

Joint plan for immediate actions

Issues identified	Envisaged actions	Timing
<p>Functioning of Notified Bodies</p>	<ul style="list-style-type: none"> • Commission to propose an implementing measure, based on Article 16(2) of Directive 93/42/EEC, to ensure a consistent application of the criteria to be met for the designation of Notified Bodies by the Member States 	<p>October 2012</p>
	<ul style="list-style-type: none"> • Check list detailing the items to be verified by the Notified Bodies during an audit to be developed and adopted as a part of a Commission Recommendation 	<p>September 2012</p>
	<ul style="list-style-type: none"> • Member States to revisit their list of designated Notified Bodies and to provide the Commission with an updated list of the Notified Bodies designated for Class III medical devices 	<p>September 2012</p>
	<ul style="list-style-type: none"> • Notified Bodies responsible for Class III medical devices to be audited by a team involving national and Commission staff 	<p>As from 2013</p>
	<ul style="list-style-type: none"> • Member States to require their designated Notified Bodies to perform unannounced audits of the manufacturers to which they have 	<p>September 2012</p>

	<p>delivered certificates. The frequency of these unannounced audits should be defined by the Commission in a Commission Recommendation, based on the risk of the devices, after consultation with the Member States</p> <ul style="list-style-type: none"> • Member States to ask their designated Notified Bodies to report back to their authority on the frequency and results of these unannounced audits • Member States to ensure that the communication of vigilance reports to the Notified Bodies is part of the contractual arrangement between the manufacturers and their Notified Bodies • Possibility for Notified Bodies to be granted access to vigilance reports contained in Eudamed, subject to confidentiality principles 	<p>April 2012</p> <p>Discussion starting in March 2012</p>
<p>Market surveillance</p>	<p>Member States to reinforce their market surveillance in accordance with Directive 93/42/EEC and Regulation (EC) No 765/2008</p> <p>In particular</p> <ul style="list-style-type: none"> • Member States to perform appropriate checks on the characteristics of products on an adequate scale, by means of 	

	<p>documentary checks and, where appropriate, physical and laboratory checks on the basis of adequate samples.</p> <ul style="list-style-type: none"> • Where necessary and justified, market surveillance authorities to enter the premises of economic operators and take the necessary samples of products • Member States to report back to the Commission on how they fulfil their information and organisation obligations laid down in Articles 17 and 18 of Regulation (EC) No 765/2008 • Member States to provide information on the powers, resources and knowledge they make available for the proper performance of their market surveillance activities 	<p style="text-align: center;">July 2012</p> <p style="text-align: center;">July 2012</p>
<p>Coordination</p>	<ul style="list-style-type: none"> • Coordinated analysis to take place when an increased frequency of vigilance reports is identified by a Competent Authority and/or by the Commission for a certain device or a certain type of device • Coordinated inspection on the market and in the premises of manufacturers / importers of such 	<p style="text-align: center;">As from July 2012</p>

	<p>devices established on the European territory by the concerned Competent Authorities to be organized, when appropriate, followed by the adoption of the necessary corrective actions</p> <ul style="list-style-type: none"> • Increased coordination, in particular in the field of audits and market surveillance, to be established in the framework of the confidentiality arrangements signed with international partners 	<p>As from February 2012</p>
<p>Communication and transparency</p>	<ul style="list-style-type: none"> • Commission to adopt a Recommendation providing general guidance to Member States regarding the establishment of a unique device identification system 	<p>December 2012</p>
	<ul style="list-style-type: none"> • Commission to engage a dialogue with healthcare professionals and Member States about implantation registers 	<p>May 2012</p>
	<ul style="list-style-type: none"> • Member States to request healthcare professionals and encourage patients to report adverse incidents involving medical devices to their Competent Authority 	<p>July 2012</p>