

CMC WORK ITEM

Proposed work item

Development of procedures to deal with critical multi lateral vigilance and market surveillance issues

Rationale for application

On the basis of made experiences the CMC identified the need to develop special procedures to deal with critical multinational cases in the field of vigilance and market surveillance.

The CMC considers that some CAs had recently to face critical issues with a big impact on several member states : FR after observation of incidents has suspended the marketing of PIP breast implants broadly used in several countries, and HU has restricted the designation of the Notified Body BEMKI which had an impact on several manufacturers in 4 countries with devices marketed in several other European countries.

The already established procedures seem to be not sufficient to handle such cases in an appropriate way.

New procedures have to ensure that there is

- A fast and comprehensive exchange of all available information between the relevant CAs
- A possibility to have a technical discussion between experts and to share expertise between member states very soon
- A support and encouragement by the hierarchy of the different CA

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?

These issues have been discussed and followed in different WGs, at the MDEG and CMC levels.

It could be useful to build procedures on the basis of these two experiences, to improve and to harmonize the management of critical situations by CAs.

In 2006 there was already an initiative to develop an “emergency mechanism” for vigilance cases.

Due to concerns that a new mechanism could also mean a new bureaucratic and resources binding procedure and due to personal changes in the COM the project was not started. There were also some concerns considering the project as a first step to shift responsibility from the CA to a European group.

Action/Decision proposed by applicant

Request from COEN and the MDEG Vigilance WG the development of a procedure for critical multilateral issues

Proposal for the lead official:

Lead official for the MDEG vigilance group: to be discussed by the CMC

Lead official for COEN: to be discussed by the CMC

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? <input type="checkbox"/> Yes <input type="checkbox"/> No Is Proposal mature for CMC ? <input type="checkbox"/> Yes <input type="checkbox"/> No Recommendations:
Rationale for application	Description complete? <input type="checkbox"/> Yes <input type="checkbox"/> 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? <input type="checkbox"/> Yes <input type="checkbox"/> No Recommendations:
Proposal for the lead official	Accepted? <input type="checkbox"/> Yes <input type="checkbox"/> No Proposed alternative candidate:
Supporting information (Working Groups, CAMD, etc.) + History: provide here the list of links to relevant documents (eg. CIRCA)	Documentation complete? <input type="checkbox"/> Yes <input type="checkbox"/> No Recommendations:

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PART C: RECOMMENDATION FROM CMC-BOARD TO CMC

CMC meeting date	
CMC meeting agenda item	
Transfer to CMC meeting	<input type="checkbox"/> For consideration <input type="checkbox"/> For appointment of the lead official <input type="checkbox"/> For allocation of work <input type="checkbox"/> For decision
Action/Decision proposed	
Proposal for the lead official:	
Proposal for the allocation of potentially necessary additional preparatory work:	
Proposed work planning and timing to output:	
Conclusion of the CMC-Board	
Date:	

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PART E: FOLLOW-UP OF THE CMC DECISION

Status of the action of the implementation

Date: