

PRESS RELEASE of February 26th, 2013
from TEAM-NB
The European Association for Medical Devices of Notified Bodies
on vision on Revision

A workshop on regulations on Medical Devices (MDs) and in vitro Diagnostic Medical Devices (IVDs) was organized by both rapporteurs respectively, Mrs Dagmar Roth-Behrendt and Peter Liese on February 26th, 2013.

Gert Bos, the president of our association was invited by Mrs Dagmar Roth-Behrendt, rapporteur for the workshop as a panellist in the third panel, titled “*Are the expertise and structure of notified bodies sufficient for ensuring the necessary safety of medical devices and fulfilling their obligations?*”

The room with a 140 capacity was overcrowded.

Mrs Dagmar Roth-Behrendt asked the panellist to address the following questions:

1. Do the notified bodies have the scientific medical expertise necessary to conduct their assessments?
2. Is the scrutiny procedure of the quality and delivering of notified bodies by Member States sufficient?
3. Is the former variety of nature of notified bodies (public, private, etc.) appropriate?
4. Is the high number of notified bodies in the whole EU mirroring the necessity or needs?

As she told the audience, these questions gave a good idea on her ideas on the subject.

Mr Bos presentation is available on the Team-NB web site in the section Events. The document is titled: TEAM-NB vision on revision medical device regulations - presentation in EP workshop 26-2-2013.pdf and a photo of the panellists is joined.

Many notified bodies have resources to perform regulatory reviews in the EU and also have sufficient expertise to support other Regulatory Authorities in the United States, Canada, Australia, Japan, Saudi Arabia, South Korea, Hong Kong and Taiwan. Moreover, Mr Bos points that the most crucial question for NBs is the ratio risk benefice.

Mr Edelhauser, president of NBOG, notices that CAs have improved the way they are monitoring NBs. In their meetings CAs set up guidelines and criteria.

Probably it is better to concentrate on competencies such as for examples described in the Code of Conduct all the members signed.

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