# Making Medicines Authorisation Procedures Work for Patients

Policy Recommendations | 8 October | Download PDF

A study recently published in The Milbank Quarterly, *Approval of cancer drugs with uncertain therapeutic value: a comparison of regulatory outcomes in Europe and the United States*, compares outcomes of medicines marketing authorisation procedures for the European Medicines Agency (EMA) and the United States Food and Drug Administration (FDA) for 21 cancer-drug pairs.

Based on the findings of this paper, we have drawn up a series of recommendations for regulatory authorities to ensure that medicines approval procedures work in the best interest of patients. Our specific recommendations fall under the following areas:

- We need more safeguards to ensure pharmaceutical companies evaluate their products in a meaningful way.
- The inconsistency in authorisation decisions between the EMA and FDA and diluting evidence standards are of serious concern.
- Transparency will allow for thorough scrutiny of study quality and risks of bias, and will allow for uptake and use of new knowledge by others. This prevents the unnecessary duplication of costly studies both in terms of public resources and human costs.

Read the full recommendations here.