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EMA must not roll back clinical trial transparency policy

BEUC is calling on the European Medicine Agency's management board to veto new proposals on the publication of and access to clinical trial data or else risk EMA's commitment to move towards more transparency. The EMA board – comprised mostly of representatives from EU member state health authorities¹ – is scheduled to vote June 12th.

The European Consumer Organisation deems the draft policy which is subject of the vote steps away from EMA's original plans and the provisions of the new EU Regulation on clinical trials².

In a letter dated May 23rd, BEUC summed up its concerns to the Agency's Director, pinpointing that the Agency was stepping considerably back from its pledge to allow public scrutiny of trial data in June 2013.

Then, EMA stated "clinical trial data cannot be considered commercially confidential information". This is a far cry from the new proposal, which opens the floodgates to many restrictions on the use of trial data.

Ilaria Passarani, Senior Health Policy Officer at BEUC, commented:

"Public health interests should outweigh any consideration of commercial confidentiality. EMA's U-turn from earlier promises for more transparency is unacceptable. Should the plans go through as they are, consumers and researchers would have only partial access to trial reports, in "screen-only" mode and with no possibility to save, print or transfer the information.

"The European Ombudsman, Members of the European Parliament, academics, healthcare professionals and many others have raised a range of concerns on the new draft policy. It is the role of board members to ensure all these concerns are adequately addressed before the policy is finalised. Consumer trust in the Agency and EMA's very reputation are at stake.

"EMA is about to set an important precedent which could inspire regulators of medicines in the EU and beyond, provided transparency is put back at the heart of its new policy. We hope EMA will live up to expectations."

ENDS

¹ e.g. Representatives from national medicines agencies, ministries of health, healthcare professionals, and patients' organisations, European Parliament and European Commission.

² Adopted in April 2014 by the European Parliament and the Council. See our news piece: <http://bit.ly/1g6ZPIA>