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Joint Action on Market Surveillance (JAMS) 2.0: Europe at the ANSM on 14 and 15 November 2023

VIE DE L'AGENCE - INSTANCES

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In the context of the "EU4health" programme, the ANSM is leading the European JAMS 2.0 project. This project intended to reinforce market surveillance of medical devices (MD) and in vitro diagnostic medical devices (IVMD) brings together 24 European countries. Work on the project will continue until the end of 2026.

On 14 and 15 November, we will play host to work package leaders coordinating eight working groups as part of the European JAMS 2.0 (Joint Action on Market Surveillance of medical devices) project at our premises.
This meeting, which will also be attended by representatives from the HaDEA (European Health and Digital Executive Agency) and the European Commission, marks the official launch of the project, which will be conducted over a period of three years.

JAMS 2.0 follows on from the first JAMS project (2016-2019), for which the ANSM took over coordination following the withdrawal of the UK agency MHRA. JAMS 1 resulted in improved mutual understanding, collaboration and cooperation between the 18 participating states. It reinforced the capacities of national competent authorities by providing them with technical guides, tools and training opportunities, and also helped to improve the general level of surveillance of medical devices in Europe.

JAMS 2.0 aims to ensure the continuous improvement of collaboration between competent authorities in the field of MDs/IVMDs, be it through joint inspections, signal detection operations or harmonised market surveillance campaigns. The objective is also to create training tools and facilitate the sharing of information between competent authorities.

This project, with a total budget of €4.8 million, funded to the tune of 80% by the HaDEA and 20% by the consortium member states, comprises eight working groups, each led by a national agency:

1. **Coordination (France)**: overall coordination of the project, to ensure that it is implemented properly, that the budget is monitored and that deadlines are met.
2. **Dissemination (France)**: actions to promote the project and its results to all stakeholders.
3. **Assessment (Poland)**: development of specific indicators to monitor the project's progress. An assessment plan and monitoring tools will also be developed to analyse the implementation of the project.
4. **Sustainability (Slovenia)**: actions to identify and control aspects that could threaten or contribute to the viability of the project and its results.
5. **Signal detection and vigilance (Malta)**: development of harmonised European vigilance signal detection practices.
6. **Inspection (Belgium)**: harmonisation of inspection activities across Europe through joint inspections and training activities.
7. **Market surveillance campaign (Spain)**: development of standardised European criteria and procedures in order to conduct harmonised market surveillance campaigns.
8. **MD/IVMD university (France)**: creation of tools for training and experience-sharing between competent authorities on MD/IVMD market surveillance topics.

The results of JAMS 2.0 are expected by the end of 2026.

List of participating countries: Austria, Belgium, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Malta, Netherlands, Norway, Poland, Portugal, Romania,

Slovenia, Spain and Sweden.

For more information on the European JAMS project:



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