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**NOTE**

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from : Presidency/Council Secretariat

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to : Permanent Representatives Committee (part I)/Council

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Subject : **Preparation of the EPSCO Council on 6 June 2011**  
Innovation in the medical device sector  
- Adoption of Council conclusions

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1. Following the High Level Health Conference on innovation in medical technology held in Brussels on 22 March 2011, the Presidency drew up a set of draft Council conclusions.
2. Those draft Council conclusions were examined by the Working Party on Pharmaceuticals and Medical devices on 1 and 15 April 2011. On 5 May 2011, the Working Party reached agreement on the draft Council conclusions in the Annex.
3. On this basis, the Permanent Representatives Committee is asked to invite the Council (EPSCO) to adopt, at its meeting on 6 June 2011, the draft Council conclusions set out in the Annex.

**Draft Council Conclusions on innovation in the medical device sector**

THE COUNCIL OF THE EUROPEAN UNION:

1. **RECALLING** the Council Conclusions of 26 June 2002<sup>1</sup> and of 2 December 2003<sup>2</sup> and the subsequent amendments to the legislative framework for medical devices<sup>3</sup>,
2. **DRAWING ATTENTION TO** the Conclusions<sup>4</sup> of the High Level Health Conference on innovation in medical technology held in Brussels on 22 March 2011,
3. **BEARING IN MIND:**
  - the major long-term societal challenges facing Europe, such as an ageing population, which will call for innovative healthcare systems;
  - the importance of medical devices in health- and social care, their contribution to improving the level of health protection and the fact that medical devices today account for a significant amount of public health expenditure;

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<sup>1</sup> Doc. 10060/02.

<sup>2</sup> Doc. 14747/03.

<sup>3</sup> Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market *OJ L 247, 21.9.2007, p. 21–55*

<sup>4</sup> [http://ec.europa.eu/consumers/sectors/medical-devices/files/exploratory\\_process/hlc\\_en.pdf](http://ec.europa.eu/consumers/sectors/medical-devices/files/exploratory_process/hlc_en.pdf)

- that the development of medical devices may deliver innovative solutions for diagnosis, prevention, treatment and rehabilitation, that could improve health and quality of life for patients, disabled persons, and their families, could contribute to mitigating the shortage of healthcare professionals and could contribute to addressing the sustainability of healthcare systems;
- that innovation in medical devices should contribute to the continued improvement of patient and user safety;
- the European Innovation Partnership on Active and Healthy Ageing launched by the European Commission with the aim of tackling societal challenges through innovation;
- that the medical device sector in Europe comprises around 18000 small and medium-sized enterprises (SMEs) and that this fact must be considered when future legislative and administrative measures are being adopted at European Union level and at national level;
- the need to adapt EU medical device legislation to the needs of tomorrow so as to achieve a suitable, robust, transparent and sustainable regulatory framework, which is central to fostering the development of safe, effective and innovative medical devices for the benefit of European patients and healthcare professionals;
- the importance of having the EU continue to play a leading role in the field of international regulatory convergence and best regulatory practice regarding medical devices, for instance through the Global Harmonisation Task Force, and be party to global initiatives such as global vigilance and global instruments for improving identification and traceability of medical devices.

**4. STRESSING** that in order for innovation to benefit patients, healthcare professionals, industry and society:

- Innovation should be increasingly patient- and user-centred and demand-driven *e.g.* through increased involvement of patients, their families and users in the research, innovation and development processes in order to improve individual health and quality of life;
- Innovation should be a more integrated process, building on experience and knowledge acquired in other sectors, such as IT and the development of new materials;
- Innovation should be based on a holistic approach (*i.e.* it should take into account the whole healthcare process and all patients' needs - physical, social, psychological etc);
- Innovation should focus on public health priorities and healthcare needs *inter alia* in order to improve cost-effectiveness;
- There is a need to increase research in order to identify public health needs and priorities still to be addressed and to better define patients' medical needs;
- Future legislative actions in this area must, when adapting the European regulatory framework, specifically aim to increase patients' safety while at the same time creating a sustainable legislative framework favourable to medical device innovation that can contribute to a healthy, active and independent life.

**5. INVITES THE COMMISSION AND THE MEMBER STATES** to

- promote measures that make use of valuable innovative solutions with proven benefit, and improve information and training for healthcare professionals, patients and patients' families regarding their use;

- further map and share national and European best practices regarding innovation and enhance the deployment of research to facilitate, where relevant, the transfer of experiences gained in national or regional studies and pilot projects to the multinational, multiregional or European level;
- ensure stronger collaboration and dialogue between the various actors involved in the innovation process (*e.g.* through networks and clusters);
- promote valuable innovation through public procurement policies while taking into account safety aspects;
- take existing measures into account, and when necessary consider further measures which enhance the capacity for innovation, for instance the use of innovative funding systems directed, in particular, towards SMEs and that are designed to make optimum use of resources from the private and public sectors;
- pay particular attention to interoperability and safety issues related to the integration of medical devices in e-Health systems, especially Personal Health Systems and mobile health systems (m-Health) while bearing in mind that the deployment of health ICT systems is entirely a matter of national competence;
- encourage better consideration of the needs of patients and healthcare professionals in the design process of medical devices;
- consider further improving the involvement of patients and healthcare professionals in vigilance in order to improve the system of notification of adverse incidents relating to the use of medical devices;
- promote early dialogue between manufacturers, scientific and clinical experts, competent authorities and, where appropriate, notified bodies regarding "new products" in particular, and their classification;

- enhance cooperation between authorities of relevant sectors, where appropriate;
- examine how and at which level the promotion of medical devices can be regulated in the most effective and efficient way.

**6. INVITES THE COMMISSION** to take the following considerations into account in the course of its future legislative work:

- Mechanisms are needed to enhance reliability, predictability, speed and transparency in decision-making, and make sure that it is based on scientifically validated data;
- The system of risk based classification should be improved (in particular for *in vitro* diagnostic medical devices and “new products” as appropriate);
- Clinical data from pre-marketing studies and post-marketing experience (vigilance reports, post-marketing clinical follow-up, European registers) must be collected in a transparent way and to a greater extent in order to provide the clinical evidence which fulfils regulatory purposes and can, where appropriate, assist health technology assessment, whilst fully recognising and respecting national competences for the latter. Consideration should also be given to methods for ensuring that notified bodies are better equipped with the appropriate expertise to analyse such data in a meaningful way;
- There is a need for clearer and simpler rules defining the obligations and responsibilities of all economic operators and the role of other stakeholders (in particular national competent authorities and notified bodies);
- The development of a modern IT infrastructure for a central and publicly available database must be further pursued with a view to providing key information about medical devices, relevant economic operators, certificates, clinical investigations and field safety corrective actions. In this context, the possibility of introducing a system to improve the traceability of devices, thus enhancing safety, must be studied;

- Where necessary, clarification should be made regarding the definition of medical devices and the criteria for their classification;
- In addition, a simple and rapid mechanism must be set up for accelerated adoption of binding and consistent decisions and the implementation thereof on the determination of products as medical devices and the classification of medical devices in order to address the growing number of "borderline" cases between medical devices and other products subject to different regulatory frameworks (the framework for pharmaceuticals in particular, but also those for cosmetics, aesthetic products, food or biocides);
- As regards the oversight of notified bodies, there is a need to continue to improve the harmonised list of criteria to be satisfied before their designation. In particular the designation process should ensure that they are designated only for the assessment of devices or technologies which correspond to their proven expertise and competencies. The process should also address the need to improve monitoring of notified bodies by national authorities in order to ensure an EU-wide comparable and high-level performance of notified bodies, in this context an enhanced European coordination between competent authorities as well as between notified bodies should also be considered;
- The vigilance system for medical devices must be further developed in order to allow a coordinated analysis and a rapid and coherent EU-wide response to safety issues, if needed;
- It is desirable to consider a European coordination mechanism founded on a clear legal basis and mandate in order to ensure efficient and effective coordination between national authorities while creating a level playing field. Synergies with existing bodies with relevant expertise should be explored when deciding on the mechanisms for such coordination. Consideration should also be given to which activities are best carried out in cooperation between Member States;

- As the medical device sector is a global one, a stronger coordination with international partners is desirable in order to ensure that medical devices are manufactured according to high safety requirements worldwide;
  - There is a need for sustainable legislative framework for medical devices which ensures safety and promotes innovation;
  - It should be considered how to address regulatory gaps in the system, for instance in relation to medical devices manufactured utilising non-viable human cells and tissues;
  - The need for introducing more harmonised provisions relating to the content, presentation and comprehensibility of the instructions for use of medical devices should be further considered.
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