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 year[1] 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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