group 7 and Working Group 9 and were elected.

Ø This work will help to further deepen the technical exchange between China's medical device regulation and international medical device regulation, and better promote the coordination and trust of global medical device regulation.

- **IMDRF guidance implementation**

Ø According to the statistics of the implementation of the 38 technical documents issued by the IMF in member countries, 17 guidances were fully implemented in China, and 18 guidances were partially implemented, 3 guidances not implemented



Conclusion

1.Recent years, NMPA improve the system of regulation and standard, deepen the reform of review & approval system, strengthen the full life cycle regulation,carry out international cooperation in regulation.

2.The revised IVD classification catalogue is open for comments for 30 days.

3.Announcement of the NMPA on the implementation of GB 9706.1-2020 and parallel standards and special standards can find on NMPA website.

4.The third batch of UDI implementation for 103 class II varieties in 15 categories

5.Continue to carry out international cooperation

IMDRF International Medical Device Regulators Forum

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09:40 – 09:55

European Union

Nada Alkhayat

Policy Officer

DG SANTE, European Commission

European Commission | European Union

IMDRF International Medical Device Regulators Forum

Update on EU regulatory developments

Nada Alkhayat

European Commission

IMDRF-23 – Stakeholder session

28 March 2022

The EU single market for medical devices

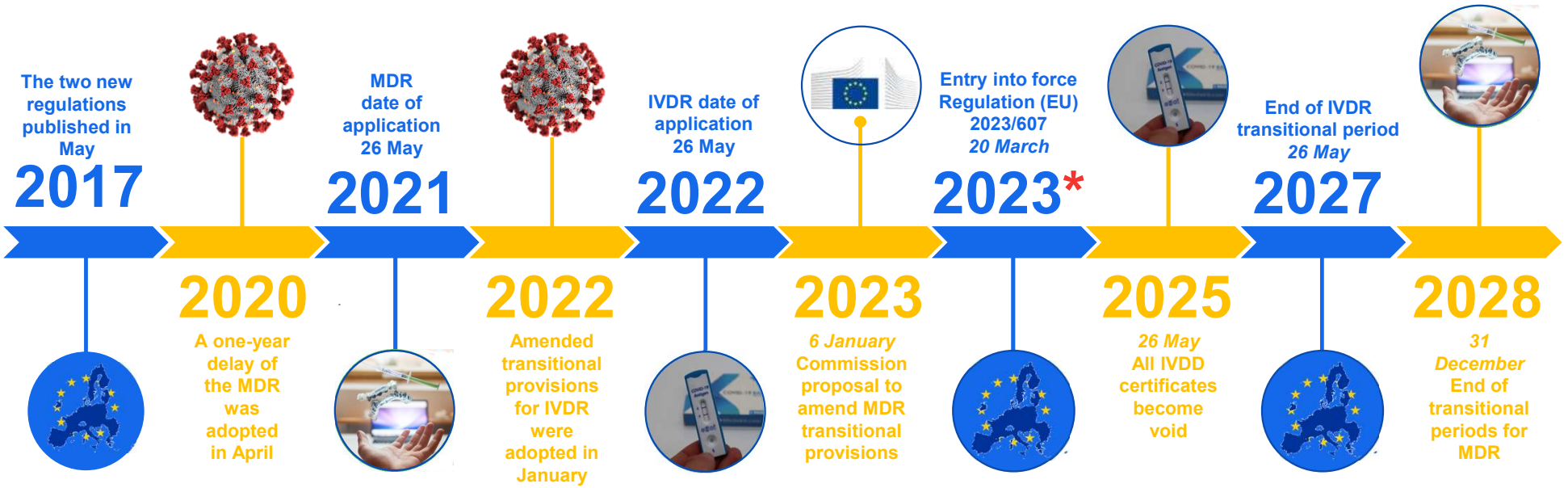
EU

EFTA/EEA

Norway, Liechtenstein, Iceland

Turkey

Timelines


The two new regulations published in May
2017
2020
A one-year delay of the MDR was adopted in April
MDR date of application 26 May
2021
2022
Amended transitional provisions for IVDR were adopted in January
IVDR date of application 26 May
2022
2023
6 January
Commission proposal to amend MDR transitional provisions
Entry into force Regulation (EU) 2023/607
20 March
2023*
2025
26 May
All IVDD certificates become void
End of IVDR transitional period
26 May
2027
2028
31 December
End of transitional periods for MDR

Guiding principles for the amendment proposal

Ensure patient access to wide range of safe and performant devices

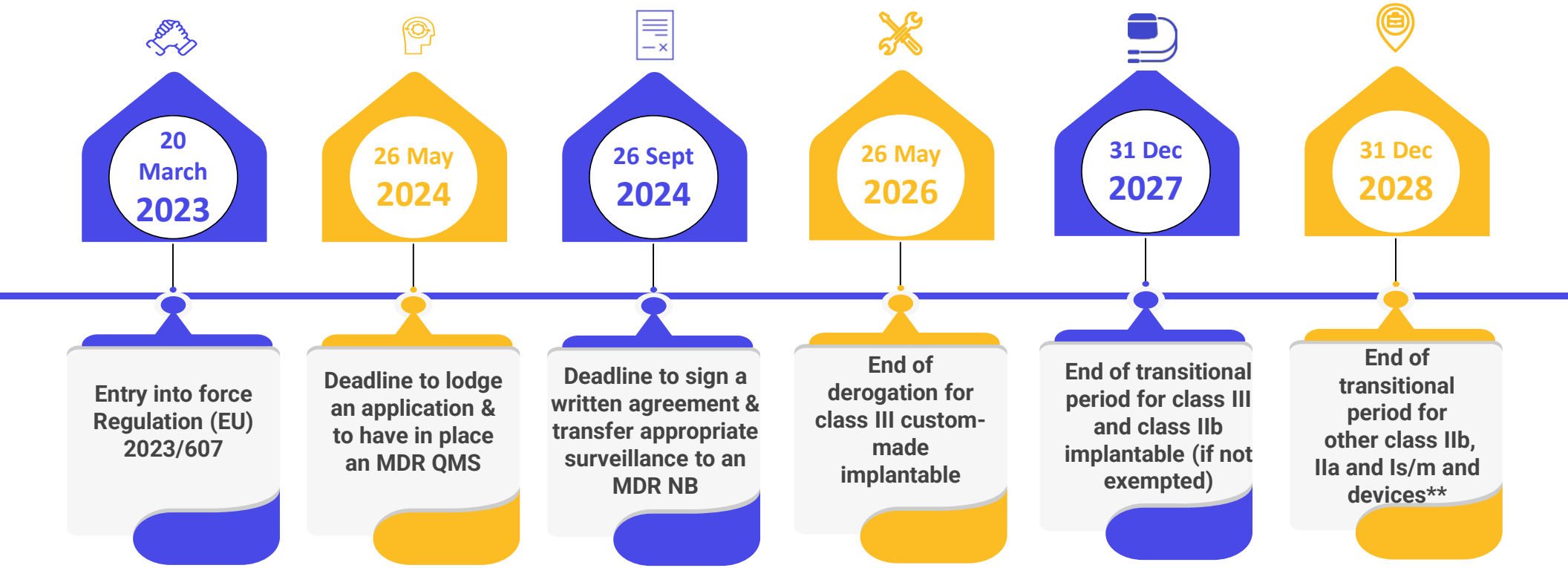
Give **more time to those** who aim to **transition**, allow NBs to complete MDR conformity assessments

Aim at full application of MDR

Avoid unnecessary disposal of safe and performant devices in the supply chain

Accompanying non-legislative actions

MDR transitional period per Regulation (EU) 2023/607



* For devices that did not require involvement of a NB under MDD (e.g. Ir)

Non-legislative actions

- Q&A on practical aspects of implementation of Reg. 2023/607
- Actions to enhance notified body capacity and ensure availability of medical devices (MDCG PP 2022-14)
- Uniform application of Article 97 MDR as temporary bridging measure regarding expired certificates (MDCG PP 2022-18)
- Gaining momentum in designation process of notified bodies
- Seeking tailored solutions for orphan devices
- Expert panel scientific advice on clinical development strategies for certain high-risk devices
- Targeted support for SMEs through Enterprise Europe Network

Non-legislative actions

Financial support actions under **EU4Health Programme**

- Monitoring implementation progress and availability of medical devices on the EU market
- Grant for capacity-building of notified bodies, better access of SMEs to notified bodies and increased preparedness of manufacturers
- Study on innovation and governance
- Orphan devices support programme, focussed on devices for children
- Joint Action on market surveillance
- Support for stronger coordination of the Notified Bodies Coordination Group

Financial support actions under **EU Horizon 2020 / Horizon Europe Programme**

- CORE-MD project - methodology for clinical data generation for high-risk devices (04/2021-03/2024)
- New call planned in October 2023

COM implementation priorities 2023 (1)

Chairing IMDRF

- Increase and promote relations with other regulatory authorities through new memberships
- Reinforce cooperation with regional harmonisation initiatives via collaboration agreements
- Develop and agree on strategic principles for IMDRF trainings between MC members
- Encourage engagement with healthcare professionals/clinicians

Facilitating a smooth transition to MDR and IVDR

- MDCG 2022-14 position paper on notified body capacity and availability of medical devices and IVDs*
- Increasing number and capacity of notified bodies: 48 (38/**50** MDR+10/**18** IVDR) notified bodies designated under MDR and IVDR*

EUDAMED

- Core actor registration module (Q4 2020) and UDI module (Q3 2021) made available
- Functional testing with users (continuous)
- Preparations for full functionality audit (ongoing) *

COM implementation priorities 2023 (2)

Scientific Structures

- Expert panels designated (2019) and designated experts (Q1 2021)
- Expert panels running (Q2 2021) and number of opinions issued
- Transfer of expert panels to European Medicines Agency (Q1 2022)*
- Call for EU reference laboratories (IVDR) (Q3 2022)*

Tertiary legislation: Common Specifications/ Implementing Acts

- Devices without medical purpose (Annex XVI devices) (draft published Q2 2022)*
- Common specifications in accordance with Regulation (EU) 2017/746 (for Class D devices) (Q2 2022)*
- Commission Implementing Regulation (EU) 2022/944 on tasks and criteria for the EURLs (Q3 2022)*
- Commission Implementing Regulation (EU) 2022/945 on fees that the EURLs may levy from notified bodies and Member States (Q3 2022)*3

UDI

- 4 issuing entities designated , 15 guidance and factsheets published + UDI helpdesk available
- UDI assignment for contact lenses delegated act in public consultation until mid April

COM implementation priorities 2023 (3)

Nomenclature

- Published for public consultation (Q2 2021)
- Final version launched available in EN, IT, FR. Validations of remaining EU languages (ongoing)
- Work program for 2023-2025 to be announced Q3 2023

Standards

- Lists of harmonised standards published (Q3 2021), (Q1 2022), (Q2 2022)
- New Standardisation request approved by relevant Committee on 31 January 2023*

IMDRF International Medical Device Regulators Forum | EU2023 EUROPEAN UNION Chair

09:55 – 10:10

Japan

Masahiro Takahata

Head, Office of Regenerative Medicine Product Evaluation

Deputy Director, Medical Device Evaluation Division, Pharmaceuticals Safety and Environmental Health Bureau

Ministry of Health, Labour and Welfare

European Commission | European Union

厚生労働省 ひと、くらし、みらいのために Ministry of Health, Labour and Welfare

Regulatory Updates on Medical Devices in Japan

Day 2 – 28 March 2023

IMDRF Stakeholder Forum

Masahiro TAKAHATA

Head, Office of Regenerative Medicine Product Evaluation,
Deputy Director, Medical Device Evaluation Division,
Pharmaceuticals Safety and Environmental Health Bureau

Ministry of Health, Labour and Welfare of Japan

Today's topics

- Marketing Approval in Emergencies
- SaMD Regulations
- PACMP (IDATEN)

Amendment of Pharmaceuticals and Medical Devices Act (PMD Act)

Aim

- **to enact a mechanism of early approval**
  conditional, time-limited marketing approval may be granted in emergencies if the efficacy of the pharmaceutical, medical device, or regenerative medicine is estimated and safety is confirmed
- to enact a mechanism of electronic prescriptions

Outline

1. Marketing Approval in Emergencies

New mechanisms to enable early marketing approval in emergencies.

(1) Eligibility of pharmaceutical, etc. to which the early approval is applicable

A pharmaceutical, etc. that needs to be used urgently in order to prevent the spread of a disease or other health hazard that could seriously affect the lives and health of people is eligible for early approval if there is no alternative existing treatment.

(2) Application standards

Assuming that safety has been confirmed, approval may be granted if the efficacy of the pharmaceutical, etc. has been estimated.

(3) Conditions and term of approval

As approval is granted at the early stage where efficacy has been estimated, conditions are provided to ensure the proper use of the pharmaceutical, etc. and restrictions are set in place that limit the duration of the approval to a short term.

(4) Special measures to expedite review process

Special measures are introduced for GMP inspections, national verifications as well as regulations on containers and packaging of the pharmaceutical, etc., in order to expedite review process for approval.

2. Creation of a mechanism for electronic prescriptions

Effective Date

The effective date (1. Marketing Approval in Emergencies): 20 May 2022

Marketing Approval in Emergencies

	Special approval of emergency
Target	Products - legally available in a country with a regulatory system - The system is equivalent to Japan
Efficacy and Safety	Efficacy: Confirmed Safety: Confirmed
Special Provisions	Require later - GMP inspection - National certification - Packaging etc.

	Marketing Approval in Emergencies *time limited approval
Target	All Pharmaceuticals, etc.
Efficacy and Safety	Efficacy: Estimated Safety: Confirmed
Special Provisions	Require later - GMP inspection - National certification - Packaging etc.

- Prevent the spread of a disease or other health hazard
- Seriously affect the lives and health of the people
- no alternative means in existence.

Fundamental reform of the Review system for SaMD

- Find out **seeds of cutting-edge SaMD at an early stage** and show the concept of the review process.
- Unify consultation services and establish a review system based on the characteristics of programmed medical devices.

Promote early approval of cutting-edge SaMD.

Review system applicable to unique characteristics of SaMD

Consideration of starting designation program for innovative SaMD

- Priority consultation/screening, enhancement of preliminary evaluation, shortening of screening period by screening partner system

Pilot program of priority review for designated SaMD (September 2, 2022)

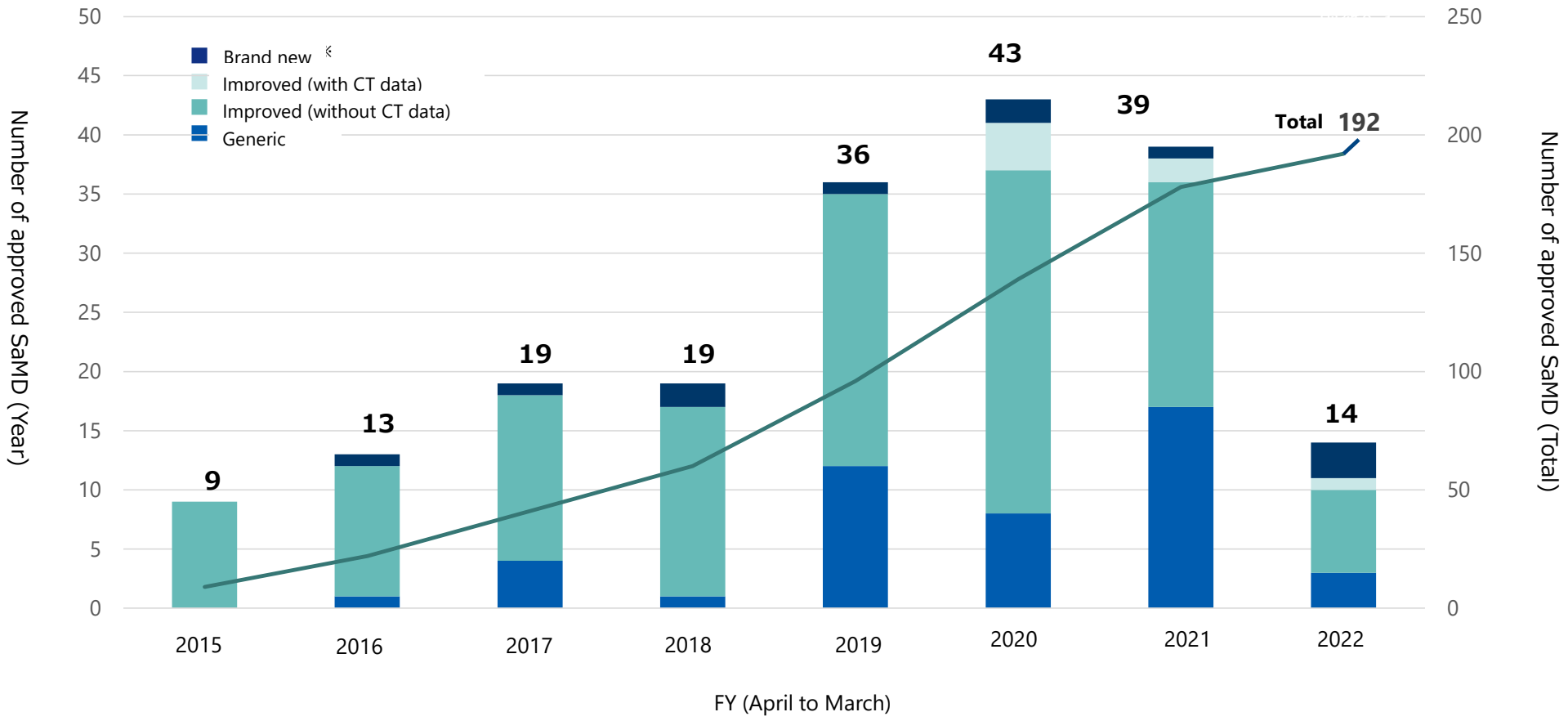
Designation criteria

(1): Innovatiion of therapeutic, diagnostic or prophylactic

(2): Clinical effectiveness for target disease

(3): intension and structure of company to develop the product prior to any region in the world

Number of Approved SaMD (not including the number of certification)



As of September 30, 2022

The number of approved/certificated SaMD

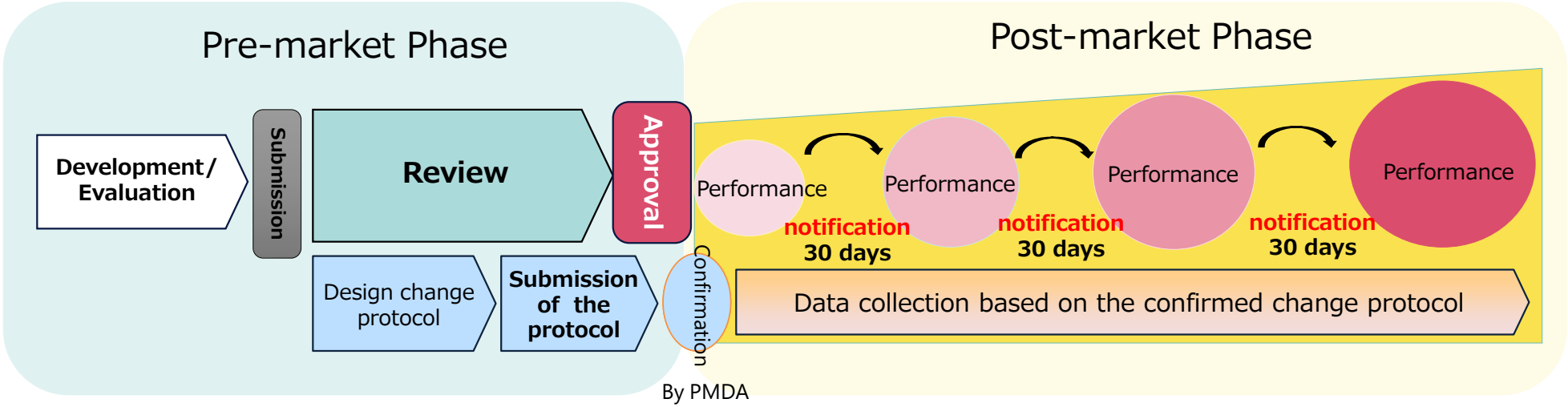
Non-SaMD	SaMD		
Not for diagnostics or treatment etc. corresponded to class I	**Class II**	**Class III**	**Class IV**
Programs intended for health control (ex: programs which give patients advice on meal or exercise for health maintainance and promotion) Educational program (ex: training programs for health care professionals) In-hospital business support program (ex: medical appointment system, electronic medical record) Programs corresponded to class I (ex: eye test, programs for color perception test)	**For treatment** Application for behavioral therapy 2	Program for therapy planning support 61 Programmer for active implantable device 2	
	For diagnostics Program for diagnostics assist for home use 2	Program for computer assisted Imaging diagnostics 301 Program for computer assisted diagnostics other than imaging 85 Program for gene mutation analysis 7	

as of September 30, 2022

Post-Approval Change Management Protocol (PACMP) for Medical Devices
IDATEN (Improvement Design within Approval for Timely Evaluation and Notice)

PACMP is introduced for medical devices to enable continuous and timely improvements through product lifecycle.

In force in 2020



4 change management protocols for medical devices are confirmed.

3 notification of change based on the protocols are filed.

Thank you for your attention

MHLW Website
https://www.mhlw.go.jp/english/

PMDA Website
https://www.pmda.go.jp/english/index.html

IMDRF International Medical Device Regulators Forum | EU2023 EUROPEAN UNION Chair

10:10 – 10:25

Singapore

Rama Sethuraman

Director, Medical Devices, Medical Devices Cluster, Health Sciences Authority (HSA)

European Commission | European Union

IMDRF International Medical Device Regulators Forum

Regulatory Updates
Health Sciences Authority, Singapore

Dr Rama Sethuraman

Director, Medical Devices,

Medical Devices Cluster,

Health Sciences Authority, Singapore

28 March 2023

Revocation of Exemption implemented to manage COVID-19 pandemic

On 31 January 2020, an exemption order to enable **import, wholesale and supply** for **specified medical devices** to facilitate access during the pandemic was implemented:

- Exemption order was applicable to the following lower risk medical devices:
  - Surgical masks, medical masks;
  - Particulate respirators e.g. surgical N95 masks;
  - Thermometers for measuring body temperature; and
  - Any protective gear for medical professionals e.g. isolation gowns and gloves

As of 1 September 2022, the Exemption Order 2020 has been revoked.

- All standard regulatory controls would apply to medical devices that were previously exempted.
- Allowed for **retail supply** of these medical devices that were imported before 1 September 2022.

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COVID-19 Tests - Transition from Special Access to Full Registration

Pandemic Special Access Route (PSAR)

Validity extended till **30 Jun 2023** for 21 essential COVID-19 tests
Authorisation lapsed on **31 Dec 2022** for 13 COVID-19 tests

Full Registration

29
Approved

This includes the following product categories:


COVID-19 Self-Test Kits


COVID-19 Diagnostic Tests

To facilitate transition to full registration, published a guide - Validation Requirements for Product Registration of COVID-19 Diagnostic Tests – Self-Tests on the key validation requirements for **full registration.**

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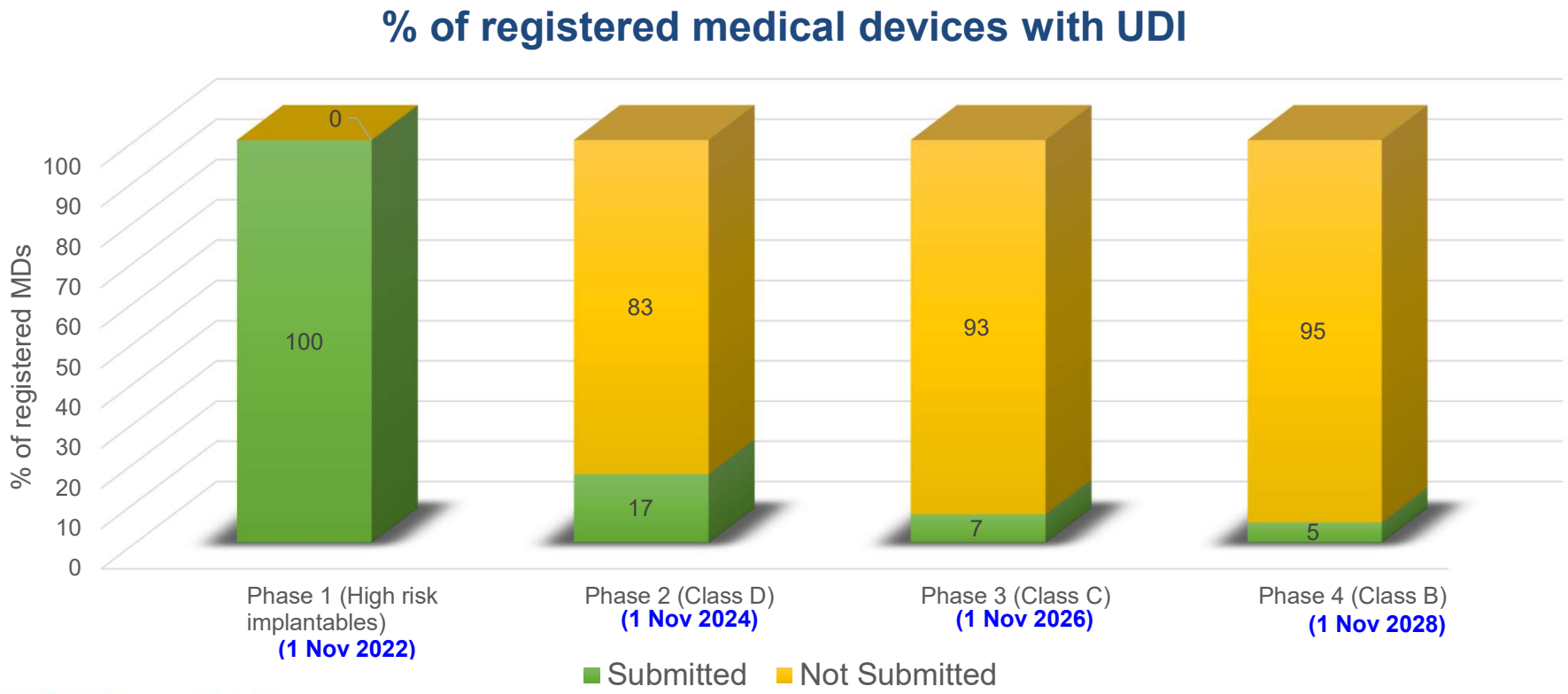
Progress of UDI Implementation

- UDI implementation has commenced with Phase 1 on 1 November 2022
  - From 1 Nov 2022, selected high risk MDs, i.e, all coronary stents, orthopaedic joint replacement implants and Intraocular lens (IOLs) to be supplied in Singapore are required to be labelled with UDI and respective companies to submit UDI related information to HSA
  - Adopting a least burdensome approach to accept the UDI barcodes as is that manufacturers have applied on their MD labels for the USA and/or EU
  - For MDs not marketed in the USA and EU, companies are required to implement UDI for Singapore based on requirements published in HSA's guidelines
  - All MDs imported into Singapore are required to be UDI compliant from the compliance date stipulated for each phase (e.g. 1 November 2022 for Phase 1 MDs)
  - Additional 6 months from the compliance date is provided for companies to deplete the stocks that have been imported prior to the compliance date and are in their current supply chain

Progress of UDI implementation - Phases 1 to 4

- 100% of implants under Phase 1 have complied with UDI requirements
- HSA has been working with industry stakeholders to kickstart the subsequent phases of implementation on a voluntary basis. See status below:



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Cybersecurity Labelling Scheme for Medical Devices – CLS (MD)

AIM: Enable healthcare purchasers to make informed decisions towards buying more secure devices; thus elevating the usage of cyber secure medical devices.

Cybersecurity Labelling Scheme FOR MEDICAL DEVICES

- The CLS (MD) is a joint initiative developed by the Ministry of Health (MOH), Cybersecurity Agency of Singapore(CSA), Integrated Health Information Systems (IHiS) and the Health Sciences Authority (HSA)
- To improve the visibility of cybersecurity status of medical devices (MDs) in Singapore to enable users to make informed choices in buying/procuring their MDs
- To encourage the embedding of a higher tier of cybersecurity measures into MDs, which will be beneficial for **patient health, safety and privacy**

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CLS-MD Framework

Levels	Descriptions
1 +	Manufacturers to meet the existing mandatory HSA requirements that are internationally aligned
2 ++	Manufacturers need to meet the enhanced security requirements titrated from MDS2, Post-market policies and existing CLS standards.
3 +++	The software of the medical device (i.e., firmware, mobile applications if available) undergo automated binary analysers to ensure no known critical software weakness, vulnerabilities or malware. **&** The device will also undergo a timebound black-box(1) penetration testing to provide basic level of resistance against common cybersecurity attacks.
4 ++++	The device undergoes a timebound white-box(2) security evaluation to provide higher level of resistance against cybersecurity attacks.

(1) *Black-box penetration test: Evaluator performs testing using only limited information (i.e. only user guidance manuals that is provided with the device).*
(2) *White-box security evaluation: Evaluator is provided with information on the design/implementation of certain security functionalities (i.e. cryptographic functions). With more information, evaluator would be able to devise targeted tests and better assess the security functionalities of the device.*

CLS-MD Scheme

- Applicable to medical devices which can be **connected** to other devices, systems and services and/or have the ability to collect, store, process or transfer personally identifiable information (PII) and clinical data.
- CLS(MD) comprises four cybersecurity levels (1 to 4).
- Currently, connected medical devices are required to meet HSA's cybersecurity requirements, which is **equivalent to the CLS (MD) level 1** requirements, before they are distributed and used locally.
- Obtaining the higher CLS(MD) levels (i.e. 2 to 4) will be voluntary and may involve independent third-party testing
- Labelled devices will be listed in the CLS(MD) product list on the CSA website

Consultation on the CLS (MD) Scheme

Public Consultation commenced in January 2023 and closed on 10 March 2023; Feedback collation and review in progress

Do write to certification@csa.gov.sg should you have queries relating to CLS-MD scheme

Guidance Documents – Key Updates

- ❑ Finalised version of the guidelines - Regulatory Guidelines for Laboratory Developed Tests (LDTs) has been published on our website post consultation period
  - Effective 1 March 2023

- ❑ Updated guidance on Medical Device Special Access Routes was published
  - Greater oversight on import and use of unregistered medical devices in healthcare facilities for essential clinical needs
  - Additional oversight from MOH on the clinical use of unregistered Class D (highest risk) MDs in public healthcare institutions

- ❑ Enhanced the current processes for applications related to changes to registered medical devices and updates to the Guidance Document on Change Notification

- ❑ Guidance documents and Guidelines can be accessed online at:

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

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Thank you/Questions

Email Sethuraman_RAMA@hsa.gov.sg