Opening up data at the European Medicines Agency

- Andreas Pott, Acting Executive Director

European Medicines Agency

Dear Dr Godlee

We are writing in response to the Analysis 'Opening up data at the European Medicines Agency', which was published by Peter C Gotzsche and Anders W Jorgensen on the website of the British Medical Journal on 11 May 2011.

The authors make what appears to be a compelling call for more transparency by the regulatory authorities. However, they do so by ignoring the steps taken by the European Medicines Agency since it was established in 1995 and the latest actions and policy adopted over the last few years.

The European Medicines Agency has taken important steps towards increasing its transparency over recent years. Mr Gotzsche and Mr Jorgensen themselves have acknowledged that the Agency's new access to documents policy which became effective in November 2010 has pushed transparency further forward than in most other drug regulatory authorities. The current policy grants wider access than ever before to documents originated, received or held by the Agency. This includes clinical trials reports submitted to the Agency as part of a marketing authorisation application. The extended access to documents and reactive disclosure of documents will be complemented by an extended proactive publication of these documents over the next years.

The recent launch of the EU Clinical Trials Register has been welcomed by patients' and healthcare providers' organisations as a major step towards transparency of medical research that will allow patients and doctors to find information about clinical trials taking place in Europe. Further developments of this system are planned in the future, including publication of summaries of clinical trial results.

In addition to its new rules on access to documents and the launch of the EU Clinical Trials Registry the Agency has launched a number of major initiatives to increase transparency of its operations over recent years, including public consultation on a policy on access to safety data contained in EudraVigilance and a new transparency policy setting out the Agency's vision of its level of openness towards its stakeholders. These policies will strengthen the Agency's approach to proactive and reactive dissemination of information on the quality, safety and efficacy of medicines.

Sincerely,

(signature on file) Andreas Pott, Acting Executive Director

Competing interests: None declared

Published 13 May 2011