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The European Association of Hospital Pharmacists (EAHP) has today given an early welcome to the recently published proposals of the European Commission to improve the regulation of clinical trials (published 17 July 2012).

In 4 key areas the Commission's proposals have met the aspirations of a recent EAHP statement on trial regulation including:

- 1) The introduction of new risk based approaches the clinical trial regulation with the concept of low-interventional clinical trials for products with existing marketing authorisation and whose use is considered as a standard treatment in the member state.
- 2) New provisions to allow co-sponsorship of trials.
- 3) Centralised application procedures to enable multinational trial applications to be submitted to a single electronic portal for delegated single assessment
- 4) The maintenance of Ethics Committees and procedures at a national level

EAHP will now scrutinise the proposals in more detail before meeting with the Commission in September. EAHP want to explore what more can be done to open up access to clinical trial data, and how participation in trials by key patient groups, such as the elderly, can be increased.

Commenting on the Commission's proposals, EAHP President Dr. Roberto Frontini said:

"I am pleased that the Commission have taken on board the comments and concerns expressed by stakeholders, including hospital pharmacists, in relation to clinical trial regulation in Europe. These proposals are certainly a step in the right direction, addressing many of the key problems of regulatory burden."

"However, one area where we undoubtedly want to see more action on is the access to clinical trial data available to health professionals such as hospital pharmacists. This is critical for many reasons, including independent review and ethical decision-making. We are certain that there is more that can be achieved and we will develop our suggestions further as we scrutinise in detail the Commission proposals in the coming months."

ENDS

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* EAHP President Dr. Roberto Frontini is available for interview on request

NOTES TO EDITORS:

1. The European Association of Hospital Pharmacists is an association of national organisations representing hospital pharmacists at European and international levels. More information about the EAHP and its history [here](#) ^[2].

2. On Tuesday 17 July the European Commission published its long awaited proposals for revisions to the regulation of clinical trials in Europe. The proposals will now go forward to the European Parliament and Council of Ministers for scrutiny. The proposals are published [here](#) [3].

3. The Statement from EAHP on clinical trial regulation was approved and passed by delegates at its recent General Assembly in Budapest (14-17 June). It is available on the EAHP website [here](#) [4].

4. Clinical trials are of critical importance in achieving continuous improvement in patient outcomes and improving survival rates for patients with acute illnesses. Europe's 21,000 hospital pharmacists are the secondary and tertiary care sector's experts in medicines, pharmacotherapy and pharmacokinetics and therefore play a central role in the implementation and conduct of clinical trials in all European countries on a daily basis.

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Links

[1] <https://www.eahp.eu/contact/info/eahp/eu> [2] <http://www.eahp.eu/about-us> [3]

http://ec.europa.eu/health/human-use/clinical-trials/index_en.htm#rlctd [4] <http://www.eahp.eu/practice-and-policy/EAHP-statements>