BEUC The European Consumer Organisation

The Consumer Voice in Europe

EMA transparency policy on clinical trial data should not be diluted

Letter sent to Prof. Guido Rasi, EMA Director General (ref.: 164/2014 – dated 22/05/2014)

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Dear Prof. Rasi,

I am writing on behalf of BEUC, the European Consumer Organization, to express our concerns regarding the draft documents you recently shared with us in the context of the stakeholder consultation for the finalisation of the new EMA policy on publication and access to clinical-trial data.

In our view, the draft "Terms of use" and "Redaction principles" represent a major step back in relation to the draft policy released for public consultation[1] in June 2013 which stressed that *"clinical trials data cannot be considered commercially confidential information (CCI)"* and that *"the interest of public health outweigh considerations of CCI".*

The volunteers who take part to clinical trials put their own life at risk of unexpected adverse drug reactions. They do so to contribute to scientific progress for the benefit of society. Therefore the results of the trials belong to them and to society at large[2]. Everybody has the right to access the evidence used by EMA scientific committees to determine the benefits and risks of medicines.

While we understand the need to prevent the use of the information for unfair commercial purposes, we believe that the large number of restrictions on the use of the data and the confidentiality requirements you envisage in the terms of use are not proportioned and hamper the fundamental right to access the information. In this respect, BEUC shares the concerns expressed by the European Ombudsman[3] regarding the lack of consistency between the draft documents and the provisions of the Regulation 1049/2001[4] on access to documents.

We also consider that the proposal to make clinical study reports (CSRs) available in a "view on-screen-only" mode is not in line with the Regulation on Clinical Trials[5] adopted by the European Parliament and the Council in April which indicates that *"the EU database should be publicly accessible and data should be presented in an easily searchable format, with related data and documents linked together… (Recital 67)".* The database should be user friendly and those who access it should be allowed to download, save, edit, print and transfer the information.

We hope that the new policy is being considered in its own merits and in light of the strong political mandate expressed by the Member States and by the European Parliament who, in the Regulation on clinical trials indicated that CSRs should not be considered commercially confidential. In particular we hope that the definition of CCI is not adversely influenced by the ongoing discussions on CCI in the context of the negotiations with the US on the Transatlantic Trade Investment Partnership. On the contrary, we wish that the new ambitious and proactive EMA policy will serve as a model for other EU national medicines agencies and for regulators in other jurisdictions, including FDA.

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[1] http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/06/WC500144730.pdf
[2] Lemmens T and Telfer C "Access to Information and the Right to Health: The Human Rights Case for Clinical Trials Transparency" (September 22, 2011). American Journal of Law and Medicine 2012; 38: 63-112. http://ssrn.com/abstract=1932436.
[3] http://www.ombudsman.europa.eu/en/resources/otherdocument.faces/en/54347/html.bookmark
[4] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:145:0043:0048:EN:PDF
[5] http://register.consilium.europa.eu/doc/srv?l=EN&f=PE%202%202014%20INIT

As intervener in EMA support in the case T-44/13 AbbVie vs EMA, we take this opportunity to ask you to clarify the impact – if any - of the settlement with AbbVie on the definition of the new policy.

We are confident you will uphold transparency and will keep the promise you made to restore public trust and confidence in the Agency by implementing a meaningful proactive publication of data and by enabling independent re-analysis.

We hope you will take these considerations into account before submitting the new policy for endorsement by the EMA Management Board.

Yours sincerely,

Monique Goyens
Director General