This contribution was prepared by Ms Sabine Lecrenier, DG SANCO

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Ladies and Gentlemen,

Medical devices represent an important benefit for patients and healthcare providers and it is therefore of the utmost importance that this sector benefits from the best regulatory environment. This is crucial to ensure the highest level of health protection while promoting at the same time both the competitiveness and the innovation capacities of the medical device sector.

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As you know, Directive 2007/47/EC has amended Directive 90/385/EEC on active implantable medical devices and Directive 93/42/EEC on medical devices *(Slide 2).*This Directive has brought important improvements to the regulatory framework for medical devices (*e.g.* requirements of clinical evaluation clarified and reinforced, conformity assessment procedures strengthened, consultation of pharmaceuticals authorities clarified for combination products, some new essential requirements added etc.). In addition to these improvements, Directive 2007/47/EC has also empowered the Commission to adopt binding legal acts in several fields *(Slide 3).* Some implementing measures are under preparation (*e.g*. EUDAMED Decision, E-labelling for implantable devices and fixed installed devices, active implantable medical devices manufactured utilizing tissues of animal origin, vigilance procedures).

Through Directive 2007/47/EC, the legislator also mandated the Commission to prepare a report on the reprocessing of medical devices by September 2010 *(Slide 4).* A public consultation was launched in 2007 on the issue, followed by a workshop in 2008. Further to a request from the Commission the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) is in the process of adopting a scientific opinion on the safety of reprocessed medical devices marketed for single use. On the basis of all the

available information the Commission will finalized its report to the European Parliament and to the Council and will prepare any appropriate proposal in order to ensure a high level of health protection.

Last but not least, further to a request from the United Kingdom, the Commission services are currently preparing an amendment to Directive 98/79/EC in order to include blood screening, diagnostic and confirmatory vCJD assays to List A of Annex II *(Slide 5)*. In addition, Common Technical Specifications for vCJD blood screening assays are also under preparation to ensure an appropriate level of safety and performance of these tests. This is the result of a fruitful cooperation between all the relevant stakeholders.

The changes introduced by Directive 2007/47/EC, albeit important, have nonetheless left some structural shortcoming unresolved *(Slide 6).* Therefore, despite the latest changes and the foreseen implementing measures, there is need for a more systemic revision of the general regulatory framework for medical devices. This will guarantee the great social and economic benefit that the medical devices sector brings to society taking into account the rapidly evolving technology and ensuring the highest level of patient safety. In this spirit, the Commission services consulted stakeholders in 2008 on the Recast of the European legal framework for medical devices *(Slide 7).* The Commission received 200 responses. In December 2008 a summary report of the responses was published on our website. The feedback to the public consultation proved that many of the concerns which the Commission expressed in its questionnaire were shared by Member States and stakeholders. However, contributions suggested taking more time for the preparation of the legislative proposal. In that context, the Commission did not adopt its proposal in 2009 but has continued until now to gather data to further identify the improvements of the legal framework which are needed, in close collaboration with the Competent Authorities of the Member States, the medical devices industry and other stakeholders. In addition, taking into account the specificities of *in vitro* diagnostic medical devices, and to further in-depth discussions with relevant interested parties, the Commission services intend to launch in the coming weeks a public consultation procedure targeting specific issues related to *in vitro* diagnostic medical devices in order to complement the data assembled via the 2008 public consultation. The data collected will serve as a fundamental basis for the Commission in drafting the impact assessment of its future proposals. Due to the transfer of the medical devices sector to DG SANCO as from the 1st March 2010, the timelines for the Commission proposals are now under discussion

with our new Commissioner, Mr John Dalli, but the Commission proposals are expected in the second half of 2011.

In the proposed Recast of the medical devices legislation the Commission intends *(Slide 8)*:

Firstly, to maintain a high level of health protection in a properly functioning Internal Market. These two aspects are linked, as the proper functioning of the Internal Market implies that the medical devices circulate without restrictions but also that they ensure a high level of health protection.

To achieve this goal it will be necessary for instance:

- to assess whether the scope of the current Directives should be extended, for instance to cover devices manufactured utilising non-viable tissues and cells of human origin, invasive/implantable devices for aesthetic purposes or tests currently not covered by the IVD medical devices legislation;
- to explore how to build the future of pioneering technologies in Europe, in particular to ensure that high risk devices are assessed in a harmonized and appropriate way before being placed on the Community market;
- to strengthen the control of the notified bodies in terms of demonstration of competence, impartiality and transparency.
- to create a system that ensures timely and uniform action in the areas of vigilance and market surveillance so that only safe and reliable products are on the Community market;
- to strengthen and clarify the requirements regarding clinical evidence in order to better demonstrate the safety and performance of the medical devices;
- to establish mechanisms to address in a timely and effective manner the increasing number of borderline products falling between the medical device sector and areas such as pharmaceuticals, cosmetics or biocides to ensure that products on the Community market are appropriately regulated.

Secondly, in this period of globalisation of the medical devices market, to further promote international trade, for instance by further convergence on the guidelines of the Global Harmonisation Task Force.

Thirdly, to address challenges of worldwide dimension, such as counterfeiting which put patient safety at risk. A study on counterfeiting has been conducted, and in that context,

the Recast offers the opportunity to bring innovative answers to these global challenges, for instance by regulating the distribution and traceability of medical devices

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Ladies and Gentlemen,

- The recently adopted Directive 2007/47/EC has brought important improvements to the European regulatory framework for medical devices. Some implementing measures will also contribute to strengthen the system (Slide 9).
- However, despite the changes brought by Directive 2007/47/EC, there is a clear need for further improvement in the framework if we want to continue to ensure the highest level of health protection while promoting at the same time the competitiveness and the innovation capacities of the medical device sector.
- Through the Recast, we need to build together an appropriate legal framework in a long term vision, keeping in mind our objectives of protecting the health and safety of patients, ensuring the proper functioning of the internal market and the competitiveness of the sector.
- I am confident that – through the continuing collaboration between the European Commission, the Member States, the medical devices industry and other stakeholders – we will achieve significant results.
- These achievements will make the European Union a place where innovative medical devices contribute to the scientific progress and to the health and the well being of our citizens.

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