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Press release

European Medicines Agency holds international workshop on clinical trials in the context of global medicines development

Participants from around the world emphasise the need for cooperation to ensure a robust global framework for clinical trials

On 6-7 September 2010 the European Medicines Agency (EMA) held an international workshop with a broad cross section of stakeholders from around the world to discuss a way forward for a global framework of clinical trials that has at its heart the protection of the rights, safety and wellbeing of patients participating in clinical trials anywhere in the world.

The workshop was part of the consultation process on the Agency's 'Reflection Paper on ethical and Good Clinical Practice (GCP) aspects of clinical trials of medicinal products for human use conducted in third countries and submitted in marketing authorisation applications to the EMA'.

Some 170 participants from around 50 countries from the Americas, Asia, Africa and Europe came to the meeting at the Agency in London to provide their feedback on the draft Reflection Paper and discuss international cooperation in this context. They represented patient organisations, health-related non-governmental organisations, clinical trial sponsors, pharmaceutical industry, ethics committees, regulatory authorities from all continents and intergovernmental organisations.

The Reflection Paper responds to the challenges arising from the increasing globalisation of clinical research. In marketing authorisation applications submitted to the Agency between 2005 and 2009, only 38.8% of patients enrolled in pivotal clinical trials received their treatments at clinical trial sites within the EU and EEA. These trials involved more than 44,000 clinical trial sites in 89 countries. The data generated was used to support 347 marketing authorisation applications as well as some applications for a variation or a line extension of the existing marketing authorisation.

"Wherever in the world we stand, the majority of clinical trials are being conducted somewhere else in the world, under a different regulatory framework and in different cultural settings. However, we all rely on the same trials to make decisions: as regulators, to allow or disallow marketing authorisations, and, as patients and healthcare providers, to use or not to use a medicine", said Fergus Sweeney, Head of Inspections at the European Medicines Agency.

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A number of practical proposals and recommendations are set out by the Reflection Paper. It was considered that EU regulators should only expect or require studies in support of an EU marketing authorisation application that would also be ethically acceptable in the EU. There should not be a different standard applied to trials conducted in the EU compared to those conducted elsewhere.

The discussions over the course of the two-day conference highlighted three main points:

- The need for cooperation and networking between regulatory authorities and also ethics committees involved in the supervision of clinical trials, including capacity building activities.
- The need for greater transparency of clinical trials, including clinical trials registers and the provision of information about ethical and GCP aspects in the European Public Assessment Report (EPAR).
- The need to involve patients early on in the design of protocols to ensure the adequate protection of clinical trials subjects.

Thanking the workshop participants for their contributions, the Agency's Executive Director, Thomas Lönngren, said: "What is needed is a robust framework for the oversight and conduct of clinical trials, no matter where in the world the clinical investigator's sites are located and patients recruited. The Agency is committed to build and extend its relationship with regulators in all parts of the world and with international organisations to work to standards agreed and recognised by all."

The consultation on the Reflection Paper is open until 30 September 2010 and comments should be sent to ctrefpaper@ema.europa.eu. All comments received during the consultation phase, including the workshop, will be thoroughly reviewed and inform the finalisation of the Reflection Paper, expected by mid 2011.

Notes

1. The Draft Reflection Paper on Ethical and Good Clinical Practice (GCP) Aspects of clinical trials of medicinal products for human use conducted in third countries and submitted in marketing authorisation applications to the European Medicines Agency is available here
2. Comments on the Reflection Paper should be sent to ctrefpaper@ema.europa.eu.
3. A conference report, including the presentations is due for publication on the Agency's website by October 2010.
4. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website: www.ema.europa.eu

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