AMCHAM EU
AMERICAN CHAMBER OF COMMERCE TO THE EUROPEAN UNION
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Adonis Georgiadis
Health Minister
Ministry of Health and Social Solidarity
Aristoteloys, 17-19
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Wednesday 26 March 2014

Dear Minister Georgiadis,

We appreciated the opportunity to meet with you in Athens during the American Chamber of Commerce to the European Union (AmCham EU) Presidency Group delegation visit on 4 December 2013. As discussed during that meeting, we would be very pleased to collaborate with you on some critical health-related dossiers, such as clinical trials, pharmaceutical fees and eHealth.

As you requested, we have attached additional information detailing some of the key issues on the medical devices regulation. As you may know, AmCham EU strongly supports a modern and effective regulatory system for medical devices which balances patients' safety with continued access to the latest medical developments. We would be grateful to have the opportunity to have a further exchange with you and your colleagues on this issue, particularly because we understand you are working to secure a partial agreement of the regulation by the June Employment, Social Policy, Health and Consumer Affairs (EPSCO) Council meeting.

We would also like to provide you with an electronic copy of the AmCham EU report *"Forever Healthy: The 2020 Healthcare Consumer"*. This report provides concrete recommendations on how the health sector can support the goals of the Europe 2020 Strategy, ensure sustainable and inclusive growth and a sustainable and predictable business environment. One of the recommendations of our report is that policies and resources need to be directed towards improving health and IT literacy of citizens to empower them to take more responsibility of their own health.

We would be pleased to welcome you to AmCham EU on your next visit to Brussels to meet with more of our Committee members to discuss these important issues. Pierre Bouygues, AmCham EU Secretariat (pbo@amchameu.eu) +32 (0)4 760 72 495), will be in contact with your office to see if there if we could set up a meeting here in Brussels at your convenience.

Thank you again for your time and we look forward to working with you to support your efforts to develop an effective medical device regulation.

Yours sincerely,

Alexander Roediger,
Chair, Healthcare Committee, American Chamber of Commerce to the EU

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AmCham EU's priorities for medical devices regulation (MDR)

AmCham EU strongly supports a modern and effective regulatory system for medical devices which balances patients' safety with continued access to latest medical developments. We believe such a system should contain the following elements:

Decentralised system: The revised regulatory system for medical devices should continue to provide citizens' access to innovative and cost-efficient medical technology while strengthening the oversight and the coordination of the relevant regulatory bodies. AmCham EU does not believe pre-market approval of medical devices is required; it would neither enhance patient safety nor prevent illegal activities (e.g. recent breast implant scandal).

Harmonisation: There should be better harmonisation of procedures and criteria for MDR to increase product safety across Europe. Two examples include strengthening and harmonising the designation of Notified Bodies; and harmonising a process for classification and borderline decisions to enhance legal certainty throughout the EU.

Transparency: The revision of the regulatory system for medical devices is an opportunity to increase the availability of relevant information for patients and healthcare professionals, but also to increase their involvement in the reporting and surveillance system. Towards this end, AmCham EU welcomes the creation of EUDAMED – the European Databank on Medical Devices.

Better coordination in the market surveillance: The revised regulatory system for medical devices should provide better reporting and more stakeholder involvement. Two examples of what is needed are: an EU coordinated system for unannounced visits to manufacturing sites; and an EU centralised reporting and surveillance system. However, improved coordination among Member States' regulatory authorities should not be used to justify disproportionate rises in national regulatory fees or charges to manufacturers. This would compromise European competitiveness.

Changing the definition of "Medical Device": The European Parliament's proposals to change the European Commission's definition of medical devices is not helpful and could create more, rather than less divergence from globally agreed definitions. Particular care needs to be taken when considering "medical" software. The proposed regulation is not designed to regulate applications and other software solutions. Attempts to bring these into its scope are likely to cause confusion and delay.

On-going US-European discussions on transatlantic trade: The Presidency of the EU and the Council should take into consideration the on-going US-European discussions on transatlantic trade and the need for better harmonisation of regulatory and technical standards for medical devices. Further convergence would bring benefits to the medical devices sector which operates globally, and to patients by lowering costs.

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