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Press release | 02.04.2014

Clinical trials for medicines

Greater transparency under EU rules essential for credibility of clinical trials

New EU legislation on clinical trials was today adopted by the European Parliament. The Greens welcomed the outcome of the vote, with Green health spokesperson **Margrete Auken** stating:

"Confidence in the effectiveness and reliability of clinical trials has been hit by a host of scandals with different medicines in Europe in the past. It is essential that citizens can have utmost faith in clinical trials and their ability to guarantee that authorized medicines pose no unacceptable risks for those using them. The new legislation endorsed by MEPs today will address this by ensuring access to the results and the supporting data from clinical trials under the new legislation.

"These new rules will bring a welcome end to the days when big pharmaceutical firms could decide what data to publish and what not. As soon as the new law is in force (1), there will be clear and robust transparency requirements for the data generated in clinical trials. The people that participate in clinical trials do so to support the advancement of medical research – not for the sake of the generating corporate profits. It will no longer be possible for pharmaceutical companies to withhold the actual data from clinical trials on medicines for which they seek authorization. The new law ensures that as soon as the decisions are taken about market authorisation, clinical study reports will be made generally accessible to the public without it having to ask for such data.

"The revised law will also ensure that clinical trials can only go ahead if they did not get a negative opinion of the ethics committee involved. While this does not go as far requiring a positive opinion by an ethics committee, which the Greens wanted, it at least ensures a clear role for the ethics committee, which was not foreseen in the initial Commission proposal."

(1) The law will apply at the earliest two years after its entry into force.

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Margrete Auken

Member

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