

PROPOSAL FOR NEW WORK ITEM



PROTECTING PUBLIC HEALTH TOGETHER

PART A: TO BE FILLED IN BY THE APPLICANT

Title Proposed work item (Max 5 keywords)

Specific designation criteria for NB

CMC-Board History (list of references of all relevant communication to/from CMC-Board concerning this work item)

Applicant

➤ Applicant member of CMC

- AT BE BG CH CY CZ DE DK EE
 ES FI FR GR HR HU IE IS IT
 LI LT LU LV MT NL NO PL PT
 RO SE SI SK TR UK

➤ Applicant not within CMC-members

- Working Group Name WG:
 Other: Name Organisation:
Address:

Contact person:

Telephone No: Fax No:

E-mail:

Date:

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Proposed work item

To develop a proposal for more specific and mandatory criteria for designation and operation of notified bodies of medical devices, e.g. by modification of Annex XI of 93/42/EEC and the equivalent Annexes.

Rationale for application

Member States and the European Commission identified a need for more specific and mandatory designation criteria – especially in the fields of competency, qualification, and impartiality – to improve the performance of notified bodies system for medical devices.

The set of criteria (revised Annex) should potentially include text from Decision 768/2008/EC (e.g. R17), the NBOG designating authority handbook, MEDDEV 2.10/2 and GHTF SG4 documents.

Application of those criteria should enable consistency in NB performance, help to ensure fair competition between NBs and enhance harmonisation of procedures applied by Authorities to designation and monitoring of notified bodies.

Arguments pro and against NWI

Supporting information (Working Groups, CAMD, etc.)

Is there a consensus among Member States?

What are the main reasons of lack of consensus?

There is broad consensus between MS, COM and Industry on the necessity of this NWI. The NWIP is in line with the [Prague Resolution on recast of medical devices directives](#) and following discussion in CAMD, MDEG, Prague Uppsala Group (PUG). Art. 16 (2) of 93/42/EEC could be used as a legal instrument to amend Annex XI.

For the recast, the right to initiate changes of the existing legislation lies within the Commission.

Action/Decision proposed by applicant

CMC should agree on a proposal to the European Commission to amend Annex XI of MDD 93/42/EEC (and others) in an appropriate way.

Proposal for the lead official:

IR Niall MacAleenan

Supporting information (Working Groups, CAMD, etc.)

+ History of discussion: provide here the list of hyperlinks to relevant documents (eg. CIRCA)

CAMD Resolutions, see <http://www.nbog.eu/5.html>

Decision 768/2008/EC <http://eur-lex.europa.eu/768/2008>

Regulation (EC) No. 765/2008 <http://eur-lex.europa.eu/765/2008>

GHTF SG4 documents <http://www.ghf.org/sg4/>

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NBOG designating authority handbook <http://www.nbog.eu/>,

- MEDDEV 2.10/12 etc <http://ec.europa.eu/meddev/>.

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PART B: TO BE FILLED IN BY THE CMC-BOARD

<p>Proposed work item</p>	<p>Within scope of CMC? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Is Proposal mature for CMC ? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Recommendations:</p>
<p>Rationale for application</p>	<p>Description complete? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Recommendations:</p>
<p>Arguments pro and against NWI Supporting information (Working Groups, CAMD, etc.) Is there a consensus among MS? What are the main reasons of lack of consensus?</p>	<p>Description complete? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Recommendations:</p>
<p>Proposal for the lead official</p>	<p>Accepted? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Proposed alternative candidate:</p>
<p>Supporting information (Working Groups, CAMD, etc.) + History: provide here the list of links to relevant documents (eg. CIRCA)</p>	<p>Documentation complete? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Recommendations:</p>

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PART C: RECOMMENDATION FROM CMC-BOARD TO CMC

CMC meeting date	23.02.2011
CMC meeting agenda item	8 a Give NBOG the task to specify the criteria for designation
Transfer to CMC meeting	<input checked="" type="checkbox"/> For consideration <input checked="" type="checkbox"/> For appointment of the lead official <input checked="" type="checkbox"/> For allocation of work <input type="checkbox"/> For decision
Action/Decision proposed Acceptance of the NWIP, Start of the preparatory work	
Proposal for the lead official: IR Niall MacAleenan	
Proposal for the allocation of potentially necessary additional preparatory work: NBOG	
Proposed work planning and timing to output: Start: Next NBOG meeting on the 22 nd June 2011 Finalisation: CMC-meeting in Autumn 2011	
Conclusion of the CMC-Board CMC should consider the acceptance of the NWIP Date: 25.01.2011	