BEUC The European Consumer Organisation

The Consumer Voice in Europe

Transparency should be the default option

BEUC response to the EMA Public Consultation on the Implementation of the EU Clinical Trials Regulation

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General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	I. BEUC welcomes the opportunity to contribute to the EMA public consultation on the application of transparency rules to the EU Clinical Trials Regulation. However we regret that the consultation runs for less than one month and that EMA didn't comply with the European Commission guidelines for public consultations that foresee a minimum consultation period of 12 weeks. This is particularly difficult to understand taking into account that the Clinical Trials Regulation will not be in operation before 28 May 2016. Such a tight deadline on a highly technical document is likely to generate an imbalance in the input gathered via the consultation in favour of more resourced stakeholders.	

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	II. Overall we consider that the EMA interpretation of what constitutes commercially confidential information is too broad. Some of the specific provisions outlined in the draft proposal for an Addendum will hinder the proper access to clinical trials data as intended by legislators when they adopted the new European Clinical Trials Regulation (EU) No 536/2014. III. According to the Helsinki Declaration[1], all authors have a duty to make the results of their research on human subjects publicly available and are accountable for the completeness and accuracy of their reports. Making clinical trial data available is necessary to ensure competent authorities have complete and reliable information to carry out safety and cost/effectiveness analyses, avoid exposing patients to unnecessary risks and waste of public resources on ineffective medicines.	

1 Article 30 and 33 of the WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects http://www.wma.net/en/30publications/10policies/b3/

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	Disclosure of trial data empowers patients, promotes a better quality of healthcare and contributes to a restoration of public confidence in regulators following recent scandals which have affected the medical sector. BEUC calls for these principles to be better reflected in the Addendum.	

Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
Lines 90-92		Some have been using misleading arguments about patients' privacy to undermine the transparency developments. To avoid any confusion we think the document should better stress the distinction between anonimised patient data sets useful for reanalysis and personal information which should remain fully protected.	
Lines 147-158		We acknowledge the need to balance the consumers' rights to access the information with the "*legitimate interest of the sponsors*" but greater weight should be given to public health arguments (see also comment III above).	
Lines 261-268		We understand that the Transparency rules of the Regulation (EU) No 536/2014 only apply to new trials and that clinical trials conducted under the current legislation are registered in the EudraCT database. However we would like to take this opportunity to encourage EMA to work with trials sponsors and national medicines agencies to	

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		explore options to disclose results of past trials on the treatments in use today.	
Line 324		The full protocol and not just "the protocol summary" should be made publicly available at the time of the decision of the trial.	
Lines 351 – 355		While we accept that the investigational medicinal product dossier (IMPD) quality section will not be made public as it contains confidential information on the manufacturing process we see no good reason to foresee the possibility to defer the disclosure of IMPD safety and efficacy sections. These sections should be published as soon as possible after the end of the trial.	
Lines 454 - 484		The EMA definition of commercially confidential information is far too broad and not in line with the intention of legislators when they adopted the Regulation No 536/2014. The EMA definition of what is considered a sponsor legitimate economic interest is so encompassing that it would undermine any	

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		meaningful disclosure of information. For example EMA indicates (line 469 -471) that "*information may be commercially confidential because the clinical trial forms part of the development of a medicinal product for commercialization of that product (i.e. seeking a marketing authorisation or variation* " or "*because the clinical trial is conducted to further basic or applied research on medicines and as such may be part of a process for which research funds have been obtained or may contribute to the obtaining of future research funds"* (lines 471 - 473). We consider these interpretations unacceptable.	
Lines 485-490		EMA indicates that "*specific situations may occur where the overriding public interest would prevail in ad hoc situations over and above the general transparency rules established for the database and documents and data not usually made public may be published or made public at an earlier time point than would be usual"* and that "*a decision making process will need to be established in order to invoke use of the*	

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		overriding public interest in such ad hoc cases". This part of the Addendum is too vague and should be further elaborated and detailed. More generally we think that throughout the document it should be clear that public disclosure is the general rule and that non-disclosure is the exception. Transparency should be the default option. It is up to the sponsors to prove that the disclosure of certain information could damage their economic interests.	
Lines 586 - 605		BEUC supports the less restrictive option 1.1 "once a marketing authorization has been issued, by at least one Member State, for the active substance contained in that medicinal product". Information from all trials on a given product should be made public, including those for non-approved indications.	
Lines 652-703		BEUC supports the "Proposal One". The study specific and product specific documents should be	

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		made public at the time of the decision on the trial. Proposal two, three and four are not in line with the Regulation (EU) No 536/2014 and therefore they should not be considered. Phase IV clinical trials provide vital information on the safety of medicines currently used by many patients. There should not be an option to defer the publication of information about clinical trials on medicinal products with marketing authorization.	
Lines 704 - 721		BEUC doesn't support any of the two options 6.5.1 and 6.5.2 as there should be no triggers for timing of publication.	
Lines 851 - 856		Sponsors should not be allowed to redact the report of unexpected events made public in accordance with Article 53 and urgent safety measures in accordance with Article 54.	

END