JAMS STAKEHOLDER CONFERENCE
BRUSSELS, DECEMBER 12th, 2019
Reinforcing the market surveillance system for medical devices: key results of JAMS

Bernard Celli, Head of Inspection Division, ANSM (FR)
Nicola Hickie, Regulatory and Policy Manager, HPRA (IE)
Mariana Madureira, Coordinator of MD sector, INFARMED (PT)
JAMS with numbers

- **18** Member States
- **3** Years
- **1,4€** Grant for Joint Action co-financed with MS

Co-funded by the Health Programme of the European Union
Joint Action on Market Surveillance of medical devices

MDR articles:

• SECTION 3, Article 93 Market surveillance activities:
  • 9. The competent authorities of the Member States shall coordinate their market surveillance activities, cooperate with each other and share with each other and with the Commission the results thereof, to provide for a harmonised and high level of market surveillance in all Member States. Where appropriate, the competent authorities of the Member States shall agree on work-sharing, joint market surveillance activities and specialisation.

• CHAPTER VIII, Article 102 Cooperation:
  • 1. The competent authorities of the Member States shall cooperate with each other and with the Commission.
Main objective: reinforcing market surveillance between member states across Europe

Key principles:
• Share and develop best practice, training, knowledge, and resources to increase public health protection in the medical devices sector
• Improve coordination and help to develop skills and capacity in the market surveillance network

Scope: Joint Manufacturer Inspection / Clinical resource & process

Benefits: improved market surveillance

Ensuring a consistently high level of health and safety protection for EU patients using medical devices
Co-funded by the Health Programme of the European Union

JAMS organisation

WP1-3 Coordination, dissemination and evaluation

WP4 Joint inspections of manufacturers

WP5 Clinical process and resources development

Advisory Board:
WP leaders + CPME, Team NB, MedTech Europe
DG GROW (observer)
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Key results from WP4: Joint inspections of manufacturers

Mariana Madureira,
WP4 Co-leader, Coordinator of MD sector, INFARMED (PT)
European Commission publishes proposal for two new EU regulations for medical devices which include firmer market surveillance requirements

Entry into force of two new regulations for medical devices and in-vitro diagnostic medical devices (EU 745/2017 and EU 746/2017) with new market surveillance procedures

2010

2012

2013

2016

2017

2010 PIP breast implant scandal

Entry into force of the implementing regulation (EU 920/2013)

JAMS commences October 2016

2012 PIP Joint Action plan published by European Commission, which focuses on areas for improvement including market surveillance
Previous initiatives...


- Desk review of the reprocessing instructions provided by the manufacturers shown that the overall quality of the information was insufficient ... regarding compliance to the MDD... class I devices tend to be less compliant...

- (Joint) Inspections- To evaluate whether the reprocessing validation data fulfil the legal requirements. Evidence: none of the inspected manufacturers/European authorised representatives could show reprocessing validation data being fully compliant to the legal requirements.

New requirement in the MDR Art.52 (7) the involvement of a Notified Body is required for the conformity assessment of class I reusable surgical instruments.
Joint Action on Market Surveillance of Medical Devices

Article 93 (1-3) MDR

The competent authorities shall perform appropriate checks on the conformity characteristics and performance of devices including, where appropriate, a review of documentation and physical or laboratory checks ...

To fulfil this obligations the competent authorities:

- Desk review(...)
- Inspections of the premises of economic operators(...)
  - Announced
  - Unannounced

...Suppliers and/or subcontractors
...where necessary, at facilities of professional users

Draw up annual surveillance activity plans
Article 93 (9) MDR

Competent authorities of the Member States shall coordinate their market surveillance activities, cooperate with each other and share with each other and with the Commission the results thereof, to provide for a harmonised and high level of market surveillance in all Member States.

Where appropriate, the competent authorities of the Member States shall agree on work-sharing, joint market surveillance activities and specialisation.
# WP4 Participants

<table>
<thead>
<tr>
<th>Beneficiaries (9)</th>
<th>Collaborators (5)</th>
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<tr>
<td>Austria, AGES</td>
<td>Belgium, FAGG</td>
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<td>Cyprus, CYMDA</td>
<td>Estonia, Terviseamet Health Board</td>
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<td>France, ANSM</td>
<td>Latvia, VI</td>
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<td>Ireland, HPRA</td>
<td>Norway, NOMA</td>
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<td>Italy, DGDMF</td>
<td>UK, MHRA</td>
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<td>Portugal, INFARMED</td>
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<td>Spain, AEMPS</td>
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<td>Sweden, MPA</td>
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<td>The Netherlands, NLNA</td>
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What are the key objectives of JAMS – WP4

Identify and collect the national policies on planning inspections

Delivery tools, templates, information resources and procedures to facilitate joint inspections of manufacturers

Map specialist expertise inspectors across the system

Organise an inspector training course

Identify areas and candidates to coordinate expertise at EU level
Our deliverables

• D4.1 – Proposals Joint Inspections of MD manufacturers in Europe

• D4.2 – Guidance document «Joint Inspection Initiation»

• D4.3 – Inspectors Training Course & Establishment of Inspectors Expert Group

• D4.4 – Guidance on conduct of Joint Inspections
Our deliverables

Deliverable D4.1 Proposals Joint Inspections of MD manufacturers in EU

Terminology/Definitions:
• Joint inspection of manufacturers, lead inspector

Inspector profile:
• Competence, qualification
Our deliverables

Deliverable D4.2 - Guidance document «Joint Inspection Initiation»

- Overview of joint inspection process
- Joint Inspector Group for medical devices
- Sources of input into the joint inspection process
- Request for joint inspection
- Joint inspection planning
- Pilot phase
Our deliverables

Draft deliverable D4.3 Inspectors Training Course

73 participants
26 NCAS
Our deliverables

Draft deliverable D4.4 - Guidance on conduct of Joint Inspections

- Following the process of Joint Inspection of MD manufacturers
- Harmonised necessary templates
- Post joint inspection activities
JAMS WP4 Achievements

Paving the way for Joint Inspections of MD Manufacturers in EU, by:

- Delivering tools, templates, information resources and procedures to facilitate joint inspections of manufacturers;
- Training inspectors to perform joint inspections according to an agreed approach
JAMS WP4 Achievements

Contributing to the implementation of Medical Device Regulations
Reinforcing the market surveillance system for medical devices: key results of JAMS

Key results from WP5: Clinical process and resources development

Nicola Hickie
WP5 Leader, Regulatory and Policy Manager, HPRA (IE)
Reinforcing market surveillance for medical devices

Report from WP5

- Political agreement on MDR/ IVDR
- JAMS project commences
- Implementation of MDR

Co-funded by the Health Programme of the European Union
Key Deliverables of JAMS WP5

- Establish communication platform & protocols for information exchange
- Identify training & development needs for evaluation of clinical data
- Identify process to prioritise devices requiring Common Specifications
Work Plan

- Survey
- Workshops
- Call to CAMD
- Solutions focussed
- Process/Matrix
- Steer/Strategy
- Development
- Proposals

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Who is involved?

<table>
<thead>
<tr>
<th>Beneficiaries (6)</th>
<th>Collaborating Stakeholders (7)</th>
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<tr>
<td>AGES (AT)</td>
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<td>MHRA (UK)</td>
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What has been delivered:
CS prioritisation process

Collation of existing guidance in other regulatory regions
Guidance & Template Documents drafted
Prioritisation process developed
Coordination process and Communication portal

- Communication Process on Coordination defined
- Option identified for Communication Platform
- Development of Pilot Portal
Clinical Training Materials Developed

- Workshop on clinical training needs
- Strategy document developed
- Training materials developed
Benefits gained and alignment with MDR

Clinical and training priorities

Optimise Resource & Expertise

Implementation

Increased cooperation

Establish coordinated processes
Next Steps

- Continue to develop and use learnings from this process
- Commission – tools for prioritising Common Specifications
- NCAs – training materials and future development areas identified
- NCAs and working groups – process for coordinating on market surveillance issues
- NCAs and working groups – tool for real time exchange of information
Conclusion

Regulators
- Clear roles & responsibilities
- Greater confidence
- Better processes, systems & tools
- Resources & funding

Industry
- Predictability
- Consistency
- Proportionality
- Innovative environment
- Stability

Patients
- Public confidence
- Better standards of protection
- Information and transparency
- Access to new technologies

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Conclusion
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