Medicines & Healthcare products Regulatory Agency

MHRA

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

European Commission

Medical devices

Medical devices cover a wide range of products, from sticking plasters to hip replacements, from contact lenses to wheelchairs and implanted pacemakers, blood glucose meters and pregnancy test kits. Medical devices can be found in every health centre, hospital and many are used in households across Europe. The sector is highly innovative and it includes manufacturers of both large multinational groups and small-to-medium sized enterprises (SMEs).

Manufacturers of medical devices are responsible for placing compliant products that are CE marked on the market.

About CE Marking

To make sure medical devices are acceptably safe and perform as intended, market surveillance authorities check and ensure that medical devices comply with the requirements of the legislation and do not endanger public health and safety.

The letters "CE"' appear on many products that are traded on the single market in the European Economic Area (EEA). A CE mark indicates that a product meets the requirements for safety and performance for medical devices under European law.

The CE mark indicates:

- the manufacturer has checked that the medical device meets EU safety and performance requirements
- the device's compliance with EU legislation
- an independent pre-market review of this compliance has been conducted by a specialist certification organisation called a notified body
- compliance to allow the free movement of products within the European market

A notified body is an independent specialist certification organisation that has been designated by an EU Member State to assess medical devices based on the specific expertise of that notified body. Notified bodies are overseen by authorities like MHRA on an ongoing basis to ensure they are conducting their assessments effectively.

About Joint Action and EU added value

Joint Actions are designed to encourage Member States to work together across Europe. European added value can be achieved in many different ways such as:

- Implementing EU legislation, achieving economies of scale, promoting best practice, fostering EU networks.
- Working together at European level, maximising available resources and coordinating efforts have a greater impact than the sum of what could be achieved by several national initiatives.

About this Joint Action

The Medicines and Healthcare products Regulatory Agency (MHRA) signed a Grant Agreement with the Consumers, Health, Agriculture and Food Executive Agency (Chafea) – an executive agency of the European Commission – to lead a Joint Action on Market Surveillance of Medical Devices. The Joint Action is jointly funded by Chafea and Competent Authorities having signed an agreement with Chafea.

Aims and objectives

Increasing the protection of public health

The Joint Action on Market Surveillance of Medical Devices aims to reinforce market surveillance between Competent Authorities and to harmonise the approach taken across all Member States. Best practice, training, knowledge and resources will be shared between Competent Authorities to increase the protection of public health achieved by the medical devices sector. This will help to ensure that medical devices are acceptably safe, perform as intended and do not pose unnecessary risks to patients and users in the EU.

An important aim is to improve coordination and help Competent Authorities with fewer resources to develop skills and capacity through a European market surveillance network for medical devices. It will help to ensure a consistent and proportionate approach across all Competent Authorities in joint manufacturer inspections and clinical process and resource development.

The work of the Joint Action will be finalised in October 2019.

Who is affected by the Joint Action?

There are a number of target groups who are affected by the Joint Action in different ways.

Patients and consumers of medical devices

Safer medical devices for all
Improving the European market surveillance system through consistent and ongoing dialogue with all stakeholders will improve protection of public health and lead to more confidence and stability in the regulatory system. Reinforcing the market surveillance system will also help to ensure that the EU regulatory system can allow for safe and timely introduction of new devices offering a greater array of diagnostic and therapeutic possibilities.

Health care professionals and clinicians

Improved patient safety and public health
Safety and performance of medical devices will be reinforced by the work of the Joint Action. Health Professionals and clinical experts could have at their disposal safer and more effective medical devices. The Joint Action will also seek to engage clinical experts more directly with the regulatory system through defined communication processes.

Competent Authorities

Directly affected by the Joint Action results
Improved cooperation between Competent Authorities will foster opportunities for best practice, consistency and collaboration. This will also result in optimising the expertise and resources available within the network leading to improved performance and a more efficient and effective regulatory system. The development of tools identified throughout the work packages will facilitate this cooperation and collaborative working within the network.

Notified bodies, manufacturers, suppliers and service providers

Work with us to improve medical devices safety
Establishing common principles and best practice in the areas of manufacturer inspections and clinical data assessment will have an impact on many of the actors in the medical devices sector and help the development of the European industry, as safer and more effective products are more competitive in a world market. Actors include:

- Notified bodies
- Manufacturers and authorised representatives of medical devices
- Critical suppliers
- Original equipment manufacturers (OEMs)
- Critical service providers
- Industries Associations.

Delivering the Joint Action

Our approach to delivering the Joint Action will be through:

- Delivering work packages
- Working with partners to help support the delivery or work packages
- Communicating the outcomes to our target groups

Work Packages

The Joint Action is divided into five Work Packages to help with sharing the work load.

Work packages 1-3: Coordination; Dissemination; Evaluation, led by UK

MHRA in the UK is responsible for:

- **Coordination of the project:** MHRA has to verify that the Joint Action is completed on time, within budget, and with high–quality deliverables
- **Dissemination of the information:** MHRA has to collect and circulate the deliverables to the target groups
- **Evaluation:** MHRA has to check that the implementation of the project is developed as planned.

Work package 4: Joint Manufacturer Inspections, led by the Netherlands

Health Care Inspectorate
Ministry of Health, Welfare and Sport

As part of their work package to improve manufacturer inspections, the Health Care Inspectorate (IGZ) in the Netherlands, in collaboration with European partners, is responsible for:

- **Developing methods, agreed tools and guidance for a joint, consistent and proactive approach to manufacturer inspections by Competent Authorities:** At the beginning of the project, it is expected to identify various approaches and differences between Competent Authorities as how they approach market surveillance. A guidance document intended to define and specify good practice by sharing and exchanging information on performing inspections will be developed.
- **Establishing specific inspection scopes and objectives to complement those conducted by conformity assessment bodies:** The joint manufacturer inspections will be complementary to the existing system in order to reinforce the current performances and permit the harmonisation of manufacturer inspections and not current national manufacturer inspections. The Netherlands will develop a harmonised guidance regarding joint inspection planning strategies.
- **Identification of sources of information to be used to focus on during the Joint inspections to achieve maximum public health impact:** An inspector training course will be developed to prepare inspectors to perform intended joint inspections and to perform inspection according to the joint approach.
- **Developing and delivering collaborating mechanisms designed to maximise the efficiency and effectiveness of resource deployment:** Competent Authorities will initiate a joint manufacturer inspection regime to reinforce market surveillance.

Work package 5: Clinical Process and Resource Development, led by Ireland

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

As part of their work package to improve clinical process and resource development, the Health Products Regulatory Authority (HPRA) in Ireland is coordinating the following:

- **The identification and establishment of communication platforms and protocols:** A communication platform will allow Competent Authorities the opportunity to discuss market surveillance issues in particular in the clinical arena that affect some or all European Competent Authorities in real time and provide a platform to discuss specific market surveillance issues in a confidential setting.
- **Establish current practices and identify development and/or training needs in the evaluation of clinical data by authorities:** Based on the findings from workshops and surveys, a training strategy will be defined. Training material will be developed to provide practical guidance on the assessment and review of clinical data as part of market surveillance activities.
- **Identify and prioritise medical devices which require development of common specifications to define clinical criteria for safety and performance:** Under the new proposals for a regulation on medical devices and in vitro diagnostic medical devices, common specifications will be developed addressing the clinical requirements for safety and performance. The work of the Joint Action will help identify the priorities for developing common specifications and help inform the activities for implementing the new regulations.

Working with partners

There are two types of partners involved in the Joint Action: beneficiaries and collaborating stakeholders.

- **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 Chafea and 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.

Communicating the outcomes and keeping in touch

Further communication will be made to the target groups throughout the duration of the Joint Action.

Visit **camd-europe.eu** to find out more about this progress of the Joint Action.

Partner support for the Joint Action

Key:
Beneficiaries
Collaborating stakeholders


UK

MHRA: ***Joint Action leader***
Lead for Work Packages 1-3: Coordination; 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


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


CROATIA

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


CYPRUS

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


CZECH REPUBLIC

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


DENMARK

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

ESTONIA

Terviseamet: *Collaborative 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: *Collaborative 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: *Collaborative stakeholder partner in Work Package 4: Joint Manufacturer Inspections*

NORWAY

Norwegian Directorate of Health Hesedir: *Collaborative 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*

SWEDEN

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

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