

**WRITTEN REPORT TO MDEG
30 November 2010**

PROGRESS REPORT FROM THE NOTIFIED BODY OPERATIONS GROUP

Agenda Point: 6.2 NBOG

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MAIN ACTIVITIES/PRIORITIES SINCE THE LAST MDEG REPORT (JUNE 2010) – WORK PROGRAMME FOR 2011:

Since the last MDEG meeting NBOG met twice on 1 July and 11 November 2010.

Main activities/work items

- With the finalisation of three further key documents early this year¹ work can now focus on the work packages to be defined by the Member States Working Group, the so-called “Prague-Uppsala Group”. This group identified three areas for improvement in the Notified Body sector: 1. To develop a **criteria document** defining detailed and binding requirements for Notified Bodies, 2. to describe a revised **designation process** with the intervention of representative(s) of other Member States as “second opinion” prior to the final decision by the relevant Designating Authority, and 3. further detailing of the **peer review process** with the development of a criteria set for Designating Authorities.
- A related work item agreed at the last CA Meeting in Liège September this year is the revision of checklists and forms for Designating Authorities currently being part of the [Designating Authorities Handbook](#). These “tools” for Designating Authorities should be published in the newly created [checklist section](#) of the NBOG website.
- Another new work item will be the development of guidance documents already being referenced as “separate guidance” in [NBOG BPG 2009-1](#) Guidance on Design-Dossier Examination and Report Content. They should specify the handling of changes and the renewal of certificates. Here, a close co-operation with NB-MED and their already existing draft documents is planned.
- Part of the current work programme is also the revision of [NBOG BPG 2010-3](#) “Certificates issued by Notified Bodies with reference to Council Directives 93/42/EEC, 98/79/EC, and 90/385/EEC”. The document has been endorsed by the Competent Authorities during their Meeting in Madrid in March 2010 but in addition the start of a deeper revision was decided.

Other work items having been discussed were i.a.

- the first experience gained with the implementation of the new requirements on technical documentation assessment on a representative basis for class IIa/IIb devices. Here Designating Authorities should monitor the activities of their Notified Bodies closely to achieve a more harmonised approach across Europe,
- the 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” and the respective new notifications in [NANDO](#) related to the implementation of directive 2007/47/EC. There are still some inconsistencies in the system, which should be solved with the NANDO

¹ See report on the first [NBOG meeting 2010](#)

unit. Amendments to the scope expressions would be made not prior to the beginning of next year,

- an update on the peer review programme 2010. There is a steady increase in the assessments being performed in the last years. It is expected that around 2/3 of the 25 Designating Authorities having designated Notified Bodies will be assessed until end of 2010,
- recent cases on breast implants and drug-eluting balloon catheters,
- 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 potential impact of recent activities in the field of accreditation, e.g. the IAF Medical Device Conformity Assessment Scheme (MDCAS), which is seen critically in respect to Notified bodies.

For **further information** please see www.nbog.eu.

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