NBOG meeting

On 15 January 2008, NBOG have met for their first meeting in 2008. Representatives from more than 20 Member States, EFTA and accession countries and the European Commission were present.

Various work items have been on the agenda. Especially, progress was made on

- a guidance document on the content of design dossier examination reports;
- the guidance document “Notified Bodies and the vigilance system”;
- the review of Notified Body recommendations, e.g. on “Accessories and other Parts of AIMD“ and “Technical Documentation”;
- the peer review programme between the Designating Authorities. A first analysis on the outcome of the survey on the status quo of the designation and monitoring processes within the Member States was presented and the next steps in the observed assessment programme have been defined;
- the description of the scope of designations on Notified Bodies. Consensus was achieved for the description of the scope under Directive 98/79/EC but the description of the scopes for Directives 93/42/EEC and 90/385/EEC need some more discussion. A small group will work on a proposal taking into account CEN TR 15133.

Other work items having been discussed were

- the setting up of a publicly available list of NBOG contact points on the website of the European Commission. This will be done in conjunction with the redesign of the NBOG website;
- the content of a guidance on the role of Notified Bodies in the own brand labeller (OBL) situation;
- the content of a guidance on the tasks of Notified Bodies to assess technical documentations on a sample basis as defined by Directive 2007/47/EC, and
- the implementation of GHTF documents like “SG4/N30R20:2006 Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 2: Regulatory Auditing Strategy” and “SG4/N33R16:2007 Part 3: Regulatory Audit Reports” in Europe.

As decided by the Competent Authorities meeting in Lisbon July 2007, a new work item of NBOG will be the elaboration of a guidance document relating to the Notified Body’s tasks in auditing quality system audits with respect to subcontractors of medical device manufacturers. Currently, there is a notable difference in the way this is approached by Notified Bodies.

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