Trade Secrets Directive Will Threaten Access to Medicines Safety and Efficacy Data

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Health Action International criticises European Parliament for failing to protect researchers, journalists and whistle-blowers in faulty legislation adopted today

AMSTERDAM—Health Action International is deeply disappointed with today's adoption of the European Union (EU) Trade Secrets Directive by Members of the European Parliament. Under the Directive, researchers, journalists and whistle-blowers that expose illicit practices by the pharmaceutical industry, or reveal important medicine safety and efficacy information, will not be adequately protected under law. The Directive's broad definition of what constitutes a 'trade secret', and its lack of clarity on exceptions to unlawful use or disclosure, create legal uncertainty.

The burden of proof will be placed on individual citizens. Citizens may face costly trials against big corporations and, if they lose, could endure hefty economic penalties. And given that the Directive allows Member States to enact far-reaching provisions to protect trade secrets, these citizens could even face incarceration.

Although the Directive states that it will not affect the application of public disclosure obligations by EU and national institutions, the implications of this provision in real practice remain uncertain. The European Medicines Agency and national medicines agencies may take a safe course of action in their interpretation of what constitutes commercially confidential information and become less inclined to disclose information—such as clinical trial data—that is in the public interest. Trade secret protection has long been a recurring argument by the pharmaceutical industry to justify data secrecy. In fact, the trade secrets argument was used recently by the company sponsoring the clinical trial in France where one person died and others were injured.

This push for increased secrecy of business information, including information about the medicines we prescribe and take, comes at a time when the competition authorities and the current Netherlands EU Presidency is questioning whether excessive intellectual property protection on medicines is the appropriate driver for innovation in the pharmaceutical sector. Giving companies another way to shroud the results of pharmaceutical research in secrecy seems more likely to delay innovation.

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