NBOG meeting

On 4 February 2010, NBOG have met for their first meeting in 2010. 25 Representatives from 20 Member States, EFTA and accession countries and the European Commission were present.

Key aspects of the meeting were

- the finalisation of the "Guidance for Notified Bodies auditing suppliers to medical device manufacturers". The document takes into account recent discussions of GHTF Study Groups 3 and 4 and is based on their respective documents GHTF SG3/N17 and GHTF SG4(WD)N84R12. After the last NBOG meeting in 2009, a new draft was sent out for comments also to the Notified Bodies Group. The finalised document was endorsed by the Competent Authorities during their Meeting in Madrid in March 2010 and is now published as NBOG BPG 2010-1 on the NBOG website www.nbog.eu.
- the finalisation of the "Guidance on Audit Report Content". This document is the European implementation of GHTF SG4/N33R16 : 2007 Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 3: Regulatory Audit Reports. The finalised document takes into account comments provided by the Notified Bodies Group. It was endorsed by the Competent Authorities during their Meeting in Madrid in March 2010 and is published as NBOG BPG 2010-2 on the NBOG website www.nbog.eu.
- the revision of NBOG BPG 2006-2 "Certificates issued by Notified Bodies with reference to Council Directives 93/42/EEC, 98/79/EC, and 90/385/EEC". An urgent revision was necessary to align the document with the changes introduced by directive 2007/47/EC. The Competent Authorities endorsed the revised document during their Meeting in Madrid in March 2010. It is published as NBOG BPG 2010-3 on the NBOG website www.nbog.eu. Member States decided also that a deeper revision should start as part of the amended NBOG work programme.
- the finalisation of the "Clinical data checklist", which is a tool for Designating Authorities in assessing their Notified Bodies. The finalised checklist takes into account comments from the European Clinical Investigation and Evaluation Working Group and was endorsed by the Competent Authorities during their Meeting in Madrid in March 2010. It is published as NBOG CL 2010-1 on the NBOG website www.nbog.eu.
- the finalisation of a template for notifications between Member States and the European Commission on certificates suspended, re-instated, withdrawn or refused. The document was developed in cooperation with the EUDAMED Working Group and defines the information required for such notifications. The finalised form was endorsed by the Competent Authorities during their Meeting in Madrid in March 2010 and is now published as NBOG F 2010-1 on the NBOG website www.nbog.eu. It should also be used for information exchange on falsified certificates.
- an update on the peer review programme 2009 and 2010. In 2009 eight observed assessments have been performed. For 2010 more than 12 are already planned.

Other work items having been discussed were i.a.

- the implementation of directive 2007/47/EC and the related review of existing scopes of designated Notified Bodies according to NBOG BPG 2009-3 "Guideline for Designating

Authorities to Define the Notification Scope of a Notified Body Conducting Medical Devices Assessment". It was agreed that the first necessary amendments to the scope expressions in this document would be made not prior to the beginning of next year,

- conformity assessment and related Notified Body issues within the planned revision of the IVD directive,
- the role of Notified Bodies within the regulation on Advanced Therapy Medicinal Products (ATMPs) for those ATMPs incorporating one or more medical devices, and
- the NBOG annual report 2009, which should be published in the second quarter of 2010.

April 2010, re