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COCIR – Regulation and Policy Updates from Brussels

The European Commission's proposal for a new Medical Device Regulation is now going through the European Parliament and EU member states for consideration. In January, COCIR – the trade association representing the European Medical Imaging, Electromedical and Healthcare ICT Industry - published its High-Level Contribution on Medical Device Regulation as an input to the debate.

The future of medical device regulation could potentially have a significant impact on COCIR member companies' technologies and their ability to continue to provide highly innovative products and services. In the paper, COCIR considers the regulatory compliance costs at a time of economic crisis when we are all being asked to do 'more with less' and examines the role of the EU Notified Bodies among other concerns.

COCIR believes that the current regulatory framework for its technologies is adequate and calls on the EU institutions to ensure that these existing regulations are properly enforced, particularly in the post-market surveillance area. However, there is a need to modernise and strengthen legislation to enhance the traceability of products and their critical components, harmonising EU member states' engagement and allowing better coordination of the future regulatory framework.

It is essential that the regulation matches the specificities of the medical technology sector, while continuously improving but also avoiding an increase in the time to market or creating an unnecessary administrative burden. We need to ensure that future regulations do not hamper innovation. Europe should maintain the highest level of safety for citizens and ensure support for European healthcare and ICT-related technologies. The High-Level Contribution is available on the COCIR website under Position Papers.

The EC has published its EU eHealth Action Plan 2012-2020, entitled 'Innovative healthcare for the 21st century'. As the European leading voice of the healthcare ICT industry, COCIR welcomed the eHealth Action Plan as it provides a comprehensive roadmap for smart and sustainable healthcare in Europe. The four pillars of the eHealth Action Plan are fully aligned with COCIR's own vision and efforts developed to accelerate the deployment of eHealth.

COCIR and other stakeholders are actively participating in providing eHealth solutions through the European Innovation Partnership and the Active and Healthy Ageing Initiative. EU investment in Research is key particularly in interoperable patient records and for demonstrating best practice in the widespread deployment of telemedicine.

Our industry has worked hard over the last years to improve systems interoperability in partnership with user organisations and authorities and to supply the technologies required to make eHealth a reality. COCIR feels that the new eHealth Action Plan takes the right steps in supporting the sustainability of these efforts. The support of the EU Member States is now crucial if such an EU-wide interoperability framework is to be deployed.Adoption of eHealth by healthcare providers is another challenge to deployment and realising the full benefits of eHealth.

For more information please visit **www.cocir.org**

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