14-20120628A

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)

Define content of market surveillance

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

NA

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: 28.06.2012

Proposed work item

The aim is to provide the answer on the question:
"What is market surveillance, what are the key elements ?"

Member States are requested by Commissioner Dalli to enhance their market surveillance within the sector of medical devices.
In COEN, there has been a 'tour de table' where all present MS have been asked to present their view on and activities in the context of market surveillance. Different aspects have been mentioned, and the diversity in replies indicated a high variation in actions performed.

Rationale for application

Commissioner Dalli requests Member States to reinforce their market surveillance in accordance with Directive 93/42/EEC and Regulation (EC) No 765/2008.

Art 2 of the MDD request that:
"Member States shall take all necessary steps to ensure that devices may be placed on the market and/or put into service only if they comply with the requirements laid down in this Directive when duly supplied and properly installed, maintained and used in accordance with their intended purpose."
IVDD adds "This involves the obligation of Member States to monitor the security and quality of these devices."

And Regulation (EC) No 765/2008 defines:
"'market surveillance' shall mean the activities carried out and measures taken by public authorities to ensure that products comply with the requirements set out in the relevant Community harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection;"

In order to organise market surveillance in an efficient way, a common understanding is necessary among MS with regard to the definition of market surveillance.
Also, after having defined what are the crucial elements for an efficient market surveillance, it paves the way towards a better planning of spread or coordinated activities and sharing of resources and a better communication on performed activities/actions.

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?

At the CA Meeting 2011-10-27/28 Sweden, together with Portugal, Finland and Austria, were commissioned to prepare a step by step guide for market surveillance.
The aim of this guide is to describe a logical sequence of surveillance activities based on the existing medical device directives and the New Legal Framework (NLF). The guide shall indicate the steps to take from the initial event triggering to the final communication of actions taken.
The following documents will form the basis for the development of the guide:

- "Draft model for a national market surveillance handbook" (Tampere 2006)
- The Prosafe report "Best Practice techniques in Market Surveillance"
- SOGS-MSG document N016 Risk assessment for market surveillance needs Towards a methodology for assessing risks presented by industrial products placed on the EU market in the framework of Registration 765/2008
- SOGS-MSG document N017 Overview of market surveillance (including safeguard mechanism) in the area of harmonised products.

In that context, a common interpretation/definition of market surveillance in relation to the sector of medical devices directives is the basis of the document.
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) •

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:		

PART C: RECOMMENDATION FROM CMC-BOARD TO CMC

CMC meeting date	**17.07.2012**
CMC meeting agenda item	
Transfer to CMC meeting	☒ For consideration ☒ For appointment of the lead official ☒ For allocation of work ☐ For decision
Action/Decision proposed CMC should decide to accept the NWI	
Proposal for the lead official:	
Proposal for the allocation of potentially necessary additional preparatory work: Sweden together with Portugal, Finland and Austria, in the context of the "Step by step guide for market surveillance"	
Proposed work planning and timing to output: Final draft before end of 2012	
Conclusion of the CMC-Board CMC should accept the NWI, Date: 28.6.2012	