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European drug regulations need to change, say experts

How can we regulate medicines better?

European drug regulations need changing to ensure they meet the needs of patients and doctors, argue experts in this week's BMJ.

Licensing of new drugs in Europe is increasingly controlled by the European Medicines Agency (EMEA), yet new drugs have only to show they are equivalent to current treatments rather than show superiority.

This favours the interests of drug companies, say Silvio Garattini and Vittorio Bertele from the Mario Negri Institute for Pharmacological Research in Italy. They believe that new drugs should be required to have some added value to current treatments or be cheaper.

One way to ensure this would be to introduce some element of independent research by a non-profit organisation, they say. At present, manufacturers prepare the reports seeking approval for a new drug or a new indication and independent research occurs only after approval.

Another concern with the European agency is transparency, they write. Unlike the US Food and Drug Administration, the EMEA keeps almost all its information secret, yet there is no reason to hide toxicological and clinical information, which is essential to understand why a new drug has been approved or a new indication granted.

Other information they suggest should be made transparent includes the size of the majority that approved a given drug, the reasons of the minority for opposing approval, conflicts of interest, and post-marketing commitments and their fulfilment.

They also believe that the regulatory system is subject to bias and suspicion and call for the European pharmacovigilance system to be implemented.

They conclude: Some of our suggestions will make the approval of new drugs and new indications more difficult and prolong the time needed for their introduction into the market. We may therefore need to be more flexible to encourage industrial research.

One possibility would be to prolong product patents in exchange for better, safer, more trustworthy, and more affordable innovation. We believe the changes will not only be important for patients but will help stimulate innovative research by drug companies.‹/p>

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