



NBOG meeting

On 13 November 2008, NBOG have met for their third meeting in 2008.

31 Representatives from Member States, EFTA, accession countries and the European Commission were present. For dedicated agenda items, also the Vice chair of the Notified Bodies Group NB-MED participated.

Key aspects of the meeting were

- the presentation of a new NBOG website www.nbog.eu describing briefly the terms of reference, membership, work programme and working methods of NBOG. Sub-sites contain NBOG's endorsed documents, national contact points and reports and news – all aiming for a better transparency for the work of NBOG.
- the finalization of the guidance document on Design Dossier Examination and Report Content, taking into account all comments made by the Notified Body Group NB-MED / NBRG. The document will be forwarded to the Competent Authorities Meeting in Prague for approval.
- discussion on the draft guidance document Notified Bodies and the vigilance system. Comments made by the Notified Body Group NB-MED / NBRG and the Vigilance Working Group were debated and accepted. Due to delayed comments, the document was scheduled to be finalized at the next meeting.
- discussion on a draft guidance document relating Notified Body's Tasks of Technical File Assessment on a Representative Basis. The draft document is in line with the Competent Authorities decisions taken in their meeting in Paris on questions relating to timing, kind and depth of assessment, reporting and sampling.
- discussion on a draft guidance on the Role of Notified Bodies in Own Brand Labeller (OBL) Situations. Due to controversial opinions NBOG stopped working on this item and will ask for a decision by the Competent Authorities.
- discussion of the European Commission's Note to the MDEG on the use of GHTEF STED document and its use in Europe. NBOG clearly expressed that the STED (Summary Technical Documentation, GHTEF/SG1/N011 : 2008) may be helpful but not sufficient e.g. for a design dossier examination. They suggested that the use of the STED to assist in the demonstration of conformity to the Directive should be addressed within the revision of the NB-MED recommendation on technical documentation.
- discussion on a draft guidance document on the scope of designation and related comments received. This item is part of the peer review activities and aims for harmonization of scope expressions, which is necessary for better consistency within the medical device sector of the NANDO database.

Other work items that were discussed were a standardized reporting format for the observed assessments, the peer review planning for 2009 and the re-introduced NBOG report for the period 2005 – 2008.