

Joint plan for immediate actions

Issues identified	Envisaged actions	Timing
Functioning of Notified Bodies	• 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	October 2012
	• 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	September 2012
	• 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	September 2012
	• Notified Bodies responsible for Class III medical devices to be audited by a team involving national and Commission staff	As from 2013
	• Member States to require their designated Notified Bodies to perform unannounced audits of the manufacturers to which they have	September 2012

	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 • 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	April 2012
	• Possibility for Notified Bodies to be granted access to vigilance reports contained in Eudamed, subject to confidentiality principles	Discussion starting in March 2012
Market surveillance	Member States to reinforce their market surveillance in accordance with Directive 93/42/EEC and Regulation (EC) No 765/2008 In particular • Member States to perform appropriate checks on the characteristics of products on an adequate scale, by means of	

	documentary checks and, where appropriate, physical and laboratory checks on the basis of adequate samples. • 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	July 2012 July 2012
Coordination	• 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	As from July 2012

	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	
	• 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	As from February 2012
Communication and transparency	• Commission to adopt a Recommendation providing general guidance to Member States regarding the establishment of a unique device identification system	December 2012
	• Commission to engage a dialogue with healthcare professionals and Member States about implantation registers	May 2012
	• Member States to request healthcare professionals and encourage patients to report adverse incidents involving medical devices to their Competent Authority	July 2012