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Council adopts new rules on clinical trials

The Council today[1] approved a draft regulation aimed at facilitating and speeding up the authorisation procedure of clinical trials, following the first-reading agreement reached with the European Parliament in December (*PE-CONS 2/14* + *8245/14 ADD 1*).

This means that the regulation is now adopted. It will enter into force 20 days following its publication in the Official Journal of the European Union and apply six months after a EU portal for the submission of data on clinical trials and a EU database identifying each clinical trial have become fully functional (but not earlier than two years after the regulation's publication).

The main objective of the regulation is to make the European Union more attractive for clinical research and to invert the decreasing number of investigations of medicines in humans conducted in the EU, while maintaining the high standards of patient safety. Between 2007 and 2011 the number of applications for clinical trials decreased by 25% in the EU. While member states will continue to make their independent assessment of notably ethical issues, the draft regulation provides for a uniform application of common rules.

[1] The decision was taken at the Agriculture Council.

P R E S S

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Medicines are clinically tested in human volunteers to

– test the safety and effectiveness of new products,

– test new applications for existing medicines or to

– compare two treatments.

Clinical trials are hence essential to develop new medicines and to improve medical treatment by increasing the knowledge about the effects of existing medicines to the benefit of patients. At the same time, clinical trials are essential for promoting growth and jobs in a highly innovative sector with strong links to advanced research in the EU.

The regulation sets the timeline for authorisation of clinical trials at 60 days. If no decision is taken within this period the authorisation is deemed to be given ("tacit approval"). Decisions on applications for substantial modifications of clinical trials must be taken within 49 days. In the absence of decision the authorisation is considered to be given.

The agreement also streamlines the authorisation procedure for clinical trials. In the future one single application will be sufficient for conducting clinical trials in several member states. Under the current directive an application must be submitted to each member state where the clinical trial will be conducted.