JAMS STAKEHOLDER CONFERENCE

Katie Gallagher
Senior Policy Advisor
European Patients’ Forum

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Reinforced European market surveillance for better patient safety

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JAMS Stakeholder Conference

“" A STRONG PATIENTS’ VOICE TO DRIVE BETTER HEALTH IN EUROPE ""
About EPF

• European Patients’ Forum
  - Independent & non-governmental
  - Umbrella organisation
  - Active since 2003
  - EU patients’ voice

• Our members
  - 70+ patients’ groups
  - EU disease specific organisations & National patient coalitions
Patients’ Perspective

- **Safer medical devices:** high level of patient safety and quality of care throughout the lifecycle of the device

- **Improving transparency and information to patients:** to empower patients and ensure public trust and confidence in the safety of medical devices

- **Patient involvement:** Individually and collectively, in the development process of medical devices and direct involvement of patients in key decision making bodies and scientific committees

- **Equitable access** according to patients’ needs

“Seeing patient safety being in the centre of two major European pieces of legislation is a great achievement which now needs to be optimally implemented.” Nicola Bedlington, Special Advisor to EPF and Past EPF Secretary General
Key Expectations

Potential benefits for patients in an optimally implemented MDR

Important changes expected for patients:

✔ **Stronger safety requirements** particularly for high-risk devices,
✔ **Strengthened transparency of clinical evidence** and
✔ **Strengthened post-market surveillance**
The MD regulation promises better information to patients and increased transparency.

- To empower patients and ensure public trust and confidence in the safety of medical devices.

However, transparency and public access to information remains a concern.
The regulation promises increased transparency through EUDAMED but concerns about transparency due to limited public access to information remain. Delay in public accessibility of EUDAMED database to May 2022:
- Risks of dysfunctionality
- Persistent patient uncertainty
Greater Transparency and Patient Safety

Safety

Introduction of public **Summary of Safety and Clinical Performance (SSCP)** of high-risk class III devices and implantables

Important source of information for patients and Healthcare professionals

**BUT** misses pre-clinical data and clinical evaluation assessment report
Stronger Safety with Patient Involvement

Three stages for Patient Safety:
1. Clinical investigation (tested)
2. Conformity assessment (safety and performance)
3. Post-market vigilance and safety monitoring

Need for more effective patient involvement
The regulation promises reinforced European market surveillance for improved patient safety through strengthening competent authority knowledge and capacity. • Quality joint manufacturer inspections to improve safety of MDs • Sharing of best practices • Training course (building capacity) • Communication platform and Training material on clinical evaluation in the field of market surveillance
Access Concerns for Patients

Capacity of notified bodies and other players

Potential lack of capacity of notified bodies → Risk of delay in (re) certification of products → Delay in ACCESS → Need for urgent investment
Call for Meaningful Patient Involvement

In continued competent authority cooperation

POs’ involvement is a condition to ensure information to patients on medical devices is of high quality, easily understandable, accessible and appropriately tailored AND a condition to ensure the patients’ perspective is considered on matters that affect them such as safety concerns and surveillance.

Patients have a unique expertise as users of medical devices.

EPF advocates for the fundamental right of patients and their organisations to be meaningfully involved in the optimal implementation of the MDR and IVDR regulations.

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More information
www.eu-patient.eu
info@eu-patient.eu

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