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)

Time periods for corrective measures

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:

Proposed work item

To provide guidance how to enforce corrective actions when the breaches does not impose a significant risk to the user/patient or other persons. Such situations may occur when

- a market surveillance activity has revealed an administrative breach (e.g. label)
- a decision taken will affect the classification of a group of products
- the scope of a notified body is restricted

The guide shall be based on the directives principles for risk management and proportionality and include guidance when to allow transitional periods.

Rationale for application

CA's in all member states take actions against medical devices put on the market in violation with the directives. According to the MDD MS are required to give the manufacturer an appropriate time frame to renew the conformity with the regulation in cases of detected non- compliances not causing an unacceptable risk to the patient, user or others.
Today CA's take very different measures even when the breaches are very similar or even identical. A manufacturer may in one country get a specified (varying from MS to MS) timeframe to align with the regulatory system while a manufacturer in another country may face an immediate ban from the market.

These differences will have a serious effect on the manufacturer's situation (possibility to survive) in the different MS and are an indication for a fragmented market. MS should take action to harmonise the enforcement of decisions taken to eliminate regulatory breaches. (Focus should be on measures taken with a reference to MDD article 18/IVDD article 17/AIMDD article 13 as these decisions are not foreseen to be examined by the COM.)

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

To ask COEN to set up a guide according to this proposal. The guide should be ready for presentation early 2012.

Proposal for the lead official:

SE Lars Johansson

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

Proposed work item	Within scope of CMC?	☒ Yes	☐ No
	Is Proposal mature for CMC ?	☒ Yes	☐ No
	Recommendations:		
Rationale for application	Description complete?	☒ Yes	☐ No
	Recommendations:		
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?	Description complete?	☐ Yes	☒ No
	Recommendations:		
Proposal for the lead official	Accepted?	☒ Yes	☐ No
	Proposed alternative candidate:		
Supporting information (Working Groups, CAMD, etc.) + History: provide here the list of links to relevant documents (eg. CIRCA)	Documentation complete?	☐ Yes	☒ No
	Recommendations:		

REFERENCE N° CMC-Board**:**

PART C: RECOMMENDATION FROM CMC-BOARD TO CMC

CMC meeting date	**23.02.2011**
CMC meeting agenda item	**8f NWIP** Agree on consistent rules in respect of “periods of grace” to be allowed to manufacturers in order to allow non-conformities to be addressed or in cases of reclassification of devices
Transfer to CMC meeting	☒ For consideration ☒ For appointment of the lead official ☒ For allocation of work ☐ For decision
Action/Decision proposed Give COEN the task to provide a proposal	
Proposal for the lead official: SE Lars Johansson	
Proposal for the allocation of potentially necessary additional preparatory work: COEN	
Proposed work planning and timing to output: Finalisation until first CMC-Meeting in 2012	
Conclusion of the CMC-Board CMC should consider the acceptance of the NWIP Date: 25.01.2011	