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CAMD
Competent Authorities for Medical Devices

Joint Action on Market Surveillance of medical devices

JAMS Final report – Layman version
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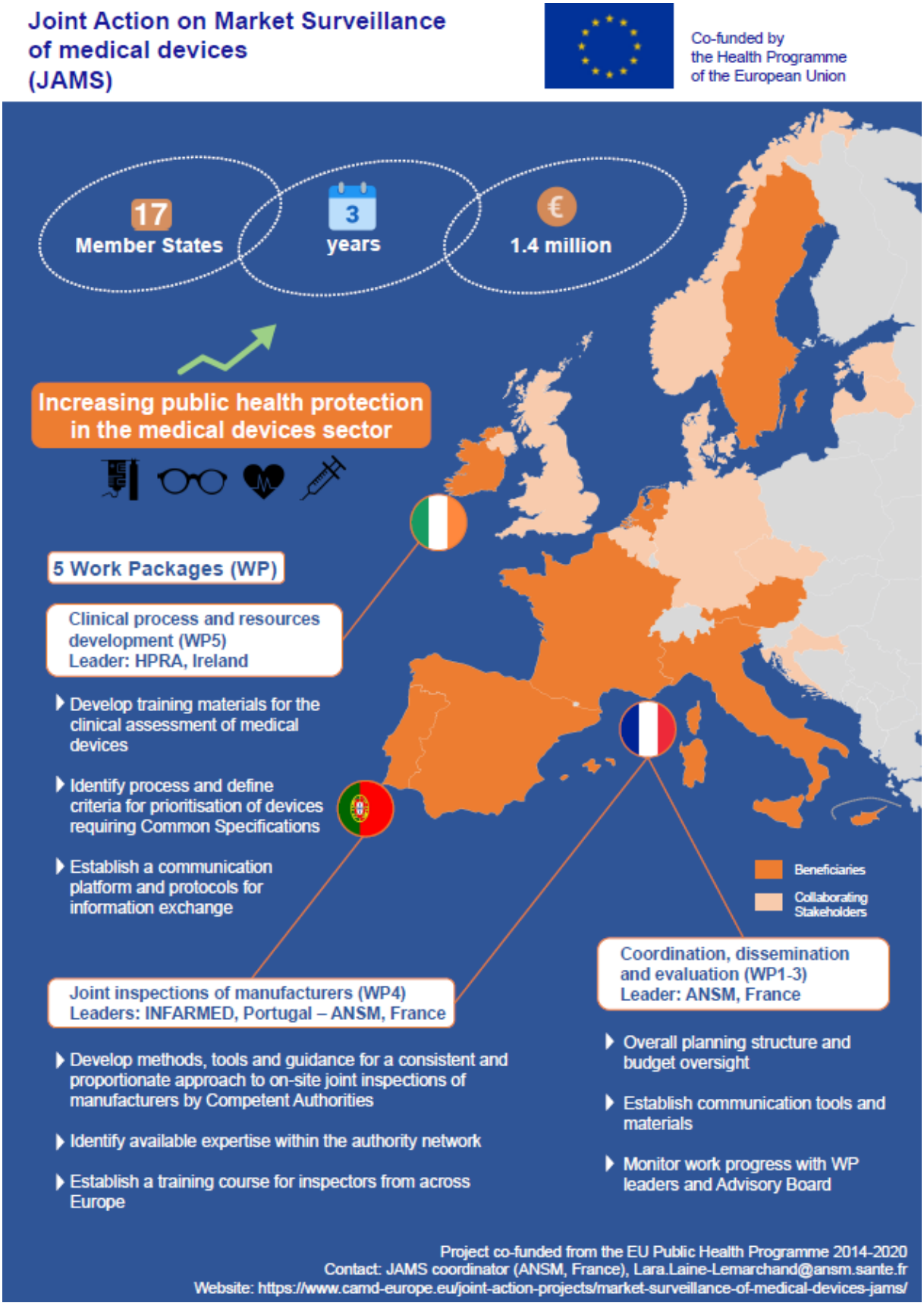
Agence nationale de sécurité du médicament et des produits de santé

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Infarmed
Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.



Poster created for the EU Health Programme Conference in September 2019. More information available on the CAMD website.

Foreword

This report is part of the project / joint action “723964 / JAMS” which has received funding from the European Union’s Health Programme (2014-2020).

The work completed to date by the Joint Action on Market Surveillance would not have been achieved without the tireless efforts of beneficiaries, collaborating stakeholders, third countries and willing volunteers who all share the same vision of improving the safety of medical devices within Europe, through proactive and collaborative market surveillance.

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I. General summary of the Joint Action

The Joint Action on Market Surveillance of medical devices (JAMS) was set up to reinforce market surveillance between Competent Authorities and to harmonise the approach taken across all Member States. Launched in October 2016, the Joint Action gathered 18 countries and was implemented over 39 months, ending in January 2020.

Through this project activities and outputs, best practice, training, knowledge, and resources have been shared between National Competent Authorities (NCAs) to increase the protection of public health achieved by the medical devices sector. This helps to ensure that medical devices are safe, perform as intended and do not pose unnecessary risks to patients and users in European Member States.

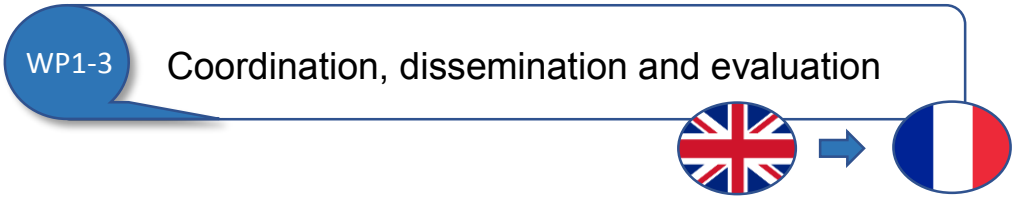
An important aim has been to improve coordination and help NCAs with fewer resources to develop skills and capacity through the European market surveillance network for medical devices. It fosters a consistent and proportionate approach across all NCAs in joint manufacturer inspections, in coordinating on EU high profile issues and in clinical resource development.

The need for a collaborative effort between NCAs to improve oversight of the medical devices market, enhance the processes used for information sharing and coordinate market surveillance activities has been highlighted further by high profile events in the past (e.g. PIP breast implant) and legislative changes within the medical devices sector, reflected in the medical device regulations. This Joint Action has also helped to prepare for the implementation of the EU Regulation where a better cooperation between NCAs is expected and encouraged.

JAMS has been contributing directly to the achievement of the objectives of the Health Programme by delivering tools and guidance to aid the implementation of joint inspections of manufacturers and to enhance the clinical processes and market surveillance coordination between Member States.

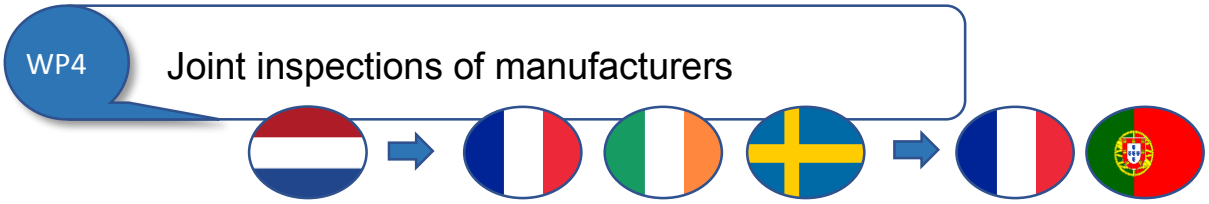
This Joint Action has also resulted in improvements to the level of scrutiny which medical devices within Europe are subjected to by NCAs. The regulatory systems in place governing the medical devices industry are better equipped to efficiently and effectively maintain oversight of the industry. This has a positive impact on the safety of medical devices in Europe, and the level of confidence which patients, consumers and healthcare professionals can have in the European medical devices market. As such, this initiative is an important contribution to the implementation of medical device regulations. Through its dissemination work, the Joint Action has also been further promoting the importance of the contributions which all stakeholders are able to make towards market surveillance of medical devices.

The Joint Action is divided into 5 work packages (WPs). Each of them focuses on achieving specific objectives which contribute to the overall aims described above. The various objectives of the work packages are summarised on the next page.



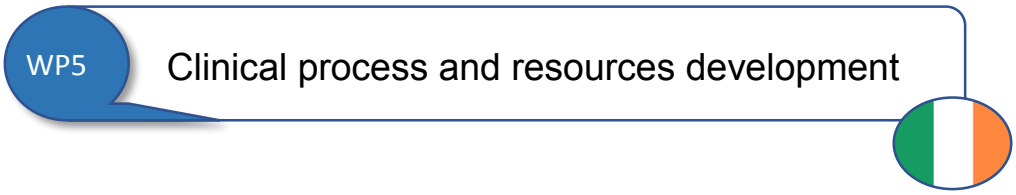
Work packages 1-3 Coordination, dissemination and evaluation: These WPs are specifically about facilitating the work of the Joint Action through monitoring of the project plan, producing resources which communicate and promote the work of the project with key stakeholders and critically evaluating the progress of the project to ensure the objectives of the Joint Action are realised.

At the start of the joint action, WP1, WP2 and WP3 were led by the Medicines and Healthcare Products Regulatory Agency (MHRA) of the United Kingdom. The JAMS coordination role has been transferred to the National Agency for the Safety of Medicines and Health Products (ANSM) of France in April 2019, following the MHRA's announcement of its withdrawal as a Joint Action beneficiary.



Work package 4 Joint inspections of manufacturers: For a harmonised inspection approach: delivering tools, templates, information resources and procedures to facilitate joint inspections of manufacturers. An inspector training course has also been developed to prepare inspectors to perform joint inspections according to an agreed approach.

WP4 was led by the Healthcare Inspectorate (IGZ) of the Netherlands at the start of JAMS. The French ANSM, the Health Products Regulatory Authority (HPRA) of Ireland and the Medical Products Authority (MPA) of Sweden jointly took over this coordination role. The National Authority of Medicines and Health Products, I.P. (INFARMED) of Portugal has been co-leading WP4 with ANSM from February 2019 to the end of the Joint Action.



Work package 5 Clinical process and resource development: Delivering a process for prioritisation of common specifications for medical devices (where a need is confirmed), a clinical training programme, and identifying an effective communications platform which enhance and facilitate coordination on high profile market surveillance issues within the EU network which the new regulations introduce. The Health Products Regulatory Authority (HPRA) of Ireland has led the WP5 activities since the start of JAMS.

II. Implementation methods

The methods through which the aforementioned objectives have been met included:

- Face to face meetings as planned at various stages throughout the project, including workshops and WP leaders meetings;
- Webinars and teleconferences at strategic intervals within the project plan, as well as ad-hoc web and teleconference meetings as the needs arose;
- Online collaboration and document sharing using the Competent Authorities for Medical Devices (CAMD) website members area;
- Dissemination of information to key audiences using leaflets, websites, social media, and oral presentations in accordance with the dissemination plan;
- Development of evaluation tools.

The JAMS implementation has also been supported by the engagement of stakeholders from the medical devices sector who provided advice and steered to the Joint Action at strategic intervals. These stakeholders were represented in the JAMS Advisory Board, composed of the WP leaders and of representatives of the European Commission, the Standing Committee of European Doctors (CPME), Medtech Europe and Team-NB.

III. JAMS work packages activities and results

1. Work package 1 - Coordination

WP1 has ensured that technical and financial reports are received from all beneficiaries at the required intervals. It has successfully continued to manage and coordinate the financial and technical aspects to ensure the project plan is implemented. WP1 prepared and submitted the JAMS interim and final reports.

WP1 has implemented monthly teleconferences to ensure that WP leads are able to regularly discuss progress, escalate concerns, exchange knowledge and share best practices across working groups. Numerous phone calls and teleconferences have taken place during the reporting period. At strategic intervals the leads of each work package have also formally met face to face to review progress and forward plan. Five meetings of this project core group occurred within the reporting period. The WP leaders also met face to face informally during CAMD meetings.

Moreover, WP1 organised six JAMS advisory board meetings, allowing stakeholders to provide direction and input into the project delivery.

JAMS has successfully achieved all the expected deliverables. Regarding WP1, the interim (D1.1) and final reports (D1.2), of which this publishable summary constitutes a high-level overview, provide information on the results achieved during (respectively) the first reporting period, October 2016 - April 2018, and the second reporting period, May 2018 - January 2020.

2. Work package 2 - Dissemination

The dissemination work through WP2 has resulted in the publication of a general leaflet (D2.1) designed to inform stakeholders (including patients, healthcare professionals, notified bodies and manufacturers) of the scope, purpose and aims of the Joint Action. Four additional stakeholder specific leaflets (extra deliverable) have also been developed and published. The leaflets aim to inform specific stakeholders on the Joint Action as well as to explain the role of stakeholders within market surveillance of medical devices, in a more engaging manner.

JAMS also created the website (D2.2) of the CAMD network to facilitate dissemination efforts on the Joint Action and on the network's market surveillance activities. In addition to presenting specific web-pages on JAMS, the CAMD website hosts the general and specific leaflets, as well as all the JAMS technical deliverables on the public area or on the secure storage space of the website (depending of the dissemination level of each deliverable). It has been beneficial to project participants since it has provided an online centralised hub where information and data have been shared and stored for the coordination and progression of the work of the Joint Action. It has also been useful to inform stakeholders on the project progress, events and outputs (specific pages on JAMS, news section of the website).

To ensure good information of stakeholders on the project results, JAMS organised the "JAMS Stakeholder Conference" on December 12th 2019 in Brussels. The conference brought together representatives from 24 Competent Authorities for medical devices, the European Commission (DG GROW, DG SANTE, CHAFEA) and 15 key stakeholder representatives. The presentations were disseminated by emails to participants and made available for download on the CAMD website.

In addition to these dissemination efforts, members of the Joint Action have been active in attending numerous meetings at both a national and European network level to ensure that the work of JAMS is communicated to relevant stakeholders. In this way, NCAs, notified bodies, manufacturers, other economic operators, patients and healthcare professionals have all been targeted. The advisory board, composed of stakeholder representatives, has also been a dissemination channel for WP leaders on the Joint Action progress and results.

3. Work package 3 - Evaluation

During the project lifetime, WP3 activities aimed at monitoring the implementation process, improve the work in progress and increase the likelihood of the project success. In addition, at the end of the Joint Action, an outcome evaluation was performed in order to assess whether the project objectives were achieved (results) and whether the outcomes met the needs of the target groups (quality). This final evaluation took the form of an evaluation report which was prepared using two evaluation methods: surveys and documentation review. It shows that both in terms of results and quality, the project was successful. All the deliverables were achieved and, when they could be measured, the foreseen success criteria were met. On the dissemination efforts, the JAMS evaluation report shows that the dissemination activities, notably the JAMS Stakeholder conference, were successful in informing Member States and stakeholders on the Joint Action objectives, progress, and outputs.

4. Work package 4 - Joint inspections of manufacturers

WP4 activities

Over the 3 years of JAMS, WP4 organised six workshops and seven additional face to face coordination meetings between the WP leaders. Numerous teleconferences have also taken place, either with all WP4 participants or only between the WP leaders.

JAMS WP4 has established a process for joint inspections of manufacturers by promoting convergence through guidelines and best practices. Three linked and interdependent guidance have been issued:

- Deliverable 4.1 “Proposals: Joint Inspections of Medical Device Manufacturers in Europe”;
- D4.2 “Joint Inspections of European Manufacturers: Joint Inspection Initiation”;
- D4.4 “Joint Inspections of European Manufacturers: Guidance on conduct of Joint Inspection”.

In addition, a fourth deliverable (D4.3) consisted of the first European medical devices inspectors training and the establishment of both a Joint Inspector Group and an inspector expert group at the European level. The training course was held on November 27th-29th 2019, bringing together 74 participants from 28 countries.

WP4 has been keen to ensure the work produced is disseminated to the appropriate audiences. The proposal for joint inspections of manufacturer were shared with the Compliance & Enforcement working group for medical devices (COEN) working group, as well as with the participants of WP5. All the WP4 deliverables were shared with the European network of medical device regulators. They are available for download on the secured area of the CAMD website for NCAs.

WP4 main outputs

The WP4 deliverables provide NCAs with methods and tools for a consistent and proactive approach to manufacturer inspections as response to specific threats to patient and public health. The D4.1 “Proposals for Joint Inspections of medical device manufacturers in Europe”, along with the analysis of a survey which provides an overview of inspection practices across Europe, identifies a number of recommendations in the areas of definitions, inspector competence, prioritisation of joint inspections, joint inspection process and post-inspection activities. Anonymised data on current market surveillance practices across European NCAs gathered by WP4 has been used to help inform market surveillance implementation strategies in forums such as CAMD and COEN.

The D4.2 "Guidance for Joint Inspection Initiation" consists of a comprehensive guidance document on the initiation of the joint inspection process, identifying sources of information to be used for focusing joint manufacturer inspections. The D4.4 “Joint Inspections of European Manufacturers: Guidance on conduct of Joint Inspection” brings together a compilation of templates to be used by the inspection team to conduct a joint manufacturer inspection (before, on site and after the inspection). The work of WP4 partners has also led to the creation of a Joint Inspections Group (JIG) at the European level, which is supported by the European Commission and brings together inspectors from several NCAs.

In addition, WP4 has established the first European inspector training course (D4.3), providing training materials and intending to be the precursor of future events to improve market surveillance. The WP has also set up an inspector expert group (D4.3), identifying medical devices inspectors across Europe and mapping their competences and expertise. Using the competences map, training actions can be identified and contribute to the harmonisation of EU inspectors' qualifications.

5. Work package 5 - Clinical process and resources development

WP5 activities

Over the project lifetime, WP5 organised six workshops and regular teleconferences with all the work package participants. WP5 has produced several key deliverables in accordance with the defined milestones:

- Deliverable 5.1 consisting of an online communication platform, protocols for cooperation and process for expert engagement;
- D5.2 documents: training strategy document and training materials for clinical assessment;
- D5.3 papers: "Criteria and Process for Common Specification" and "Guidance documents developed for medical devices in regulatory regions outside the EU".

To inform their activities and ensure the relevance of their three deliverables, WP5 partners made sure to liaise with relevant EU working groups and relevant professional and technical societies. Particularly, the WP5 team prepared a lighter version of the training material, without any references to specific cases or confidential information, and shared the document with the interested stakeholders upon their request. All the WP5 deliverables were shared with the European network of medical device regulators. They are available for download on the secured area of the CAMD website for NCAs.

WP5 main outputs

WP5 has also successfully produced the expected deliverables. Firstly, a communication platform and a coordination process (D5.1) have been established to promote communication, foster cooperation, and coordination between NCAs on market surveillance for medical devices, in relation to assessment of clinical data. The D5.1 outputs facilitate greater exchange of information and help in establishing a common approach in market surveillance activities during the investigation stage of an issue within the network. WP5 has also developed a process for expert engagement for European coordinated market surveillance on medical devices.

Secondly, WP5 partners have issued a training strategy document outlining the training and development needs for clinical data assessment. A training material document has also been developed and disseminated to NCAs to encourage and facilitate trainings in this field. It is intended to help assessors to identify and better rationalise the public health risks they identify, as well as to provide some key principles with respect to how clinical assessors might engage with experts.

Thirdly, the D5.3 Criteria and Process for Common Specification consists of a guidance and template to help identify a process for prioritising medical devices that may require common specifications. An additional document has been developed to explore guidance documents developed for medical devices in regulatory regions outside the EU. These outputs are an important step towards identifying the high priority devices requiring common specifications development. They are very relevant for the EU Commission in developing common specifications in accordance with the new EU Medical Device Regulation.

IV. Achieved outcomes compared to the expected outcomes

The outcomes achieved by JAMS have fully met the expected outcomes foreseen at the start of the project. Through WP activities and its outputs, JAMS has achieved greater mutual understanding, collaboration and cooperation between participating EU Member States. It has made significant contribution to strengthening European cooperation and NCAs' capacities by providing them with guidance, tools and training opportunities.

On the one hand, JAMS WP4 has established a harmonised approach to manufacturer inspections and has developed harmonised inspection tools and mechanisms to foster efficiency across NCAs. Policies and practices of the EU Member States regarding manufacturer inspections have been shared and discussed between EU Member States and Commission services through CAMD interventions, surveys, deliverables dissemination and training.

Through the Joint Inspectors Group (JIG) created at EU level as a result of WP4 partners' efforts, manufacturers of medical devices will be inspected by experienced and trained inspectors of Competent Authorities, via a harmonized and transparent approach based on agreed tool-kits and methods. The JIG will perform joint inspections of manufacturers and ensure WP4 deliverables are used and evaluated during a pilot-phase of two years after the completion of JAMS. It will also support the continuous strengthening of the European network of inspectors started with JAMS. The JIG will help the Medical Devices Coordination Group in the development of the European market surveillance programme as foreseen in article 93 of the medical devices regulation and in the development of the tasks identified in point 6.3 of the CAMD roadmap for implementation.

On the other hand, JAMS WP5 has established one single communication platform for NCAs to share information and facilitate communication and cooperation within the network on market surveillance for medical devices, particularly in relation to assessment of clinical data. Collaborative approaches have been identified and coordinated work practices are now in place across the network regarding high profile market issues. The developed tools and guidance help improve transparency across the system, facilitate expert engagement and optimise resources. The work achieved also contributes to building a harmonised approach to clinical data assessment by NCAs. On top of the communication platform, the training strategy and materials developed by WP5 are an important step to foster the harmonisation of practices and strengthen competences across the network.

WP5 has also elaborated a proposal paper on the process and criteria for consideration in justifying the need for common specifications. Along with a paper on available clinical guidance

across non-EU regulatory networks, this document lays the ground for the development of common specifications in accordance with the new EU medical device regulations.

All in all, by strengthening the regulators network and providing them with collaborating mechanisms, the JAMS outputs have contributed to give an answer to trends of increasing diversity, complexity and amount of medical devices on the market. The training activities took into account these evolving trends and made sure to cover emerging topics such as software.

Through its training activities, JAMS has allowed Member States to share their expertise, competences and knowledge. By providing NCAs with meeting and experience-sharing opportunities, JAMS has been strengthening the European market surveillance network and helping lower-resourced Member States develop skills and capacity in the network. The results are already being seen at field level with increased regular contact, information-sharing and collaboration between JAMS participants on their market surveillance activities.

Conclusion

JAMS has produced deliverables which are making significant contributions to the implementation of European regulations and enhancement of market surveillance practices, particularly in the fields of inspection and clinical data assessment and resources.

The Joint Inspection Group will play a key role in the joint inspection approach implementation and in the development of the European inspector network. Via the consistent and proactive approach developed through JAMS, joint inspections of medical device manufacturers in Europe support safety of the system and provide a specific response to threats on patient and public health. Closer collaboration and cooperation between Member States result in increased performance, increased efficiency, harmonised practices and optimised resources. Joint inspections via trained inspectors and closer cooperation across Europe will lead to better and safer medical devices for Union citizens.

The work achieved relating to clinical process and development contributes to harmonise the approach to the assessment and oversight of clinical data as part of the activities of medical devices NCAs. Through a consistent, robust and scientific approach to clinical data assessment, through each phase of the life-cycle, the quality of clinical data demonstrating the safety and performance of medical devices on the European market will improve and this in turn will lead to protection and enhancement of public health. The establishment of a coordination mechanism and building cooperation amongst Member States on clinical data assessment can be used as a basis for broader coordination and cooperation and this can be expanded to all areas of market surveillance in the future.

As a result of this Joint Action, the Competent Authorities' collaborative network is strengthened and public health is reinforced: providing tools and cooperation mechanisms to NCAs helps them ensure that medical devices across Europe conform to the requirements of the European regulation, in particular those relating to safety and performance.

The data collected through the evaluation activities, demonstrating the good level of satisfaction of stakeholders with the project, allow to establish recommendations for the JAMS outputs follow-up and for future Joint Actions. The positive feedback received at the 2019 JAMS Stakeholder Conference and the evaluation report indicate the JAMS deliverables are and will be used and followed-up by National Competent Authorities and the European regulatory network.

JAMS partners

The following countries and agencies have taken part in the JAMS activities, contributing in a variety of ways to the outcomes of this work.

Beneficiaries


AEMPS


AGES


ANSM


CYMDA


HPRA


IGZ


INFARMED


MPA


SANITA

Collaborating Stakeholders


BfArM


DKMA


FAMHP


Halmed


MHRA


MZCR


NoMA


TERVISEAMET


VI

Open Keywords

Medical device, competent authorities, market surveillance, medical device regulation, joint inspection, clinical, clinical resource, clinical expert, expert, common specification, training, communication, prioritisation, best practice, guidance, public health, patient, notified body, healthcare professional, medical devices manufacturers

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