

Improving how medical devices are checked and monitored across the European Union

An introduction for patients and consumers



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 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.



What is a medical device?

Medical devices cover a wide range of different products and can take the form of instruments, wound dressings, external support products, and diagnostic equipment to name a few. Most importantly, they are products used to treat or diagnose people and are different from drugs/medicines in the way they work. These devices will be used by all of us at some point in our lifetime. Medical devices are given risk classifications from low-risk to high-risk. An overview of risk classification under the new regulations is provided in the table below.

Risk <i>Examples of medical devices/ in-vitro diagnostic medical devices and their risk classification</i>	Medical Devices (MDs) 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	In-Vitro Diagnostic Medical Devices (IVDs) 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
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More than 600,000 medical devices can be found across every health centre, hospital and in many households across Europe, benefitting people in different ways, every day. Just as medicines must meet a certain standard of safety and efficacy before they can be sold, medical devices must meet a number of essential requirements before they are made available to users. Medical devices which have satisfactorily met the requirements for safety and performance, must be CE marked as a means of the manufacturer declaring their claim that the relevant requirements within EU law have been met. [Find out more about the CE mark.](#)



What checks are carried out on medical devices and by whom?

Enforcing the law and acting where requirements are not met

Competent authorities are organisations in each member state which are responsible for overseeing the medical device industry in their own territory. This work is known as 'market surveillance'. They also work closely with each other to share information. Market surveillance also involves competent authorities receiving and acting on information about faulty devices, performing on-site and off-site inspections of manufacturers of medical devices and on [notified bodies](#).

Recent events in the medical devices industry have highlighted the need for improved coordination between member states in the area of market surveillance. One of these events was the 'Poly Implant Prothese' (PIP) scandal that emerged throughout 2010/2011 and that involved a medical device manufacturer 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 silicone¹.

The scandal highlighted the risk that a fraudulent manufacturer could still 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 in a more timely manner.

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



What is the joint action on market surveillance doing?

Bringing European medical device regulators together

Joint actions are projects which are designed to encourage competent authorities across Europe to work together more effectively. The Joint Action on Market Surveillance of Medical Devices (JAMS) aims to reinforce market surveillance between member states. Best practice, training, knowledge, and resources will be shared to increase public health protection in the medical devices sector.

The UK's Medicines and Healthcare products Regulatory Agency (MHRA) is coordinating and managing the work of JAMS. The Dutch Healthcare Inspectorate (IGZ) and Ireland's Health Products Regulatory Authority (HPRA) are leading the two work packages which will deliver key outputs intended to meet the overall objectives of JAMS. The joint action is divided into five work packages:

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)



How does JAMS relate to you?

Increasing the protection of public health

Medical devices are used every day at home and in healthcare settings, like hospitals, clinics, and doctors' surgeries, to assist in the diagnosis, treatment, and care of patients. It's likely that you have already been in contact with some of them.

The Joint Action on Market Surveillance of Medical Devices (JAMS) aims to introduce improvements and recommendations that will affect the standard of service provided by competent authorities in the work of market surveillance. This will mean medical devices and their manufacturers will be monitored more effectively by regulators, information will be shared more effectively about safety concerns, and therefore consumers will be able to have more confidence in the medical devices they use.

The competent authorities for the 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. You should contact them if you wish to contribute directly to the project (see page 6 for contact details).

What can you do to contribute to the work?

Your actions make a difference

Effective market surveillance is reliant upon the information you provide about the medical devices you use. Each competent authority has dedicated staff and contacts working in the area of market surveillance.

Please report any problems relating to defective or suspected faulty medical devices, especially where a user/patient has been negatively affected while using/ being near such a medical device.

[You can find the right vigilance contacts for your country here.](#)

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.

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**
- **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**
- **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.

Partner support for the Joint Action

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 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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