The European Association of Hospital Pharmacists (EAHP) this week met with officials at the European Commission to share the hospital pharmacy perspective on clinical trial regulation.

The meeting took place following the passage of a policy statement on trial regulation by the EAHP General Assembly in June 2012, and came after the publication of Commission proposals for reforming clinical trial regulation in July.

EAHP welcomed the Commission's commitment to introducing greater distinction between high intervention and low intervention trials in terms of regulatory requirements, as well as other aspects of the recent proposal including harmonisation of authorisation procedures through a centralised electronic submission process, and reduction of bureaucracy through the appointment of a lead 'Reporting Member State'.

EAHP gained useful clarity that the proposal will enable greater transparency of information in relation to trial results through the operation of the Commission-led submission portal and database. The database will contain all relevant information as regards a clinical trial and, with strong safeguards for the security of personal data, the information in the database will be public.

Whilst the Commission understood EAHP's concerns in relation to the need to improve the participation rates of key patient groups such as the elderly, females and children, it was not felt to be within the scope of the Commission's recent proposal on Clinical Trials as this was limited to the submission and assessment processes.

EAHP also raised the issue of fair reimbursement to hospital pharmacies for their participation in trials. Anecdotal reports suggest that, with much pharmacy labour being spent on fulfilling the regulatory requirements of trials, the consequence can be diversion of personnel from their clinical roles, with current reimbursement rates for trial activity often not covering the labour time. The Commission hoped that the reduction in bureaucracy that the July 2012 proposal aims to achieve may improve the situation.

EAHP highlighted that often in the case of trials taking place in more than one country, regulatory authorities in one country might require that Good Manufacturing Practice (GMP) be adhered to in the trial. EAHP President Roberto Frontini expressed his view that this could often be a disproportionate requirement and have the effect of adding significant additional time and cost to the process, potentially disincentivising trials from taking place. The Commission understood the scenario and, while the autonomy of national authorities in such areas will remain, the Commission are currently developing guidelines to address these kind of matters.

EAHP President Dr Roberto Frontini said:

“I would like to thank officials at the European Commission for taking time to hear the views of hospital pharmacists in relation to clinical trials. Hospital pharmacists across Europe are involved in trials in every country and on a daily basis. They are amongst the key healthcare professionals who enable trials to happen, and help to safeguard the patient in the process.

“We are generally positive about the Commission’s recent proposals for improving the regulatory framework under which trials are submitted and assessed, and will seek, alongside other stakeholders, to assist their passage through the European Parliament and Council of Ministers in the months ahead.

“However EAHP still has some outstanding issues of concerns about the conduct of trials, though we understand not all of these can be tackled through this current proposal. These include increasing particular patient group participation in trials and increasing the transparency of observational trial results. We will be discussing with our stakeholder partners how best to achieve these additional improvements in the weeks ahead”

ENDS

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

NOTES TO EDITORS:

1. EAHP 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. EAHP are campaigning for reduced bureaucracy in the clinical trial process, better participation from key patient groups, and greater transparency of clinical trial data. More information **here** [3]**.**

3. The European Commission published new proposals to improve clinical trial regulation in July 2012. These are available **here** [4].

7 September 2012

Links

[1] https://www.eahp.eu/contact/info/eahp/eu [2] http://eahp.cxn.be/about-us [3] http://www.eahp.eu/practice-and-policy/clinical-trial-regulation [4] http://ec.europa.eu/health/files/clinicaltrials/2012_07/proposal/2012_07_proposal_en.pdf