WRITTEN REPORT TO MDEG 28 May 2015 PROGRESS REPORT FROM THE NOTIFIED BODY OPERATIONS GROUP	
Agenda Point:	**8.3**
Contact Person:	**Rainer Edelhäuser**

MAIN ACTIVITIES/PRIORITIES SINCE THE LAST MDEG REPORT (NOVEMBER 2014):

NBOG had one meeting in December 2014 with representatives from more than 20 Member States, EFTA countries, MRA partners and the Commission (including representatives from FVO, the Food and Veterinary Office).

Key aspects of the meetings were

- The **mandatory joint assessments** concerning the performance and designation of Notified Bodies in the medical devices sector. The joint assessments are operated by a **coordination group** composed of representatives from the Commission and NBOG. Joint assessment teams consist of experts from other national Designating Authorities and Commission experts from FVO. They accompany national Designating Authorities when they perform (re-)designation assessments of their notified bodies. The coordination group also discusses procedural and content aspects arising from the joint assessments.

  For information on the **voluntary programme** see the FVO Joint Assessment Programme **Final Overview Report** published in April 2015 on the Commission's PIP Action Plan website http://ec.europa.eu/growth/sectors/medical-devices/pip-action-plan/index_en.htm.

- The work items relating to the discussion on and questions arising from the **Commission implementing regulation (EU) No 920/2013** on the designation and the supervision of notified bodies:

  - a "Best practice" document describing the (re-)designation process flow including time lines from the application up to the final decision by the designating authority. A model assessment plan and an application review form have been developed, which will be formally endorsed after having gained sufficient experience.
  - a "Best practice" document and a checklist to minimise "diverging opinions"; it was agreed that the checklist should have the form of an aide memoir
  - aspects relating to the "pool of assessors" including training activities

  Based on the practical experience gathered in the various mandatory joint assessments progress was made but up to now the discussions are still ongoing.

- Discussion of questions arising from the Commission recommendation 2013/473/EU on the audits and assessments performed by notified bodies in the field of medical devices.

- Discussion on a document on testing within unannounced audits drafted by the Notified Body Recommendation Group (NBRG). Comments to NBRG have been provided in written prior to their meeting in April 2015.

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- Discussion on the revision of NBOG BPG 2006-1 “Change of Notified Body” where special focus was put on the status of certificates issued by a Notified Body in case that it will not be re-designated or re-designed for a reduced scope only. It was agreed that the discussions in the Council Working Party on the new medical device regulations should be taken into account prior to further work on the document.
- Discussion on the Radar television program (NL) where notified bodies were approached to review a file for a vaginal mesh like product and whether such pre-submission reviews were good practice. In addition, critical examples of promotion by notified bodies at conferences where consultancy services for medical devices had been offered and other questions concerning independence and impartiality were discussed. The Designating Authorities involved were asked to investigate and the group agreed to strengthen the monitoring of notified bodies with regard to these aspects.
- Discussion on the various communication flows between authorities and **cooperation between working groups**. In addition to the already decided cooperation of COEN and NBOG representatives analysing necessary steps for improving the currently used tools for information exchange another coordination group between the Clinical Investigation and Evaluation Working Group (CIE) and NBOG has been initiated to work on special aspects
- Information and discussion on various IMDRF, standards and European co-operation for Accreditation issues

WORK PROGRAMME

NBOG will continue to focus on work items relating to the implementation of

- the Commission Implementing Regulation (EU) No 920/2013 on the designation and the supervision of notified bodies
- the Commission Recommendation on audits and assessments performed by notified bodies in the field of medical devices
- the preparation of tasks resulting from the revision of the medical device directives, esp. on the scope of NB designation under the future IVD regulation.

Dr. Rainer Edelhäuser
Current Chair of NBOG

ZLG – Zentralstelle der Länder für Gesundheitsschutz
bei Arzneimitteln und Medizinprodukten
Central Authority of the Laender for Health Protection
with regard to Medicinal Products and Medical Devices
Heinrich-Böll-Ring 10
D-53119 Bonn
Fon: +49 228 97794 10
Fax: +49 228 97794 44
E-Mail: rainer.edelhaeuser@zlg.nrw.de
Website: www.zlg.de, www.nbog.eu