



## PROPOSAL FOR NEW WORK ITEM

### Proposed work item

Development of detailed measures necessary to ensure consistent application of the criteria on the designation of Notified Bodies.

The measure shall include:

1. Proposals to enable the joint assessment process similar as developed by the CMC.
2. More specific criteria on Notified Bodies to enable a consistent application thereof.
3. A proposal around a mandatory peer review system between designating authorities to ensure that Notified Bodies always meet the designation criteria.

### Rationale for application

Competent Authorities have, since February 2008, requested several times that the Commission improve the current Notified Bodies designation system by using the implementing measure described in article 16(2) of the MDD and article 11(2) of the AIMDD. The Competent Authorities have pointed out the critical need to improve the consistency in the application of the designation criteria for Notified Bodies to ensure that they are overseen effectively and perform their conformity assessment activities to a high standard and consistent with their competencies.

In Spring 2012, the COM started to develop such an implementing measure. It is planned that later in 2012 experts from Member States will vote on a draft implementing measure via the "article 7 committee". It is the general view of the CAs that the proper functioning of NB is a crucial element of the current legislation. The implementing measure will be the only legal means of achieving a better and harmonised performance of Notified Bodies within the next number of years and in advance of the broader legislative revision currently being undertaken by the COM. Therefore it is important that the new legal provisions indeed lead to better and harmonised designation and monitoring of NB in the EU.

The COM has already indicated, that the implementing measure will contain changes of the designation process, more specific requirements on NB and non-binding requirements on a peer review system.

The CAMD with the Prague-Uppsala-Group and the CMC have already identified critical barriers leading to an inconsistent application of the designating criteria. They have also developed proposals on practical measures to improve and harmonise the performance of Notified Bodies by modifying the designation process (involving a joint assessment by authorities), by more specific NB criteria and by introducing a mandatory peer review system amongst designating authorities.

These proposals are supported by a qualified majority of CAs. There is the intention that these proposals will be implemented into the legislation during the lawmaking process on the ongoing revision of the European medical devices regulation. Due to the transitional character of the intended implementing measure there is the need to modify the CMC and CAMD proposals appropriately in line with the legal limitations of article 16(2) MDD and the current legal framework.

Therefore COM is invited to use the proposals as a basis for an implementing measure.

### 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?

### Action/Decision proposed by applicant

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CMC should decide to start the NWI

**Proposal for the lead official:**

Niall MacAleenan

**Supporting information (Working Groups, CAMD, etc.)**

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

- Findings of the Prague-Uppsala Group presented to and agreed by the CAMD
- CAMD Resolution from the 21<sup>st</sup> CAMD in Brdo
- [http://cmc-md.eu/mediapool/97/978504/data/NWIP\\_1\\_Specific\\_designation\\_criteria\\_for\\_NB\\_1.pdf](http://cmc-md.eu/mediapool/97/978504/data/NWIP_1_Specific_designation_criteria_for_NB_1.pdf)
- <http://cmc-md.eu/mediapool/97/978504/data/Ap11dnw4.pdf>
- COM draft on a NB regulation

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

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|---|---|
| <p><b>Proposed work item</b></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><b>Rationale for application</b></p>   | <p>Description complete?                    <input checked="" type="checkbox"/> Yes                    <input type="checkbox"/> No</p> <p>Recommendations:</p>  |
| <p><b>Arguments pro and against NWI</b><br/>         Supporting information (Working Groups, CAMD, etc.)<br/>         Is there a consensus among MS?<br/>         What are the main reasons of lack of consensus?</p> | <p>Description complete?                    <input type="checkbox"/> Yes                    <input checked="" type="checkbox"/> No</p> <p>Recommendations:</p>  |
| <p><b>Proposal for the lead official</b></p>  | <p>Accepted?                                      <input checked="" type="checkbox"/> Yes                    <input type="checkbox"/> No</p> <p>Proposed alternative candidate:</p>   |
| <p><b>Supporting information (Working Groups, CAMD, etc.)</b><br/>         + 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**

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| <b>CMC meeting date</b>   | <b>17.07.2012</b>  |
| <b>CMC meeting agenda item</b>  | <b>10</b>  |
| <b>Transfer to CMC meeting</b>  | <input checked="" type="checkbox"/> For consideration<br><input checked="" type="checkbox"/> For appointment of the lead official<br><input checked="" type="checkbox"/> For allocation of work<br><input type="checkbox"/> For decision |
| <b>Action/Decision proposed</b><br>CMC should decide to accept the NWI  |  |
| <b>Proposal for the lead official:</b><br>Niall MaAlleenan  |  |
| <b>Proposal for the allocation of potentially necessary additional preparatory work:</b><br>Small group of NBOG and CMC members and COM |  |
| <b>Proposed work planning and timing to output:</b><br>End of September 2012  |  |
| <b>Conclusion of the CMC-Board</b> CMC should accept the NWI<br>Date: 28.06.2012  |  |