Market surveillance of medical devices

A joint action on market surveillance of medical devices to reinforce public health protection

Information for healthcare professionals

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).

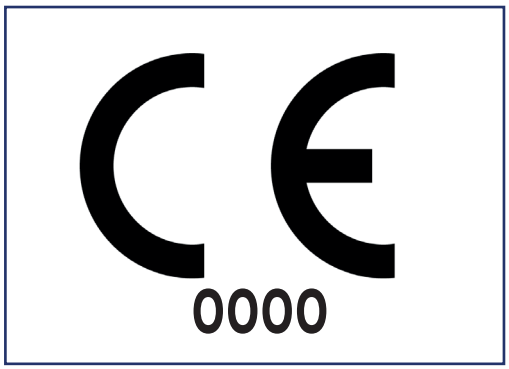
'Market surveillance' typically refers to all the activities that a public authority undertakes to ensure products comply with the requirements set out in the relevant legislation and do not endanger health, safety, or any other aspect of public interest protection.

How are medical devices regulated in Europe?

Medical devices and CE marking
Medical devices (and in vitro diagnostic medical devices) are required to be CE marked by their manufacturer, prior to being sold or placed onto the market. However, there are always specific safety, performance, and compliance requirements that the manufacturer must meet before the CE mark can be applied to the device and its packaging. The exact requirements that must be fulfilled always depend upon the exact nature of the medical device. Medical devices are categorised according to risk. In general, the higher the risk associated with a medical device, the higher the scrutiny applied to it before it may be placed onto the market. The scrutiny applied to a medical device before it is placed onto the market or sold is called 'conformity assessment'.

Risk	**Medical Devices (MDs)**	**In-Vitro Diagnostic Medical Devices (IVDs)**
Examples of medical devices/ in-vitro diagnostic medical devices and their risk classification	Class I: Non-powered wheelchair Active implantable medical devices: cardiac pacemaker Class IIa: Sticking plaster wound dressing Class IIb: Dental implant Class III: Drug eluting stent	Class A: Products for general laboratory use, specimen receptacles Class B: Self-test pregnancy kit Class C: Blood grouping test kit Class D: HIV test kit

CE marking shows that the manufacturer has checked that the medical device meets the relevant European safety and performance requirements, and overall demonstrates that a product meets requirements set out in EU legislation. For medium and high risk medical devices, it shows that a specialist certification organisation called a 'notified body' has independently reviewed the product and that it meets the requirements set out in EU legislation, before the product reaches the market. If a notified body has carried out the conformity assessment, their 4-digit identification number appears next to the CE mark. CE marking allows the free movement of products within the European market, specifically within the European Economic Area (EEA). Find out more about the CE mark.



Notified bodies
Where a CE certificate is required before the medical device may be placed onto the market, a notified body is required to carry out the conformity assessment.

Countries that are members of the European Union (EU Member States), signatories to the EEA, Switzerland and Turkey, designate specialist organisations to act as notified bodies. The authority responsible for notified bodies (designating authority) in each respective country – which is the competent authority in many member states – then oversees the notified bodies that operate in that country to make sure they conduct their activities effectively.

Market surveillance of medical devices
Market surveillance encompasses the activities which competent authorities undertake to check and make sure that medical devices placed onto the market are safe, and meet the requirements of EU law. This is an important obligation of all competent authorities.

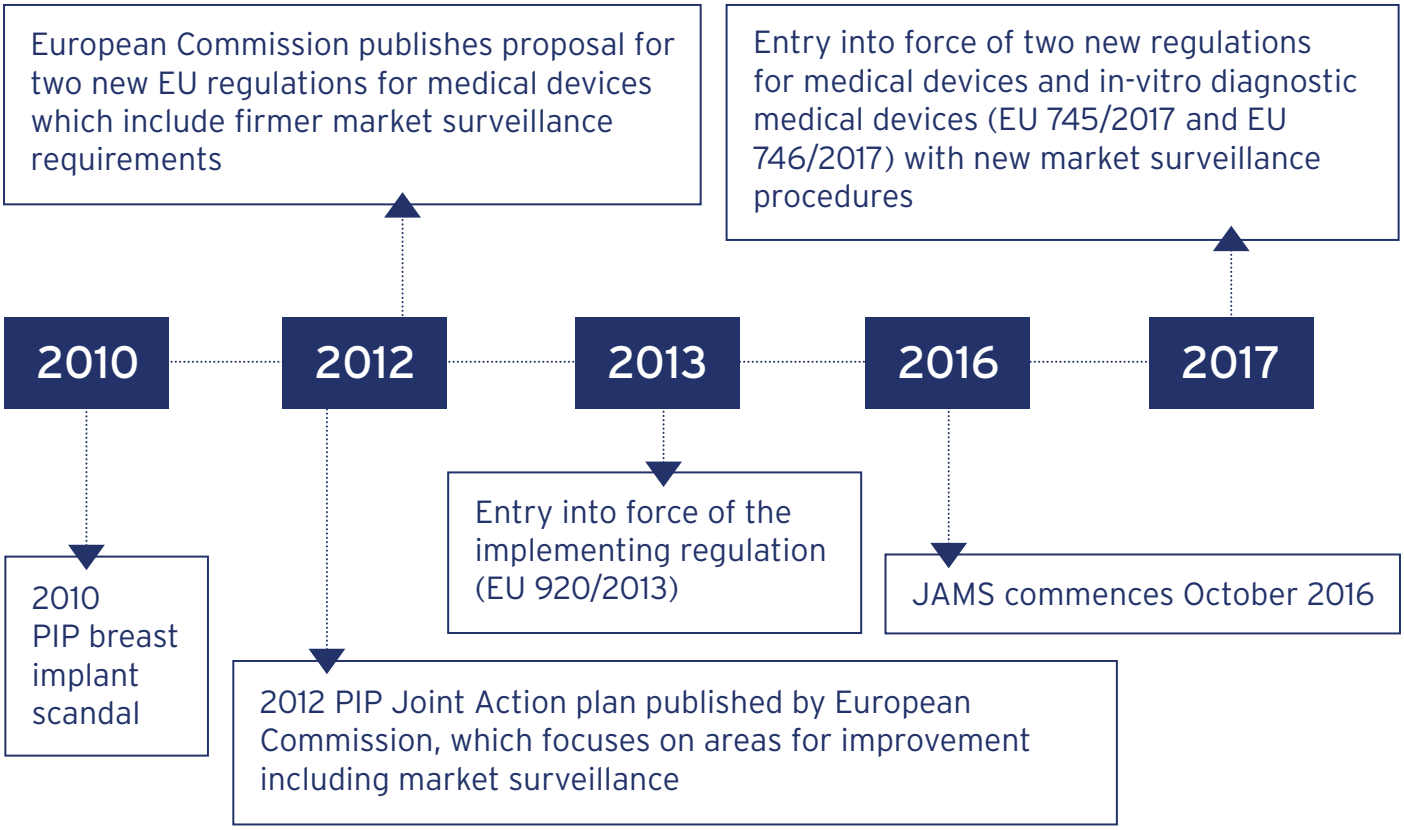
Market surveillance (activities of competent authorities)

- Monitoring devices and incidents occurring during their use
- Analysing market data/identifying signs of possible problems
- Reviewing technical documentation
- Identifying unsafe or non-compliant medical devices
- Inspecting manufacturers' premises reactively/proactively
- Removing unsafe devices from the market.

When competent authorities take action
In general, competent authorities must act when there is information which indicates that: there is an unacceptable risk to patient safety posed by a medical device that has been placed onto the market, or there is a medical device placed onto the market that is non-compliant with the requirements within EU law which apply to it. Action may be in the form of seizing medical devices, destroying non-compliant or unsafe products, or could mean helping the manufacturer to bring the product back into compliance with the legal requirements.

Why is there a need for this project?

Recent events in the medical devices industry have highlighted the need for improved coordination between member states 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 Prosthese (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[1].

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[2] 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:

[1] 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/scenihr_cons_14_en
[2] Commission Implementing Regulation (EU) No 920/2013

PIP Action Plan

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

Two new European Regulations[3] 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[4].
- More action by member states using appropriate methods to raise awareness among healthcare professionals, users, and patients about the importance of reporting incidents[5].

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.

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.

[3] Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in-vitro diagnostic medical devices, specify amongst other needs
[4] Recital 84 of both Regulation (EU) 2017/745 and Regulation (EU) 2017/746
[5] Recital (76) of Regulation (EU) 2017/745 and Recital (77) of Regulation (EU) 2017/746

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.

How does JAMS support HCPs?

Further ensuring safe medical devices for patients
There is a broad range of medical devices currently available and there are many more being developed, undergoing clinical trials, and preparing to enter the market. Medical devices are used every day in healthcare settings to support the diagnosis, treatment, and care of patients. You have already used some of them to treat your patients. The vision for the project is of competent authorities in Europe developing and sharing the same guidance, best practice, and training material to help bring about a more consistent approach to market surveillance, all underpinned by the robust and transparent market surveillance procedures introduced within the new regulations.

The harmonisation that the Joint Action on Market Surveillance of Medical Devices (JAMS) will establish should lead to a more robust and predictable regulatory system. This will result in improved standards of development of medical devices within Europe, ultimately benefitting patients, as the safety and performance of medical devices will be reinforced.

JAMS will also seek to engage your community (clinical experts) more directly with the regulatory system. Reinforcing the market surveillance system will help to ensure that you will have access to safe medical devices and in vitro diagnostic medical devices, offering a greater array of diagnostic and therapeutic possibilities.

What can you do to contribute to the work?

Your actions make a difference
Identifying clinical expertise to facilitate implementation of new regulatory requirements is one of the focal areas of the project. As such, the Joint Action on Market Surveillance of Medical Devices (JAMS) welcomes the input of clinical experts on this subject.

The competent authorities of 18 participating countries all play an active role in delivery of the project, as well as representing the views and interests of the consumers from within their territory. The project has strong ties with many international medical device regulatory forums including European groups such as Compliance and Enforcement Group (COEN) and Medical Devices Coordination Group (MDCG) but also international forums such as the International Medical Devices Regulators Forum (IMDRF). There is also excellent representation from countries around the world.

More generally, good market surveillance is reliant upon the information you provide about the medical devices you use. Each competent authority has dedicated staff and contacts to whom you should report any encounters with defective or suspected faulty medical devices, especially where a user/patient has been affected by the use of such a medical device.

You can find the right vigilance contacts for your country here

You should contact your national competent authority should you wish to contribute to the project (see below for contact details of the 18 participating countries). You can also contact the project directly through the CAMD website.

More information

Further communication will be made by JAMS as the project progresses. At the end of the project, a stakeholder meeting will take place and a final report will be made publicly available.

The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. To find out more about the medical professions' view of the new medical device regulations, visit www.cpme.eu/policy-areas/medical-devices.

Visit camd-europe.eu to find out more about the progress of the joint action.

The joint action has also developed the following leaflets that are available on 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 notified bodies**
- **Market surveillance of medical devices – A joint Action between competent authorities on market surveillance of medical devices – Information for manufacturers**

CAMD
Competent Authorities for Medical Devices

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.

Working with partners

Key:
Beneficiaries
Collaborating stakeholders

UK

MHRA: ***Joint Action leader***
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 Hesedir:

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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