EMA/240810/2013

Submission of comments on 'Policy 0070 on publication and access to clinical-trial data'

Comments from:

Name and affiliation
European network for Health Technology Assessment, EUnetHTA

Please note that these comments and the identity of the sender (not contact details) will be published unless a specific justified objection is received.

When completed, this form should be sent in Word format (not PDF) to: ctdatapolicy@ema.europa.eu

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Comments on text

Line number(s) *(e.g. 20-23)*	Comment	Proposed changes, if any *(If changes to the wording are suggested, they should be highlighted using 'track changes')*
27 - 35	EUnetHTA strongly supports improved publication and access to clinical trial data as described in EMA's draft policy. Full trial information and results (for all trials, involving medicines, devices or other healthcare interventions) are needed for HTA agencies to be able to provide appropriate and meaningful assessments of drugs and other health technologies within their remit. There is overwhelming evidence, that trial data published in scientific journals are insufficient to provide a complete and unbiased picture of a given drug. HTA needs other independent and high quality data sources. Data submitted to regulatory agencies are therefore essential for HTA agencies. A key aim of HTA is to estimate relative or comparative effectiveness. Methods used by HTA require full information about study methods, e.g. for the assessment of risk of bias. Extended information about patient populations included in clinical trials is needed, e.g. to understand to what extent the study results are relevant for real-world populations. HTA comparative effectiveness research also uses indirect comparisons. For this type of analysis full information on study methods including e.g. operationalisation of study endpoints and full information on patient populations is required to allow for assessing assumptions on similarity	
36 - 43	EUnetHTA supports protection of personal data. The measures described in the policy are considered sufficient to ensure this protection. A guidance document should be developed	
44 - 47	It should be noted that patient data are already used for publications in scientific journals\conferences and other scientific activities aimed at knowledge evaluation and dissemination. Transparency, clinical trial data analysis and verification\appraisal of results – e.g. in HTA comparative effectiveness assessments - all work towards the "development and assessment of a particular medicine that is useful for treatment of their disease" and towards	

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	"the advancement of science and public health".	
49 – 51 Annexes 1 and 2	EUnetHTA strongly supports the statement that clinical trial data (indeed for all trials, involving medicines, devices or other healthcare interventions) cannot be considered commercially confidential information (CCI), and that the interests of public health outweigh consideration of CCI for clinical trial data. EUnetHTA also supports the classification of documents with regard to CCI in Annexes 1 and 2, i.e. that trial information other than sections 2.7.1, 5.3.1. and 5.3.2 of the CTD are not considered CCI.	
77 - 82	Since HTA is very often comparing new interventions to currently available therapies, full information on study methods and study results is required for all drugs in current use. EUnetHTA therefore suggests that EMA re-considers making all clinical study reports available at the agency for any drug approved in Europe. Restricting the policy to data submitted after the policy comes into effect is insufficient to meet HTA requirements in comparative research.	
94 - 97	Taking into account international definitions (Cochrane Glossary, WHO, ClinicalTrials.gov), consider using the term "Clinical study data" since this term includes both interventional and observational studies	
118 - 22	Variable definition and data derivation specifications may be essential to understand the report and should not be considered raw data	
156	Should better read: "These are essentially 'raw CT data' (see definition above) which have not been adequately de-identified" This would help to be coherent with the definition in Category 2 (• any personal data in the document have been adequately de-identified (line 143)) and clarify that the main distinction between Category 2 and Category 3 is not based on aggregate versus raw/individual data, but on de-identified or not de-	

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	identified.	
194 - 196	Meta-analysis requests later on may want to include the data sets. How should this be handled?	
203 - 205	One year does not seem very "reasonable "for a Systematic Review\Meta-analysis of all studies for HTA comparative effectiveness purpose, though it might be reasonable for assessing an EMA regulatory decision (which is not the purpose of HTA). Destruction of accessed CT data risks being in conflict with best practice in scientific publishing (ensure accessibility to data for replication of analysis) which peer review journals require (some journals are considering enforcing publishing rules, which require complete CT data to be made fully accessible for articles reporting clinical trials' results).	
210 - 15	EUnetHTA agrees in requiring that a protocol of the analysis is published either as a protocol article or in a database of protocols of SR - ex. Cochrane Database, Prospero – or where relevant as a protocol of an HTA project in EUnetHTA.	
248 - 261	Since HTA is very often comparing new interventions to currently available therapies, full information on study methods and study results is required for all drugs in current use. EUnetHTA therefore suggests that EMA re-considers making all clinical study reports available at the agency for any drug approved in Europe. Restricting the policy to data submitted after the policy comes into effect is insufficient to meet HTA requirements in comparative research.	
278 - 81	The avoidance of retroactive identification of individuals particularly if many indirect identifiers appear jointly for the same individual needs to be clearly described in practical terms in a guidance document	

Please add more rows if needed.