EUROPEAN COMMISSION

MEMO

Brussels, 20 December 2013

Health Commissioner, Tonio Borg, welcomes agreement on the revision of EU rules on Clinical Trials

"I welcome the agreement reached at COREPER today on the revision of the EU rules on clinical trials. I thank the Lithuanian Presidency for the progress on this important text for people's health and EU competitiveness. The agreement reached today makes the final adoption of this Regulation possible[1] before the end of the European Parliament's current term.

Clinical trials are indispensable for developing and improving medicines and ensuring that EU patients can have access to the most innovative and effective treatments, under high safety and ethical standards.

The revised rules will ensure that the EU remains an attractive location for clinical research – which is of vital importance for Europe's competitiveness and innovation capacity.

I welcome that the new rules will take the form of a Regulation, which is directly applicable throughout the European Union.

While the Commission would have hoped for a more ambitious approach in line with its original proposal, the new Regulation introduces some significant measures which will contribute to boost clinical research in Europe, for example:

- A streamlined application procedure via a single entry point - an EU portal and database, for all clinical trials conducted in Europe. Registration via the portal will be a prerequisite for the assessment of any application;
- A single authorisation procedure for all clinical trials, allowing a faster and thorough assessment of an application by all Member States concerned, and ensuring one single assessment outcome and authorisation per Member State;
- The extension of the tacit agreement principle to the whole authorisation process which will give sponsors and researchers, in particular SMEs and academics, more legal certainty;
- Improved conditions for conducting multinational clinical trials, which are key for rare and serious diseases;
- Strengthened rules on the protection of patients and informed consent;
- More transparency on the conduct and results of the clinical trial, thanks to a compulsory prior registration on the EU portal; and
- The possibility for the Commission to conduct controls in Member States and third countries to ensure the rules are being properly supervised and enforced."

[1] The political agreement is subject to technical finalisation and formal approval by the co-legislators.

More information:

http://ec.europa.eu/health/human-use/clinical-trials/index_en.htm