

**WRITTEN REPORT TO MDEG
14/15 January 2013**

PROGRESS REPORT FROM THE NOTIFIED BODY OPERATIONS GROUP

Agenda Point: 8.3 NBOG

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MAIN ACTIVITIES/PRIORITIES SINCE THE LAST MDEG REPORT (JANUARY 2012):

In 2012 NBOG held three meetings in February, June (2 days) and November with representatives from on average 16 Member States, EFTA countries, MRA partners and the Commission.

Key aspects of the meetings were

- The **PIP breast-implant scandal**. NBOG discussed various measures for improvement in auditing (e.g. unannounced audits, sample testing) as well as the expected revisiting of and reporting on the list of designated notified bodies for class III medical devices, which are now part of former Commissioner Dalli's **Joint Plan for Immediate Action**.

The group pointed out that the use of such actions like unannounced audits, which are already existing possibilities within the Directives, will only work if appropriate mechanisms for a harmonised implementation are established because they will have direct effect on notified body competition.

A major issue to be taken into account is a "redesign" of the information obligations and the information system and information flow in order to establish an efficient use of resources. NBOG recommended that information sources (e.g. FDA warning letters, device alerts) should be screened centrally and relevant information relating to manufacturers and devices should be provided via a database accessible to Competent Authorities and notified bodies for their use for preparation of audits / inspections. Critical information needs to be forwarded actively.

In addition, the Designating Authorities committed to review notified body activities on breast implants, especially the assessment of design dossier examinations.

- Discussions on the future **designation criteria** for notified bodies and a **revised process for the designation and monitoring of notified bodies** for medical devices. Both work items have been taken up by a CMC/NBOG subgroup. The model for a new designation process has been endorsed by CMC¹. Both work items need to be seen in connection with the NBOG recommendation on establishing a **peer review system** for designating authorities, which was agreed by the Competent Authorities already in 2011. This and the work on the designation criteria flow in the Commission proposals for the new regulations on medical devices.
- Multiple discussions on various drafts of the "**Commission implementing regulation on the designation and the supervision of notified bodies** under Directives 90/385/EEC on active implantable medical devices and 93/42/EEC on medical devices" and of the "**Commission Recommendation** on the audits and assessments performed by notified bodies in the field of medical devices". NBOG focused primarily on the implementing regulation, discussed various options and sent several sets of comments to the Commission.
- Discussions on the articles published by The Daily Telegraph and the British Medical Journal on an undercover action challenging the performance of notified bodies in various Member States. This discussion revealed the need for prioritizing the pilot program activities for **joint assessments** as part of the Joint Plan for Immediate Action and to revitalize the peer review program. The joint assessments will start in January 2013 and the pilot program will be coordinated by a small group composed of representatives from the Commission, the CMC and from NBOG.

¹ See http://www.cmc-md.eu/mediapool/97/978504/data/CMC_decision_nb-designation-process.pdf

- Starting the revision of [NBOG BPG 2006-1](#) "Change of Notified Body" in order to include recent experience made in this area and
- The revision of [NBOG BPG 2010-3](#) "Certificates issued by Notified Bodies with reference to Council Directives 93/42/EEC, 98/79/EC, and 90/385/EEC". Due to different views in NBOG and the release of the Commission proposals on the future medical device regulation it was agreed that this work item will be followed up as a work item of the Central Management Committee (CMC)². This work should also help the Council Working Party dealing with the proposals.
- Revisions of the scope expressions in [NBOG BPG 2009-3](#) "Guideline for Designating Authorities to Define the Notification Scope of a Notified Body Conducting Medical Devices Assessment". Some changes and new scopes (e.g. "non-active devices for ingestion") were agreed and will be used for future designations.
- Discussions on the "Code of Conduct for Notified Bodies" (version 2.7) drafted by a group of notified bodies. NBOG provided comments to NB-Med and Team-NB.
- Discussion on the use of ISO/CASCO 17000 series of standards and their use in the designation and notification of notified bodies. NBOG was informed on a follow-up study³ of the German Commission for Occupational Health and Safety and Standardization (KAN) on its Report "[Accreditation of conformity assessment bodies](#)" analysing relevant ISO/IEC 17000 (draft) standards with respect to the **presumption of conformity** compared with provisions in decision 768/2008/EC.

WORK PROGRAMME 2013:

In addition to the follow-up of the ongoing combined work with CMC and the above mentioned work items Revision of [NBOG BPG 2006-1](#) "Change of Notified Body" and Revision of [NBOG BPG 2010-3](#) "Certificates issued by Notified Bodies ..." NBOG will resume its activities on the postponed work items

- Guidance on "**Handling of Changes**"
- Guidance on "**Renewal of Certificates**"
- Revision of **checklists and forms** for Designating Authorities currently being part of the NBOG [Designating Authorities Handbook](#)" and especially
- Work items emerging from the **pilot program on joint assessments**, e.g. training of assessors from designating authorities, setting up of general assessment plans, reporting and clarification and harmonisation when different interpretations are identified.

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Current Chair of NBOG

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² See http://www.cmc-md.eu/mediapool/97/978504/data/NWIP_3_Content_of_Notified_Bodies_Certificates.pdf

³ See http://www.kan.de/fileadmin/user_upload/docs/Fachbeitraege/Articles_EN/AnhaengeZ_Akkreditierung-en.pdf