EU4Health to support implementation of the Regulations on medical device

Information Session - 10th May 2022

European Commission – DG SANTE

Unit B6 – Medical Devices and HTA

Joint Action –

Reinforced market surveillance of medical devices and in vitro medical devices

European Commission

EU4Health 2022 Work Programme and Medical Devices

JOINT ACTION on: reinforced market surveillance – objective

- To reinforce market surveillance between Member States by sharing information, best practice, training, knowledge, and resources to increase public health protection in the medical devices sector.

EU4Health 2022 Work Programme and Medical Devices

JOINT ACTION on: reinforced market surveillance – Policy context

- Reinforced market surveillance is a key feature in the new regulatory framework
  - requires Member States' to coordinate their market surveillance activities (incl. requirements for device checks and handling of non-compliances), cooperate and share information with each other and with the Commission to provide for a harmonised and effective implementation of market surveillance in all Member States
  - calls on the Commission to provide the necessary support to Member States' authorities to coordinate and ensure that the new regulatory system is uniformly implemented at Union level.
- There is a need to support Member States in strengthening coordination considering the highly decentralised market access path for medical devices.
- The EPSCO Council Conclusions in June 2021 welcomed strengthening joint efforts.
- Member States have called for increased coordination and cooperation on market surveillance activities and to build on the previous joint action on market surveillance financed under the 3rd Health Programme.

European Commission

EU4Health 2022 Work Programme and Medical Devices

JOINT ACTION on: reinforced market surveillance * – WHAT

(a) support regular exchange of market surveillance information between Member States' competent authorities, […] and collaboration on enforcement activities including capacity building activities e.g. assessment of non-compliances

(b) support the cooperation of inspectors from national competent authorities responsible for market surveillance of medical devices […]

(c) support joint inspections of manufacturers of medical devices, and other economic operators as appropriate, to be performed by a team of inspectors from different Member States […] with a view to harmonisation of inspections at Union level (

* *EU4Health Work Programme 2022 pages 72,73*

European Commission

EU4Health 2022 Work Programme and Medical Devices

JOINT ACTION on: reinforced market surveillance –results/outcome

The expected results include:

- securing a smooth and timely implementation of the MDR/IVDR requirements for market surveillance and increasing coordination and work-sharing amongst Member States,
- capacity sharing and building up of expertise on market surveillance,
- aligning produces for performing device checks (inspections),

The joint action will contribute to the increased safety of medical devices by ensuring that non-compliant devices are kept off the Union market.

Thank you

European Commission