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Council of the European Union Reaches Conclusions on Innovation in Medical Device Sector

After a meeting of the Employment, Social Policy, Health and Consumer Affairs Council in Luxembourg on the 6th June 2011 the Council issued its conclusions on innovation in the medical device sector.

Taking into consideration the major long-term societal changes facing Europe, which will call for innovative healthcare systems, the Council of the European Union recognises the important role medical devices play in healthcare. These devices may deliver innovative solutions for the diagnosis, prevention, treatment and rehabilitation, improving the lives of patients and their families and could also contribute to mitigating the shortage of healthcare professionals and address the sustainability of our healthcare systems.

The Council also recognised the need to adapt EU medical device legislation to the needs of tomorrow with a transparent and sustainable regulatory framework and emphasised the important role the EU plays in the field of international regulatory convergence and best regulatory practice regarding medical devices.

It was stressed that innovation should be patient- and user-centred and demand driven, involving patients and their families in the process while also focusing on public health priorities, healthcare needs and cost-effectiveness. Future legislative actions in this area must, when adapting the European regulatory framework, specifically aim to increase patient 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.

The Council invited the Commission and 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. National and European best practices regarding innovation should be mapped and shared. Other top priorities include interoperability, safety issues and the notification of adverse events.

On a legislative level, the Council invites the Commission to take into consideration the following issues:

- Mechanisms to enhance reliability, predictability, speed and transparency in decision-making and make sure that it is based on scientifically validated data;
- A system of risk-based classification;
- Clinical data must be collected in a transparent way to provide the best clinical evidence;
- Clearer and simpler rules defining the obligations and responsibilities of all economic operators and role of other stakeholders; and
- A vigilance system to facilitate a rapid and coherent EU wide response to safety issues.

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