

CMC WORK ITEM

Proposed work item

Decision to establish a small group, which shall look at the possibility of establishment of a jointly accessible database of Helsinki summary reports

Rationale for application

One of the most important questions in the daily work of CAs – is product a medical device or not and if yes, what directive/ rule shall be applied, are the main source for Helsinki Enquiries and Helsinki Procedures.

Annually about (or sometimes more than) 20 of such enquiries are distributed among CAs.

After sending out the summary by the originator of the enquiry, probably each CA collects those files in national databases or in national archives.

Lack of one central storage place does not allow to check before sending a new enquiry if the question has been evaluated previously, when such national databases are not maintained.

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?

Database could be an useful tool for borderline and classification questions which would arise during CAs work.

Action/Decision proposed by applicant

Establishment of small group to work on this NWI

Proposal for the lead official:

PL Joanna Kilkowska

Supporting information (Working Groups, CAMD, etc.)

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

- First proposal of collecting all summaries in one place made by Finish colleagues - Tampere CAMD
- Borderline and Classification manual does not contain all results of enquires

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PART B: TO BE FILLED IN BY THE CMC-BOARD

Proposed work item	Within scope of CMC? X Yes <input type="checkbox"/> No Is Proposal mature for CMC ? X Yes <input type="checkbox"/> No Recommendations:
Rationale for application	Description complete? X 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? X Yes <input type="checkbox"/> No Recommendations:
Proposal for the lead official	Accepted? X 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? X Yes <input type="checkbox"/> No Recommendations:

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PART C: RECOMMENDATION FROM CMC-BOARD TO CMC

CMC meeting date	07-06-2011
CMC meeting agenda item	9b
Transfer to CMC meeting	<input checked="" type="checkbox"/> For consideration <input checked="" type="checkbox"/> For appointment of the lead official <input type="checkbox"/> For allocation of work <input type="checkbox"/> For decision
Action/Decision proposed	
<p>To establish a small group of CMC-members, which shall explore the possibilities to establish a jointly accessible database of all the results of the enquiries under the Helsinki procedure. This small group of CMC-members will report to the CMC on the results on their exploration of the feasibility of such a database and will make recommendations to the CMC on how to proceed.</p>	
Proposal for the lead official:	
Poland	
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: