

Experts call to end secrecy surrounding approval of new drugs

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Changes are urgently needed to end the secrecy surrounding approval of new drugs in Europe, argue experts in the British Medical Journal today.

Questions about the benefits of the flu drug [oseltamivir](#) in otherwise healthy people have fuelled debate about the secrecy surrounding the documentation submitted by drug companies to obtain approval of [new drugs](#), write Silvio Garattini and Vittorio Bertele' from the Mario Negri Institute for Pharmacological Research in Italy.

They believe that greater transparency "would open drug dossiers to evaluation by the scientific community and help independent interested parties define the benefit-risk profile of new medicines before they are allowed on to the market."

And they suggest that the recent movement of the European Medicines Agency (EMA) to the Health and Consumer Policy Directorate (DG Sanco) rather than the Enterprise and Industry Directorate "presents an opportunity to introduce more openness."

The industry considers it has the right to secrecy, in order to protect the substantial investments made to develop a new drug. But the authors argue that the public is an "essential partner" in new discoveries and therefore has "the right of access to all relevant information."

Secrecy about clinical data "implies undue exploitation of the rights of doctors and patients participating in the studies," they say.

Transparency of the regulatory system is also required "to overcome several dysfunctions in the drug industry's behaviour" and "cast light on deviations from trial protocols," they add.

The abolition of confidentiality would help make the system more transparent and enable clinicians and patients' representatives to obtain information on which to base constructive criticism, establishing [public confidence](#) and improving research in the industry itself, they explain.

Abolition of secrecy by EMA would also boost the regulatory authorities' credibility and show that patients' health has priority over industrial interests, they conclude.

Provided by British Medical Journal

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