

The European Commission chief for Health John Dalli has given a speech in which he called on the pharmaceutical industry to acknowledge its own role in the declining numbers of clinical trials taking place in Europe.

Speaking to an audience of attendees at a European American Business Council (EABC) dinner in Washington DC, Mr Dalli said that while the number of trials in Europe has fallen 25 per cent between 2007 and 2011, the EU Clinical Trials Directive was not the only cause. He told his audience: "There are many other factors not linked to regulation – R&D commitment by industry, its cooperation with academic research, availability of venture capital as well as return on investment, to name just a few."

EAHP's recent General Assembly in Budapest passed a new policy statement which sets out the hospital pharmacist perspective on clinical trial regulation and makes a number of recommendations for improvement, including:

- a single electronic portal for submitting trials for assessment;
- greater distinction being made in the assessment process between high risk and low risk trials;
- a process to be created to enable multi-sponsor trials; and
- more open access to clinical trial data, including making it a condition of licence applicants to publish all available trial data provided to the European Medicines Agency in peer-reviewed Journals.

EAHP will meet with the Commission to discuss its suggestions for regulatory change in the early Autumn.

In the rest of Mr Dalli's speech he outlining progress by the Commission in

- coordinating Member States approach to ehealth solutions;
- resolving data protection barriers to the secondary use of data for public health benefit;
- agreeing a Memorandum of Understanding between the EU and the USA on ehealth interoperability; and,
- modernising the regulatory framework supervising the operation of the European medical device industry.

Speech [here](#) [1].

EAHP statement on Clinical Trials [here](#) [2].

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Links

[1] http://ec.europa.eu/commission_2010-2014/dalli/docs/speech_27062012_us_eu_health_en.pdf [2]
<http://www.eahp.eu/Advocacy/Statements>