HIGH-LEVEL CONFERENCE

EXPLORING INNOVATIVE HEALTHCARE

THE ROLE OF MEDICAL TECHNOLOGY INNOVATION AND REGULATION

22 March 2011, Brussels

CONCLUSIONS OF THE CHAIR

MORNING SESSION
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INNOVATION IN MEDICAL DEVICES AS RESPONSE TO EUROPE'S HEALTHCARE CHALLENGES

Europe is facing major long-term societal challenges, such as ageing population, which are short-term overshadowed by the efforts to overcome the economic and financial crisis. Scientific progress and technological innovation, such as e-Health, although they offer possibilities to meet these challenges, may put further pressure on healthcare systems to adapt.

In response to these challenges, medical devices can play a key role: through their rapid technological development, medical devices can deliver innovative solutions for diagnosis, prevention and treatment, improve the health and quality of life and address the sustainability of healthcare in Europe. They can also provide answers to the increased incidence of chronic diseases, contribute to shifting from treating illness to managing health, offer alternatives to hospitalisation through the promotion of medical devices suitable for home use and bring solutions to the shortage of healthcare professionals.

During the Exploratory Process on the Future of the Medical Device Sector[1] - an initiative launched in 2009 - stakeholders strongly endorsed the need for a clear political vision of the role of the medical device sector in the health of citizens and in the economy.

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Promoting innovation in the medical device area benefits patients, healthcare professionals, industry and society.

- **Participants agreed that:**

  - **Innovation should be more patient-centred** (*e.g.* through increased involvement of the patients and their families in the innovation process **with an aim to optimise individual health**);

  - **Innovation should be more integrated, and not only sector oriented** (*i.e.* further built on the experience and knowledge acquired from other sectors: such as IT, new materials developments …);

  - **Innovation must be cost-effective** (*i.e.* innovation should help **to contain the increase of healthcare spending** and **contribute to provide more effective healthcare**);

  - **Innovation should take a holistic approach** (*i.e.* innovation should take into account all the needs of patients: physical, social, psychological …).

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[1] http://ec.europa.eu/consumers/sectors/medical-devices/files/exploratory_process/final_report_en.pdf

The European Union, its Member States and regions have developed many instruments to promote innovative technologies.

The European Commission has launched the European Partnership on Innovation in order to engage stakeholders at all levels[2] (public and private, European, national and regional) across the entire innovation chain. It will mobilise efforts, bring together resources and optimise the use of existing instruments. The Partnership creates a framework that aims to overcome the obstacles slowing down the path from research to market. This initiative should be seen as an opportunity to bypass existing barriers to innovation by promoting dialogue and ensuring better coordination between existing instruments in the EU (e.g. Framework Programmes, national research programmes, structural funds, company investments in R&D).

- **Participants wanted:**

  - To enhance research on public health needs and priorities still to be addressed;

  - To encourage demand-driven innovation where healthcare and other professionals (*e.g.* scientists, engineers), patients and patients' families are more involved in the research and development process;

  - To further map and share national and European innovation **best practices and enhance the deployment of research** to facilitate the transfer of national or regional studies and pilot cases to a multinational, multiregional, or European level;

  - To ensure stronger collaboration and dialogue between the different actors involved in the innovation process (*e.g.* through networks and clusters);

  - To promote measures that demonstrate the added value of innovative solutions, and improve **information and training** of healthcare professionals, patients, patients' families **regarding their use**;

  - To promote innovation through public procurement policies.

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[2] http://ec.europa.eu/health/ageing/policy/index_en.htm

The medical device sector is built upon around 18,000 Small and Medium Sized Enterprises and therefore has specific needs.

- **Participants concurred that:**

  - There is a need to **increase support to SMEs,** for instance through patents (*e.g.* filing, enforcement) or through innovative funding systems (*e.g.* public/private partnerships);

  - **SMEs' specificities should be further taken into consideration** in particular with regard to access to appropriate expertise, information and training.

An adapted and robust regulatory framework, ready to cope with the future, is central to fostering safe and innovative medical devices for the benefit of European patients and Healthcare Professionals.

- **Participants pointed out to the need:**

  - To adapt the **European regulatory framework in order to secure patients' safety while favouring innovation**;

  - To pay particular attention to the **interoperability issues** related to the integration of medical devices in e-Health systems, especially with regards to future plans to deploy Personal Health Systems, and the foreseen developments of mobile health systems (m-Health);

  - To ensure that the **regulatory environment** is **adapted to allow for safe and innovative homecare solutions and home use devices**;

  - To develop tools to **enhance the traceability of medical devices** in order to improve patient safety (*e.g.* improved recalls and adverse incidents reporting, fight against counterfeiting).

AFTERNOON SESSION
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ADAPTING THE EU'S MEDICAL DEVICE LEGISLATION TO THE NEEDS OF TOMORROW

The primary purpose of governance of medical devices is to ensure a high level of protection of patients and users within the internal market. A supportive regulatory framework is also key to fostering innovation in medical technology for the benefit of European patients. While recognising the strengths and good results of the European regulatory system, participants nevertheless considered that improvement is necessary to reinforce the trust in the system. Full account would need to be taken of the specificities of medical devices which require a regulatory system that respects the particularly short life-cycle of these products.

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A robust, transparent and proportionate regulatory framework is essential to ensure safety of medical devices, to encourage the development of innovative technology and to reinforce the confidence in the system.

- **Participants considered that:**

  - **Reliability, predictability, scientific validity and transparency in decision-making** should be enhanced;

  - **Patients and healthcare professionals** should be appropriately **involved** in the process;

  - **Clinical data,** from **pre-market studies** and **post market experience** (*e.g.* vigilance reports, post-market clinical follow-up, European registers) should be collected to a greater extent to **support the clinical evidence** needed for regulatory and for reimbursement purposes;

  - Regulators should explore ways to establish an EU-wide mechanism which would allow **timely access to beneficial innovative technologies to address unmet public health needs** while still gathering clinical evidence (concept of "conditional CE marking");

  - Regulators should adopt **clearer and simpler rules** which define the obligations and responsibilities of all players and ensure a **transparent and SME-friendly** decision-making process;

  - The Commission should pursue the development of a modern IT infrastructure for a **central and publicly available database** to provide key information about medical devices, their manufacturers / authorised representatives, importers, clinical investigations and field safety corrective actions. This should include a system to allow the **traceability** of devices thus enhancing safety and fighting counterfeiting;

- A mechanism should be set up for **the categorisation of products** to address the growing number of "borderline" cases between medical devices and other products which are subject to different regulations (*e.g.* pharmaceuticals, cosmetics, food, biocides).

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Stronger coordination between authorities in the pre- and post-market phases is essential to ensure harmonised interpretation and application of the legal requirements throughout the EU. Particular emphasis was put on the need to secure a uniformly high level of conformity assessment by Notified Bodies.

- **Participants proposed:**

  - As regards **the oversight of Notified Bodies,** to set up a process ensuring that Notified Bodies are designated only for the assessment of devices or technologies which correspond to their proven expertise and competences;

  - With regard to the **post-market safety** of devices, that **serious incidents** should be **centrally notified** and, where appropriate, analysed in a **coordinated way** which would allow, if needed, a **rapid and coherent EU-wide response** to safety issues.

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The medical device sector is a global one where international trade involves more and more countries other than the traditional manufacturing countries.

- **Participants considered necessary:**

  - to engage in a **stronger international coordination** to ensure that medical devices are manufactured according to high safety requirements worldwide.

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Current and future constraints on public budget may have some consequences on the health of the European citizens.

- **Participants emphasized:**

  - The added value of **EU mechanisms allowing the pooling of limited resources and expertise** between national competent authorities thus avoiding duplication of work and unnecessary delays;

  - That at the same time, **a funding mechanism** should be considered to ensure appropriate resources **at national level**.

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The current fragmentation of the implementation of the European regulation on medical devices and the absence of a European oversight risk compromising the good management of the system.

- **Participants agreed on the need:**

  - to ensure an **efficient and effective coordination** between national authorities to create a level playing field. This could be achieved through a European coordination mechanism with a clear legal basis and mandate;

  - to explore **synergies with existing bodies** with relevant expertise when deciding about the most appropriate mechanism;

  - to keep the management of the system **unbureaucratic** in order not to stifle innovation.