Industry perspective on the EU medical device regulatory system

Perspectives on how the EU MDR should evolve and introduce a Priority Review

Andrea Rappagliosi, Sr VP Public Affairs EMEACLA, Edwards Lifesciences

17th April 2024

ESC
European Society of Cardiology

The issue at stake

Equity in Access

Ensuring an **equitable access for patients** that need access to treatment based on medical devices rather than medication, or that are based in the EU rather than outside the EU

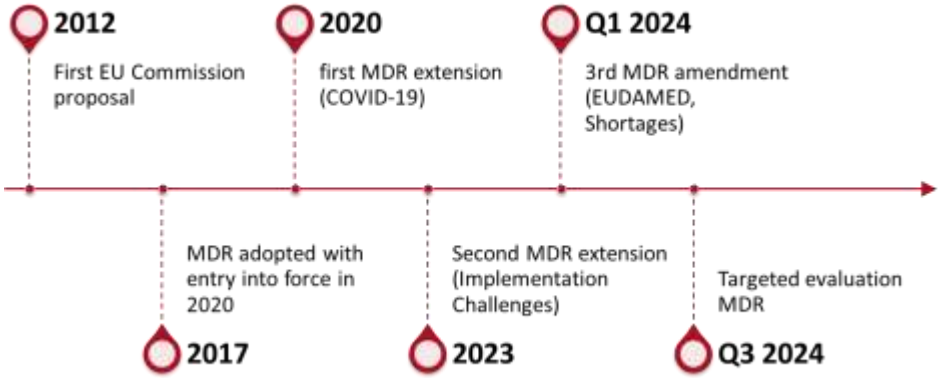
Public Health

Timely introduction of innovations addresses **needs of patients** with unmet needs, life-threatening diseases or highly-debilitating diseases

Competitiveness

Creating a **predictable and globally competitive regulatory environment** will favour **investment** into clinical excellence and innovation in the EU

MDR: The Need for A Critical Path to Close The Gap between Patient Needs and Innovation

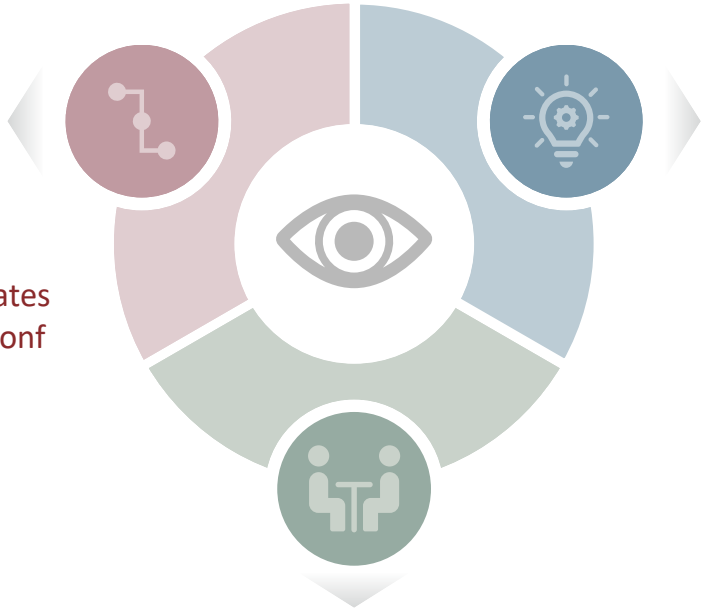


Broader MedTech Vision for where the MDR should be: A 3-pillared approach proposed by MEdTech Europe

Ensuring **Efficiency**

Including:

- Digitizing the system
- Remove validity of certificates
- Reducing bureaucracy in Conf Assessment



Fostering **Innovation**

Including:

- Accelerated assessment pathways
- Early dialogues
- Adopt evidence requirements (RWE, EFS)

Improving **Governance**

- Incl a centralized governance structure and a structured stakeholder dialogue

Source: https://www.medtecheurope.org/resource-library/the-future-of-europes-medical-technology-regulations/

Zooming in on the Role of MDR to Foster Innovation:

The need to Set Accelerated Innovation Paths from Early Evidence to Value Reward

Our Objectives

1. Ensure equal access for patients regardless of the treatment they require
2. Enhance EU regulatory pathways, including MDR, for the benefit of patients
3. Improve clinical excellence and related investments in the region, bringing value and efficiency to the healthcare system

Early innovation is attracted to Europe

Set an EU EFS Methodology

Regulations enable innovation access and launches

An EU Priority Review for Breakthrough Innovations

The holistic value of innovation is recognized

An Adaptive Assessment approach, leveraging RWE/RWD

Value of Innovation is rewarded

VBP and PPIs to reward innovations

IHI HEU-EFS Project: A Unique Public Private Partnership to Attract Innovation and Improve Clinical Excellence in Europe

1. Improve Early Patient Access
2. Elevate Clinical Excellence in European centres
3. Accelerate Investment into the European Union

HEU-EFS: A Harmonised Approach to Early Feasibility Studies for Medical Devices in the EU

1

Research & Analysis

State of Play, barriers, best practice

2

EU EFS Methodology

Incl blueprints, templates, database

3

Pilot Use-Cases

Pilots to test & validate the methodology

20 Million EUR ('23 – '27) - 22 Partners – with University of Bocconi & Edwards as leader – ESC in Advisory Board - www.heuefs.eu | @HEU-EFS

A MD Priority Review: the Missing Process for Innovation

A Priority Review exists for medicine in the EU, and for medical devices in other regions

For Medicine

- EMA Conditional Marketing Authorisation
- Voluntary PRIME Mechanism to enhance support for development of medicine

For Devices

- Voluntary Fast-Track Breakthrough Program for certain medical devices and device-led combination products

- New UK IDAP pilot to accelerate the development of innovative medical devices that meet an unmet clinical need

For Medicine & Devices

- Pharmaceuticals and Medical Devices Act (PMD Act) introduces fast-track review process for pioneering devices

EU, European Medicines Agency, Conditional Marketing Authorisation:, ***PRME*** Priority Mechanism ***for medicine*** | **US Food and Drug Administration,** Fast-Track Breakthrough Program | **UK,** **https://www.gov.uk/government/publications/the-innovative-devices-access-pathway-idap** | Japan **Pharmaceuticals and Medical Devices Act (PMD Act), Link to Fast-Track Review in Japanese**

What is a Priority Review

A Priority Review process aims to:

1. Address inequity in patient access by closing the gap between innovation and treatment and cure.
2. Ensure the option of an accelerated, robust and transparent evaluation pathway
3. Set a predictable, timed process with strict eligibility criteria

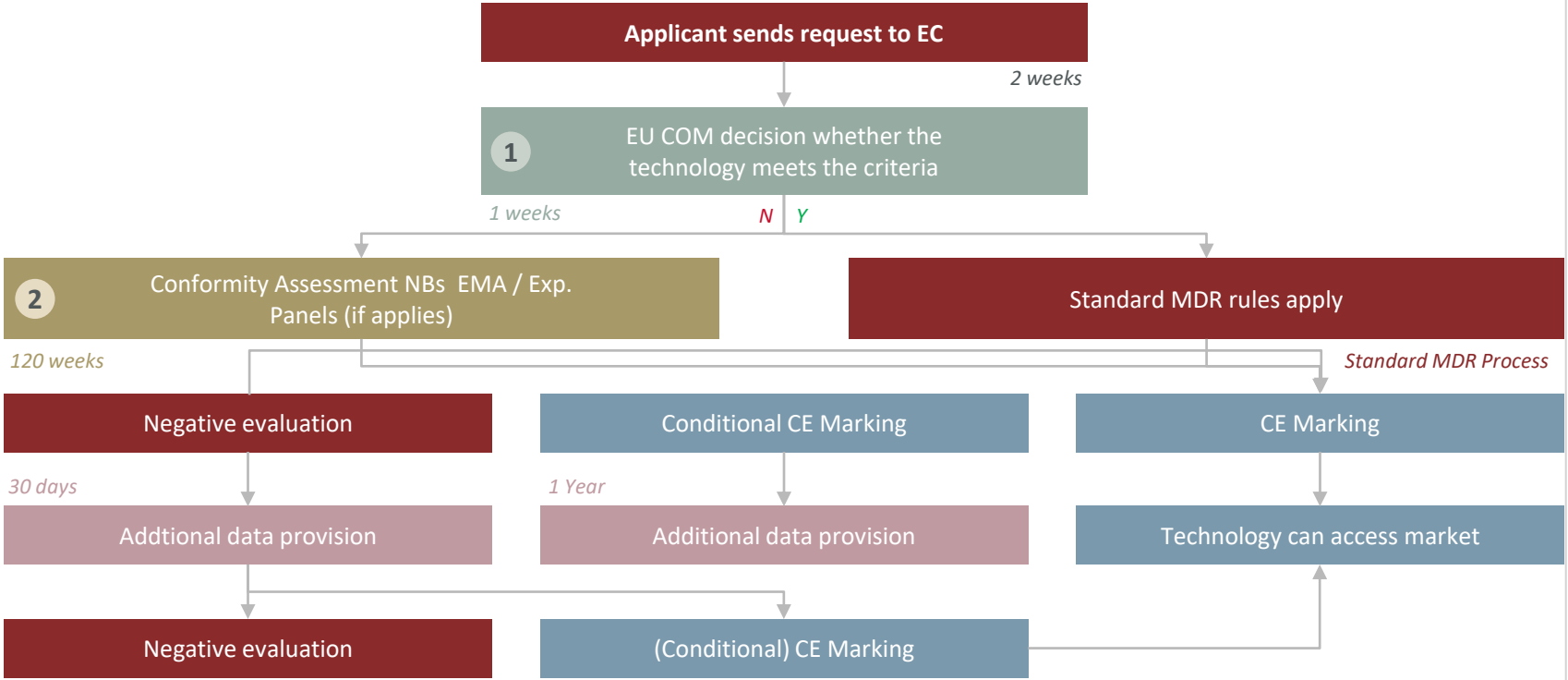
A Priority Review is limited to certain innovations addressing unmet medical needs:

1. Treats a life-threatening or severely debilitating disease without an authorised treatment in the Union or if the disease still has high morbidity or mortality despite existing treatments.*
2. Innovations are **first-in class**, or a technological **breakthrough**, or offer a **significant improvement** compared to approved alternatives
3. The benefit of the innovation's **immediate availability** to patients is greater than the risk inherent in the fact that additional data are still required

EU, European Medicines Agency, Conditional Marketing Authorisation:, *PRME* Priority Mechanism *for medicine* | US Food and Drug Administration, Fast-Track Breakthrough Program | UK, Medicines and Healthcare Products Regulatory Agency, [Insert title of report] (publishing.service.gov.uk); EC Proposal 2023/ 0132, Article 83 resource.html (europa.eu)

* Designated orphan products are automatically regarded **as addressing unmet medical needs**.

An MD Priority Review: A proposed 120 days predictable and timely process



Setting a EU Holistic and Effective Innovation Adoption

- Key challenge: ensuring that EU can continue to **provide innovative care** to patients
- Need of comprehensive approach to bring **the efficiency and predictability** that decision-makers, patients and innovators needs.
- An accelerated pathway for innovation will ultimately also benefit sub-groups, such as **orphan** devices or **paediatric** applications.

- Innovation **cannot be divided 'artificially' into sub-sets** (i.e. orphan products or paediatric applications). Similar to the new Pharmaceutical legislation, orphan products should automatically be regarded as addressing unmet needs and would fall into the category of the priority review.
- Having separate pathways for these niche applications risk to create confusion **and missing the overall objective** to ensure that patients can have access to the innovations that they need.

Thank you !

Andrea Rappagliosi
Senior Vice-President Public Affairs EMEA, Canada, Latin America
Edwards Lifesciences
Andrea_Rappagliosi@edwards.com