26th June 2012

European Hospital Pharmacists from 31 countries have voted unanimously to approve a statement that calls for urgent changes to the framework for clinical trial regulation across the European Economic Area (EEA).

The statement, issued by the European Association of Hospital Pharmacists (EAHP), highlights the declining number of trials taking place since the introduction of a Commission Directive on the subject in 2001, and adds the Association's support to the number of organisations calling for streamlined assessment and approval mechanisms.

More specifically, the statement supports:
• the suggestion of a single electronic portal for submitting trials for assessment;
• the maintenance of ethical assessment of trials at a national level;
• greater distinction being made in the assessment process between high risk and low risk trials; and,
• a process being created to enable multi-sponsor trials.

The statement goes on to explore the identified problem of underrepresented participation in trials by key patient groups such as the elderly, children and females. The EAHP calls on the Commission to acknowledge and examine this issue within the scope of forthcoming changes to the regulation. EAHP suggest that the EU Paediatric Regulation of 2007 has helped to improve the consideration of children within the trial process and that other regulatory solutions of a similar nature could be available.
Finally the statement calls for an opening up of access to clinical trial data for the purposes of independent analysis and the development of predictive models. The EAHP recommend that it should be a condition of licence applicants to publish all available trial data provided to the European Medicines Agency in peer-reviewed Journals.

Commenting on the statement, Dr. Roberto Frontini, President of the EAHP, said:
"The 21,000 Hospital Pharmacists across Europe are the secondary and tertiary care experts in medicines, pharmacotherapy and pharmacokinetics. On a daily basis, they play a central role in the implementation and conduct of clinical trials in every European country. This statement is a product of that experience, and our profession's desire to achieve better regulation that enables improvements to new medicine development.
We look forward to meeting the Commission later in the summer to discuss our proposals. The proposed reform of the regulation presents a unique opportunity to streamline

assessment, give more attention to particular patient groups, and improve access to essential trial data. We want to ensure the opportunity is not missed."

ENDS

For further information please contact info[at]eahp[dot]eu [1]

* 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. The new Statement from EAHP was approved by delegates at its recent General Assembly in Budapest (14-17 June). It is available on the EAHP website **here** [3].

3. According to European Commission figures, between 2007 and 2010 there has been a 15% decline in both the number of clinical trial studies within EU sites and the number of EU subjects participating in these studies. Although other issues are involved as well, there is a consensus within the health sector that a major factor attributed to this decline in trial activity relates to the EU Clinical Trials Directive (2001/20/EC), including:

- differing interpretations of requirements in different member states;
- separate definitions of key terms across Europe; and,
- a lack of guidance in implementing and complying with the Directive.

4. It is estimated by some organisations that the Directive has contributed to a 65 per cent increase in the time it takes researchers to get approval for their studies, and a 75 per cent increase in administrative costs . Another assessment undertaken by the Impact on Clinical Research of European Legislation (ICREL) found that non-commercial sponsors required an increase from 1.5 to 2.8 FTE (full-time equivalent) staff to manage administrative tasks associated with a Clinical Trial Authorisation, and that there was an increase in time between finalisation of protocol and first patient recruited from 144 to 178 days.

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Links

[1] https://www.eahp.eu/contact/info/eahp/eu [2] https://www.eahp.eu/about-us [3] https://www.eahp.eu/sites/default/files/files/EAHP%20Statement%20on%20Clinical%20Trials_June2012.pdf