



NBOG meeting

The first NBOG meeting this year took place in Brussels on 12 June 2007. Representatives from 15 Member States, 2 EFTA countries, and the European Commission were present.

Within the meeting, progress reports on the actual tasks of NBOG's work programme were presented and respective draft documents were discussed. These comprise

- the revision of MEDDEV 2.10/2 "Designation and Monitoring of Notified Bodies within the Framework of EC Directives on Medical Devices", especially within the light of the new ISO/IEC 17021 "Conformity assessment – Requirements for bodies providing audit and certification of management systems";
- a guidance document on the content of design dossier reports;
- guidance on the role of Notified Bodies in the own brand labeller (OBL) situation;
- the review of Notified Body recommendations, e.g. on "Combination of CE and non-CE marked devices" and "Technical documentation";
- the peer review programme between the Designating Authorities. Next steps are a data collection on the status quo of the designation and monitoring processes within the Member States and the implementation of the audit programme agreed by the Competent Authorities;
- the description of the scope of designations on Notified Bodies. The aim of this task is to develop a common description consisting of an adequately detailed hierarchy of terms, which not only should help Designating Authorities to describe the scopes of Notified Bodies in a comparable and sufficiently detailed manner but also to minimize the "distortions" within the NANDO database identified by the public.

NBOG discussed also the current status and necessary comments on GHTF documents on

- "Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance on Medical Devices (STED)" (GHTF SG1) and
- "Regulatory Audit Reports" (GHTF SG4)

and ways to improve the use of GHTF documents within the European system.

Based on a decision of the last Competent Authorities meeting, a new work item of NBOG will be the elaboration of a guidance document relating to the Notified Body's tasks in quality system audits to assess design documentations of the product(s) concerned on a representative basis. The document should specify how Notified Bodies should interpret the respective changes in Annexes II, V and VI of the revised MDD.

June 2007, re