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Clinical trials for medicines

Greater transparency under EU rules essential for credibility of clinical trials

Draft new EU legislation on clinical trials was today voted on by the European Parliament's environment and public health committee. The Greens welcomed the outcome of the vote, with Green health spokesperson **Margrete Auken** stating:

"It is essential that citizens can have utmost faith in clinical trials and their ability to guarantee that authorised medicines pose no unacceptable risks for those using them. Confidence in the effectiveness and reliability of clinical trials has been hit by a host of scandals with different medicines in Europe. MEPs have taken a step towards addressing this by voting to strengthen access to the results and the supporting data from clinical trials under the proposed legislation.

"There need to be clear and robust transparency requirements for the data generated in clinical trials. The people that participate do so to support the advancement of medical research – not for the sake of the generating corporate profits. It is no longer acceptable that pharmaceutical companies can withhold data from clinical trials on medicines for which they seek or already have obtained authorisation. Clinical study reports should be made publicly accessible because nothing in them is commercially confidential. The outcome of today's vote would provide for this and we hope this will be reflected in the final legislation.

"MEPs also voted to support the inclusion of another crucial provision by which clinical trials would be subject to the approval of an ethics committee. This provision, which would ensure the EU complies with the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects, is also essential for the credibility of clinical trials."

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Responsible MEPs

Margrete Auken

Member

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