02 OCTOBER 2013

The European Association of Hospital Pharmacists (EAHP) has responded to a European Medicines Agency (EMA) consultation giving its strong support to the organisation's proposed policy of increasing the transparency of clinical trial results. Trial results are submitted to the agency in respect of marketing authorisation for new medicines.

The EMA's proposed change in policy comes in the context of a European Ombudsman recommendation that clinical trial study reports, and other associated items of trial result information, should not necessarily be considered 'commercially confidential' and should therefore be made more openly available for the purposes of social and public benefit.

In its response to the EMA consultation, EAHP emphasised that greater transparency in the reporting of clinical trial results is required in order:

- to prevent duplication of research effort and support the development of future trials by building on previously conducted work;
- to offer opportunities for independent scrutiny of the methodology and results of any conducted trial;
- to enhance patient safety by improving knowledge sharing in relation to adverse drug reactions experienced in conducted trials; and,
- to meet the expectation of participating patients that results will be well utilised and available for the purposes of progressing medicine.

Speaking about the consultation, EAHP President Dr Roberto Frontini said:

"Hospital pharmacists right across Europe are involved on a daily basis in the management and conduct of clinical trials. We therefore have a direct interest in being able to access key fields of information about previously conducted trials in order to best direct our efforts in this area, and take the correct steps in relation to protecting patient safety and the patient interest.

We support the proposed change of policy by EMA. It is right, and in keeping with transparency developments in so many fields of public policy, that a step change in availability of trial result information is made.

EAHP expresses confidence in the experience and competence of the EMA to manage this process in a fair manner, respecting both the need to protect patient confidentiality and to make determination about when any concerns of commercial confidentiality could be considered legitimate."

ENDS

For further information contact info[at]eahp[dot]eu [1], 00 322 741 6835 or 00 44 7895 292 076

NOTES TO EDITORS:

1. EAHP is an association of national organisations in 34 countries which represents hospital pharmacists at European and international levels. More information about the EAHP and its history **here** [2].

2. The EMA consultation on its proposed change in policy on publishing information it holds about clinical trial results was published on 26th June 2013 and closed on 30 September 2013. More information **here** [3].

3. On closing the consultation the EMA announced over 150 individuals and organisations had responded. A final decision on future EMA policy in this area is scheduled to be made in December. More information **here** [4].

4. The EAHP response to the consultation is available **here** [5] and **here** [6].

5. EAHP is a signatory organisatIon to the www.alltrials.net [7] campaign which brings together over 400 organisations worldwide to make the case for greater transparency in the reporting of clinical trial results. EAHP encourages members of the public to add their name to the more than 57,000 current signatories to the alltrials petition. More information **here** [8].

6. Relevant information about the European Ombudsman's recommendations to the EMA on publishing clinical trial result data is available **here** [9] and **here** [10].

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Links
[1] https://www.eahp.eu/contact/info/eahp/eu [2] http://www.eahp.eu/about-us [3] http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/06/news_detail_001825.jsp&am [4] http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/10/news_detail_001905.jsp&am [5] https://www.eahp.eu/sites/default/files/files/EAHP%20response%20to%20EMA%20CTD%20consultation(1).pdf [6] https://www.eahp.eu/sites/default/files/files/EAHP%20response%20to%20EMA%20CTD%20consultation_2.pdf [7] http://www.alltrials.net [8] http://www.alltrials.net/ [9] http://www.ombudsman.europa.eu/press/release.faces/en/4940/html.bookmark [10] http://www.ombudsman.europa.eu/en/cases/summary.faces/en/5646/html.bookmark