Market Surveillance

Safeguarding market integrity

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Introduction

- Market surveillance is the activity carried out by authorities to ensure that products on the market are conform to the applicable laws and regulations and comply with the existing EU health and safety requirements. It is crucial to keep the European market safe and to foster trust among consumers and economic operators. It also helps maintain a level playing field to those companies that comply and thus avoid losing market share to rogue traders.

- This report provides information on Member States' reviews and assessments of the functioning of market surveillance activities carried out between 2010 to 2016 period based on data from the European Commission ("EC"). This intends to give businesses an indication of how European Union ("EU") countries are likely to ensure effective surveillance of the artificial intelligence ("AI") market under the EU AI Act (the "EU AI Act"). These are drawn from insights relating to medical devices – an equivalent product to AI systems – across five countries, including key insights (average) as well as focus areas.

- **Article 74(2) (Market surveillance and control of AI systems in the Union market)** of the EU AI Act states, "…….*the market surveillance authorities shall report annually to the Commission and relevant national competition authorities any information identified in the course of market surveillance activities that may be of potential interest for the application of Union law on competition rules. They shall also annually report to the Commission about the use of prohibited practices that occurred during that year and about the measures taken.*"

Key Insights

High Incidence of Product-Related Accidents/User Complaints: The significant increase in the number of product-related accidents per user (498.2) in the 2010-2013 period raises concerns about the safety and quality of medical devices in the sector. This emphasizes the need for more robust market surveillance activities to address and mitigate potential risks, especially with emerging technologies like AI systems that may introduce new complexities.

Proactive Inspection Approach with Customs Collaboration: The high number of self-initiated inspections (20) and inspections prompted by customs (17.6) reflect a proactive surveillance approach. Collaboration with customs further indicates an awareness of the potential for international trade to impact the quality and safety of medical devices. This proactive stance aligns with the evolving landscape of medical devices, including those incorporating AI systems, where early identification of risks is crucial.

Limited Finding of Non-Compliance and Effective Corrective Measures: The relatively low number of inspections resulting in non-compliance findings (13.2) suggests that a significant portion of the inspected medical devices comply with regulations. Moreover, the high number of corrective actions taken by economic operators (8.4) indicates a cooperative industry response to identified issues. This may signify a positive trend in terms of the industry's commitment to maintaining compliance, which is relevant when considering the integration of AI systems in medical devices.

Budget and Staffing Challenges: The budget available to market surveillance authorities, both in nominal terms (€1,231,496.4) and as a percentage of the total national budget (0.00000578%), is relatively low. Additionally, the available staff (8.704 full-time equivalent units) and inspectors (1.2 full-time equivalent units) may pose challenges in adequately monitoring and regulating the growing and technologically complex medical devices market, including those incorporating AI systems. Adequate resources are crucial to ensuring thorough assessments and evaluations of AI-driven devices that may have unique risks and complexities.

Limited Cross-Border Collaboration: While there is evidence of collaboration with other Member States (2.6 inspections), the relatively low number suggests a potential area for improvement. Given the international nature of the medical devices market, fostering stronger collaborations with other countries is essential. This becomes particularly relevant in the context of AI systems in medical devices, where standardized approaches and shared knowledge can contribute to more effective market surveillance activities on a global scale.

Cyprus

Proactive Inspection Approach with Limited Resources

The data suggests a proactive approach to market surveillance with all 50 inspections being self-initiated. However, the relatively low budget (€94,000) and limited staffing (4 full-time equivalent units) pose challenges. This highlights the importance of optimizing resources and potentially adopting more efficient methodologies, especially when dealing with emerging technologies like AI systems in medical devices, which may require specialized knowledge and additional surveillance efforts.

Effective Industry Cooperation and Compliance Measures

The high number of corrective actions taken by economic operators (31 out of 34 non-compliance findings) indicates a cooperative industry response. This suggests that the market surveillance activities have been successful in fostering compliance among economic operators in the medical devices sector. This cooperative approach is vital when considering the integration of AI systems, where adherence to regulatory standards is crucial for ensuring the safe and effective use of these advanced technologies in healthcare.

Limited Cross-Border Collaboration

The absence of inspections where other Member States were invited to collaborate (0) points to a potential gap in international cooperation. Given the global nature of the medical devices market and the potential inclusion of AI systems, which often involve cutting-edge technologies, enhancing collaboration with other Member States becomes crucial. Shared insights and best practices can contribute to more effective surveillance of evolving technologies, fostering a harmonized approach to ensuring the safety and quality of medical devices across borders.

Denmark

Low Inspection Activity with Minimal Proactive Measures

The data indicates a low number of inspections (18) during the 2010-2013 period, with no self-initiated or reactive inspections. This suggests a less proactive approach to market surveillance in Denmark during this timeframe. For the effective oversight of medical devices, including those incorporating AI systems, a more proactive stance is typically required to identify and address potential risks early in the product lifecycle.

Limited Non-Compliance Findings and Lack of Corrective Actions

The absence of findings of non-compliance and corrective actions taken by economic operators suggests a relatively compliant industry or potentially a lack of rigorous enforcement. While this could reflect positively on the industry's commitment to regulatory standards, it may also indicate a need for more thorough surveillance, especially in the context of emerging technologies like AI systems. Vigilant monitoring is essential to ensure that medical devices, including AI-driven ones, adhere to safety and quality standards.

Substantial Budget Allocation with Limited Impact

Denmark allocated a substantial budget (€2,032,300) to market surveillance authorities, but the impact appears limited given the low number of inspections and absence of proactive measures. This suggests a potential mismatch between the allocated resources and the enforcement activities carried out. When considering the incorporation of AI systems in medical devices, which may introduce new complexities, optimizing resource allocation becomes crucial to ensure effective oversight and regulatory compliance in the rapidly evolving healthcare technology landscape.

*All data sourced from European Commission (2023)

Latvia

Effective Reactive Measures and Limited Resources

The data suggests that market surveillance activities in Latvia during the 2010-2013 period were characterized by a notable number of reactive inspections (5 out of 34 total inspections). While this indicates a capacity to respond to identified issues promptly, the limited resources, with only 1.5 full-time equivalent units for staff and inspectors, suggest potential challenges in sustaining such reactive measures. As the landscape evolves with the incorporation of AI systems in medical devices, ensuring sufficient resources for both proactive and reactive surveillance becomes critical to address emerging risks.

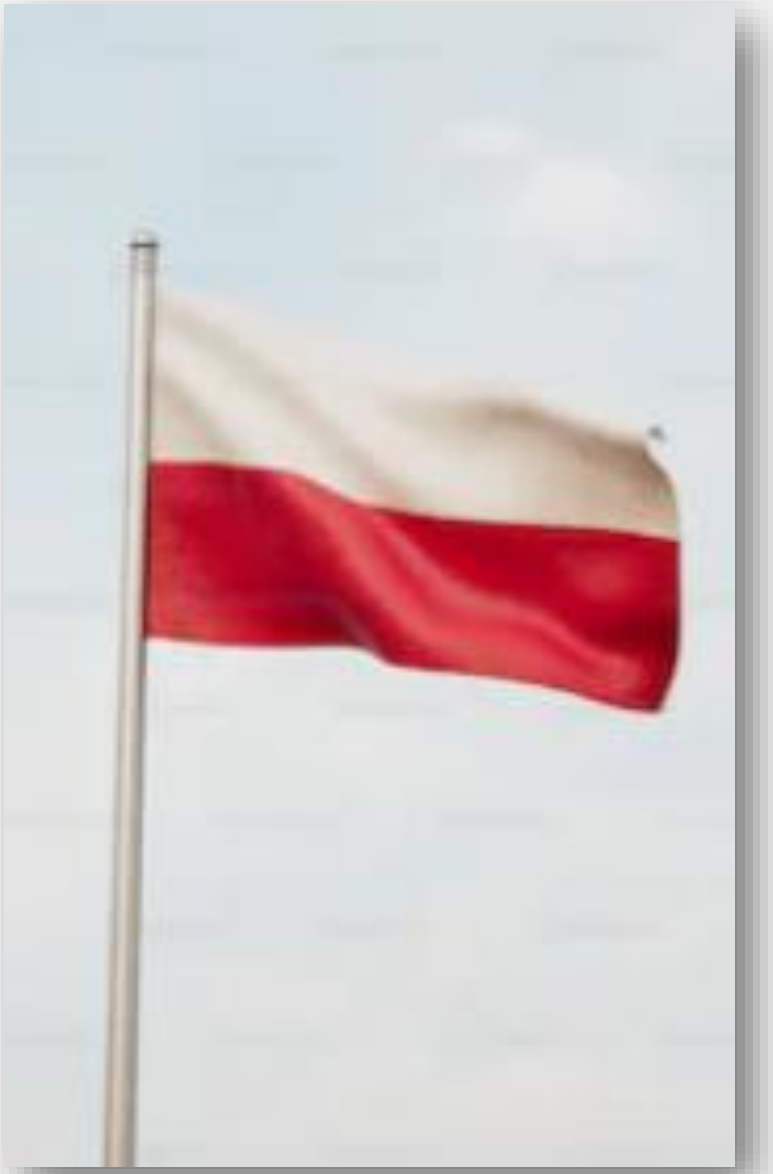
High Customs-Prompted Inspections with Minimal Collaborations

The substantial number of inspections prompted by customs (84) indicates an awareness of the impact of international trade on the medical devices market. However, the absence of collaborations with other Member States suggests a potential gap in leveraging shared insights and expertise. Given the increasing integration of AI systems in medical devices and the global nature of the healthcare industry, fostering international collaborations becomes crucial for harmonized surveillance and effective regulation.

Budget Constraints and Limited Compliance Measures

The nominal budget available to market surveillance authorities (€21,299) is relatively low, and there is no indication of corrective actions or voluntary measures taken by economic operators. This raises concerns about the adequacy of resources for enforcing compliance, especially in the context of emerging technologies like AI systems. Ensuring that market surveillance activities are well-funded is crucial for monitoring the safety and quality of medical devices, particularly those involving advanced technologies that may require specialized expertise and attention.

Poland



High Incidence of Product-Related Accidents with Limited Enforcement Actions

The substantial number of product-related accidents per user (516) raises concerns about the safety and quality of medical devices in Poland during the 2010-2013 period. However, the absence of findings of non-compliance, corrective actions, or voluntary measures by economic operators suggests a potential gap in enforcement actions. This highlights the need for more effective and targeted market surveillance activities, especially in the context of emerging technologies like AI systems, which may introduce new risks and complexities.

Proactive Inspection Approach with Budgetary and Staffing Challenges

The data indicates a proactive approach to market surveillance with both self-initiated and reactive inspections. However, the absence of budgetary allocations and staffing resources (0 in both cases) suggests significant challenges. Adequate resources are crucial for effectively implementing proactive measures, especially considering the dynamic nature of the medical devices sector and the integration of AI systems. Ensuring sufficient funding and staffing levels becomes critical for comprehensive oversight and enforcement.

International Collaboration despite Resource Constraints

Despite budgetary and staffing limitations, Poland has engaged in collaborations with other Member States, as evidenced by 13 inspections involving such collaborations. This reflects an understanding of the importance of international cooperation in addressing challenges in the medical devices sector. Considering the increasing use of AI systems in medical devices, sharing knowledge and resources through international collaborations becomes even more vital for effective market surveillance. However, resource constraints should be addressed to maximize the impact of these collaborations in regulating advanced technologies.

Sweden

Proactive Inspection Approach with Limited Resources

The data suggests a proactive approach to market surveillance in Sweden during the 2010-2013 period, with both self-initiated and reactive inspections being conducted. However, the absence of budgetary allocations (0 in nominal terms) and staffing resources (0 full-time equivalent units for staff and inspectors) raises concerns about the sustainability and effectiveness of this proactive stance. Adequate resources are crucial for implementing thorough market surveillance activities, especially when dealing with evolving technologies like AI systems in medical devices.

Effective Enforcement Actions Despite Budgetary Constraints

Despite the lack of budgetary resources, Sweden has implemented significant enforcement actions, including the application of sanctions/penalties (11 instances) and the imposition of restrictive measures (2 instances). This suggests that Sweden has been successful in leveraging its limited resources to enforce compliance within the medical devices sector. However, this may also indicate a need for increased budgetary support to sustain and enhance these enforcement efforts, particularly with the introduction of advanced technologies like AI systems in medical devices.

Active International Collaboration

Sweden's engagement in 13 inspections where other Member States were invited to collaborate reflects a commitment to international cooperation in market surveillance activities. This collaboration is essential, especially in the context of AI systems in medical devices, as it allows for the sharing of knowledge, best practices, and resources. While Sweden has demonstrated a proactive international approach, addressing resource constraints would further amplify the impact of such collaborations in regulating and overseeing the safety and quality of medical devices, including those incorporating AI.

Focus Areas

Resource Allocation and Proactive Oversight

- The market surveillance activities for medical devices in various countries emphasize the importance of allocating adequate resources for effective oversight. Providers of AI systems should learn that proactive surveillance, including both self-initiated and reactive inspections, is crucial to identify and address potential risks early. Investing in skilled staff, inspectors, and budgetary allocations is essential to navigate the evolving landscape of AI in medical devices, ensuring compliance with regulations and swift responses to emerging issues.

International Collaboration for Global Impact

- The data indicates instances of international collaboration in market surveillance activities. Providers of AI systems should recognize the global nature of the healthcare industry and the importance of collaborative efforts. Establishing partnerships with other countries, sharing insights, and harmonizing regulatory approaches can enhance the effectiveness of market surveillance for AI-driven medical devices. Learning from successful cross-border collaborations can contribute to creating standardized practices and addressing challenges on a global scale.

Balancing Enforcement with Industry Cooperation

- The enforcement actions, such as sanctions/penalties and restrictive measures, taken in response to non-compliance highlight the need for a balanced approach. Providers of AI systems should learn that while enforcement is crucial for maintaining regulatory standards, fostering cooperation with the industry is equally important. Encouraging voluntary measures and corrective actions by economic operators demonstrates a collaborative approach, fostering a culture of compliance. Striking a balance between enforcement and cooperation is essential for building trust and ensuring the safe and responsible deployment of AI systems in medical devices.

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