

# Market surveillance of medical devices

A joint action between  
competent authorities on market  
surveillance of medical devices

Information for notified bodies



# Introduction

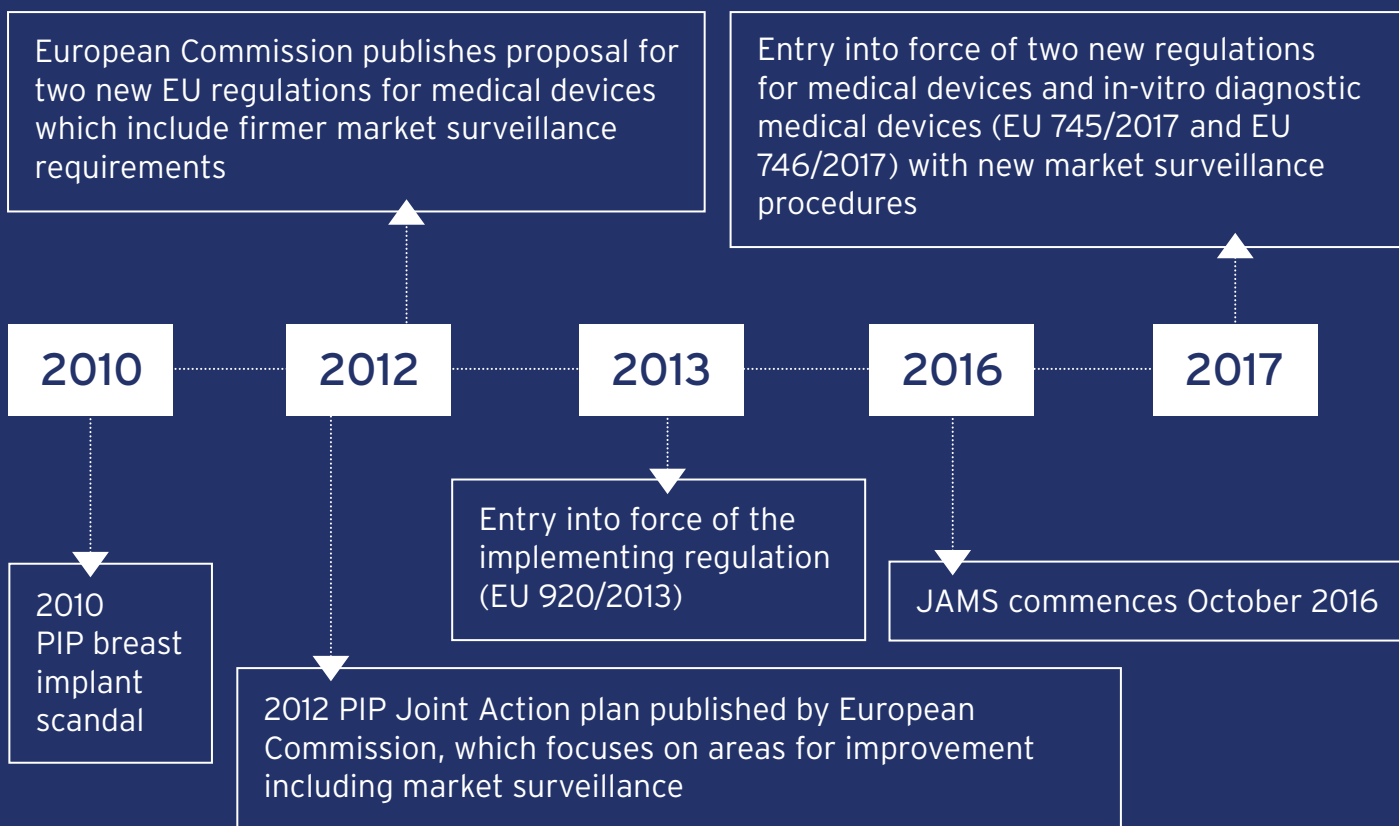
The European Commission has made funding available to a group of European countries that agreed to participate in a three-year project which commenced in October 2016. This project aims to find ways for regulators of medical devices in Europe to improve the checking and monitoring of medical devices. In this leaflet, you will be able to find out more about the Joint Action on Market Surveillance of Medical Devices (JAMS).

**'Joint actions'** are projects that are designed to encourage competent authorities across Europe to work together more effectively.

**'Market surveillance'** typically refers to all the activities that a public authority undertakes to ensure their products comply with the requirements set out in the relevant legislation and do not endanger health, safety, or any other aspect of public interest protection.

## Why is there a need for a Joint Action on Market Surveillance?

**Recent events in the medical devices industry have highlighted the need for improvements in the area of market surveillance.**



## The PIP Action Plan

The 'breast implants scandal' that emerged throughout 2010/2011 involved a medical device manufacturer - Poly Implant Prothese (PIP) - deliberately using the incorrect grade of silicone within the breast implants it manufactured, and then concealing this activity. This led to an estimated 400,000 women worldwide receiving breast implants that did not contain a medically approved grade of silicone<sup>1</sup>.

The scandal highlighted the risk that a fraudulent manufacturer could claim that their product meets the requirements by CE marking their medical device while knowing that this is not actually true. Market surveillance activity, if effectively planned and intelligently targeted, can help identify such non-compliances more quickly.

Following the PIP breast implant scandal, a joint plan for immediate action – the so-called [PIP Action Plan](#) – was developed by the European Commission and the member states to restore confidence and security in medical devices. Numerous measures were taken to improve control, based on existing legislation. The PIP Action Plan also accelerated the publication by the Commission of an implementing regulation<sup>2</sup> in September 2013.

The PIP Action plan focused on the need for more control in four main areas of the regulatory system for medical devices:

### PIP Action Plan

- functioning of notified bodies
- market surveillance
- coordination as regards vigilance
- communication and transparency.

### Two new European Regulations<sup>3</sup> were published in May 2017 and introduced amongst other measures:

- Closer coordination between competent authorities through information exchange and coordinated assessments, particularly in the area of market surveillance of devices<sup>4</sup>.
- More action by member states using appropriate methods to raise awareness among healthcare professionals, users, and patients about the importance of reporting incidents<sup>5</sup>.

Overall, the Joint Action on Market Surveillance of Medical Devices (JAMS) aims to improve the coordination between competent authorities and to develop a better common understanding of market surveillance.

<sup>1</sup> EUROPEAN COMMISSION, European Commission website, Health and Food Safety, Scientific Committee website; accessed 22 February 2018: [https://ec.europa.eu/health/scientific\\_committees/consultations/public\\_consultations/scenih\\_r\\_cons\\_14\\_en](https://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scenih_r_cons_14_en)

<sup>2</sup> Commission Implementing Regulation (EU) No 920/2013

<sup>3</sup> Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in-vitro diagnostic medical devices

<sup>4</sup> Recital 84 of both Regulation (EU) 2017/745 and Regulation (EU) 2017/746

<sup>5</sup> Recital (76) of Regulation (EU) 2017/745 and Recital (77) of Regulation (EU) 2017/746

# What is the joint action on market surveillance doing?



## Bringing European medical device regulators together

The Joint Action on Market Surveillance of Medical Devices (JAMS) aims to reinforce market surveillance between member states across Europe. Best practice, training, knowledge, and resources will be shared to increase public health protection in the medical devices sector. An important aim is to improve coordination and help lower-resourced member states to develop skills and capacity in the market surveillance network. It will help to ensure a consistent and proportionate approach to the work of manufacturer inspections, and clinical process and resource development.

### Work package 1

Coordination of the project (Led by UK)

### Work package 2

Dissemination of information (Led by UK)

### Work package 3

Evaluation of the project (Led by UK)

### Work package 4

Joint inspections of manufacturers (Led by Netherlands)

### Work package 5

Clinical process and resources development (Led by Ireland)

## Work packages 1-3

These work packages are specifically about facilitating the work of JAMS through monitoring of the project plan, producing resources that communicate and promote the work of the project with key stakeholders, and critically evaluating the progress of the project to ensure the aims of JAMS are realised.

## Work package 4

Delivering tools, templates, information resources and procedures to facilitate joint inspections of manufacturers. An inspector training course will also be developed to prepare inspectors to perform joint inspections according to an agreed approach.

## Work package 5

Delivering a common specifications prioritisation procedure and process, a clinical review training programme, as well as establishing a coordinated communications process and endorsing an effective communications platform. Work package 5 aims to enhance the existing clinical review process, and facilitate implementation of the clinical process and market surveillance requirements/obligations which the new regulations introduce.

# Who is participating in this Joint Action?

## **Ensuring industry has a voice**

The Joint Action on Market Surveillance of Medical Devices (JAMS) is reliant upon the efforts and commitment of 10 beneficiaries and 10 collaborating stakeholders to complete the work necessary to achieve the objectives of the project. A list of the partners of JAMS is included at the end of this leaflet.

**Beneficiaries:** these are organisations that receive EU co-funding following the successful application and the signature of the Grant Agreement.

**Collaborating stakeholders:** organisations that do not have a contractual relationship with The Consumers, Health, Agriculture and Food Executive Agency (Chafea) and who do not receive any EU funding. They contribute to increase the technical and scientific content of the Joint Action, as well as its relevance for different users in the European Union.

Representatives of the European medical device industry, EU Notified Bodies, and healthcare professions also play a crucial role in providing advice, direction, and feedback to the project at periodic advisory board meetings. There are established communication lines between the work packages and each national competent authority, numerous EU medical device working groups such as the COEN (Compliance and Enforcement) working group, and the International Medical Devices Regulatory Forum (IMDRF). The project also endeavours to remain conscious of the work ongoing across Europe, especially regarding the implementation of the new Regulations.



# How might JAMS benefit notified bodies?

## Harmonising market surveillance practices across Europe

### **Competent authorities in Europe will develop and share the same guidance, best practice, and training materials**

This will lead to greater transparency of market surveillance activities at the level of competent authorities. Notified bodies will be operating under a more robust legal framework, introduced by the new regulations, which will be implemented in a more harmonised way by competent authorities/designating authorities who share the same market surveillance tools, guidance, and practices - as delivered by JAMS.

### **Joint inspections of manufacturers should be complementary to current Notified Body audits.**

Joint inspections of manufacturers will encourage a more robust and safe market for medical devices. The results of the joint inspections will be communicated amongst competent authorities, further helping to encourage transparency.

### **Agreement of a standardised communication network**

This will support better sharing of information, promoting communication, fostering cooperation between competent authorities on market surveillance for medical devices, in relation to assessment of clinical data and making communication with stakeholders more effective and efficient.

### **Common specifications prioritisation**

Medical device stakeholders will be able to escalate the need for new common specifications quickly and fairly to be considered for development.

# What can notified bodies do to contribute to the work?

## Your views matter

[Team-NB](#) is a member of the JAMS advisory board, and a member of this association is invited to attend each advisory board meeting. In this way the interests, views and advice which notified bodies wish to contribute to the work of JAMS is recognised as valuable and important. If you would like to share some specific information for JAMS to consider, please contact: [secretary@team-nb.org](mailto:secretary@team-nb.org)

## More information

The project continues to communicate with stakeholders regularly, and will continue to do so throughout the three years the project will run. At the end of the project, a stakeholder meeting will take place and a final report will be made publicly available.

Visit [camd-europe.eu](http://camd-europe.eu) to find out more about the progress of JAMS.

The joint action has also developed the following leaflets that are available on [camd-europe.eu](http://camd-europe.eu):

- **Market surveillance of medical devices - A joint action to reinforce public health protection and medical devices monitoring by implementing joint manufacturer inspections and improving clinical process and resource development**
- **Improving how medical devices are checked and monitored across the European Union - An introduction for patients and consumers**
- **Market surveillance of medical devices - A joint action between competent authorities on market surveillance of medical devices - Information for manufacturers**
- **Market surveillance of medical devices - A joint action on market surveillance of medical devices to reinforce public health protection - Information for healthcare professionals**



The European Union (EU) Competent Authorities for Medical Devices (CAMD) project was established to enhance collaborative working, communication and surveillance of medical devices across Europe.

CAMD is an umbrella group, under which the national competent authorities in the EU work to enhance the level of collaborative work in what is a single market for medical devices.

The Joint Action for Market Surveillance of Medical Devices (JAMS) is being led by members of the CAMD network. To find out more visit [camd-europe.eu](http://camd-europe.eu).

# Working with partners

## Key:

**Beneficiaries**

**Collaborating stakeholders**



UK

### **Joint Action leader**

**MHRA:** *Lead for Work Packages 1-3: Co-ordination; Dissemination; Evaluation  
Beneficiary partner in Work Package 4: Joint Manufacturer Inspections  
Beneficiary partner in Work Package 5: Clinical Process and Resource Development*



IRELAND

**HPRA:** **Lead for Work Package 5: Clinical process and resource development**

*Beneficiary partner in Work Package 4: Joint Manufacturer Inspections  
Beneficiary partner in Work Package 5: Clinical Process and Resource Development*



THE  
NETHERLANDS

**IGZ:** **Lead for Work Package 4: Joint Manufacturer Inspections**

*Beneficiary partner in Work Package 5: Clinical Process and Resource Development*



AUSTRIA

**AGES:** *Beneficiary partner in Work Package 4: Joint Manufacturer Inspections*

*Beneficiary partner in Work Package 5: Clinical Process and Resource Development*



BELGIUM

**FAMHP:** *Collaborating stakeholder partner in Work Package 4: Joint Manufacturer Inspections*



CROATIA

**Halmed:** *Collaborating stakeholder partner in Work Package 5: Clinical Process and Resource Development*



CYPRUS

**CYMDA:** *Beneficiary partner in Work Package 4: Joint Manufacturer Inspections  
Collaborating stakeholder partner in Work Package 5: Clinical Process and Resource Development*



CZECH  
REPUBLIC

**MZCR:** *Collaborating stakeholder partner in Work Package 4: Joint Manufacturer Inspections*





DENMARK

**DKMA:**

*Collaborating stakeholder partner in Work Package 5: Clinical Process and Resource Development*



ESTONIA

**Terviseamet:**

*Collaborating stakeholder partner in Work Package 4: Joint Manufacturer Inspections*

*Collaborating stakeholder partner in Work Package 5: Clinical Process and Resource Development*



FRANCE

**ANSM:**

*Beneficiary partner in Work Package 4: Joint Manufacturer Inspections*

*Beneficiary partner in Work Package 5: Clinical Process and Resource Development*



GERMANY

**BFARM:**

*Collaborating stakeholder partner in Work Package 5: Clinical Process and Resource Development*



ITALY

**SANITA:**

*Beneficiary partner in Work Package 4: Joint Manufacturer Inspections*

*Beneficiary partner in Work Package 5: Clinical Process and Resource Development*



LATVIA

**VI:**

*Collaborating stakeholder partner in Work Package 4: Joint Manufacturer Inspections*



NORWAY

**Norwegian Directorate of Health Heselir:**

*Collaborating stakeholder partner in Work Package 4: Joint Manufacturer Inspections*



PORTUGAL

**INFARMED:**

*Beneficiary partner in Work Package 4: Joint Manufacturer Inspections*

*Beneficiary partner in Work Package 5: Clinical Process and Resource Development*



SPAIN

**AEMPS:**

*Beneficiary partner in Work Package 4: Joint Manufacturer Inspections*

*Collaborating stakeholder partner in Work Package 5: Clinical Process and Resource Development*



**MPA:**

*Beneficiary partner in Work Package 4: Joint Manufacturer Inspections*



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