IMDRF International Medical Device Regulators Forum

Regulatory update from Australia

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

Overview

- **An Action Plan for Medical Device**
  - Medical Device Vigilance Program (MDVP)
  - Point-of-Care Manufacturing of medical devices
  - Proposed Application Audit Framework for Medical Devices
  - Mandatory Reporting of adverse events by healthcare facilities
- **TGA Strategic Activities and Transformation**

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]

The Medical Devices Vigilance Program (MDVP)

The MDVP was developed after receiving public and Government support of the proposal – 2020 *Proposed enhancements to adverse event reporting for medical devices* consultation paper.

The MDVP will complement and enhance existing post-market surveillance activities:

- with an educational self-assessment tool - a resource for sponsors and a screening tool for the TGA
- through desktop audits and on-site inspections that will review and confirm compliance with post-market regulatory requirements.

Medical Device Vigilance Program (MDVP)

- MDVP pilot commenced 14 September 2023
- Sponsors will complete the Sponsor Vigilance Self-Assessment Tool containing 18 questions
- TGA will take a risk based approach to selecting sponsors for the desktop audits and inspections
- On-site inspections, reviewing systems and procedures to demonstrate compliance
- A MDVP Inspection Report will be provided to sponsors summarising findings

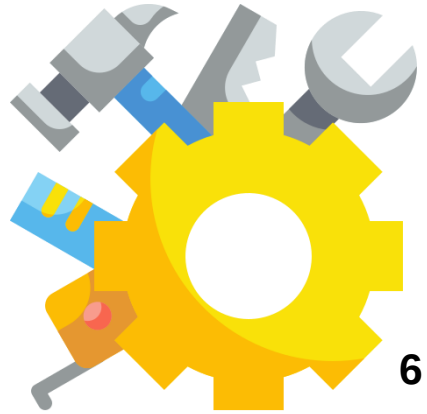
Point of Care Manufacturing of Medical Devices

TGA is focusing on how the Personalised Medical Devices Framework applies to manufacturing at the point-of-care to ensure regulation is appropriate without introducing unnecessary burden for point-of-care facilities.

Four surveys conducted (mid 2023) about point of care manufacturing activities in four sectors:

- Allied health sector
- Dental sector
- Manufacturing hubs at the point-of-care
- Hospital and healthcare facilities

Medical devices manufactured at the point-of-care - Analysis of survey results by sector | Therapeutic Goods Administration (TGA)



Point of Care Manufacturing of Medical Devices

Overview and insights

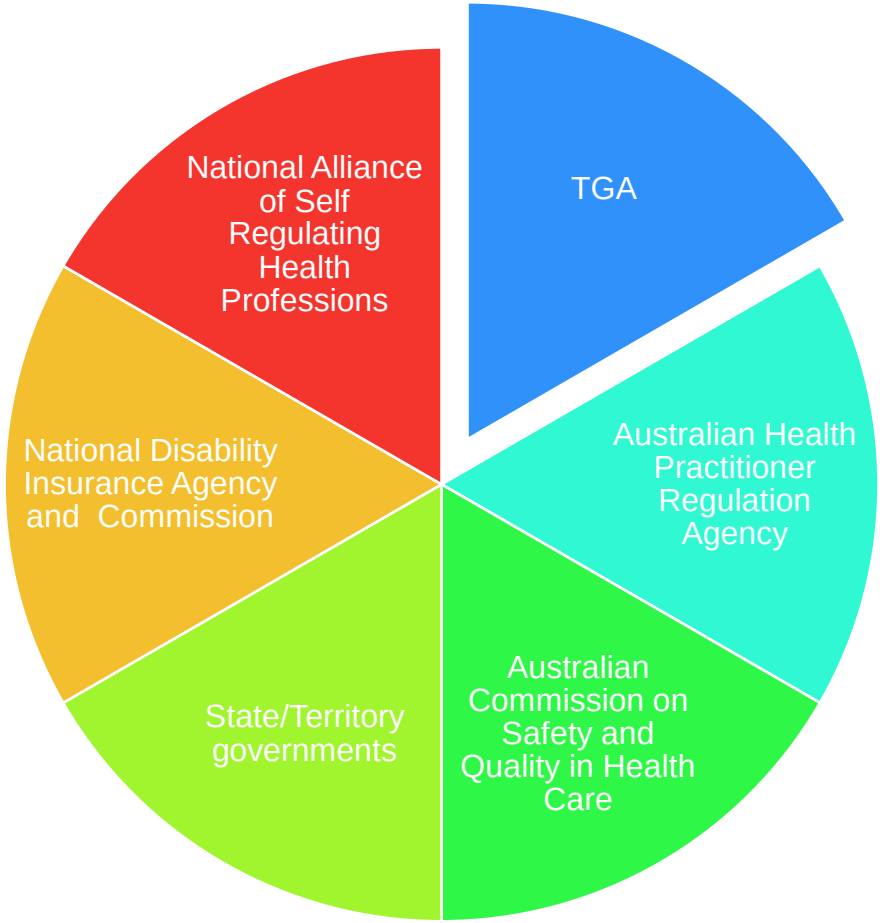
- Many healthcare professionals and practitioners did not realise they are regulated by TGA
- Many are not compliant with existing TGA regulatory requirements
- In many cases manufacturing models differ from mass-production and commercial models
- Increasingly the manufacture of devices is not aligned with the training of the healthcare practitioner/professional
- Requiring many stakeholders in healthcare sectors to comply with current regulatory requirements is likely to disrupt supply and cause impacts on consumers/patients

"Direct communication and engagement between the TGA and State, Health Service and Hospital Governance Teams is required to meet regulatory requirements. There appears to be very limited understanding on what the regulatory obligations are for personalised medical devices produced within public health services."

Point of Care Manufacturing of Medical Devices

National symposium held June 2023

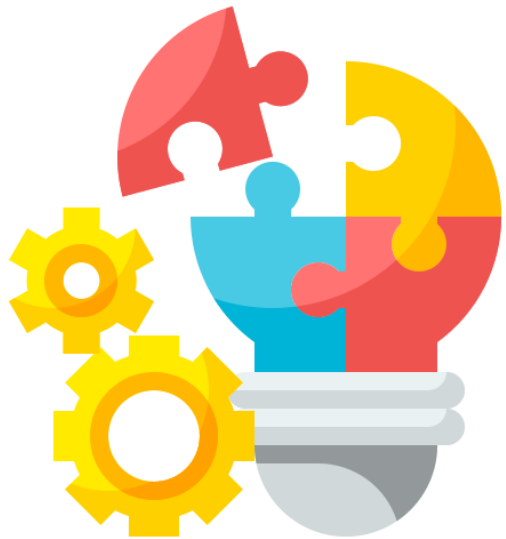
- What devices are made at the point of care?
- Who is making them?
- What are the risks associated with these devices?
- What is the most appropriate way to manage them?
- Who is best placed to regulate?



Point of Care Manufacturing of Medical Devices

The work ahead

- Over-arching steering committee
- Sector-specific working groups
- Mapping existing frameworks
- Identifying gaps
- Changes to frameworks
- Implementation, communication and education



Proposed Application Audit Framework

Before medical devices can be supplied in Australia, an application needs to be submitted to the TGA and approved to include the product in the Australian Register of Therapeutic Goods (ARTG).

We assess the application against the *Therapeutic Goods Act 1989* and the *Therapeutic Goods (Medical Devices) Regulations 2002*. Some applications are audited, which is a more thorough review/assessment.

Currently reviewing the framework for how applications for audit are selected and conducted – due to:

- changes to the EU regulations, including enhanced standards, processes, and clinical evaluation requirements
- regulatory amendments in Australia to enhance recognition of MDR certificates vs MDD certificates
- concerns raised by industry about existing processes, timeframes, and predictability
- a need to flexibly target our premarket assessment resources to areas of risk

Proposed Application Audit Framework

The audit framework needs to allow regulatory effort to be aligned with risk and be streamlined to reduce regulatory burden and cost.

The proposed new application audit framework aims to:

- enable a more responsive, risk-based approach to selecting applications for audit, based on post-market signals, regulatory reforms, and regulatory intelligence
- provide more predictability and transparency regarding types of applications likely to be selected for audit, their focus and expected timeframes
- appropriately target regulatory effort
- analyse trends and enable findings to inform advice to industry about the quality of applications and continuous improvement of the audit framework.

Mandatory Reporting of medical device adverse events by healthcare facilities

The *Therapeutic Goods Act 1989* was amended in March 2023 making **it mandatory for Australian** public and private hospitals and any other **health facilities** (prescribed by regulations) to **report medical device related adverse events** to the TGA.

Regulations to support implementation due by **March 2025**.

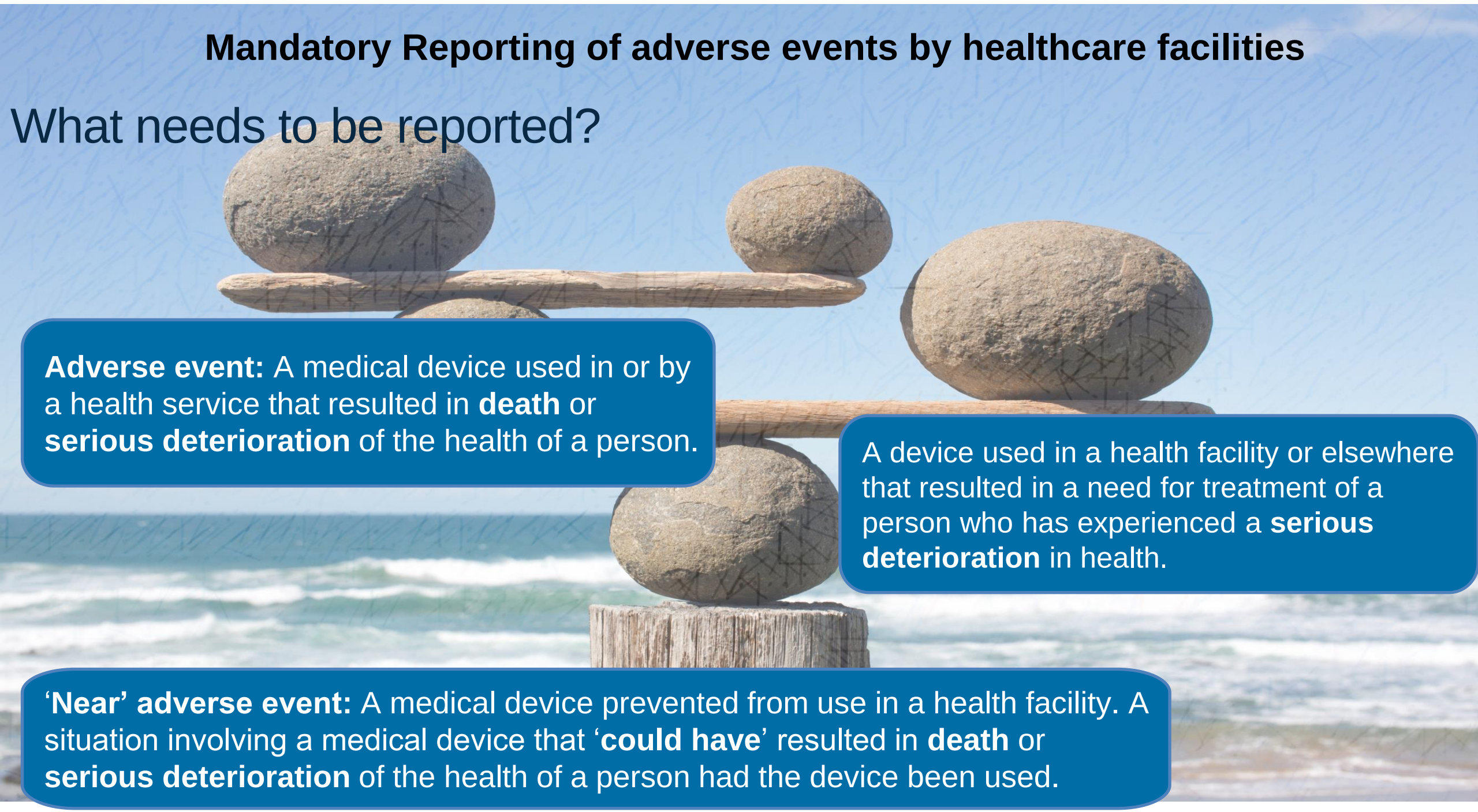
In parallel, the Australian Commission on Safety and Quality in Health Care will update the National Safety and Quality Health Service Standards to include mandatory reporting of medical device adverse events to the TGA.

Why the change? Lack of reports impacting surveillance capability

- metal hip prosthesis
- breast implants
- trans-vaginal mesh implants

Mandatory Reporting of adverse events by healthcare facilities

What needs to be reported?



Adverse event: A medical device used in or by a health service that resulted in **death** or **serious deterioration** of the health of a person.

A device used in a health facility or elsewhere that resulted in a need for treatment of a person who has experienced a **serious deterioration** in health.

‘**Near’ adverse event:** A medical device prevented from use in a health facility. A situation involving a medical device that ‘**could have**’ resulted in **death** or **serious deterioration** of the health of a person had the device been used.

Mandatory Reporting of adverse events by health care facilities

Next steps

- **Complete discussions with hospital stakeholders**
- **Consolidation of information and follow-up**
- **Develop proposed Implementation Strategy & Options**
- **Undertake Regulatory impact analysis**
- **Consult on Regulatory amendments**
- **Identify IT solutions and data transfer processes to support implementation**
- **Draft Guidance & other resources**

TGA Strategic Activities

Strategic priorities

A focus on four strategic priorities to foster international partnerships:

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

Activities for this include:

- Continued engagement, domestically and internationally
  - to build flexible and robust regulatory evaluation processes to ensure rapid access for Australian patients and healthcare professionals without compromising our regulatory standards
- Working with National Regulatory Authorities within the Pacific and South East Asia
  - to strengthen regulatory systems, for faster access to products for communicable diseases and reducing supply of products that are of poor quality or present health risks.

TGA Transformation

- The Transformation Program's purpose is to reduce the regulatory burden to make it easier and simpler to do business with the TGA. Examples:
  - Modernise the TGA website to make it easier to access regulatory information
  - Single portal for all interactions and business with the TGA with new authentication processes
  - Future improvements to the Australian Register of Therapeutic Goods (ARTG) search experience and data quality - remediating errors and establishing long term improvements.

- Medical Device IT specific projects
  - Enhance Australian Unique Device Identification Database (AusUDID) to provide storage and online access options for Patient Information Leaflets (PILs), and Electronic Instructions for Use (eIFU)
  - Enhance Clinical Trials Notification form to improve data collection to allow better oversight, improved monitoring to ensure of the safety of medical device clinical trials without adding regulatory burden.

Personalized Medical Devices (PMD) Working Group Update

Publications

- Definitions for Personalized Medical Devices (IMDRF/PMD WG/ N49) *Published November 2018*
- Personalized Medical Devices – Production V&V (IMDRF/PMD WG/ N74) *Published April 2023*
- Personalized Medical Devices – Regulatory Pathways (IMDRF/PMD WG/ N58) *Published September 2023*

Personalized Medical Devices (PMD) Working Group Update

PMD Production Verification & Validation (N74)

- Document published 11 April 2023
- Builds on the definitions and concepts in N49 Definitions of Personalized Medical Devices and N58 Personalized Medical Devices – Regulatory Pathways
- Technical guidance on verification and validation aspects of

  - specified design envelope (patient-matched medical devices)

  - medical device production systems

PMD Regulatory Pathways (N58) – Revisions

- Scope of N58 revisions include:
  - revising the MDPS definition and framework to better represent real world applications, and facilitate its adoption
  - expanding the scope of Appendix 2 to incorporate a broad range of devices, not limited to PMDs
- Feedback from public consultation (Sept – Nov 2022) considered in developing the revised N58
- Revisions approved for publication by the MC, published in September 2023

Opportunities and Challenges

- Developing timely and fit-for-purpose recommendations to address risks introduced by new and emerging technologies in PMDs
- Consistent interpretation and understanding of the document by all stakeholders
- WG intends to:
  - promote IMDRF PMD documents and educate stakeholders
  - develop training/guidance materials for stakeholders in line with N76 recommendations
  - monitor implementation and collect feedback
- Inviting stakeholders to provide suggestions on developing effective training and guidance materials to ensure consistent interpretation of the documents


Thank you

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Regulatory Updates – Brazil

Augusto Bencke Geyer, Medical Devices Office

ANVISA – Brazilian Health Regulatory Agency

26 September 2023 – Berlin

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

- Consolidation of comments/suggestions carried out between the jurisdictions that are part of Mercosur - Argentina, Brazil, Paraguay and Uruguay
- Final text approved by Mercosur in September 2023 – Ready to be incorporated to the MD Brazilian regulatory framework
- Based on IMDRF documents:
  - Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices (IMDRF/GRRP WG/N47FINAL:2018)

Clinical Investigations Requirements Revision

- Public Consultation took place between 27 October and 27 December 2022 – 8 contributions with 124 comments/suggestions
- 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
- One of Anvisa's directors requested a review of the regulatory process for greater alignment with regulations applicable to medicines

Requirements for Pre-Market Authorization of Medical Devices

- Resolution RDC 751/2022 effective since March 2023
- Definitions and classification rules updated considering new technologies
- 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
- Anvisa has facilitated a series of virtual and in-person seminars focusing on manufacturers and importers

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 already harmonized in Mercosur 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
- Expect to publish in November 2023
- Effective date will be 180 days after publication

Good Manufacturing Practices of Medical Devices Certifications Dashboard

- GMP Certification Database
- Relevant search criteria
- Geographic distribution views available
- Certification status filters
- Constantly updated (weekly)
- Widely helpful to management
- Dashboard link:

https://www.gov.br/anvisa/pt-br/setorregulado/certificados-de-boas-praticas/consultar-empresas-certificadas

Good Manufacturing Practices of Medical Devices Certifications Dashboard

Estabelecimento/Fabricante	Solicitante	Linha e Classe	País	Endereço	Resolução	Publicação	Validade	Status
Acrostak (Schweiz) AG	VR Medical Importadora e Distribuidora de Produtos Médicos Ltda	>Materiais de uso médico das classes III e IV.	SUÍÇA	Stegackerstrasse 14, Winterthur, 8409 - Suiça	RESOLUÇÃO-RE Nº 3.280, DE 30 DE AGOSTO DE 2023	04/09/2023	04/09/2025	DEFERIDO
Allergan Sales, LLC	Allergan Produtos Farmacêuticos Ltda	Materiais de uso médico da classe III.	ESTADOS UNIDOS DA AMÉRICA	8301 Mars Drive, Waco, Texas, 76712, Estados Unidos da América	RESOLUÇÃO-RE Nº 3.268, DE 28 DE AGOSTO DE 2023	04/09/2023	04/09/2025	DEFERIDO
Arrow Internacional de Chihuahua S.A de C.V.	Emergo Brazil Import Importação e Distribuição de Produtos Médicos Hospitalares Ltda.	Materiais de uso médico das classes III e IV.	MÉXICO	Av. Washington nº 3701, Interior Circuito Industrial Alta Tecnologia, Edifício 40, Col. Panamericana, Chihuahua, 31200, México	RESOLUÇÃO-RE Nº 3.268, DE 28 DE AGOSTO DE 2023	04/09/2023	04/09/2025	DEFERIDO
Aurolab	Vision Line Importação e Comércio de Materiais e Equipamentos Médicos Ltda- ME.	Materiais de uso médico das classes III e IV.	ÍNDIA	N.º 1 Sivagangai Main Road, Veerapanjan - Madurai , 625020 - Índia	RESOLUÇÃO-RE Nº 3.277, DE 30 DE AGOSTO DE 2023	04/09/2023	04/09/2025	DEFERIDO

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	412 (62,6%)

Until 31 August

Reliance Mechanisms for Pre-Market Authorizations

- Pathway for abridged review of initial submissions
- Normative Instruction for MD and IVD MD under public consultation
  - Public Consultation 1200/2023
  - Open for contributions until 25 October 2023
    - http://antigo.anvisa.gov.br/consultas-publicas#/visualizar/509352
- Main objective – Product registration certificates from Equivalent Foreign Regulatory Authorities will be used as a trigger for expedited review
- Initially from the same founding members authorities of MDSAP

2023 Medical Device Single Audit Program Forum

- Brasília, Brazil – 23rd to 27th October 2023
- Representatives from:
  - Regulatory Authorities
  - MDSAP Auditing Organizations
  - Trade organizations and device manufacturers

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Thank you/Questions

Medical Devices Office
Email ggtps@anvisa.gov.br

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Regulatory and Policy Updates Health Canada

Sally Prawdzik

A/Director, Bureau of Policy and International Programs, Medical Devices Directorate

September 26, 2023

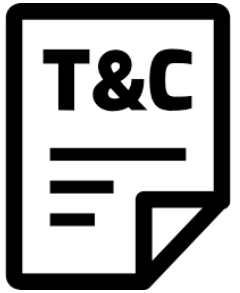
Overview

- Proposed Regulations to Address Future Public Health Emergencies
- Proposed Regulations to Expand Medical Device Terms and Conditions
- Current Public Consultations
- Upcoming Public Consultation
- IMDRF Working Group Updates

Proposed Regulations to Address Future Public Health Emergencies

- On February 22, 2023, Health Canada established a permanent regulatory framework for COVID-19 medical devices, resulting in the creation of Part 1.1 of the Medical Devices Regulations
  - Part 1.1 maintains many of the flexibilities afforded by the previous temporary regulations (known as Interim Orders)
- In order to enable faster access to devices that have an Urgent Public Health Need, Health Canada is proposing to amend these Regulations to expand the scope to address future public health emergencies
- A public consultation was held in Spring 2023 to help inform the Regulations and accompanying policy

Expanding Device Terms and Conditions



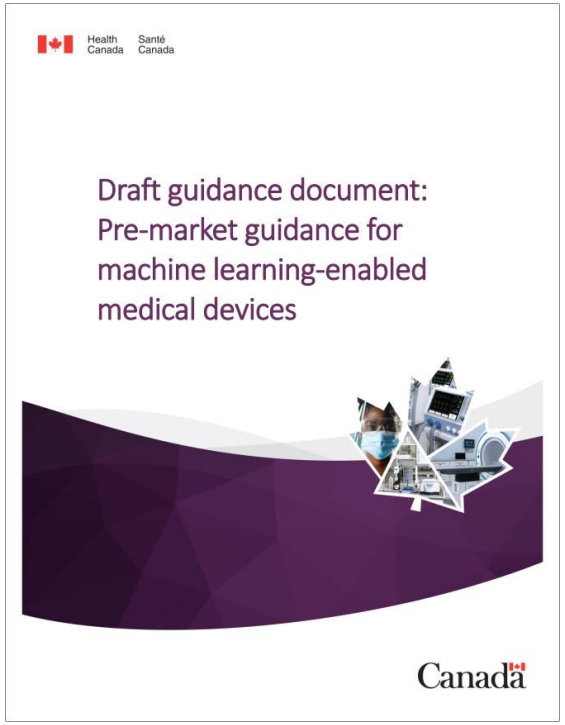
- As part of our **Agile Licensing** initiative, Health Canada is proposing expanded Terms and Conditions (T&Cs) regulations to support the life cycle approach for regulating medical devices

- These proposed regulations would 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 lifecycle

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

- A public consultation on the proposed regulations and draft guidance document was held in Spring 2023, stakeholder feedback is currently being analyzed

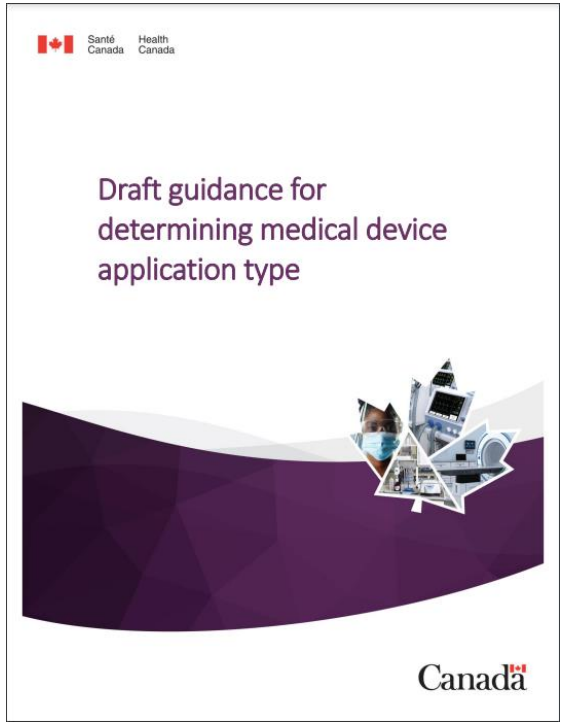
Public Consultation: Draft Guidance on Machine Learning-enabled Medical Devices (MLMD)



Draft Guidance Consultation launched in August 2023

- Intended to help manufacturers submitting an application for an MLMD
- Outlines expectations for demonstrating safety and effectiveness
- Introduces a mechanism for Health Canada to pre-authorize planned changes to address risks through a pre-determined change control plan
- Consultation closes on October 29th, 2023

Public Consultation: Draft Guidance on Determining Medical Device Application Type



Draft Guidance Consultation launched in September 2023

- Explains the different application types
- Assist applicants to determine whether certain devices, including components and parts, should be combined and submitted as 1 application
- Takes into account authorizations issued for COVID devices
- Consultation closes on November 10th, 2023
- Will replace the current *Guidance for the Interpretation of Sections 28 to 31: Licence Application Type*

Upcoming Public Consultation

- Draft Guidance: How to Interpret Significant Change of a Medical Device
  - Guidance assists manufacturers in determining when a change proposed to a licensed Class III or Class IV medical device is considered significant and requires an amendment to a medical device licence
  - Guidance is being updated to reflect Health Canada's current thinking and include additional examples
  - When finalized, will replace the existing *Guidance for the Interpretation of Significant Change of a Medical Device*
  - Public consultation is targeted for later this year

IMDRF Working Group Updates

Cybersecurity (Co-Chairs: Health Canada/FDA)

- Final documents approved at the March IMDRF meeting
  - N70: Principles and Practices for the Cybersecurity of Legacy Medical Devices
  - N73: Principles and Practices for Software Bill of Materials for Medical Device Cybersecurity

Regulated Product Submission (Co-Chairs: Health Canada/FDA)

- Public consultation for N9 and N13 closed in May 2023
  - Over 200 comments from 8 stakeholders received
  - Comments focused on improving clarity, terminology changes, minor text changes/additions, layout/organizational changes
- Working group is currently analyzing comments

IMDRF International Medical Device Regulators Forum

Thank you/Questions

Email sally.prawdzik@hc-sc.gc.ca

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Update on China Regulatory

Yuan Peng

NMPA

27th September 2023

Further optimization and adjustment of Medical Device Classification works in China

In July this year, the NMPA issued the "Opinions on Further Strengthening and Improving the Classification Management of Medical Device"

This document clarifies the next works in the classification of medical devices in China, mainly including five parts:

- Optimize the classification management system. Further clarify the responsibilities of the NMPA, Local MPA and the Medical Device Classification Technical Committee, improve the operational mechanism of the Classification Technical Committee, and improve the assessment and evaluation mechanism of experts and panels.
- The NMPA will consider to revise the "Classification Rules for Medical Devices" and based on the "Classification Rules for IVD", we will consider to revise the IVD classification catalogue, and we will establish a medical device classification and nomenclature database.

- Further clarify the application data requirements and review requirements for medical devices classification and consider to set up special procedures for special situations, such as public health emergencies. Implement dynamic adjustments to the classification catalog of medical devices.

- Focus on classification management policies research for new technology fields (previously, NMPA had issued the documents about the classification of AI medical devices), and strengthen research on medical devices classification work, and Increase training.

- Strengthen the construction of the medical device classification information system, optimize the workflow of online application and information query for medical device classification.

  Open more about the classification information, ensure transparency in work

2023.8

Announcement on Adjusting Part of the Content of the Classification Catalogue of Medical Devices (No.101)

related to 58 kinds of medical devices. for example: Ultrasound cutting hemostatic blade, ultrasound soft tissue surgical blade, ultrasound suction surgical blade, breast circumcision puncture needle and accessories, III level medical device.

https://www.nmpa.gov.cn/ylqx/ylqxggtg/20230817153633135.html

for more details

Promoting the Implementation of GB 9706 Standard in China

- GB 9706.1-2020 (Medical electrical equipment-Part 1:General requirements for basic safety and essential performance) equal to the IEC 60601-1-2012,MOD)
- 2020.4.9 the GB 9706.1-2020had been published, as the mandatory national standards and will implement on 2023.5.1
- 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 Implementation date.
- NMPA and SAMR(State Administration for Market Regulation) jointly released the notice on promoting the capacity of medical device test center, ensuring the Qualification Recognition of the New GB 9706 Series Standards

- from May 1, 2023, for the registration test application of the new GB 9706 series standards should be priority processing by medical device test center.

- The CNCA and related institutions shall carry out qualification recognition work related to the testing capabilities of the new GB 9706 series standards according to the application, accept and technical review of qualification recognition applications related to the testing capabilities of the new GB 9706 series standards priority.

Start to draw up the Medical Device management law

Open more about the classification information, ensure transparency in work

- On September 8th, the 14th Standing Committee of the National People's Congress issued a legislative plan, which included the Medical Device Management Law for the first time in the second level of "A draft law that needs to be urgently worked out and submitted for review when conditions are mature" projects.
- Regulations on the Supervision and Administration of Medical Devices(state council decree No.739), which is currently valid, was revised and issued in 2021, but as we know, there are still some issues that need to be revised in the regulations, such as the management of medical device standards
- NMPA has initiated a research project on issues related to the Medical Device Law, and preparing to draft
- This will be a long-term task, and there is no roadmap or timetable available currently, but NMPA hope to accelerate the process.

International Cooperation

- Strengthen cooperation with other countries and the IMDRF based on the GHWP platform
- On June 14, 2023, the GHWP Technical Committee held a regulatory meeting in Shenzhen, Guangdong Province, China. The GHWP chairman, Mr. Xu Jinghe, attended the opening me eting and delivered a speech.
- During the GHWP Technical Committee meeting , the NMPA and the Malaysian Medical Devi ce Administration (MDA) held a medical device regulatory exchange meeting in Shenzhen
- Discuss with the IMDRF on how to strengthen cooperation between GHWP and the IMDRF

Conclusion

1. Further optimization and adjustment of Medical Device Classification works in China
2. Promoting the Implementation of GB 9706 Standard in China
3. Start to draw up the Medical Device management law
4. Strengthen cooperation with other countries and the IMDRF

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Thank you/Questions

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Update on EU regulatory developments

Chloe Spathari

Nada Alkhayat

European Commission

IMDRF-24 Session – Stakeholder Forum

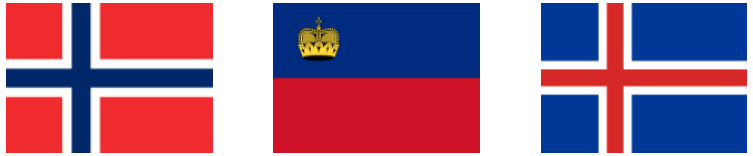
26 September 2023

The EU single market for medical devices

EU

EFTA/EEA

Norway, Liechtenstein, Iceland

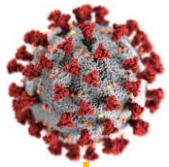


Turkey

Timelines

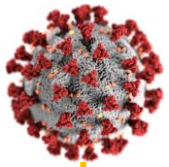
2017 — The two new regulations published in May

2020 — A one-year delay of the MDR was adopted in April



2021 — MDR date of application 26 May

2022 — Amended transitional provisions for IVDR were adopted in January



2022 — IVDR date of application 26 May

2023 — *6 January* Commission proposal to amend MDR transitional provisions

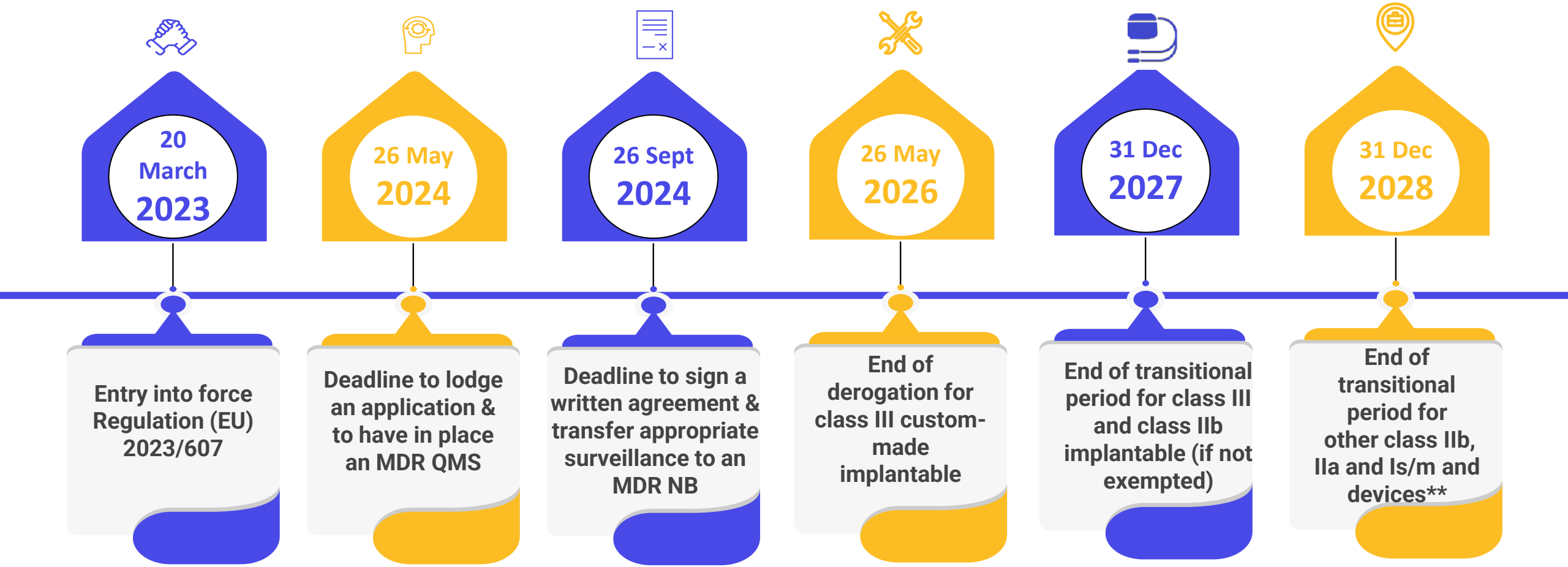
2023* — Entry into force Regulation (EU) 2023/607 *20 March*

2025 — *26 May* All IVDD certificates become void

2027 — End of IVDR transitional period *26 May*

2028 — *31 December* End of transitional periods for MDR

MDR transitional period per Regulation (EU) 2023/607



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

Supportive 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, including on inspections, supported by EU Medical Device Inspectors Task Force (MDITF), coordinated by DK
- 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)

Supportive actions

Q&A on practical aspects of implementation of Reg. 2023/607

Factsheet for authorities in non-EU/EEA states on medical devices and in vitro diagnostic medical devices

Targeted support for SMEs through Enterprise Europe Network

'COMBINE' project on combined studies involving MP/IVD/MD

Expert panel scientific advice on clinical development strategies for certain high-risk devices

Priorities for 2023

Chairing IMDRF

- Increase and promote **relations** with **other regulatory authorities** through new type of membership
- Reinforce **cooperation with harmonisation initiatives** via collaboration agreements
- Encourage **engagement with healthcare professionals/clinicians**
- Develop and agree **on strategic principles** for **IMDRF trainings between MC members**
- Deliver on the **first IMDRF training** in the form of a pilot

Priorities for 2023

Facilitating a smooth transition to MDR and IVDR

- Increasing number and capacity of notified bodies: **50** (**39 MDR**+**11 IVDR**) notified bodies designated under MDR and IVDR*
- MDCG 2022-14 position paper on notified body capacity and availability of medical devices and IVDs*

Scientific Structures

- Expert panels designated (2019) and running since (Q2 2021) with opinions issued
- Designated experts re-appointed (Q3 2023) (Q2 2023)*
- Selection of EU reference laboratories completed (IVDR) (Q2 2023)*

Priorities for 2023-2024

EUDAMED

- Modules released: actor registration (Q4 2020), UDI, notified bodies & certificates (Q3 2021)
- Modules in functional testing with users: Vigilance & PMS, Clinical Investigations & Performance Studies, Market Surveillance (continuous)*

UDI

- 4 issuing entities designated, 15 guidance and factsheets published, UDI helpdesk and platform available
- Commission Delegated Regulation (EU) xx/xx UDI assignment for highly individualised devices (specifically contact lenses) adopted
- Preparatory work on other medical devices requiring specific considerations (2024)

Nomenclature

- Published for public consultation (Q2 2021)
- Final version launched available in EN, IT, FR, HU. Validations of remaining EU languages (ongoing)
- Work program for 2023-2025 to be announced Q3 2023
- lenses)
- Preparatory work on other medical devices requiring specific considerations (2024)

Priorities for 2023-2024

Tertiary legislation: Common Specifications/ Implementing Acts

Commission Implementing Regulations:

- 2022/2346 – Common specifications for Annex XVI products **(EOF Q2 2023)***
- 2022/2347 – Re-classification of groups of certain active products without an intended medical purpose **(EOF Q4 2022)**
- 2022/945 designating EURLs and designation of 5 EURLs expected **(Q4 2023)***
- for Class D devices **(Q4 2023)***

Standards

- Lists of harmonised standards published (Q3 2021), (Q1 2022), (Q2 2022)
- First amendment to the Standardisation request was adopted on 31 January 2023, second amendment under development to adapt deadlines for adoption of new standards*
- New publication under preparation (Q4 2023) *

Implementation of MDCG Position Paper MDCG 2022-14

1. Make use of hybrid audits

2. Leveraging evidence from previous assessments conducted under the Directives

8. Gaining momentum - speed-up the assessment, designation and notification process

12. Make standard fees publicly available and take into account interest of SMEs

13. Allocate notified bodies capacity for SME manufacturers

14. Call on manufacturers to ensure timely compliance to MDR/IVDR

15. Structured dialogue before and during the conformity assessment process

16. Increase preparedness of manufacturers

18. Orphan devices

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Updates from IMDRF WGs co-chaired by the EU

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Adverse Event Terminology and Coding Working Group

Nancy Pressly/ Evan Jacobs – Food and Drug Administration, United States of America

Andrea Hanson – Health Products Regulatory Authority, Ireland.

IMDRF 24th Session – Berlin, Germany

Adverse Event Terminology WG

About the WG:

- The Adverse Event Terminology and Coding working group was established in 2015.
- The group is composed of members from 11 regions.
- The group has two Co-Chairs (FDA & HPRA) and a AEWG Maintenance Chair (MHRA).
- The group convenes every 3 weeks via teleconference. A face-to-face meeting will be held in October 2023.

Publications:

- IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure and codes IMDRF/AE WG/N43FINAL: 2020 (Edition 4), **including 7 annexes**
- Maintenance of IMDRF AE Terminologies IMDRF/AE WG/N44FINAL:2020 (Edition3)

Ongoing work

1. Leverage post-market monitoring and surveillance

a) The development of a Common Data Set for Adverse Event Data Exchange between IMDRF Regulators

b) The continued development and improvement of the Adverse Event Terminology and coding system to ensure that it is accurate, agile and moving with innovation, through the management of queries and the **annual maintenance cycle**.

2. Managing regulatory challenges for medical devices and innovative technologies by providing timely and appropriate guidance

a) The development of a training presentation / video to reinforce the key principles of the system (N43 document).

b) The development of a guidance document to support the exchange of the Common Data Set.

c) The development of a **new** guidance document and a video to further support the practical use of the Adverse Event Terminology and coding system.

Opportunities and Challenges

- Regulatory convergence with increased use of the Adverse Event Terminology and coding system.
- Increased harmonisation with use of common terminology.
- Opportunity for increased oversight and signal detection.
- Easier exchange of information.

- More guidance is needed to support the practical use of the codes.
- Confidentiality arrangement and EU General Data Protection Regulation (GDPR) need to be factored into the use and the exchange of the Common Data Set.
- Further development of analytical algorithms is required.

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Quality Management System (QMS) Working Group Update

Co-Chairs:

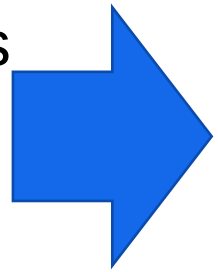
Máiréad Finucane / Maria Del Carmen Sanz – EC

Melissa Torres – US FDA

IMDRF 24th Session – Berlin, Germany

About US

- Quality management systems and risk management activities are integral principles to ensuring the design and manufacture of safe and effective medical devices
- QMS and risk management principles have evolved since the creation of the original GHTF documents (2004-2010) which were based on previous versions of ISO 13485 and ISO 14971
- Requirements within the various jurisdictions have also evolved



- The aim of the working group is to have up to date guidance on QMS and risk management requirements (outlined in ISO 13485 and ISO 14971) in order to assure an appropriate balance between pre-market and post-market requirements as part of a total product lifecycle regulatory approach to medical devices.

Working Group Establishment

Approval of work	Collaboration agreements	Working Group nominations	Documents for revision
New Work Item Proposal approved by the IMDRF Management Committee in September	Received agreement amongst leadership of IMDRF, GHWP, and ISO to do this work jointly amongst the 3 organisations	Representatives from: - IMDRF regulatory authorities - GHWP regulatory authorities - ISO TC 210 WG1 - Industry, and Notified bodies	- GHTF/SG3/N17:2008 Guidance on the Control of Products and Services Obtained from Suppliers - GHTF/SG3/N18:2010 Guidance on Corrective and Preventive Action - GHTF/SG3 N15R8: 2005 Risk Management Principles - GHTF/SG3/N99-10:2004 Process Validation Guidance

Opportunities and Challenges

- Transfer of old GHTF documents into IMDRF templates
- Prioritisation of work items
- Proposal to begin with the update supplier controls (GHTF/SG3/N17:2008 Guidance on the Control of Products and Services Obtained from Suppliers)
- First meeting of the working group to be scheduled after Management Committee meeting

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Thank you/Questions

Email nada.alkhayat@ec.europa.eu
chloe.spathari@ec.europa.eu

IMDRF International Medical Device Regulators Forum

Regulatory Updates on Medical Devices in Japan

MIYASAKA Tomoyuki
Deputy Director,
Medical Device Evaluation Division, Pharmaceutical Safety Bureau,
Ministry of Health, Labour and Welfare Japan (MHLW)
Japan

Day2 – 26 September 2023

Overview

Update for SaMD regulations in Japan

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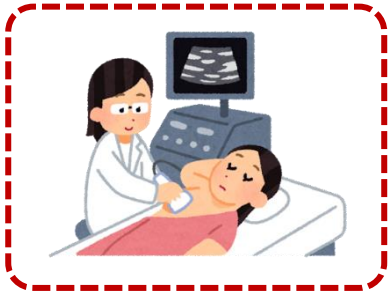
Transition of regulations for SaMD in Japan

before November 2014

program which determines performance of medical device

install



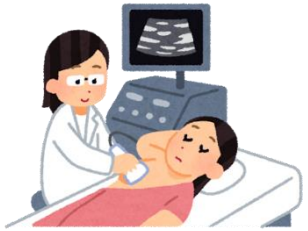
Medical device
（tangible object including software）

after November 2014

program which determines performance of medical device

Medical device
（software itself）

install



MD software classified as Class I is **NOT** subjected to regulations on PMD-Act

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Toward Further Practical Application and International Development of SaMD in Japan

- While there were high expectations for the utilization of SaMD (Software as a Medical Device), there were issues regarding the direction of efficient development of SaMD because it is still a new field for all stakeholders in Japan.

- To tackle the issues, on November 24, 2020, MHLW launched **"DASH for SaMD"** (Package Strategy for Accelerating the Commercialization of SaMD) , and the institutional infrastructure was established mainly to efficiently obtain pharmaceutical approval under the PMD Act.

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Toward Further Practical Application and International Development of SaMD in Japan

- However, in order to further promote the practical application of SaMD in the future, we need to do more, such as the following.
  - ✓ **Clarify various paths to commercialization (two-step approval scheme for SaMD, SaMD for the general public)** in cooperation between the regulatory and insurance authorities to ensure predictability from approval to insurance coverage.
  - ✓ **Accelerate research and development of Japan-originated SaMD and promote their expansion into international markets.**
- Based on the above, MHLW have just compiled a new strategy, namely **"DASH for SaMD 2"** on September 6, 2023, **with some goals for the next five years.**

DASH for SaMD 2 （2023/9/6）

- ◆ Organize and publicize the two-step approval scheme for SaMD
- ◆ Develop guidelines for approval review and marketing procedures for SaMD for the general public
- ◆ Promotion of overseas acceptance of our review results (such as English translation of review reports)
- ◆ Subsidies for development funds for SaMD developers
- ◆ Support for SaMD developers to actively business overseas

DASH for SaMD（2020/11/24）

- ◆ Setup an office to review SaMD in MHLW and PMDA
- ◆ Establishment of SaMD centralized consultation service
- ◆ Next-generation medical device evaluation index, development guidance, audit points, and certification criteria formulation
- ◆ Trial implementation of priority review, etc. for innovative SaMD
- ◆ Promote the use of IDATEN (Improvement Design within Approval for Timely Evaluation and Notice) and streamline procedures, etc.

<Expand and continue>

- ◆ Upgrade from office to Department for reviewing SaMD in PMDA
- ◆ Establishment of SaMD-specific consultation service
- ◆ (Continue)
- ◆ (Continue)
- ◆ (Continue)

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Goals for the next 5 years under DASH for SaMD 2

- Expansion of more enhanced self-care options
- Promotion of better health for the public
- Exporting more and market acquisition of innovative SaMD developed in Japan
- Shorten the development cycle time of SaMD by contributing to a smooth and efficient market introduction
- Realization of efficient commercialization of SaMD
- Creation and early commercialization of innovative SaMD
- Smooth and efficient post-marketing performance improvement of SaMD

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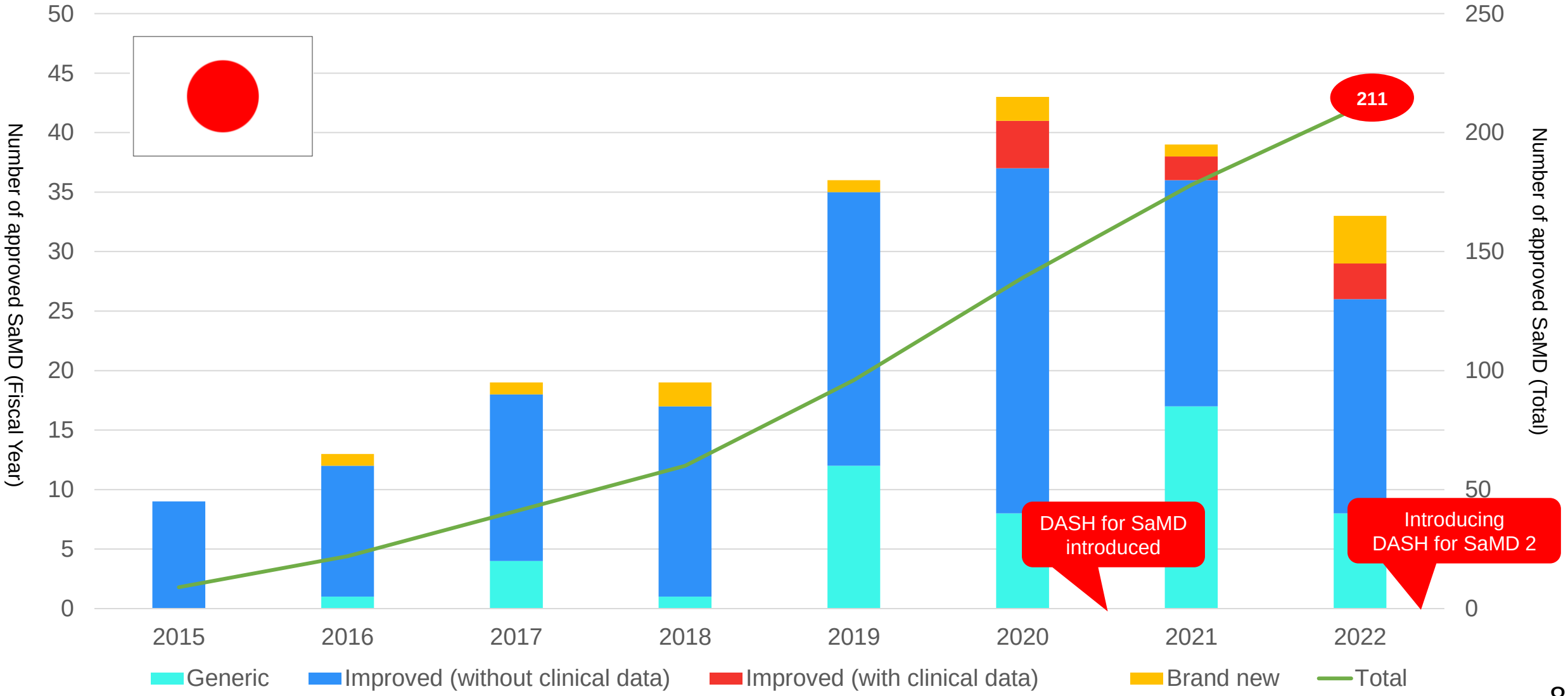
Number of Approved SaMD (not including the certificated SaMD)

As of March 2023



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As of May 2023

Non-SaMD	SaMD		
	Class II	Class III	Class IV
● 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 at home** for used exclusively at home: 2		
	For diagnostics for computer assisted Imaging diagnostics: 322 for computer assisted diagnostics other than imaging: 89 for gene mutation analysis: 11		
	For treatment Application for behavioral therapy: 3	for therapy planning support: 58 for Surgical Support: 1 for controlling MD: 3	

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Examples of approved SaMD

（Ex.1）

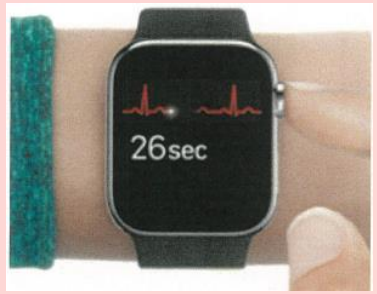
Digital Therapeutic App for Hypertension（approved in Apr. 2022）

→ Behavioral Approaches to Lifestyle Modification

（Ex. 2）

ELECTROCARDIOGRAPH SOFTWARE FOR OVER-THE-COUNTER USE（approved in Sep. 2022）

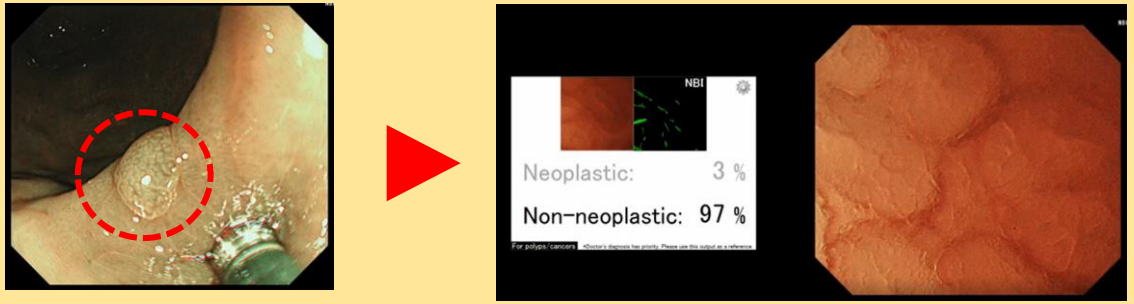
→ can provide information for identifying cardiac arrhythmias and encourage medical examination



（Ex.3）

AI-powered Colorectal Endoscopy Diagnosis Support Software（approved in Apr. 2022）

→ Support for detection and differentiation of lesions in colonoscopy



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Two-step Approval scheme for SaMD *(draft)*

- Two-step Approval scheme was introduced in 2017.
- This scheme is mainly used for diagnostic MD, and is used when the analytical performance is reliable but the clinical benefit of the analyte is not sufficient. By using this scheme, it is possible to claim that “physiologic parameter “A” can be measured" in the First-step Approval, and, after concreting the clinical benefit, claim that "measuring A will lead to diagnose of specific disease B" in the Second-step Approval.
- MHLW is currently considering that **the scheme will expand to SaMD for the treatment** such as the next slide image. In the case of SaMD for the treatment, if safety and a certain level of efficacy based on some evidences (including non-clinical trial) for Alleviation and improvement of specific symptoms caused by disease “C” can be confirmed, the First-step Approval will be granted at that point. Then, after concreting the clinical benefit, the Second-step Approval will be granted to claim the final clinical benefit.

※ *This scheme is under consideration, but is being studied with the aim of introducing it by the end of 2023.*

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Two-step Approval scheme for SaMD *(draft)*

SaMD for diagnosis

After clinical benefit concreted (Post-marketing CT, RWE)

Reliable performance for analyzing physiologic parameter “A”

First-step Approval

Diagnosis of disease “B” by analyzing physiologic parameter “A”

Second-step Approval

SaMD for treatment

After clinical benefit concreted (Post-marketing CT, RWE)

Alleviation and improvement of specific symptoms caused by disease “C”

First-step Approval

Treatment support and improvement of disease “C”

Second-step Approval

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Thank you/Questions

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

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

If you have any questions, please contact me via email (miyasaka-tomoyuki@mhlw.go.jp) or visit our website as above.

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Regulatory Updates
Health Sciences Authority, Singapore

Ms Wong Woei Jiuang

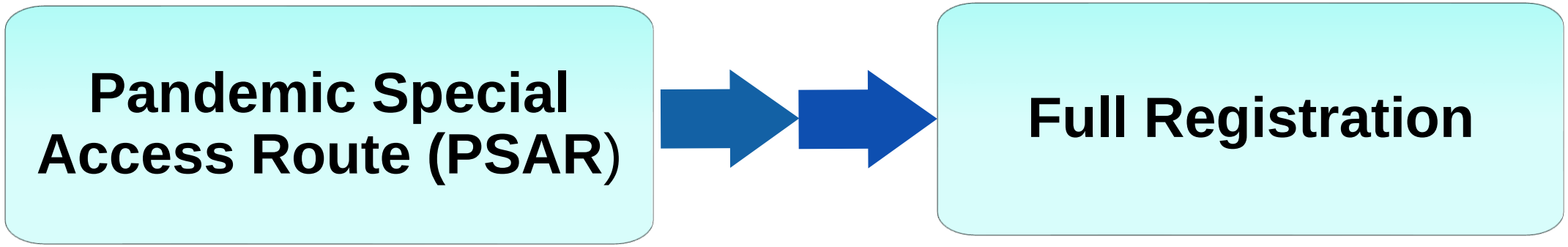
Asst Group Director,

Medical Devices Cluster,

Health Sciences Authority, Singapore

September 2023

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



- All COVID-19 tests previously authorised under PSAR have been moved to full registration
- Any new COVID-19 test will go through the standard pre-market evaluation and full registration process applicable to all IVDs
  - PSAR will no longer be applicable
- Guide on the key validation requirements for **full registration** available online - Validation Requirements for Product Registration of COVID-19 Diagnostic Tests – Self-Tests**.**

Manufacturing of dental devices in dental laboratories in Singapore

- **Dental laboratories** specialise in manufacturing or customising devices used by registered dentists to assist in providing oral heath care to their patients.
  - In Singapore, these labs mainly manufacture "custom-made medical devices" that are mainly lower risk (class A and class B) dental devices such as crowns, bridges, dentures and orthodontic appliances following the prescription/written instruction from a registered dentist
  - Each unit of these dental devices is custom-made for an individual patient and does not fit others
  - The manufactured devices are supplied to the prescribing dentists, who fits the devices for their patients

- **Dental laboratories** in Singapore operate
  - Within MOH licensed facilities under the Healthcare Services Act (HCSA) such as healthcare institutions (e.g. National Dental Centre) and dental clinics; **OR**
  - As standalone set ups (i.e. private entities)

- **Standalone dental laboratories**, which operate outside hospitals and dental clinics, are not licensed by MOH
  - No regulatory oversight on these entities, their manufacturing and supply

A titrated regulatory approach for manufacturing in dental laboratories

A risk calibrated regulatory approach based on the following considerations:

i) These dental laboratories have been supporting the practice of dentistry by manufacturing custom-made dental MDs for over 40 years

ii) To date, we have not come across any serious safety incidents associated with the custom-made dental devices (specific to an individual patient) manufactured in local dental laboratories

iii) The manufacturing activity by these dental laboratories are mainly low risk:

- They manufacture lower risk MDs (risk class A and B) and mainly custom-made dental MDs.
- They manufacture the dental MDs solely based on a prescription or written instructions from a registered dentist to an individual patient and supply to these patients only through their dentists
- There is professional oversight from a registered dentist in terms of prescribing and fitting of the dental MD

A titrated regulatory approach for manufacturing in dental laboratories

- **Notification of Manufacturing**: All standalone dental laboratories manufacturing solely lower risk dental MDs (Class A and Class B) will be required to notify their local manufacturing site and their scope of activities via an online form to HSA.
  - They are required to implement and maintain a quality management system based on ISO 13485 and may be subject to random compliance audits by HSA.

  NOTE: *A standalone dental lab manufacturing higher risk MDs (Class C and D) will be subject to standard regulatory requirements i.e. a Manufacturer's licence requirement and ISO 13485 certification of their facility, with third party audit*

- **Product Notification for traceability**: Standalone dental laboratories will be required to notify the types of dental MDs (e.g. aligners, bridges) they manufacture to HSA prior to supply

- **Post-market Controls:** They will be subject to post-market reporting requirements (e.g. mandatory reporting of adverse events related to their MDs) and other duties and obligations (e.g. maintain manufacturing and distribution records, complaint records, ensure traceability of MDs manufactured)

Medical Device Special Access Route – Strengthening Regulatory Oversight

- **Special Access Route (SAR)**: Allows import and supply of unregistered medical device in order to meet unmet clinical needs or for compassionate use on patients upon request from a doctor
  - Requesting doctor must provide clinical justification to substantiate the clinical need
  - Not subject to the standard pre-market evaluation and registration process

- HSA implemented following additional measures to strengthen the oversight on SAR requests for unregistered medical devices in the interest of patient health and safety:

Additional Measures

For **Class C and D** unregistered MDs
- Request for an unregistered MD must be endorsed by the Chairman, Medical Board (CMB) of the hospital; **and**

For specific categories of **Class D** unregistered MDs
- Prior approval is required from the Director-General of Health's (DGH) Office in MOH for the use of
  - New technologies and state-of-the-art medical devices, including novel indications for existing medical devices or technologies
  - Unregistered implants (e.g., pacemakers, breast implants)

SAR Guidance Document:
hsa.gov.sg/docs/default-source/hprg-mdb/guidance-documents-for-medical-devices/gn-35-r4-guidance-on-special-access-routes-(2023-jan)-pub.pdf?sfvrsn=a9ad0cba_2

Guidance Documents – Key Updates

- Updated Guidance on Risk Classification of *In* vitro Diagnostic medical devices published in July 2023
  - Greater alignment to the IMDRF IVD risk classification guidance
- Updated Guidance on licensing of manufacturers, importers and wholesalers of medical devices published
  - MDSAP certificates accepted as an evidence of QMS for medical device manufacturers

❑ Guidance documents and Guidelines can be accessed online at:

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

IMDRF Good Regulatory Review Practices (GRRP) Working Group Update

Dr. Lakshmidevi Balakrishnan, Health Sciences Authority (HSA), Singapore

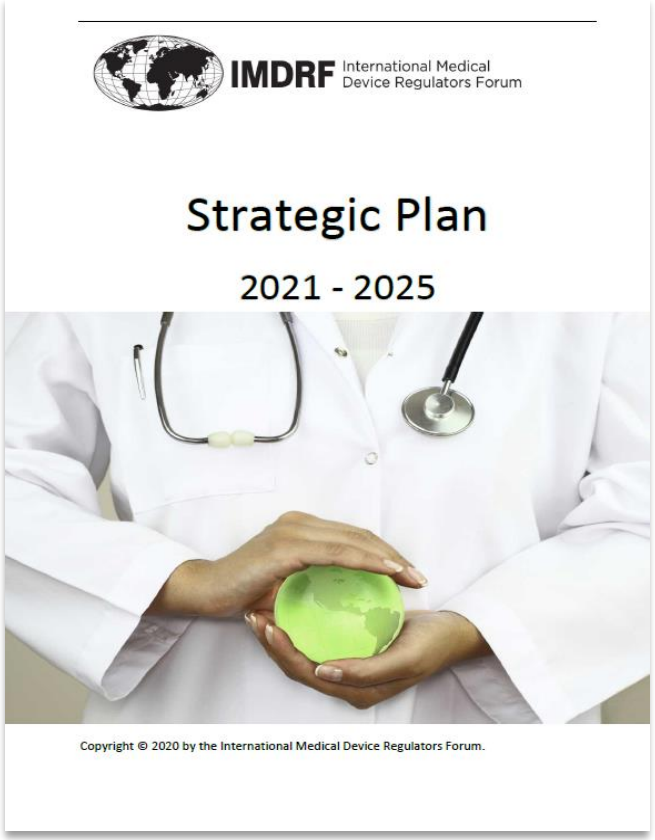
Dr. Kenneth Cavanaugh, Food and Drug Administration (FDA), United States of America

IMDRF 24th Session – Berlin, Germany

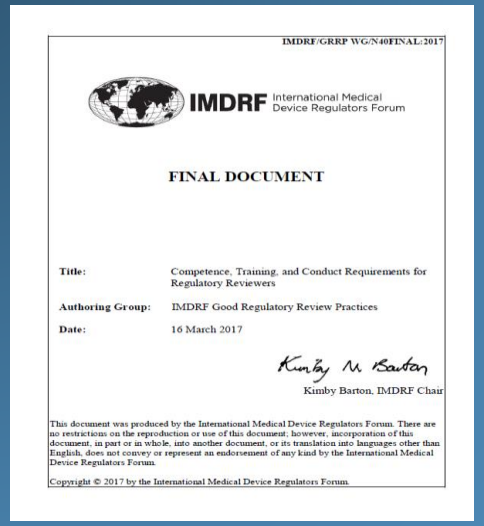
IMDRF International Medical Device Regulators Forum

IMDRF GRRP Working Group Goals

- Develop documents focused on harmonizing marketing review requirements globally.
- Documents focus on:
  - Technical requirements for conducting marketing reviews
  - Competency requirements for marketing reviewers
  - Requirements for organizations performing marketing reviews



GRRP Documents


IMDRF/GRRP WG/N40FINAL:2017

IMDRF International Medical Device Regulators Forum

FINAL DOCUMENT

Title: Competence, Training, and Conduct Requirements for Regulatory Reviewers

Authoring Group: IMDRF Good Regulatory Review Practices

Date: 16 March 2017

Kimby Barton, IMDRF Chair

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IMDRF GRRP WG/ N40 FINAL:2017

Competence, Training, and Conduct Requirements for Regulatory Reviewers


IMDRF/GRRP WG/N47 FINAL:2018

IMDRF International Medical Device Regulators Forum

Final Document

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

Authoring Group: IMDRF Good Regulatory Review Practices Group

Date: 31 October 2018

Yuan Lin, IMDRF Chair

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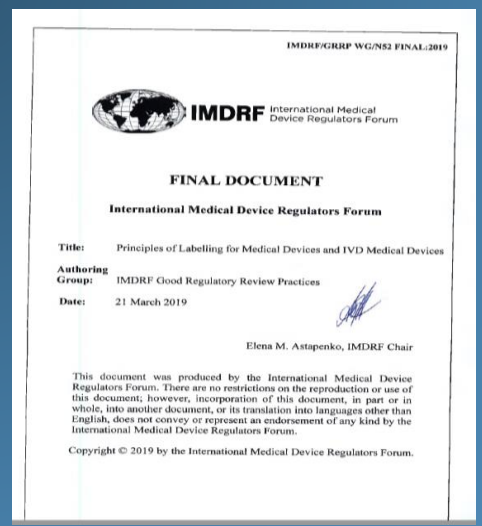
IMDRF GRRP WG/ N47 FINAL: 2018

Essential Principles of Safety and Performance


IMDRF/GRRP WG/N52 FINAL:2019

IMDRF International Medical Device Regulators Forum

FINAL DOCUMENT

International Medical Device Regulators Forum

Title: Principles of Labelling for Medical Devices and IVD Medical Devices

Authoring Group: IMDRF Good Regulatory Review Practices

Date: 21 March 2019

Elena M. Astapenko, IMDRF Chair

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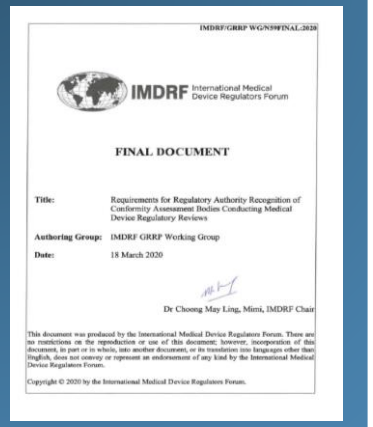
IMDRF GRRP WG/ N52 FINAL: 2019

Principles of Labelling

Marketing Review Processes

GRRP Documents


IMDRF/GRRP WG/N59FINAL:2020

IMDRF International Medical Device Regulators Forum

FINAL DOCUMENT

Title: Requirements for Regulatory Authority Recognition of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews

Authoring Group: IMDRF GRRP Working Group

Date: 18 March 2020

Dr Choong May Ling, Mimi, IMDRF Chair

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IMDRF GRRP WG/ N59 FINAL:2020

Requirements for Regulatory Authority Recognition of CABs


IMDRF/GRRP WG/N61FINAL:2020

IMDRF International Medical Device Regulators Forum

FINAL DOCUMENT

Title: Regulatory Authority Assessment Method for Recognition and Surveillance of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews

Authoring Group: IMDRF GRRP Working Group

Date: 25 September 2020

Dr Choong May Ling, Mimi, IMDRF Chair

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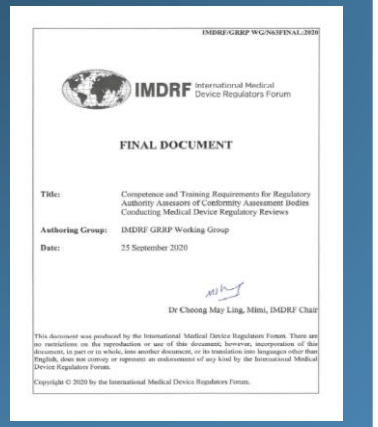
IMDRF GRRP WG/ N61 FINAL:2020

Assessment Methods for Recognition of CABs


IMDRF/GRRP WG/N63FINAL:2020

IMDRF International Medical Device Regulators Forum

FINAL DOCUMENT

Title: Competence and Training Requirements for Regulatory Authority Assessors of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews

Authoring Group: IMDRF GRRP Working Group

Date: 25 September 2020

Dr Choong May Ling, Mimi, IMDRF Chair

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IMDRF GRRP WG/ N63 FINAL:2020

Competence and Training Requirements for Assessors of CABs


IMDRF/GRRP WG/N66FINAL:2021

IMDRF International Medical Device Regulators Forum

Final Document

Title: Assessment and Decision Process for the Recognition of a Conformity Assessment Body Conducting Medical Device Regulatory Reviews

Authoring Group: IMDRF Good Regulatory Review Practices Working Group

Date: 24 June 2021

Oh-Sang Kwon, IMDRF Chair

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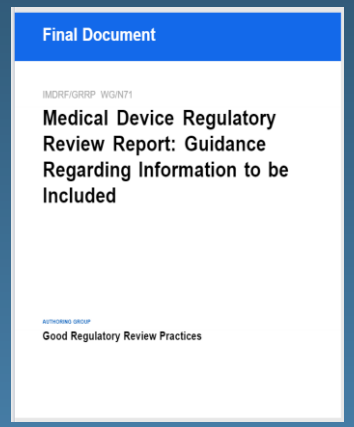
IMDRF GRRP WG/ N66 FINAL:2021

Assessment and Decision Process for the Recognition of CABs Conducting Medical Device Regulatory Reviews


Final Document

IMDRF/GRRP WG/N71

Medical Device Regulatory Review Report: Guidance Regarding Information to be Included

AUTHORING GROUP

Good Regulatory Review Practices

IMDRF GRRP WG/N71 FINAL:2023

Medical Device Regulatory Review Report: Guidance Regarding Information to be Included

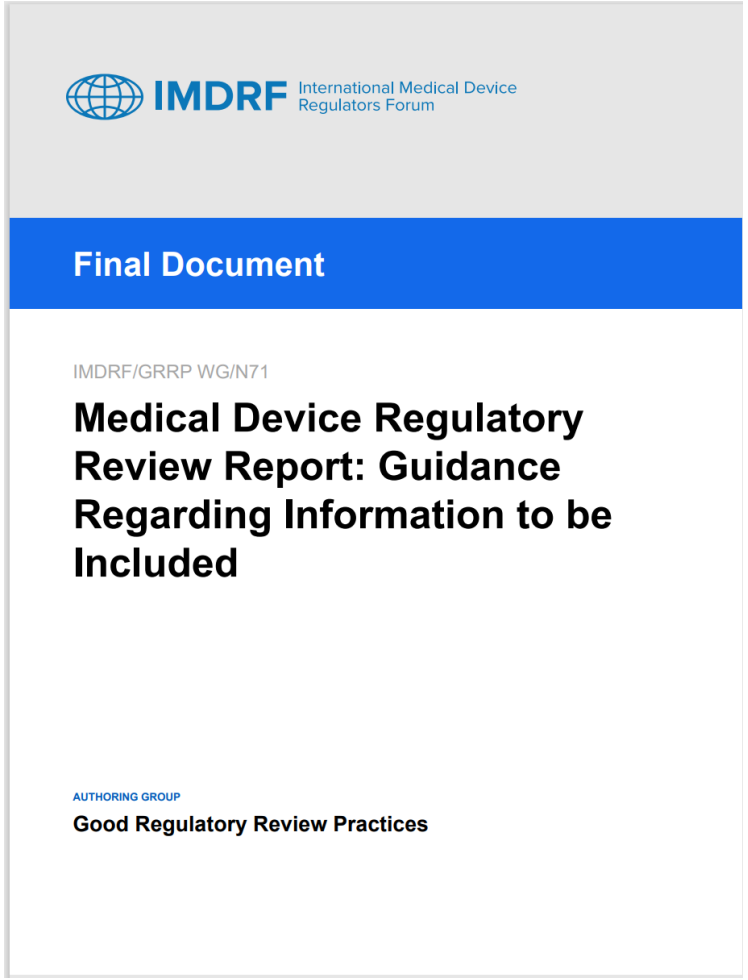
Recognition of Conformity Assessment Bodies (CABs)

Benefits of GRRP WG Documents

- Promote consistency, predictability and transparency in regulatory marketing review programs through agreed-upon sets of criteria and processes
- Provide confidence that marketing regulatory reviews conducted by CABs are rigorous enough to meet the requirements of Regulatory Authorities
- Provide opportunities for convergence of marketing review requirements
- Benefit all regulators, even those just starting to develop a regulatory medical device marketing review system

Most Recent Work Item: N71 – Medical Device Regulatory Review Report: Guidance Regarding Information to be Included

- Published in final on Feb 3, 2023
- Provides guidance regarding creation of a medical device regulatory review report
- A regulatory review report:
  - is a written record of the CAB's determination of the extent of fulfillment of specified requirements;
  - captures, in a consistent manner, the evidence of a manufacturer's conformity with the criteria for the regulatory review; and
  - will facilitate the exchange of information between RAs.
- Working group participation included CAB representatives as observers



New Work Item

- A NWIP was approved in June 2023 to update previous GRRP documents for consistency with policy and terminology in most recently published GRRP document (IMDRF/GRRP WG/N71).
  - Changes needed in order to be consistent with and inclusive of the current approaches of several RAs
  - The GRRP WG reviewed existing GRRP documents and identified four that should be revised to ensure appropriate and consistent terminology throughout the all GRRP documents
  - The proposed changes to terminology demonstrate convergence among RAs toward a common language and concepts

Goals:
To achieve consistent terminology to fulfill Priority 1 of the 2021-2025 IMDRF Strategic Plan: to develop a risk calibrated regulatory approach for innovations and promote harmonized pre-market review requirements for medical devices

Documents to be Updated

- The GRRP WG reviewed existing GRRP documents and identified four that should be revised to ensure appropriate and consistent terminology throughout the all GRRP documents : N66, N61, N63, and N59
  - These changes require more than simple search and replace since careful consideration should be paid to which term is selected and how it is used based on the specific context

- References section of other GRRP documents will also be reviewed for updates
  - To ensuring date and language in references section is up to date

Next Steps

- WG to review proposed edits and meet to discuss proposed edits from Sep- Dec 2023
- WG to submit documents for draft consultation to MC for consideration in Mar 2024
- Public consult of draft document in May 2024
- WG to deliberate comments and finalize changes by Oct 2024
- WG to submit final document for MC review in Dec 2024

Thank you!
Questions?

Email erin.cutts@fda.hhs.gov

IMDRF International Medical Device Regulators Forum

Regulatory Updates on Medical Devices in the Republic of Korea

Jeong-Rim Lee

Ministry of Food and Drug Safety

26 September 2023

MFDS Regulatory Innovation

MFDS Regulatory Innovation Tasks

➢ To secure public safety and strengthen the medical device industry based on regulatory science

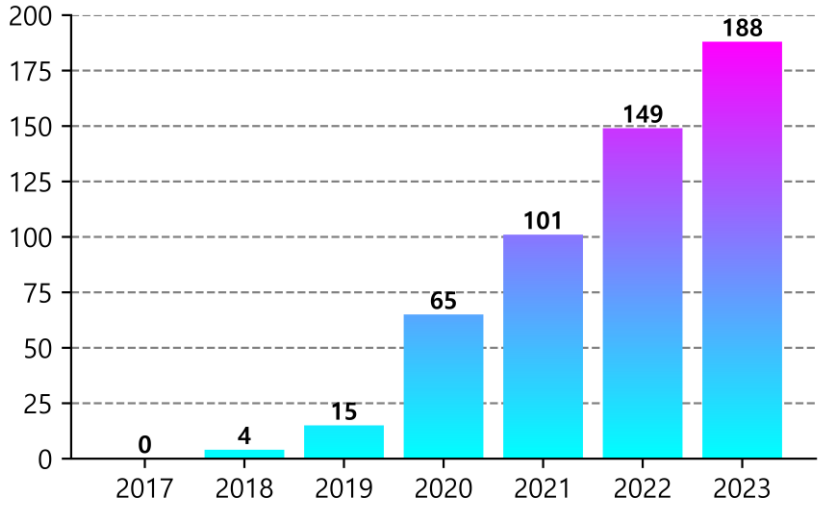
Updates to Act / Regulation

❖ Enactment of the “Digital Medical Products Act”

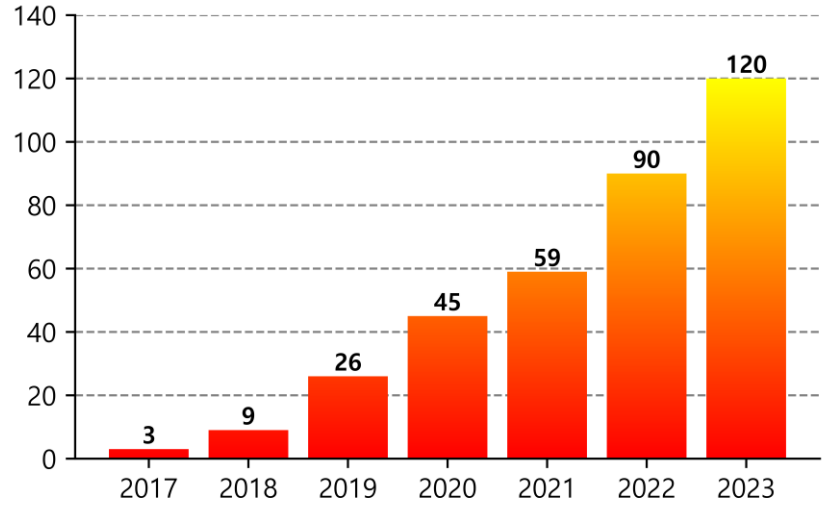
- To introduce a new regulatory framework to promote state-of-the-art digital medical products and provide regulatory support
  - ✓ [National Policy Tasks] Regulatory science and innovation for commercialization of digital and bio-healthcare products

- The Act on Digital Medical Products has been drafted and submitted to the National Assembly
  - ✓ Having discussions with 8 industry associations encompassing medical devices, pharmaceuticals, wellness products and others

❖ Statistics on AI/ML-enabled Medical Devices & Digital Therapeutics

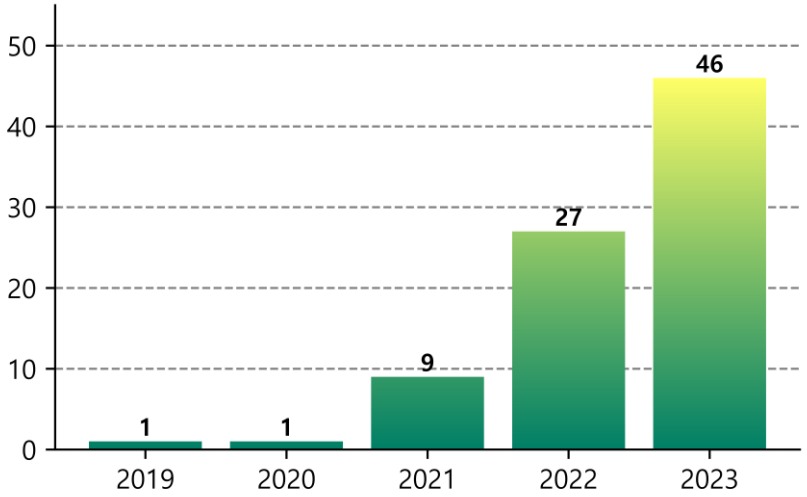


<Cumulative number of approved AI/ML MD>



< Cumulative number of approved clinical study of AI/ML MD>

<Approved 1st and 2nd DTx for insomnia>



< Cumulative number of approved clinical study of DTx>

Updates to Act / Regulation

❖ Revision of Regulations on Review and Approval System for better implementation

- Real World Evidence(RWE) is more widely accepted as clinical data for review of following medical devices
  - ✓ Orphan or urgently needed medical devices
  - ✓ Digital health medical devices (big data, AI/ML-based medical devices)

- Criteria of interim classification and code for newly developed medical devices (digital health devices)
  - ✓ For unclassified medical devices under the current classification, interim classification apply in consideration of the risk, intended use, performance and others

Regulatory Innovation 2.0

❖ Providing detailed criteria for review and approval by product item

- Detailed criteria by product item to determine whether it requires technical document review is provided
  - ✓ (Benefit) To shorten the period for review and approval with explicit criteria for determining whether it requires technical document review

Newly Published Guidance Documents

- Guidance on Review and Approval for Real World Evidence
  – Revised in July 2023
- Guidance on Review and Approval for Medical Device Software
  – Revised in July 2023
- Guidance on Performance Evaluation for Autonomous Wheelchairs
  – Developed in July 2023
- Guidance on Clinical Trial of In Vitro Diagnostics
  – To be published in November 2023
- Guidance on Safety, Performance Evaluation, and Clinical Trial Design of Digital Therapeutics for ADHD and Eating Disorder
  – To be published in December 2023

International Cooperation

❖ MOC between the MFDS and the U.S. FDA on Medical Products Using AI

- To share experiences in using AI for medical product development
- To discuss ways to promote the use of innovative technologies to develop effective and safe medical products using AI

❖ MOU between the MFDS and the DINAVISA (Paraguay)

- To recognize results of GMP audit conducted by the MFDS in the field of medical products

International Cooperation

❖ Active participation in MDSAP activities

- Submitted annual report and attended the MDSAP forum since joining MDSAP as an affiliate member
- To expand the scope of using MDSAP audit results for the initial GMP audits in South Korea

❖ Cooperation between the MFDS and the DAV (Vietnam)

- To provide support for establishment of ①regulatory framework of medical devices, ②management system and ③manufacturing and quality management system in Vietnam
- To provide capacity building training for officials at the DAV in charge of medical device safety management

IMDRF International Medical Device Regulators Forum

Thank you/Questions

Email policymfds@korea.kr

IMDRF International Medical Device Regulators Forum

UK Regulatory Update

Dr Laura Squire

26th September 2023

Overview

- Progress on UK regulatory framework
- How we are supporting innovators
- International recognition

Progress on UK regulatory changes.

Progress	Purpose	Date (actual/estimated)
Transitional arrangements	Amended The Medical Device Regulations 2002 (SI 2002 No 618, as amended) (UK MDR) to extend the acceptance of CE marked medical devices on the Great Britain market, to support the ongoing safe supply of medical devices to GB and ease the transition to the future regulatory framework .	In force from 1 July 2023
Doubling UK CAB Capacity	The Medicines and Healthcare products Regulatory Agency (MHRA) has designated three new UK Approved Bodies, almost doubling the UK's capacity to certify medical devices, supporting faster certification of safe and effective medical devices for healthcare professionals and the public.	Announced August 2023
Post Market Surveillance	Bring into force the new post-market surveillance requirements for CE marked and UCKA devices as laid out in the government response to the public consultation	WTO consultation period for statutory instrument ends this week
Part 1 – to put in place essential elements of the UK regime.	Lay a statutory instrument to bring into force the essential elements of the strengthened UK regime as laid out in the government response to the public consultation.	2024, to be in force by 2025.

How we are supporting Innovators - Innovative Devices Access Pathway (IDAP).

Aims to develop a new **pre-market** pathway for medical devices that:

- Supports innovative medical devices (including diagnostics and digital health technologies) that meet unmet needs in the health and care system and that do not currently have regulatory authorisation in the UK
- Provides access support on post-marketing surveillance requirements, further evidence generation for HTA and docking with reimbursement pathways

Healthcare Improvement Scotland | SHTG Advice on health technologies

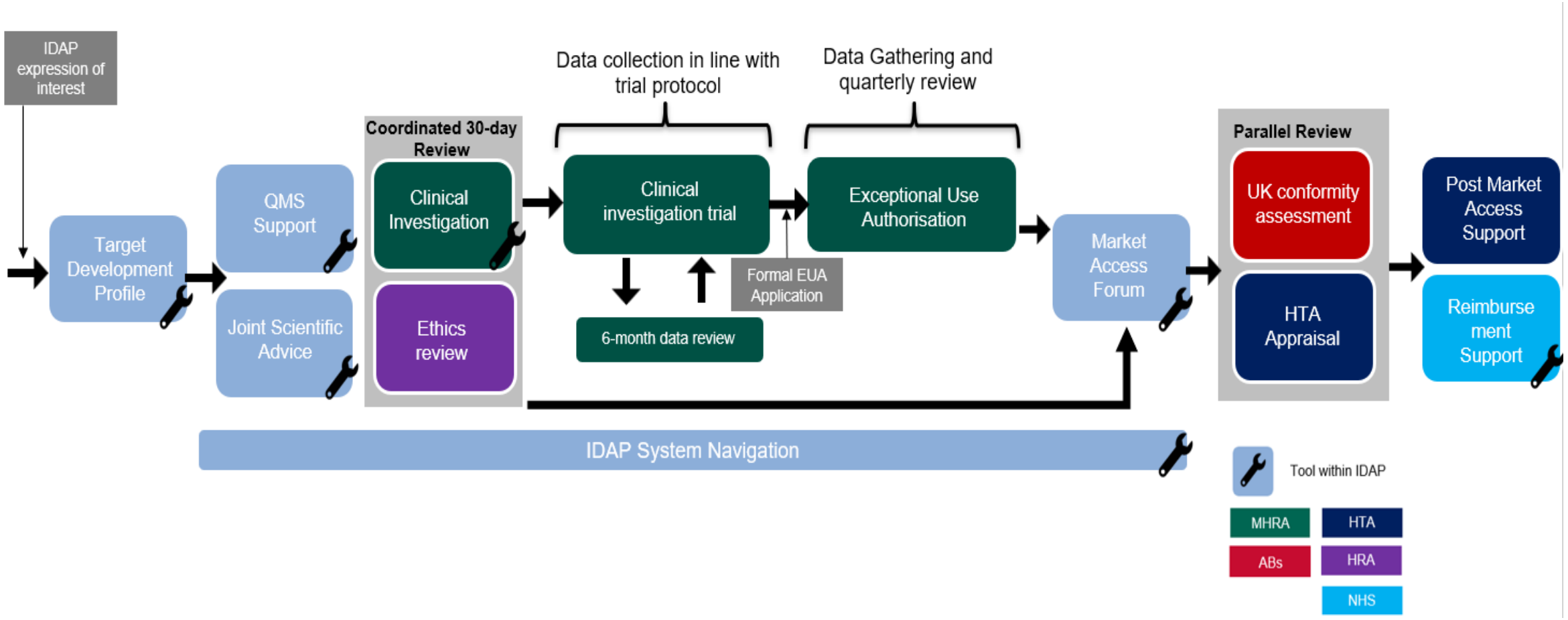
NICE National Institute for Health and Care Excellence

Medicines & Healthcare products Regulatory Agency

NHS England

Technoleg Iechyd Cymru Health Technology Wales

The IDAP Pilot Model



International Recognition

"From 2024, [MHRA] will move to a different model which will allow rapid, often near automatic sign-off for medicines and technologies already approved by trusted regulators in other parts of the world such as the United States, Europe or Japan.

At the same time from next year they will set up a swift new approval process for the most cutting-edge medicines and devices to ensure the UK becomes a global centre for their development"

Artificial Intelligence/Machine Learning-Enabled (AI/ML) Working Group

Dr Laura Squire – Chief Officer – UK MHRA

Background

- Established in summer 2023. The AI/ML Working Group (WG) seeks to prioritise consensus in the AI/ML sector, where rapid technological advancements and an influx of manufacturers from sectors beyond medical devices is seen.
- Regulatory consensus for AI/ML has a close interplay with Software as a Medical Device (SaMD) for many jurisdictions, it's therefore also a priority to maintain alignment with broader software guidance.
- The working group convenes monthly and held its first meeting on September 13th 2023.
- Currently the working group is reviewing a published document on Good Machine Learning Practice (GMLP) as a starting point for an IMDRF documents.

Guiding Principles for Good Machine Learning Practice (GMLP)*

- GMLP are accepted practices in AI/ML product development, evaluation, and monitoring that can help facilitate the safety and effectiveness of machine learning-enabled medical devices.
- Guiding principles for GMLP are intended to promote and align efforts for the development and identification of GMLP.

Good Machine Learning Practice for Medical Device Development: Guiding Principles	
1. Multi-Disciplinary Expertise are Leveraged Throughout the Total Product Life Cycle	2. Good Software Engineering and Security Practices are Implemented
3. Clinical Study Participants and Data Sets are Representative of the Intended Population	4. Training Data Sets are Independent of Test Sets
5. Selected Reference Datasets are Based Upon Best Available Methods	6. Model Design is Tailored to the Available Data and Reflects the Intended Use of the Device
7. Focus is Placed on the Performance of the Human-AI Team	8. Testing Demonstrates Device Performance during Clinically Relevant Conditions
9. Users are Provided Clear, Essential Information	10. Deployed Models are Monitored for Performance and Re-training Risks are Managed

*Published October 2021 by UK MHRA, US FDA and Health Canada

Adverse Event Terminology – Maintenance Working Group

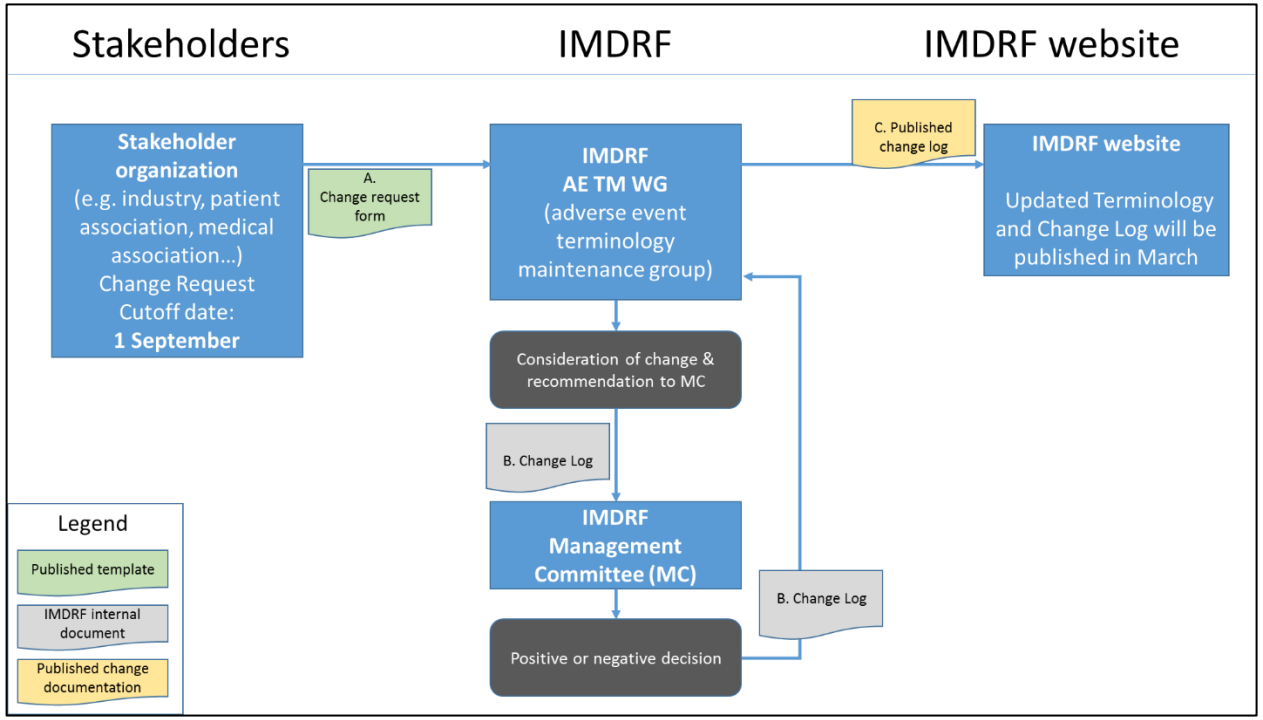
Dr Laura Squire – Chief Officer – UK MHRA

Adverse Event Terminology – Maintenance

UK now chair of Maintenance Working Group

Subgroup of main AE Terminology Working Group co-chaired by USA and EU

- 114 new or revised terms received (156 in 2022, 258 in 2021)
- Review at F2F meeting (Canada, October 2023)
- Collaborate with MedDRA on Health effect terms
- Revised version of Annexes to MC for March 2024



IMDRF International Medical Device Regulators Forum

Thank you/Questions

US FDA Update

Kenneth J. Cavanaugh Jr, Ph.D.
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
US Food and Drug Administration
kenneth.cavanaugh@fda.hhs.gov

Overview

- International Harmonization Strategic Plan
- Electronic Export Certificates
- 510(k) Program Updates
- Breakthrough Devices Program Update

US FDA/CDRH International Harmonization Strategic Plan

CDRH International Harmonization Strategic Plan

- Recognizes the importance of globally harmonized medical device regulatory policy and practices.
- Outlines specific strategies and activities towards international harmonization, convergence, and reliance over the next 4 years.
- Commits to publishing annual assessments of the international harmonization activities
- CDRH looks forward to public comment and feedback to improve our approach and efforts to provide patients in the United States and globally with safe, effective high-quality medical devices in an increasingly global regulatory environment.

CDRH International Harmonization Draft Strategic Plan 2023 (fda.gov)

CDRH International Harmonization Strategic Plan

Strategy 1	Increase engagements in international harmonization, convergence, and reliance efforts
Strategy 2	Create a mechanism for CDRH to share best practices with trusted partners
Strategy 3	Assess the extent of CDRH implementation of IMDRF technical documents
Strategy 4	Support creation of a forum to engage with stakeholders to identify opportunities for regulators to leverage one another's approach to decision making
Strategy 5	Participate in outreach activities to encourage harmonization, convergence, and reliance

Electronic Export Certificates

Electronic Export Certificates

- Export certificates are often required by importing countries as one of the requirements to market a medical device.
- FDA does not require export certificates to export human medical devices/products that can be legally marketed in the U.S.
- Importing countries often require additional steps:
  - Apostille-U.S. Department of State
  - Legalization- Embassies

Electronic Export Certificate Issuance

- U.S. Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) announced in a letter to manufacturers on July 10, 2023 the transition to electronic versions of all export documents:
    - Certificate to Foreign Government,
    - Certificate of Exportability Section 801(e)(1) or 802,
    - Non-Clinical Research Use Only Certificate,
    - Certificate to Foreign Government for Device Not Exported from the United States, and
    - Export Permit Letter.

- Requests received by December 15, 2023, will be issued as paper certificates
- Beginning January 2, 2024, all export documents will be issued electronically

- The electronic certificates (e-certificates) for human medical devices/products will be issued as a downloadable PDF through the CDRH Export Certification Application and Tracking System (CECATS).

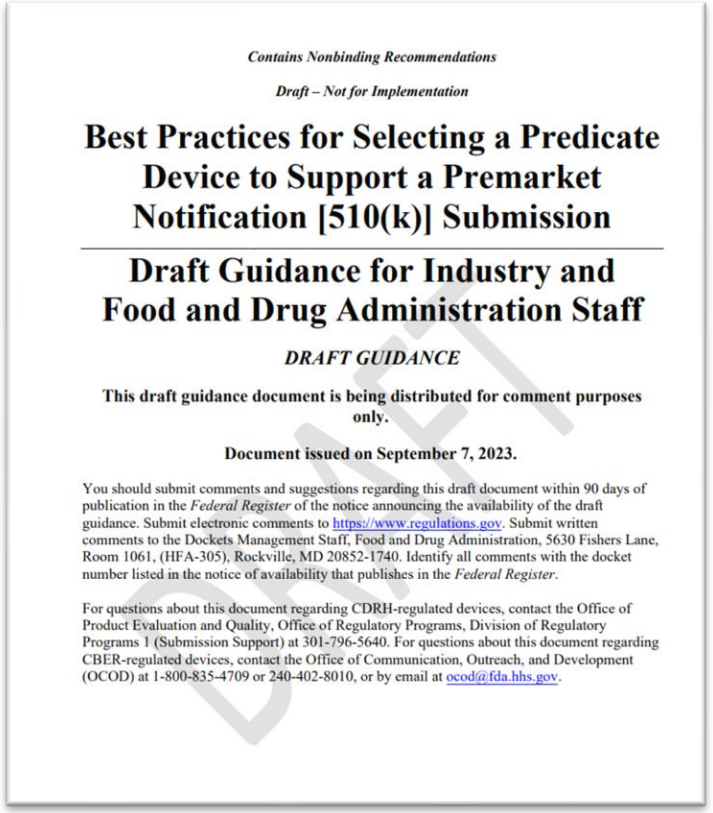
Electronic Export Certificate Issuance

- **Old process**
  - Starting January 2, 2024, Exports Certificates and documents will no longer be:
    - Printed on security paper
    - Mailed
- **Unchanged process**
    - Still requested in CDRH Export Certificate Application and Tracking System (CECATS)
- **New Process**
  - If granted after review by FDA:
    - Requester receives an email with instructions
    - One time access to print or save a PDF within 45 days
- **To validate:**
  - Access the FDA Export Certificate Validator (FECV) website
    - Enter certificate number
    - And the expiration date
  - FDA will add a unique Quick Response (QR) code to the e-certificate

510(k) Program Updates

Draft Guidance:
Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission

- Outlines best practices in selecting a predicate device in 510(k) submissions to enhance the predictability, consistency, and transparency of the 510(k) Program.
- Developed in response to public feedback, and to continue to modernize the framework for 510(k) review.
- Proposes factors for consideration for choosing a predicate device, including selecting a predicate device that was cleared using well-established methods, meets or exceeds expected safety and performance, is without unmitigated use-related or design-related safety issues, and is without an associated design-related recall.
- FDA believes use of these best practices will encourage the evolution of safer and more effective medical devices in the 510(k) Program over time.



Contains Nonbinding Recommendations

Draft – Not for Implementation

Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

Document issued on September 7, 2023.

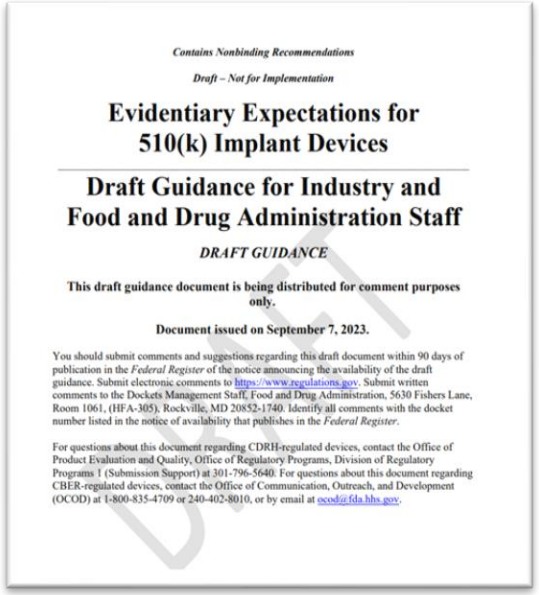
You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852-1740. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document regarding CDRH-regulated devices, contact the Office of Product Evaluation and Quality, Office of Regulatory Programs, Division of Regulatory Programs 1 (Submission Support) at 301-796-5640. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov.

DRAFT

Draft Guidance: Evidentiary Expectations for 510(k) Implant Devices

- Outlines current recommendations for implant devices subject to 510(k)
- Developed in response to public feedback, and to continue to modernize the framework for 510(k) review
- Provides recommendations for general considerations including indications for use, intended duration of implantation, and anticipated patient and physician experience
- Provides recommendations for non-clinical issues relevant to implants, such as:
  - Biocompatibility
  - Sterility and Shelf Life
  - Reprocessing and Cleaning
  - Software and Cybersecurity
  - Electrical Safety and Electromagnetic Compatibility
  - MR Compatibility
  - Animal Testing



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Evidentiary Expectations for 510(k) Implant Devices

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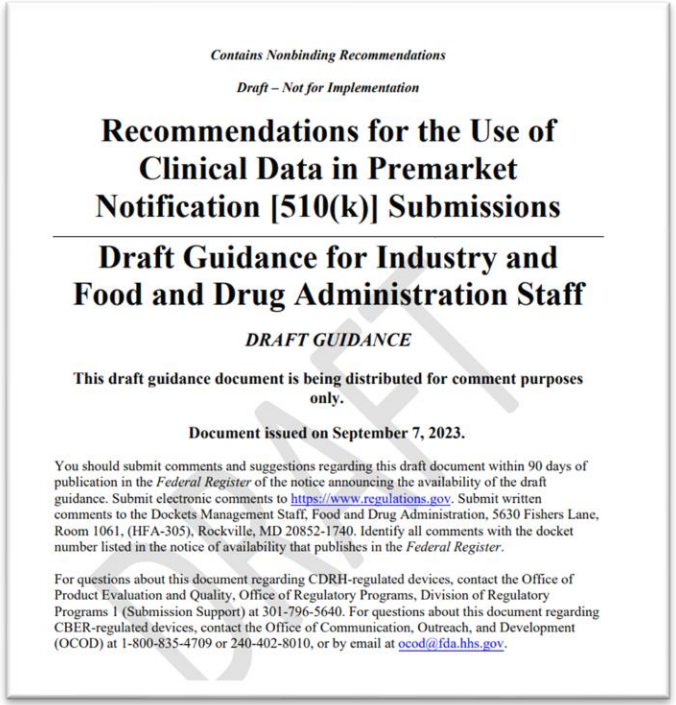
DRAFT

Draft Guidance: Recommendations for the Use of Clinical Data in Premarket Notification [510(k)] Submissions

- Clarifies and provides additional context for situations when clinical data may be necessary to demonstrate substantial equivalence (SE), including when:
  - There are differences in the indications for use
  - There are differences in the technological characteristics
  - The SE cannot be determined by non-clinical testing
  - There are newly identified or increased risks for the predicate device



Contains Nonbinding Recommendations

Draft – Not for Implementation

Recommendations for the Use of Clinical Data in Premarket Notification [510(k)] Submissions

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

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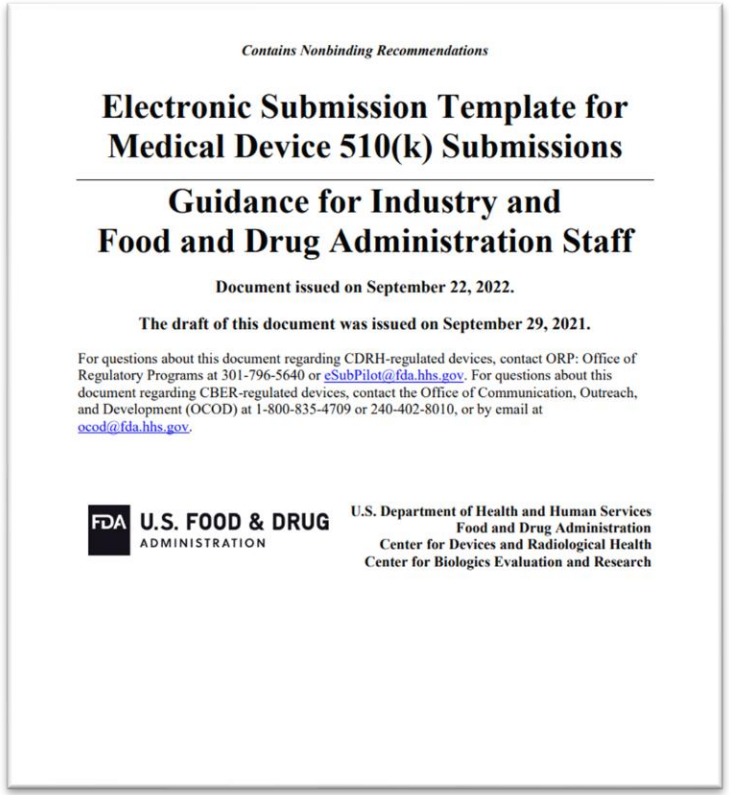
Final Guidance: Electronic Submission Template for Medical Device 510(k) Submissions

- Describes the technical standards associated with preparation of the electronic submission template for 510(k)s that enable submission of the 510(k) electronic submission solely in an electronic format (eSTAR)

- Beginning October 1, 2023, all 510(k) submissions, unless exempted, must be submitted as electronic submissions using eSTAR



Contains Nonbinding Recommendations

Electronic Submission Template for Medical Device 510(k) Submissions

Guidance for Industry and Food and Drug Administration Staff

Document issued on September 22, 2022.

The draft of this document was issued on September 29, 2021.

For questions about this document regarding CDRH-regulated devices, contact ORP: Office of Regulatory Programs at 301-796-5640 or eSubPilot@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov.

FDA U.S. FOOD & DRUG ADMINISTRATION

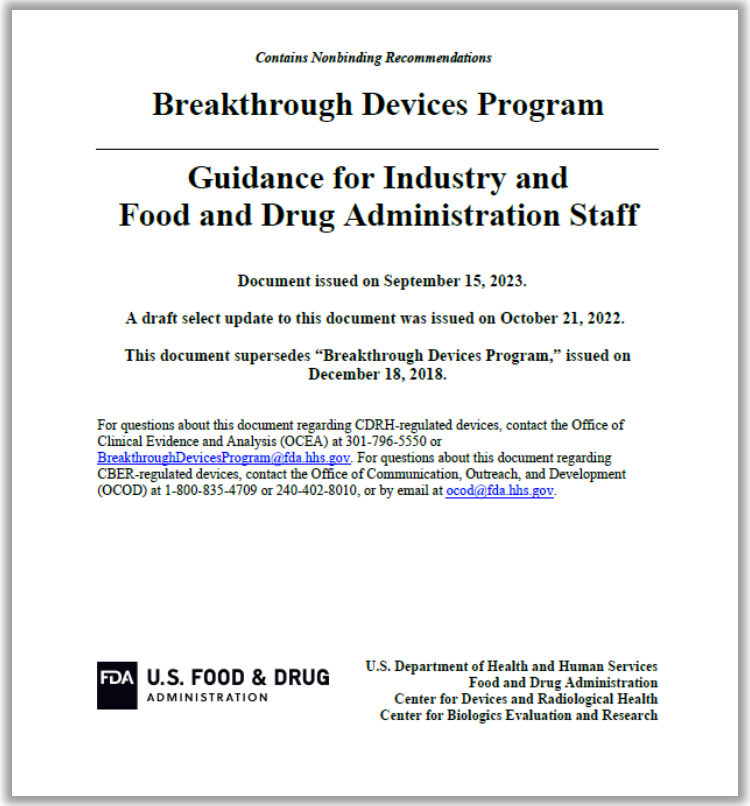
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

Breakthrough Devices Program Update

Updated Guidance: Breakthrough Devices Program

- Clarifies Breakthrough Device designation eligibility:
  - Devices that benefit populations impacted by inequities in health or health care
  - Devices that address disparities in accessibility to care
  - Non-addictive medical products intended to treat pain or addiction

- 831 designations granted as of June 30
  - 77 reported marketing authorizations



Contains Nonbinding Recommendations

Breakthrough Devices Program

Guidance for Industry and Food and Drug Administration Staff

Document issued on September 15, 2023.

A draft select update to this document was issued on October 21, 2022.

This document supersedes "Breakthrough Devices Program," issued on December 18, 2018.

For questions about this document regarding CDRH-regulated devices, contact the Office of Clinical Evidence and Analysis (OCEA) at 301-796-5550 or BreakthroughDevicesProgram@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov.

FDA U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research


FDA
U.S. FOOD & DRUG
ADMINISTRATION

IMDRF International Medical Device Regulators Forum

Software as a Medical Device (SaMD) Update

US FDA & Health Canada Co-chairs

September 2023

Ongoing Work

Goal: To refine the previously published SaMD documents to improve international alignment and ensure ongoing consistency, predictability, and transparency by:

- **Publishing a new document related to:**
  - Enhancing focus on better characterizing the device to inform downstream risk considerations
    - Drafted document includes discussion of how to clearly characterize medical device software to improve consistent understanding of these devices by regulators globally
    - Drafted document includes considerations for identifying and understanding medical devices software risks based upon information-based hazards

Progress and Planned Milestones

- June-July 2022: Identification of WG members and co-chair coordination meeting
- August 2022: Survey to WG members re: proposals for changes to existing documents
- September 2022: WG kick-off meeting, meeting every two weeks
- April 2023: 3 x half-day virtual WG meeting
- **November 2023: Planned submission of draft document to IMDRF MC**
- December 2023: Public consultation of document(s)*
- January 2024: 3/4-day WG meeting
- March 2024: Final document(s) submitted to IMDRF MC
- **May 2024: Publish final technical document(s)***

* Pending IMDRF MC Approval

IMDRF International Medical Device Regulators Forum

Thank you/Questions

Sonja Fulmer
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Marc Lamoureux
marc.lamoureux@hc-sc.gc.ca

IMDRF International Medical Device Regulators Forum

IMDRF Stakeholder Open Forum

Regulatory Updates
ANMAT- Argentina

Yesica Anastasio, M.A.

Coordinator of the International Relations Program, ANMAT

September 26, 2023

About ANMAT

ANMAT's **objective** is to control and monitor the activities, processes and technologies related to drug products, **medical devices**, foods, household sanitizing products and cosmetics; as well as to surveil their efficacy and the detection of adverse events resulting from the consumption and use of said products.

Service attitude

Confidentiality and Integrity

Commitment and sense of belonging

Response capacity

Reliability and credibility

Transparency

About ANMAT

1

National Regulatory Authority with capacities and resources based on Regulatory Science.

2

Regulatory framework adapted to international regulatory convergence and coherence criteria.

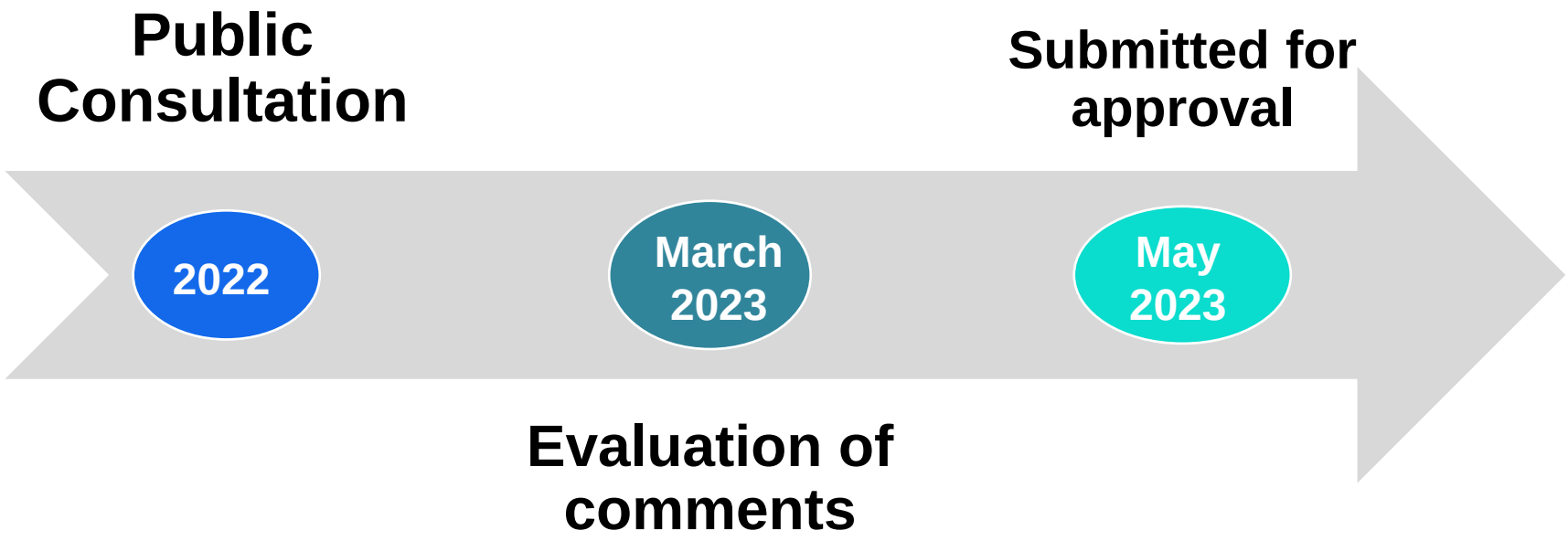
3

Active involvement in the international arena, with participation in several WGs from different fields.

4

Being a part of the convergence and harmonization processes within the IMDRF framework.

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



Based on:

IMDRF/GRRP WG/N47FINAL:2018 Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices

IMDRF International Medical Device Regulators Forum

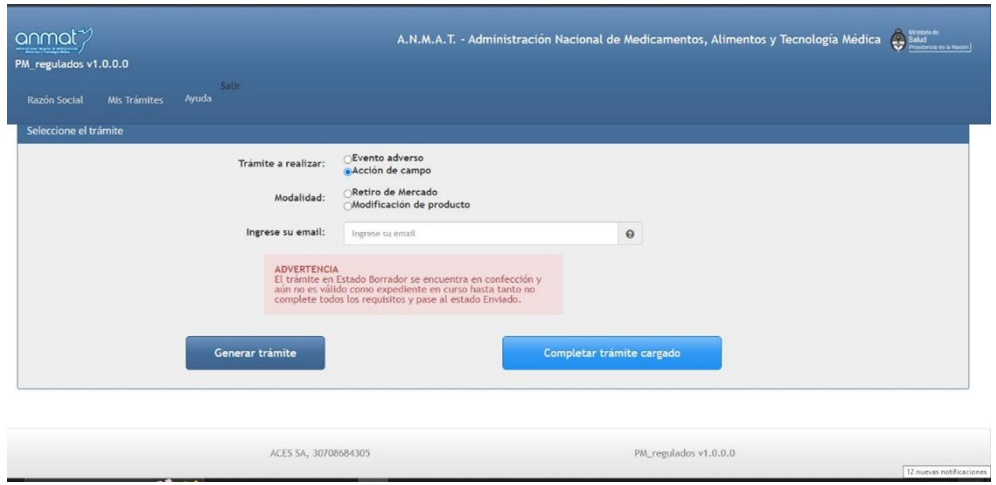
Postmarket Surveillance

Main objectives:

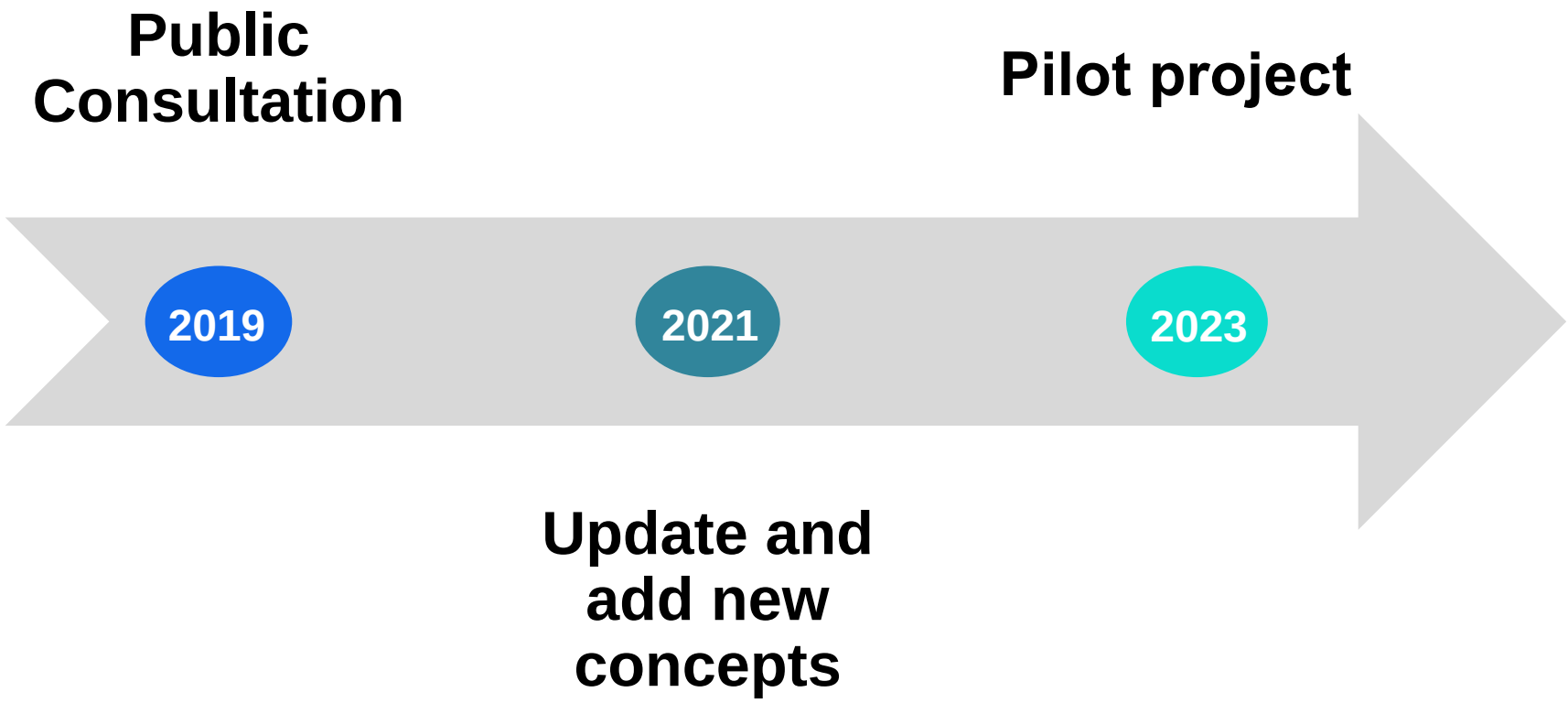
- Update the concepts of Post-Marketing Surveillance
- Establish new deadlines and notification criteria.
- Database available

INDUSTRY

ARGOS (software)



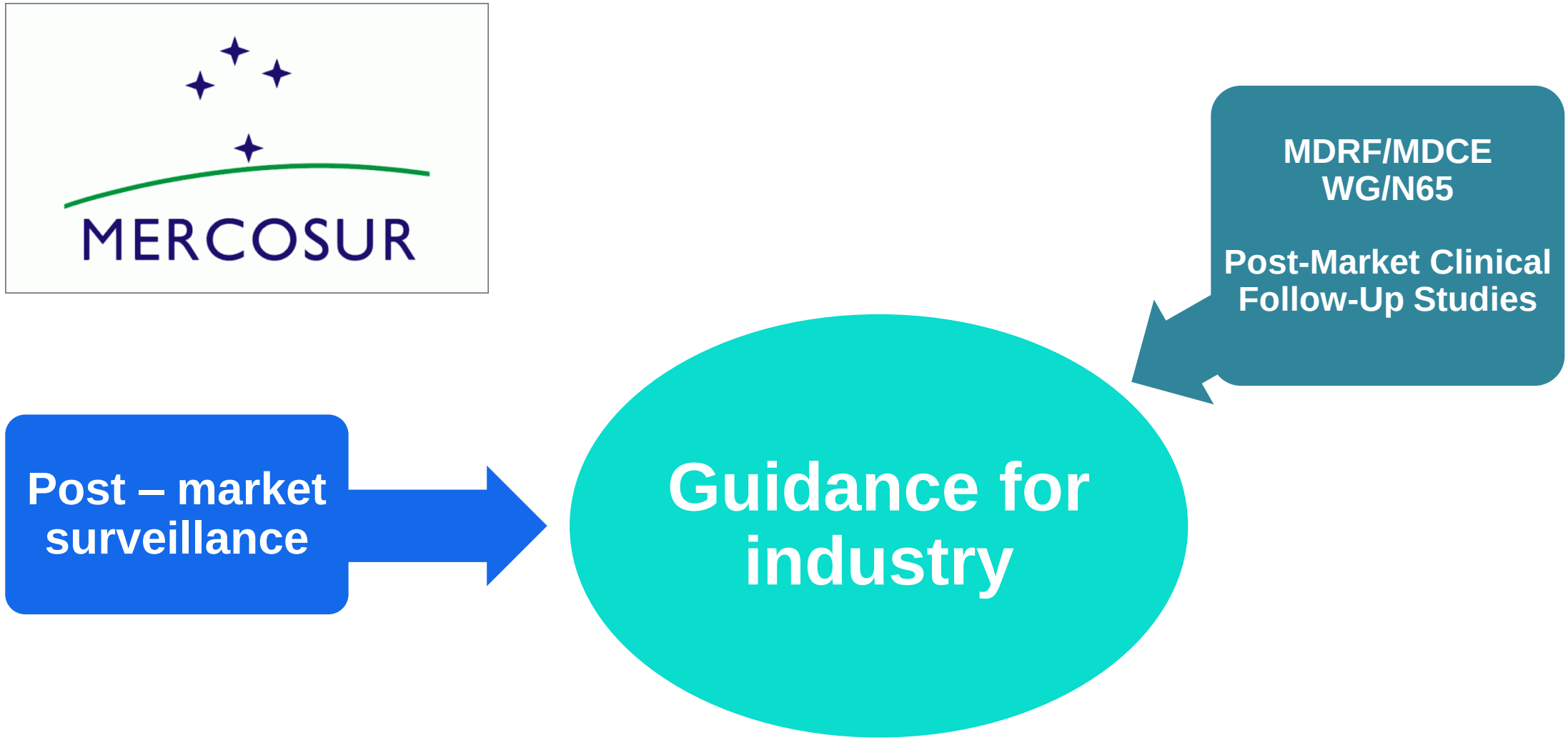
Good Technovigilance Practices



Based on:

IMDRF/AE WG/N43 – IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure and codes

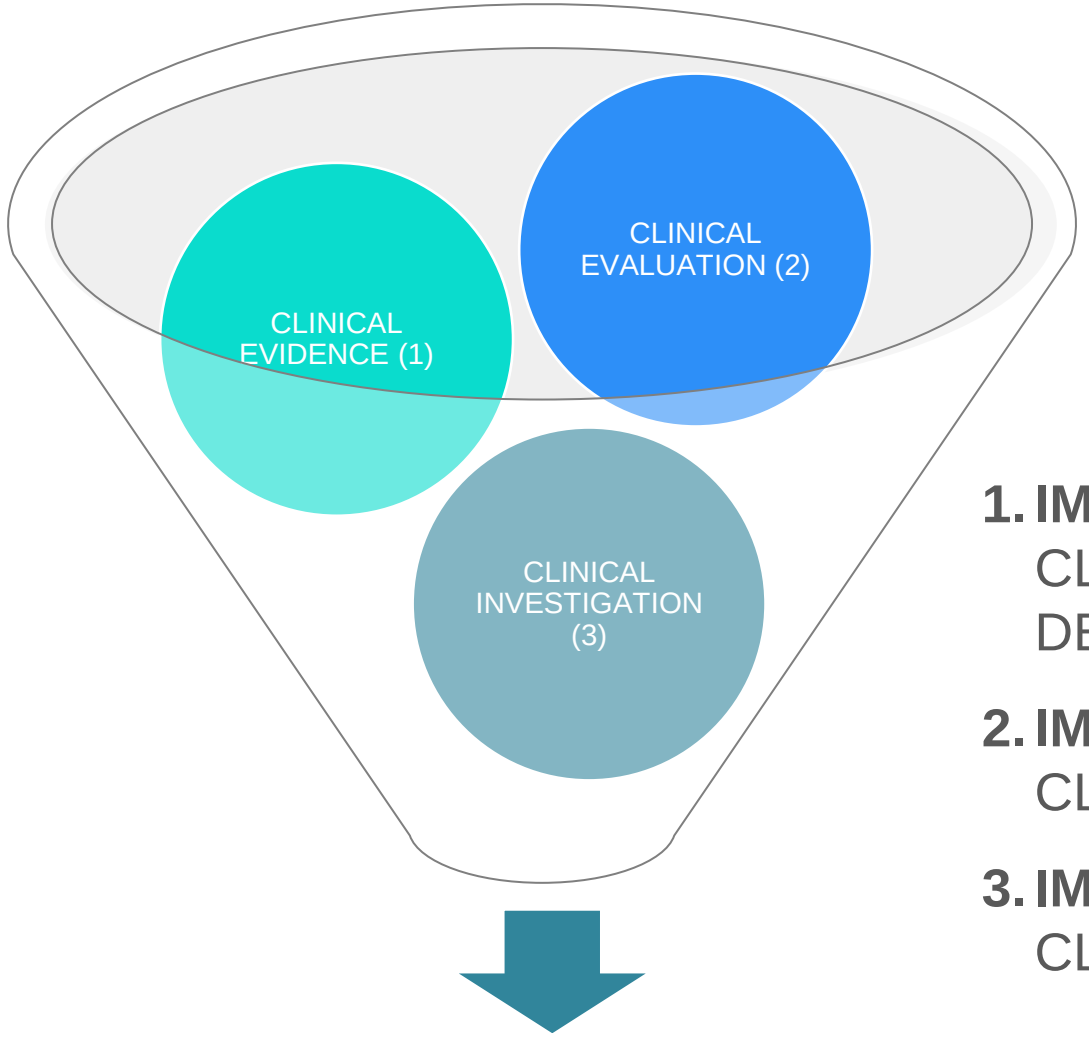
ISO/TR 20416:2020 – Post-market surveillance for manufacturers



Based on:

WHO 2021 – Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics

Medical Device Clinical Evaluation



1. **IMDRF MDCE WG/N55:19**
   CLINICAL EVIDENCE - KEY DEFINITIONS AND CONCEPTS
2. **IMDRF MDCE WG/N56:19**
   CLINICAL EVALUATION
3. **IMDRF MDCE WG/N57:19**
   CLINICAL INVESTIGATION

Internal working group for the implementation of these documents

CHALLENGES

ANMAT intends to continue joining regulatory convergence and harmonization processes that represent IMDRF foundational objectives

- ➢ Update medical device classification rules.
- ➢ New document about IVD clinical evidence
- ➢ Actively participate in new IMDRF WG.
- ➢ **Member of the Management Committee**

IMDRF International Medical Device Regulators Forum

Thank you

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IMDRF International Medical Device Regulators Forum

swissmedic

Markus Wälti
Head of Division Medical Devices Vigilance
Swiss Agency for Therapeutic Products
Berne, Switzerland

26 September 2023

About Swissmedic 1/2

Mission:

Our competence: for therapeutic products you can trust

We are the Swiss authority for the licensing and monitoring of therapeutic products. We perform the mandate conferred upon us by law and work with partner authorities at home and abroad.

We ensure that the therapeutic products we approve are of faultless quality, effective and safe. In doing so we make a significant contribution to safeguarding human and animal health and to maintaining Switzerland's role as a location for business and research.

→ https://www.swissmedic.ch/swissmedic/en/home/about-us/swissmedic--swiss-agency-for-therapeutic-products/guiding-principles.html

About Swissmedic 2/2

Swissmedic is an autonomous organisation associated with the FDHA (the Federal Department of Home Affairs)

Swissmedic finances its activities through procedural fees, supervisory levies and payments from the federal government (Art. 77 para. 2 TPA).

The following tasks and activities are funded solely by payments from the federal government in accordance with the Therapeutic Products Act (Art. 77 para. 2^{bis} TPA):

- Legislation
- Enforcement of provisions of criminal law
- Surveillance of medical devices

Working Areas related to Medical Devices 1/4

The existing laws and regulation in place for Medical Devices

Therapeutic Products Act (TPA)
812.21

Human Research Act (HRA)
810.30

Medical Devices Ordinance (MedDO)
812.213

Ordinance on In Vitro Diagnostic Medical Devices (IvDO)
812.219

Ordinance on Clinical Trials with Medical Devices (ClinO-MD)
810.306

Full text of mentioned acts and ordinances see here:
→ https://www.fedlex.admin.ch/en/cc/internal-law/81

Policy for implementation of IMDRF documents 2/4

As a long-term contributor to GHTF and EU documents, Swissmedic has aligned itself with the principles of the IMDRF and fully applies them.

Examples (non-exhaustive):

Same definitions (e.g. for manufacturer, medical device, custom-made devices), equivalent principles for classification, conformity assessment bodies conduct regulatory reviews, full reliance on international standards.

For placing a device on Swiss market, it must comply with MedDO / IvDO, meet general safety and performance requirements set out in Annex I EU-MDR or EU-IVDR and bear either the CE-mark or the Swiss MD-marking.

Information on Swiss Medical Device Industry 3/4

67’500 employees generated CHF 20.8 billion in revenue in 2021

Switzerland imported medical devices worth CHF 6.0 billion and Swiss MedTech companies exported goods worth CHF 11.9 billion

- The resulting trade surplus of CHF 5.9 billion represents 11.5% of the entire trade surplus of Switzerland.

Medical technology is traditionally one of the most research-intensive industries. Requirements for proving clinical efficacy and safety have increased, and consequently require more resources

- The weighted share of manufacturer expenditure for R&D in 2021 is 10.4%

Information for the year 2022 should be available in September
→ https://www.swiss-medtech.ch/en/documents#jahresberichte

Participation in Global Harmonization Activities 4/4

In partnership with the World Health Organization (WHO), Swissmedic devised a training course for regulatory authorities in low- and middle-income countries. Such courses are part of the WHO's programme to improve its member states' regulatory systems.

Swissmedic is a member of IMDSM (international medical device safety meeting) with monthly information exchange.

- Data protection laws and the resulting difficulties in sharing information are the biggest challenge so far.

Information on national and international collaboration of Swissmedic:
→ https://www.swissmedic.ch/swissmedic/en/home/about-us.html

Relevant Updates 1/2

MedDO and IvDO will be updated to reflect the changes to EU-MDR & IVDR in relation to Regulation (EU) 2023/607 of 15 March 2023 (extension of transition periods for “**legacy devices**” and removal of sell-off period).

MedDO will also be revised in relation to '**groups of products without an intended medical purpose**' to incorporate and align with changes made in the EU since December 2022.

swissdamed - the Swiss database on medical devices - will be publicly accessible for actor data from the beginning of 2024, and voluntary device registration is expected to be available from summer 2024.

Relevant Updates 2/2

Updated “Swiss Good Practice for the Reprocessing of medical devices”

- For healthcare facilities, that reprocess medical devices (available only in German, French and Italian, but not in English)

“Good Practice of maintenance in medical technology (brochure for hospitals)” is planned to be updated as well. Due to the very good feedback on the previous GP documents, 2 more, namely a “Good Practice for reporting serious incidents, one for hospitals and one for labs” are planned until the end of 2025.

New training concept for reprocessing, maintenance and vigilance in healthcare facilities to be implemented by year-end.

Relation with IMDRF Activities

Swissmedic has a total of 570 employees, 65 of whom work directly with medical devices. 10 of the 65 employees are actively involved in 5 of the 8 active IMDRF working groups, and 6 are nominated for 3 working groups that have completed their work items for the time being.

Swissmedic believes that international harmonization of medical device surveillance guidelines is becoming increasingly important due to the global nature of the medical device industry, the need for patient safety and quality assurance, the desire for efficiency and cost savings, the importance of collaboration and information sharing, the drive for global standards and interoperability, rapid technological advances, and the influence of international cooperation and trade agreements.

IMDRF International Medical Device Regulators Forum

Thank you/Questions

questions.devices@swissmedic.ch
https://www.swissmedic.ch/ (direct link medical devices)

IMDRF International Medical Device Regulators Forum

Update from the World Health Organization

Hiiti Sillo and Irena Prat

World Health Organization

26 September 2023

Overview

Regulatory system strengthening activities

WHO Global Model Regulatory Framework for medical devices

Technical support and reliance

Global Benchmarking Tool (GBT)

Prequalification of IVDs

Transition from EUL to PQ

Prequalification dossier assessments and inspections

Upcoming changes to PQDx

New documents

World health assembly resolutions and decisions

Revised WHO Global Model Regulatory Framework (GMRF) for medical devices

- **GMRF officially published in May 2023 following major revision**
  - **Chapter 1.** Introduction
  - **Chapter 2.** Definition, classification, essential principles, and conformity assessment of medical devices
  - **Chapter 3.** Enabling conditions for effective regulation of medical devices including IVDs
  - **Chapter 4.** Establishing a stepwise approach to regulating medical devices
  - **Chapter 5.** Regulatory pathways *New*
  - **Chapter 6.** Additional topics
  - **Chapter 7.** Implementation *New*

https://www.who.int/publications/m/item/who-global-model-regulatory-framework-for-medical-devices-including-in-vitro-diagnostic-medical-devices--annex-3 .

Dissemination workshops planned in Q4/2023

Regulatory pathways – key elements

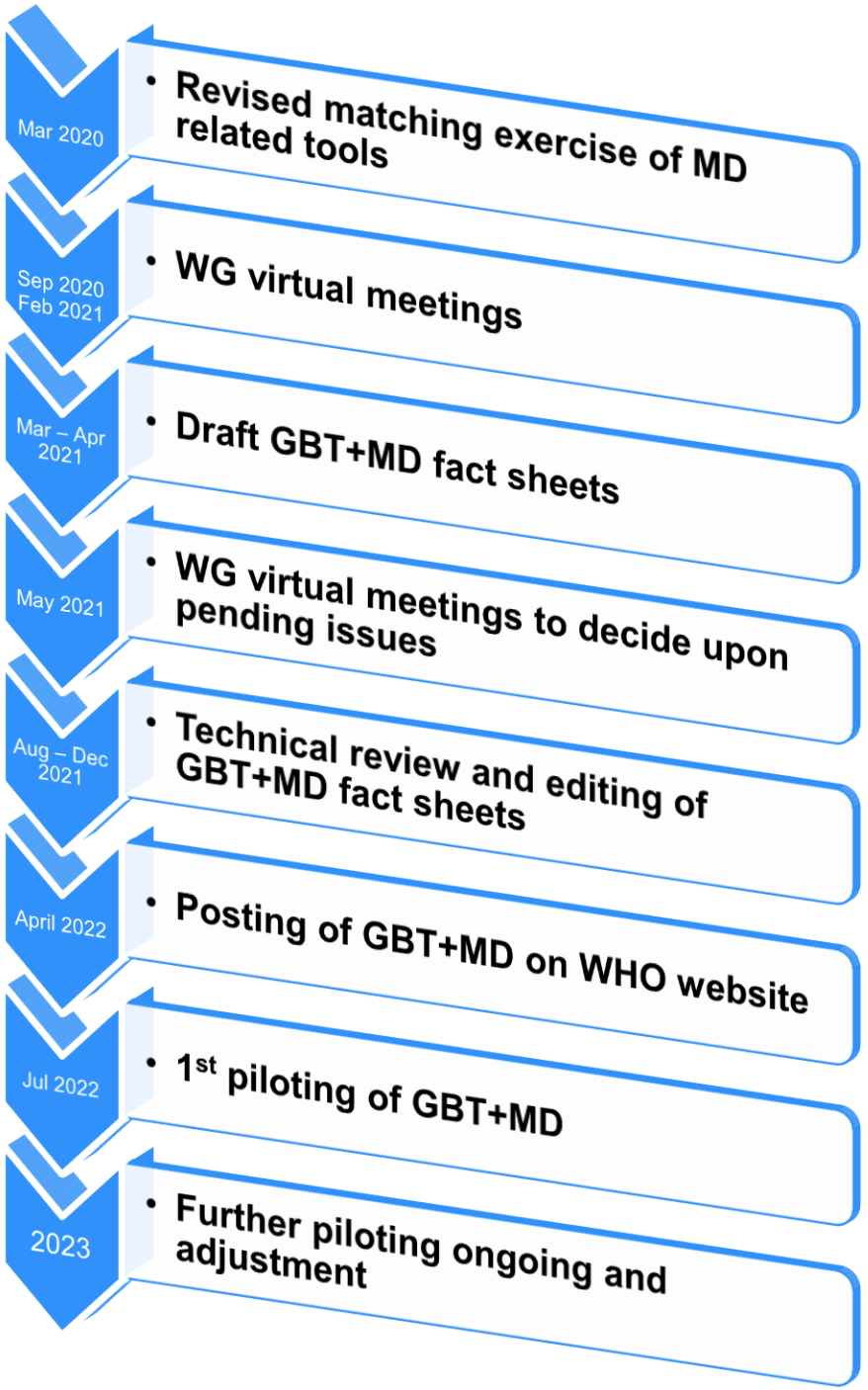
- Pathways defined for
  1. premarket conformity assessment of medical devices according to risk class
  2. premarket conformity assessment of medical devices based on reliance
  3. emergency use authorization or derogation
  4. borderline products
  5. combination products
  6. donated medical devices

Technical support and promoting regulatory reliance for IVDs

- **Technical support to countries and regional regulatory networks**
  - **In June 2023, AMRH SC endorsed Specific Considerations for Regulating Maternal, Newborn and Child Health Medical Devices — Market Authorization**
    - Developed by AMDF in collaboration with MSH/MTaPs
    - Dissemination workshop conducted early August 2023
  - **Regional training workshop on assessment of MDs technical planned in Q4 2023**
    - in collaboration with MSH/MTaPs and Tanzania Medicines and Medical Devices Authority (TMDA)
  - **Southeast Asian Regulatory Network (SEARN) WG5 on medical devices**
    - survey on regulatory landscape
    - development of workplan 2023/2024 prioritizing capacity building and reliance
- **Collaborative Registration Procedure (CRP) for IVDs**
  - 17 applications received with 7 national registrations and 10 are under assessment (***only 9 assays registered in 2022)***
  - Advocacy workshops for Francophone countries in Africa, 25-27 Sept 2023 in Cotonou, Benin
  - 11th CRP annual meeting, 12 – 15 Dec, Doha, Qatar

Global Benchmarking Tool (GBT)

- GBT represents the primary means by which the WHO objectively evaluates regulatory systems (*Resolution WHA 67.20*)
- GBT (medicines & Vaccines) introduced in 2016 and revised in 2018
- GBT replaces all tools previously used by WHO, representing the first truly 'global' tool
- Nov. 2019: GBT+Blood (whole blood, blood components and plasma derived blood products)
- **April 2022: draft GBT+Medical Devices including IVDs integrated into the GBT (link)**



GBT + Medical Devices – work in progress

- GBT+MD developed in consultation with regulators from over 20 countries in all 6 WHO regions
  - Including global and regional networks

- First piloted in June/July 2022 in Africa
  - confirmed its value & revealed areas for further improvement

- Further piloting during the week of 18 Sept 2023 in Asia
  - Lessons will help further refine/adjust the tool

- WG meetings Q4 2023 to review learnings from the pilots

WHO Prequalification: Transition of SARS-CoV-2 NAT and Ag RDTs from EUL to PQ

End of the PHEIC triggered:

- No new EUL submissions accepted
- Cancellation of ongoing assessments
- Start of transition phase EUL → PQ

EUL listed IVDs will remain eligible for procurement until Jan 31, 2024, provided that the manufacturer adheres to post-listing obligations

For products transitioning to PQ the EUL listing validity will be maintained until a PQ decision is taken

For products not undergoing PQ assessment, the EUL listing validity will not be extended beyond Jan 31, 2024

To remain eligible for procurement manufacturers of EUL listed IVDs will have until Dec 31, 2023, to apply for PQ assessment

Technical Specifications TSS-20 and TSS-21 have been published

SARS-CoV-2 IVDs (NAT & Ag RDTs) are now eligible for WHO PQ

PQDx IVD product dossier assessments and inspections

WHO PQ has implemented the **ToC format for dossiers** and review reports

A **new assessment model** is being ruled out: assessment sessions

- involvement of SMEs
- support from several IMDRF NRAs
- capacity building for NRAs with growing regulatory capacity

Inspections:

EUL QMS reviews wrapped up as part of EUL PQ transition

18/33 applicants with active applications have MDSAP

Prequalification of IVDs: upcoming changes

Based on the experience with PQ assessments, change requests assessments and pandemic:

1. Change review process under revision: new report template being piloted and new guidance for manufacturers planned
2. Abridged PQ procedure to be amended to further build on collaboration and reliance
3. Expansion of assessment capacity
4. the ePQS Portal will be live by 1 Jan 2024
5. PQDx scope expansion plan to be published soon

Prequalification of IVDs: new documents

Published:

- **TSS 20** - In vitro diagnostic medical devices used for the qualitative detection of SARS-CoV-2 nucleic acid
- **TSS 21** - SARS-CoV-2 antigen rapid diagnostic tests for professional use and self-testing

Coming soon:

- Haemoglobin A1c point of care analysers for professional use
- In-vitro diagnostic medical devices for monitoring of blood glucose in capillary blood
- Haemoglobin PoC analysers

World Health Assembly Resolutions and Decisions

WHA76.5 Increasing access to medical oxygen

…to promote the convergence and harmonization of regulations governing the provision of medical oxygen and access to safe, effective and quality assured medical oxygen sources and devices..

WHA76.3 Strengthening diagnostics capacity

..to leverage international…. collaboration for harmonizing for the regulation, manufacturing and supply of all types of diagnostics

WHA75(25) Standardization of medical devices nomenclature

to integrate available information related to medical devices, including terms, codes and definitions, in MEDEVIS

IMDRF International Medical Device Regulators Forum

Thank you/Questions

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