Clinical trials transparency partially boosted by European Medicines Agency

Pharmaceutical companies’ deliberate secrecy over clinical trial data has been partially countered in a landmark action as the European Medicines Agency (EMA) has decided clinical trials reports must be published and accessible.

Monique Goyens, Director General of The European Consumer Organisation, said:

“We are emboldened the EMA heeded public pressure and now enables researchers to consult online, save and print trial data. Crucially, those independently assessing clinical study reports can now access such information swiftly.

“Sunlight has not trumped secrecy yet though. Deplorably, the pharma industry can keep secret the information they deem commercially confidential. Though the ultimate decision on removing text rests with the EMA, too many loopholes allowing data to be cut exist. This somewhat subverts the policy’s spirit of openness.

“Should drug national regulatory authorities in the EU and beyond use EMA’s policy as a model, it would be a significant boost to transparency. But this new disclosure policy is not safe from being challenged by pharmaceutical companies, as happened in the AbbVie and Intermune cases.

“Further dangers lie in the long grass with commercial confidentiality being discussed in the Transatlantic Trade Investment Partnership. Any subsequent aggregation of standards could see today’s move reversed. The transfer of European Commission pharma policy and EMA oversight from its health services to industrial policy also augurs badly.”

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