

Bonn Resolution

The Competent Authorities for Medical Devices convening in Bonn for their 19th Meeting on the 26th and the 27th of February 2007 express their concerns about the Commission proposals for the review of the New Approach consisting of

- a Regulation of the European Parliament and the Council setting out the requirements for Accreditation and Market Surveillance relating to the Marketing of Products (COM(2007) 37 final, 2007/0029 (COD))
- a Decision of the European Parliament and the Council on a common framework for the marketing of products (COM(2007) 53 final, 2007/0030 (COD))

Considering the Member States' responsibility for the health of their citizens, the Competent Authorities have also doubts about the proposed role of the European co-operation for Accreditation (EA). Competent Authorities need to retain full control of the competence and performance of Notified Bodies. This is incompatible with the proposed concept of using accreditation as the last level of public authorities' control.

Furthermore, the concept of presumed compliance with the requirements for Notified Bodies in the case of conformity with the EN 45000 / ISO/IEC 17000 series of standards is unacceptable. These standards are not sufficient to demonstrate compliance with the requirements set out in the Medical Device Sector.

The Competent Authorities for Medical Devices affirm the essential role played by Notified Bodies in the operation of the medical devices regulatory system. The health risks associated with medical devices require a high level of protection for patients and users, therefore a common and uniform regime for the designation of Notified Bodies and market surveillance has been established. Due to the high demands on safety and performance, medical devices are only comparable to those sectors that are already excluded from the scope of the proposed regulation and decision, such as medicinal products (Directive 2001/83/EC) or blood and tissue products (Directives 2002/98/EC and 2004/24/EC).

The Competent Authorities agree that the activities of the Notified Body Operations Group (NBOG) anticipated many of the general concerns about the quality and functioning of the New Approach put forward by the Commission in justification of their proposals. They also agree that NBOG set up a system within the medical devices sector, which is far more appropriate than the Commission proposals.

The Competent Authorities therefore **request the Council and the Member States**

- to exclude the Medical Device Directives from the scope of application of the accreditation rules set out in the proposed regulation and decision;
- to take note of the fact that the designation/notification of Notified Bodies solely on the basis of conformity to the EN 45000 / ISO/IEC 17000 series of standards is inadequate in the medical devices sector; as these standards are not sufficient to demonstrate compliance with the requirements for Notified Bodies to ensure a high level of quality and safety of Medical Devices
- to take note of the fact that the current co-operation of Member States in NBOG has proven effective and should be strengthened instead of subjecting the medical device sector to rules formulated by the EA.