European Commission

Health and Consumers

NID Slovakia

JA Medical devices

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European Commission

Policy

The role of medical devices is essential to the healthcare of EU citizens. The diversity and innovativeness of this sector contributes significantly to the enhancement of both the quality and efficacy of healthcare in the EU.

- *The medical devices industry is a major employer in Europe, employing 575 000 people in the EU.*
- *Total sales amount to €100 billion.*
- *The sector represents some 25 000 companies, of which 95% are Small and Medium-sized Enterprises (SMEs).*

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The medical devices sector faces many challenges which may have an impact on their innovation capacity and overall competitiveness:

- *Public Health Systems:*
  - *In particular, emerging needs such as developing a shared understanding of healthcare goals, overcoming health inequalities, an ageing society and exploiting the potential of e-health technologies.*

- *Finding the balance between patient's needs and financial sustainability;*

- *Competitiveness and innovation:*
  - *Challenges related to R&D, emerging technologies and the green economy, as well as issues related to the EU's trade and regulatory cooperation globally. SMEs in particular face challenges in this regard.*

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What the Commission is doing

- *Enhancing competitiveness is one of the key objectives of the European Commission. As a result, the Commission regularly liaises with industry associations to explore ways of helping enterprises and maintain growth.*

- *In order to help the sector to overcome both public health and industrial challenges, an 'Exploratory process on the future of the medical devices sector' was implemented in 2009*

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- *JA COEN*

The conclusions of the Staff Working Document on the PIP (Poly Implant Prothèse) Action Plan discussed at the EPSCO Council on 20 June 2014 highlight the need for more developed and coordinated market surveillance of medical devices by Member States competent authorities. A pilot joint action with this aim was foreseen to be carried out under the 2014 Annual Work Plan. Member States have indicated their wish to develop this further with a larger scale action.

- *This action to be taken forward by national bodies mandated in this field will promote co-operation between Member States allowing development of best practice, training and knowledge and resource sharing concerning the implementation of the medical device legislation, in particular in relation to Member States tasks such as the market surveillance of devices.*

- *EUR 850,000*

Thank you!

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