

# 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)

Preparation of a pilot on a new designation procedure 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     COM

#### ➤ Applicant not within CMC-members

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

Contact person:

Telephone No:                      Fax No:

E-mail:

Date: 05.06.2012

### Proposed work item

## PROPOSAL FOR NEW WORK ITEM

The harmonised implementation and interpretation by the Competent Authorities of the expected implementing measure on the designation of NB shall be prepared in a way that in 2013 the designation and re-designation of NB can be done in accordance with the changed requirements.

This includes in particular:

1. Definition of requirements on the necessary skills and/or training of European NB Assessors from the designating authorities
2. Creation of a pool of European NB Assessors on the basis of nominations by the CA and by confirming compliance with the requirements under 1.
3. Development of a common assessment scheme/procedure
4. Development of common formats for reports etc.

### **Rationale for application**

Commissioner Dalli proposed early in 2012 that with the beginning of 2013 Notified Bodies responsible for Class III medical devices shall be audited by a team involving national and Commission staff. The criteria for these audits should be defined with an implementing act to be adopted End of 2012. Experiences with these joint assessments should be feed into the negotiations in the European Council and Parliament on the revision of the European medical devices legislation. To be able to start the joint assessments, preparatory work of the CAs (via NBOG and CMC) in close co-operation with the COM is necessary.

### **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**

CMC should decide to start the NWI

### **Proposal for the lead official:**

to be decided

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

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

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

<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> 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 type="checkbox"/> Yes                    <input checked="" type="checkbox"/> No</p> <p>Recommendations:</p>
<p><b>Proposal for the lead official</b></p>	<p>Accepted?                                    <input type="checkbox"/> Yes                    <input type="checkbox"/> No</p> <p>Proposed alternative candidate: NBOG member from UK</p>
<p><b>Supporting information (Working Groups, CAMD, etc.)</b> + History: provide here the list of links to relevant documents (eg. CIRCA)</p>	<p>Documentation complete?                    <input type="checkbox"/> Yes                    <input checked="" type="checkbox"/> No</p> <p>Recommendations:</p> <p>Consider existing NBOG guides</p>

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**PART C: RECOMMENDATION FROM CMC-BOARD TO CMC**

<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 <input checked="" type="checkbox"/> For appointment of the lead official <input checked="" type="checkbox"/> For allocation of work <input type="checkbox"/> For decision
<b>Action/Decision proposed</b> CMC should decide to accept the NWI	
<b>Proposal for the lead official:</b> CH, UK, IE	
<b>Proposal for the allocation of potentially necessary additional preparatory work:</b> small group of NBOG and CMC members and COM	
<b>Proposed work planning and timing to output:</b> Final draft before end of 2012	
<b>Conclusion of the CMC-Board</b> CMC should accept the NWI, Date: 28.6.2012	