Press release

# Clinical trials: clearer rules, better protection for patients

Committees Committee on the Environment, Public Health and Food Safety [22-01-2014 - 17:15]

**Pharmaceutical companies and academic researchers will be obliged to upload the results of all their European clinical trials to a publicly accessible database, under draft legislation informally agreed with EU ministers and approved by Public Health Committee MEPs on Wednesday.**

The draft legislation, designed to encourage research whilst protecting patients' rights, is to replace an existing directive with simpler, more uniform rules. The new text makes specific provision for low-intervention trials, clarifies the role of ethics committees in the authorisation process, and details how to obtain informed consent from patients.

"For too long, unflattering studies on new medicines have gone undisclosed. Around half of all trials are never published, usually those with negative or disappointing results. It is vital that we know about negative outcomes - otherwise trials can be conducted repeatedly before it becomes public knowledge that some products are ineffective, or even dangerous", said Glenis Willmott (S&D, UK), who is steering the legislation through Parliament. Her report was adopted unanimously.

The transparency requirements are part of a wider piece of legislation which will streamline the rules on clinical trials across Europe, facilitating cross-border cooperation to enable larger, more reliable, trials, as well as those on products for rare diseases.

The new law features simplified reporting procedures, and empowers the European Commission to perform checks. Once a clinical trial sponsor has submitted an application dossier to a member state, the member state would have to respond within fixed deadlines.

## Transparency

MEPs amended the draft to improve transparency, by requiring that detailed summaries be published in a publicly accessible EU database, with full Clinical Study Reports published once a decision on marketing authorisation for the tested product is complete or the marketing authorisation application has been withdrawn. Fines would be imposed on sponsors who do not comply with these requirements.

## Background

The Commission proposal aims to remedy the shortcomings of the existing Clinical Trials Directive by setting up a uniform framework for the authorisation of clinical trials by all the member states concerned with a given single assessment outcome. Simplified reporting procedures, and the possibility for the Commission to conduct controls, are among the key innovations of the legislative proposal.

## Next steps

The legislation will be debated and voted by the full House at the 2-3 April plenary session.


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