

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)

Improve Readability of IFU

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

Item has been proposed by CMC-members at the first CMC-Meeting 1 Dec 2010

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 improve readability of instructions for use

Rationale for application

Important issue of patient/user safety, so far efforts on improvement have not been successful

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 elaborate proposals, how to improve readability of IFU

Proposal for the lead official:

AT Wolfgang Ecker

Supporting information (Working Groups, CAMD, etc.)

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

- Not supplied at 1st CMC meeting

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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 type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p> <p>Recommendations:</p> <p>Important issue. At this stage, no detailed proposal in substance is available and would presumably need quite some time for elaboration; it is therefore outside the scope of CMC. On the other hand it seems the last opportunity time slot for the CA's to approach the COM to consider more explicit wording on improved readability of IFU within the current Revision of legislation.</p>
<p>Rationale for application</p>	<p>Description complete? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p> <p>Recommendations:</p> <p>See above</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 type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p> <p>Recommendations:</p> <p>See above</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 type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p> <p>Recommendations:</p>

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PART C: RECOMMENDATION FROM CMC-BOARD TO CMC

CMC meeting date	23.2.2011
CMC meeting agenda item	8 e NWIP Improve the readability of instructions for use
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 Transfer proposal to CAMD to examine legislation for improvement of readability of IFU and to elaborate proposal for Revision/Recast for consideration by COM	
Proposal for the lead official: AT Wolfgang Ecker	
Proposal for the allocation of potentially necessary additional preparatory work: CAMD	
Proposed work planning and timing to output: Discuss the proposal on CAMD Meeting of 24/25.2.2011 and start elaboration of a detailed proposal. Finalisation until autumn 2011	
Conclusion of the CMC-Board Proposal to improve readability of IFU is an important issue for patient/user safety; several attempts, eg. in standardization, however have been rather lengthy and not satisfactory. Elaboration of a detailed proposal is outside the scope of CMC, as it is a decision body. At this stage it seems most important and first priority to anchor more explicit core requirements on the readability of the IFU within the current Revision/Recast exercise. A more explicit foundation within legislation will then trigger improved standardization, implementation and if necessary also enforcement. Therefore the CAMD should address this issue. The results will be used to approach the COM to consider it within the current Revision exercise and to get a decision by the CMC later on. Date: 25.1.2011,	