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The Board of the European Medicines Agency
c/o Guido Rasi, Executive Director
European Medicines Agency
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UNITED KINGDOM

Brussels, 09/06/2014

Clinical Trials transparency: request to the EMA to drop 'on screen only' restrictions and provide clarification on redaction and terms of use

Dear Members of the EMA Management Board,

Across Europe, hospital pharmacists are intimately involved in the conduct of clinical trials: in their planning, conduct, development and reporting. The European Association of Hospital Pharmacists (EAHP) therefore takes a particular interest in the issue of transparency and reporting of clinical trial results.

As members of the AllTrials coalition, we share the view that failure to operate high standards in the reporting and disclosure of clinical trial results can lead to bad treatment decisions and trials being unnecessarily repeated.

As respondents to the EMA consultation on trial disclosure policy, and participants in the working groups investigating the differing aspects of the policy, we have supported EMA in its efforts to make trial information more available.

We are therefore disappointed to learn that EMA intend to impose secondary restrictions on access to trial data such as enforcing on-screen only visibility. This prevents individuals from printing, sharing or saving the results on display and falls short of our expectations of what can be meant by the term 'transparent'.

As active members of EMA's consultative working group of healthcare professionals, we hope the EMA Board will reconsider the organisation's proposed policy on trial transparency. There is clear and reasonable scope for the EMA to go further than currently proposed, and make the transparency improvement more meaningful by, for example, lifting the suggested restriction of 'on screen only' visibility of information.

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Additionally, EMA should publish a public clarification for stakeholders on how the intended Redaction Principles and Terms of Use requirements will operate in practice, especially in cases where there may be dispute between parties, as to what has, or has not, been, or should be, redacted.

We understand that the fuller requirements on transparency contained within the new Clinical Trials Regulation do not need to be met by the Agency until 2016 at the earliest. However, it is clear from: the settled will of the European Parliament contained within that legal text; the publicly made expressions of concern from consumer organisations and healthcare professional organisations such as BEUC, HAI and EAHP; the momentum of 78,000 public signatures to the AllTrials petition; and, the recent representations of the European Ombudsman, that the public have a right to expect the best efforts from EMA on trial result transparency.

We trust our communication will be received in the helpful spirit in which it is intended, and can be the basis of constructive re-consideration at your Board Meeting.

Yours sincerely,

Dr Roberto Frontini
President
The European Association of Hospital Pharmacists