Co-funded by
the Health Programme
of the European Union

CAMD
Competent Authorities for Medical Devices

ansm
Agence nationale de sécurité du médicament
et des produits de santé

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Infarmed
Autoridade Nacional do Medicamento
e Produtos de Saúde, I.P.

ansm
Agence nationale de sécurité du médicament et des produits de santé

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Infarmed
Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.

Co-funded by
the Health Programme
of the European Union

JAMS STAKEHOLDER CONFERENCE

Katie Gallagher
Senior Policy Advisor
European Patients' Forum

Brussels, December 12th, 2019

Reinforced European market surveillance for better patient safety

Katie Gallagher
European Patients' Forum

12 December 2019

JAMS Stakeholder Conference

@eupatientsforum

"A STRONG PATIENTS' VOICE TO DRIVE BETTER HEALTH IN EUROPE"

EPF European Patients Forum

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:

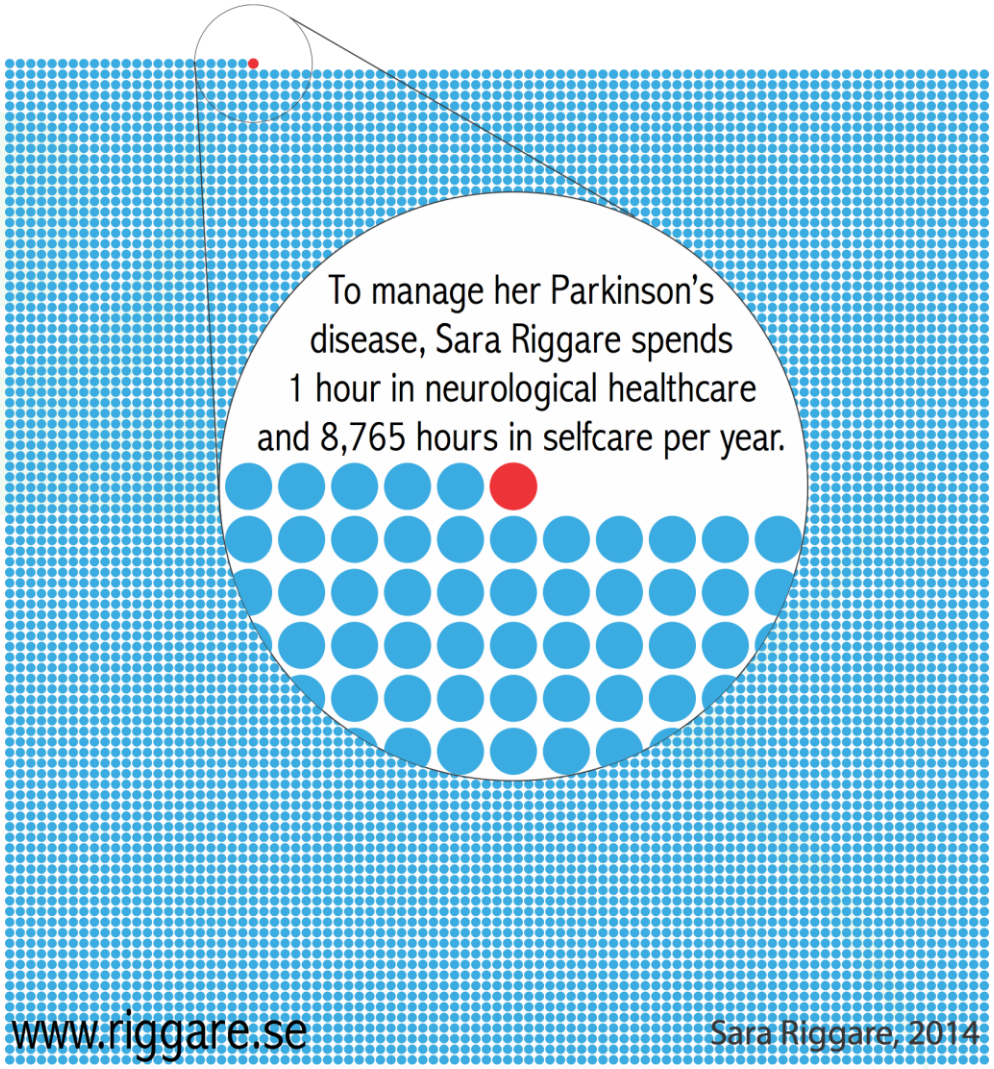
- ✓ **Stronger safety requirements** particularly for high-risk devices,
- ✓ **Strengthened transparency of clinical evidence** and
- ✓ **Strengthened post-market surveillance**

8,765 hours of Self-Management

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



Greater Transparency and Public Access to Information

Transparency

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

Strengthened Market surveillance

European Cooperation for improved safety

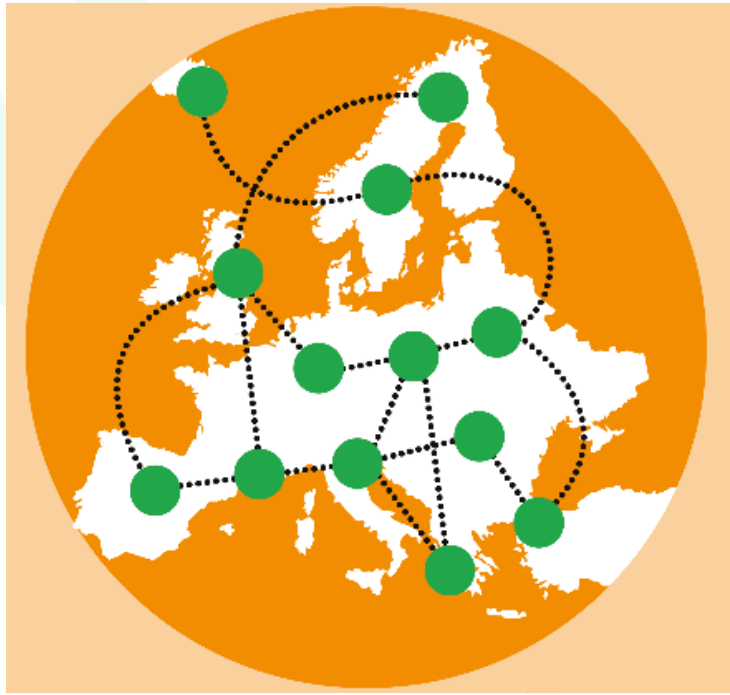
The regulation promises **reinforced European market surveillance** for improved patient safety through strengthening competent authority knowledge and capacity

- 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

THANK YOU FOR YOUR ATTENTION!

Follow us on Social Media!

/europeanpatientsforum

/eupatient

/eupatientsforum

eu-patient.eu/blog

More information

www.eu-patient.eu

info@eu-patient.eu

"A STRONG PATIENTS' VOICE TO DRIVE BETTER HEALTH IN EUROPE"

EPF European Patients Forum

Katie Gallagher – Senior Policy Adviser, European Patients' Forum
Katie.gallagher@eu-patient.eu

JAMS Project team contact :

Lara LAINE-LEMARCHAND – JAMS Project coordinator, ANSM
lara.laine-lemarchand@ansm.sante.fr

Angélique NIKOUE – JAMS Project assistant, ANSM
angelique.nikoue@ansm.sante.fr

Mariana MADUREIRA and Christine GRASMICK – WP4 Co-leaders, INFARMED and ANSM
mariana.madureira@infarmed.pt ; Christine.GRASMICK@ansm.sante.fr

Nicola HICKIE – WP5 leader, HPRA
nicola.hickie@hpra.ie

This conference is part of the project / joint action '723964 / JAMS' which has received funding from the European Union's Health Programme (2014-2020).

Co-funded by
the Health Programme
of the European Union

CAMD Competent Authorities for Medical Devices

ansm Agence nationale de sécurité du médicament et des produits de santé

HPRA An tÚdarás Rialála Táirgí Sláinte Health Products Regulatory Authority

Infarmed Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.