Bylage 2.

John Dalli
Member of the European Commission

Brussels, 09. 02. 2012

Dear Minister,

As I stated to you in my letter of last week (3 February 2012), I firmly believe that we need to act together, at once and within the existing legal framework, to tighten controls on medical devices, to protect our citizens and to restore trust and confidence in the regulatory system.

I therefore asked my services to analyse the current medical device legislation in order to establish what actions we can take immediately and in parallel to the ongoing work on the revision of the Directives already underway. I summarise below our main conclusions; further details of each action can be found in the attached table.

The first issue is the *functioning of Notified Bodies.*
Significant differences exist in the designation of Notified Bodies. As a result, the quality of the conformity assessments they perform varies considerably, and may put patient safety at risk.

I have therefore asked my services to start working immediately on an implementing measure to ensure the consistent application of designation criteria by the Member States. In the meantime, I call upon you to verify the scope of designation of the Notified Bodies under your supervision in order to ensure that only well-functioning, properly resourced and appropriately staffed Notified Bodies are authorised to conduct conformity assessment in the field of medical devices. For high risk medical devices (Class III), I ask you to report back to me on the results of your authorities' verification no later than 30 September 2012. I would also ask you to require that Notified Bodies make full use of their existing powers, in particular in terms of unannounced audits of manufacturers. This should be combined with a level playing field in terms of content and frequency of audits. In addition, we should reinforce the level of access to vigilance reports given to Notified Bodies

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The second issue is *market surveillance.*
Both Directive 93/42/EEC and Regulation (EC) No 765/2008 require Member States to carry out effective market surveillance. I rely on your diligence in meeting these obligations and again I shall be asking you to report back to the Commission on how you currently undertake this work and on what new or additional steps you will be taking in the light of the lessons learned from the PIP case.

The third issue is *coordination.*
Better coordination is of the utmost importance, in particular in the fields of market surveillance, vigilance and inspection, at European level but also globally working together with our major trading partners.

The last issue is *communication and transparency.*
Enhanced traceability of medical devices would serve patient safety. I therefore have instructed my services to start working on a Recommendation laying down some key principles governing any unique device identification system. These should be taken into account by those Member States that envisage establishing such a system at national level. We need to ensure that the individual systems are compatible with each other and also with a European UDI system which is planned as part of the future legislation.

Greater use of registers and improved reporting of adverse incidents involving healthcare professionals, as well as patients, are also in my view of utmost importance and would enable us to obtain independent feedback on the safety and quality of devices

I count on your fullest support to implement these actions, and look forward to discuss this set of actions with you

Yours sincerely,

**Encl.** List of measures for immediate action under existing legislation