Joint IMDRF/Industry Workshop on Reliance

Post-market reliance – the EU framework

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Agenda

1. Post-Market surveillance
2. Notified body role in post-market
3. Vigilance reporting and Member State coordination
4. Market Surveillance authorities and coordination

Post-Market Surveillance (PMS)

- Post-market surveillance requirements for medical devices in the EU: all activities carried out by manufacturers and economic operators, proactively collect and review experience gained from devices they have placed on the market.
- Manufacturers must put in place a post-market surveillance system that allows the collection of data and reporting of various new requirements such as:

  - ✓ Post market surveillance report for Class I devices
  - ✓ PSURs – Periodic Safety Update Reports (MDCG Guidance: MDCG 2022-21)
  - ✓ Trend Reporting
  - ✓ Analysis of serious incidents and field safety corrective actions
  - ✓ Reporting of serious incidents and field corrective actions MDCG guidance 2023-3

Surveillance activities and post-certification monitoring by notified bodies

Plan and conduct annual surveillance audits during the 5 year certification cycle as well as unannounced audits

Procedure and conduct screening of scientific and clinical data and post-market information relating to the scope of their designation. Such information shall be taken into account in the planning and conduct of surveillance activities

Assessment of vigilance cases reported by manufacturers or competent authorities and review of periodic safety update reports

Where necessary, impose specific restrictions on relevant certificates, or suspend or withdraw it

Coordination between National Authorities (NAs) in Members States in cases of Serious Incidents (SI) or Field Safety Corrective Actions (FSCA):

- **A MS evaluates:**

Based on reporting from serious incidents & FSCA → informs other MS including potential outcome

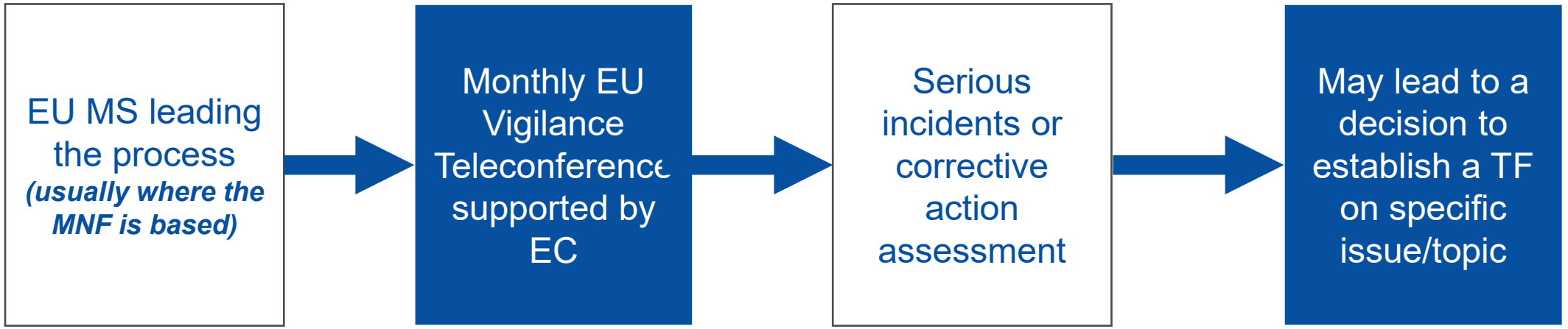
- **MS designated as a coordinator when:**

Serious incidents & FSCA of the same device or same types of devices in more than one Member States or when there are concerns on FSCA in more than one MS.

- **Coordinated procedure covers:**

✓ Designation of a MS as a coordinator
✓ Defining an assessment process including tasks and responsibilities of the coordinating competent authority

EU coordination in vigilance cases



Coordination between vigilance, market surveillance and designating authorities may be required for specific cases.

Market Surveillance

- **Who?** National Authorities in all EU Member States
- **What?** Device conformity checks, inspections, enforcement (proactive & reactive)
- **How?** Actions towards operators (falsified devices/unacceptable risk/non-compliant), reporting, surveillance plans

European Commission

European Market Surveillance Programme Framework

Common methodologies & templates

- devices checks & documentation review,
- inspections,
- reporting on surveillance activities.

Enforcement :

- harmonized risk assessment procedures;
- possible reliance on safety decisions by 1 MS in all MS marketbullet

Coordination mechanisms

- CA monthly information exchanges on safety cases and inspectors' forum,
- Mutual assistance requests for compliance & enforcement.

EU funded projects

- laboratory testing,
- joint inspections of manufacturers,
- targeted safety campaigns

Benefits of the Reliance Program

- Engagement of all EU competent authorities
- Consultation of all relevant actors
- Enhanced transparency and knowledge building
- Resource sharing, consistency and ownership of the outcome between regulatory authorities

Thank you!

Questions?

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