FACTSHEET

Financial impact of the Revision of the EU Medical Devices Directives on European SMEs and industry

MEDTECH COMPANIES' CONTRIBUTION TO EUROPE'S ECONOMY

- The European medical technology market is worth € 100 billion and the industry employs around 575,000 people.
- There are almost 25,000 medical technology companies in Europe, of which 95% are SMEs.
- Moreover, the medtech industry is a leader in innovation and has filed over 10,000 patent applications in Europe in 2012, more than any other technical field.
- Investment in R&D stands at approximately € 4 billion per year.

EU MEDICAL DEVICE REGULATION UNDER REVIEW

- The regulation of the medical devices sector is currently under review by the European Parliament and Member States (Council), following a proposal by the European Commission to update the legislation.
- Eucomed, the European medical technology industry association representing some 25,000 business entities, held a survey amongst its members to assess the financial impact from 2015 to 2020 of the current proposals for the Revision of the EU Medical Devices Directives. The initial estimates are based on the replies from small, medium and large medtech companies.

€ 7.5 BILLION INVESTMENTS THAT IMPROVE SAFETY ARE SUPPORTED BY INDUSTRY

- Industry supports the proposed improvements of the current regulatory system through the introduction of unique device identification (UDI), improvements in labelling and clinical performance data, and additional administrative requirements, which will require an investment by industry of approximately **€ 7.5 billion**.

€ 2.5 - 17.5 BILLION ADDITIONAL COSTS DEPENDING ON CHOICE OF SYSTEM

- Industry will need to invest approximately an additional **€ 2.5 billion** if the European's Commission scrutiny procedure (article 44) becomes a reality. Industry does not support the scrutiny procedure as it gives a false sense of security and suggests instead a systematic control procedure (more information on Eucomed's position can be found on page 9 in the position paper *"Towards a regulation that guarantees patient safety, ensures patient access and keeps innovation in Europe"*).

- Industry will need to invest approximately an additional **€ 17.5 billion** if the European Parliament Rapporteur's proposal including a 'centralised premarket authorisation system' becomes a reality. Industry does not support such a system as it will not improve patient safety and will lead to unnecessary delays of lifesaving medical innovations reaching patients as well as creating an enormous bureaucracy.

€ 2.5 - 17.5 MILLION ADDITIONAL COSTS FOR SMEs DEPENDING ON CHOICE OF SYSTEM

- Approximately **€ 2.5 million is** the additional cost for a SME bringing yearly a Class III product to market if it needs to comply with the European's Commission scrutiny procedure (article 44).

- Approximately **€ 17.5 million** is the additional cost for a SME bringing yearly a new Class III product to market if it needs to comply with the European Parliament Rapporteur's proposal of a centralised premarket authorisation system.

SURVEY METHODOLOGY

- To determine the increase in industry investments five areas were identified as being most impacted:

    1. Required clinical data and length of approval process
    2. Unique device identification
    3. Labelling for future new CE marks,
    4. Re-use
    5. Administrative implications (such as implant cards, input of data into central databases etc.)

- The survey was conducted anonymously among Eucomed member companies in the summer of 2013.

- Nineteen companies returned the questionnaire (8 large companies, 6 medium companies and 5 small companies). Although a limited number of companies participated in the survey, a consistency of input was available for all categories and sizes of companies.

- To determine the expected impact on industry in terms of additional investments, the respondents were asked to determine the expected additional cost implications from 2015 to 2020 (in a scale from minimum – maximum) for required clinical data, unique device identification, labelling for future new CE marks, length of approval process, re-use and administrative implications.

- An average of the minimum and maximum indication was determined based on the inputs of the small, medium and large companies.

- In order to determine the additional costs for industry to comply with the European's Commission proposed scrutiny procedure, respondents indicated that an additional investment of € 2.5 billion is required (assuming 10-20% of new class III products would go through the new scrutiny procedure).

- In order to determine the additional costs for industry to comply with the European Parliament Rapporteur's proposal including a centralised premarket authorisation system, respondents indicated that an additional investment of € 17.5 billion is required.

- To determine the costs for SMEs, the average of the minimum and maximum input from Small and Medium Size companies were considered.

- With regard to the European Commission's proposal, the estimate of a SME to bring a product to market each year until 2020 is between € 1 and 4 million.

- With regard to the European Parliament Rapporteur's proposal, the estimate of a SME to bring a product to the market each year until 2020 was between € 7 and 28 million, whereas large companies estimate a cost of at least € 15 million.