

# 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)

List of External Consultations

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

NWIP accepted by CMC-Board for 2<sup>nd</sup> CMC-meeting

### **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:

**Proposed work item**

## PROPOSAL FOR NEW WORK ITEM

Sharing knowledge about external consultations, relevant for the medical device competent authorities by establishing an oversight list of external consultations.  
Make "Consultations" a fixed agenda item for CMC-meetings. Publish a list of topical consultation on the website of the CMC

### **Rationale for application**

There is a lack of systematic oversight on consultations, relevant for the medical device competent authorities.

### **Arguments pro and against NWI**

Pro:

- it is a simple way to improve oversight of consultations
- More and enhanced contributions of medical device Competent Authorities/Member States to external consultations raises the impact, visibility and recognition of medical device Competent Authorities/Member States as a group

### **Action/Decision proposed by applicant**

1. Establish an oversight list of external consultations at the CMC-website.
2. Make the subject of consultations a fixed agenda item for CMC-meetings.

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

NL Sabina Hoekstra

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

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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 checked="" type="checkbox"/> Yes                    <input 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> + 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

<b>CMC meeting date</b>	23.02.2011
<b>CMC meeting agenda item</b>	<b>8g NWIP</b> - Coordination of external consultations
<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> Implementing the use of the template on consultations	
<b>Proposal for the lead official:</b> NL Sabina Hoekstra	
<b>Proposal for the allocation of potentially necessary additional preparatory work:</b> CMC – Board	
<b>Proposed work planning and timing to output:</b> Publication on the CMC website until March 2011	
<b>Conclusion of the CMC-Board</b> CMC should accept the NWIP Date: 25.01.2011	