IMDRF International Medical Device Regulators Forum

EU2023 EUROPEAN UNION Chair

13:45 – 14:00

Personalized Medical Devices (Australia)

Tracey Duffy

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

European Commission | European Union

IMDRF International Medical Device Regulators Forum

Personalized Medical Devices (PMD) Working Group

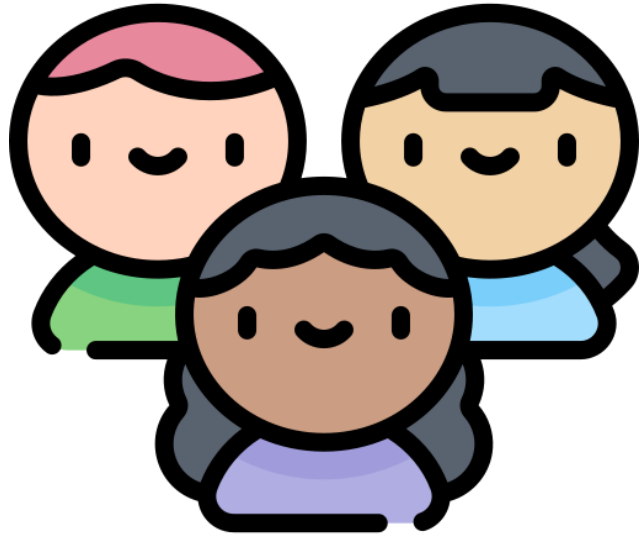
PMD Working Group Chair: Therapeutic Goods Administration, Australia

IMDRF Stakeholder Forum – 28 March 2023

Tasks given to the PMD Working Group

1. Revise PMD Regulatory Pathways (N58)
Public consultation closed 28 November 2022

2. Develop PMD Production Verification and Validation (N74)
Public consultation closed 28 December 2022



PMD Regulatory Pathways (N58)

N58, first published in 2020, is an active technical document.

In April 2022, MC approved the proposal to revise N58 to achieve the following objectives:

1. Revise the **definition** of Medical Device Production System (MDPS) to no longer limit the concept to PMDs;
2. Revise the MDPS framework to better represent **real world applications**, thereby facilitating the adoption and implementation of MDPSs by stakeholders; and
3. Expand the scope of Appendix 2 to incorporate a broad range of medical devices, **not limited to PMDs**.

Timelines & progress on the revision of N58

March 2022	• WG presents a proposal to MC to revise the existing N58
April 2022	• MC approves the proposal and tasks WG with the work
July 2022	• Working Draft N58 discussed at the WG meeting
August 2022	• Deep dive sessions to prepare the final Working Draft N58
August 2022	• Final Working Draft N58 submitted to IMDRF Secretariat for consideration at September 2022 MC meeting

Timelines & progress on the revision of N58

September 2022
- MC approved advancement from Working Draft to Proposed Document, and 60 day public consultation starting 29 September 2022

November 2022
- Public consultation closed 28 November 2022

February 2023
- Deep dive sessions to discuss and address feedback from public consultation

February 2023
- Revised version of N58 submitted to IMDRF Secretariat for MC's consideration

Public consultation – N58 PMD Regulatory Pathways

Start date: Thursday, 29 September 2022 | Closing date: Monday, 28 November 2022

- Eleven submissions received – 61 comments
- Submissions received from individuals, peak bodies representing allied health and dental sectors, and trade associations representing industry
- The WG held deep dive sessions in February 2023 to consider the feedback received in the submissions
- An updated version of the document has been submitted to the MC for consideration

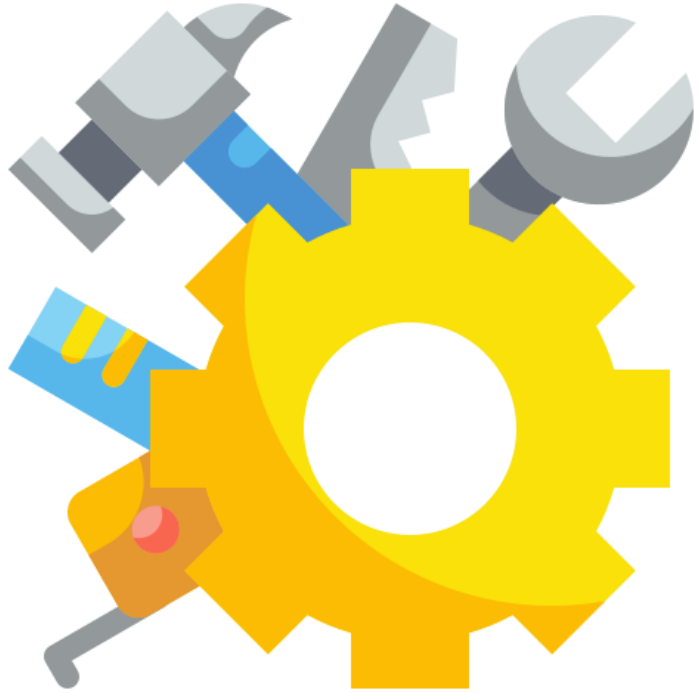
Observations from N58 public consultation

- Stakeholders broadly supported the revisions; requested further clarification on delineation of roles and responsibilities of HCF and MDPS manufacturers
- Some feedback was not within the scope of revisions:
  - changing the PMD definitions
  - seeking to have IVD medical devices included in the scope
- Stakeholders sought further clarification on how PMDs will be regulated in their jurisdiction

PMD Production Verification and Validation (N74)

New Work Item Extension (NWIE) approved by MC in September 2020 to develop technical guidance covering:

- Part I: Verification and validation aspects of **Specified Design Envelope** (salient feature of patient-matched medical device definition)
- Part II: Verification and validation **aspects** of MDPS



Timelines & progress on the development of N74

March 2020	• NWIE PMD Production Validation proposal submitted to MC
September 2020	• NWIE proposal approved by MC, Australia nominated as PMD WG Chair
December 2020	• Introductory WG meeting
March 2021	• 2nd WG meeting to discuss Version 1.0 of the Working Draft
Until July 2022	• 8th meeting of the WG to discuss Version 8.0 of the Working Draft
August 2022	• Deep-dive sessions to prepare final version of Working Draft

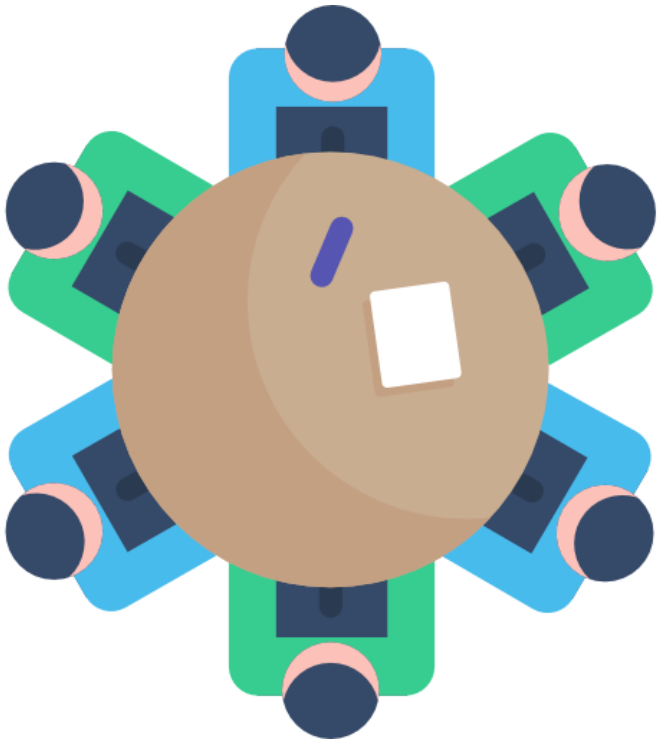
Timelines & progress on the development of N74

August 2022	• Final Working Draft N74 submitted to IMDRF Secretariat for consideration at September 2022 MC meeting
September 2022	• MC approved advancement from Working Draft to Proposed Document, and 90 days public consultation starting 29 September 2022
December 2023	• Public consultation closed on 28 December 2022
February 2023	• Deep dive sessions held to discuss and address feedback from public consultation
February 2023	• Revised version of N74 submitted to IMDRF Secretariat for MC's consideration

Public consultation – N74 PMD Production V&V

Start date: Thursday, 29 September 2022 | Closing date: Wednesday, 28 December 2022

- Four submissions received – 49 comments
- The WG held deep dive sessions in February 2023 to consider the feedback received in the submissions
- An updated version of the document has been submitted to the MC for consideration



Observations from N74 public consultation

- Limited feedback on N74, likely because the concepts presented are relatively novel and stakeholders do not have enough experience yet
- Specific feedback and broad agreement on Specified Design Envelope V&V recommendations
- Further clarification sought on the delineation of roles and responsibilities of the HCF and MDPS manufacturers at various stages of its life-cycle

Summary

- WG has met virtually 17 times since December 2020, most recently on Thursday, 2 March 2023
- WG held five deep dive sessions in February 2023 to discuss the feedback from public consultation on N58 and N74
- Outcomes from deep dive sessions in February 2023 - updated versions of N58 and N74 (Proposed Documents)
- N58 and N74 Proposed Documents have been submitted to the IMDRF Secretariat for consideration by MC at March 2023 meeting

Personalised Medical Devices Working Group (WG) members

Jurisdictions

- Argentina
- Australia
- Brazil
- Canada
- China
- Europe
- Japan
- Saudi Arabia
- Singapore
- South Korea
- UK
- USA

IMDRF International Medical Device Regulators Forum

Thank you/Questions

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