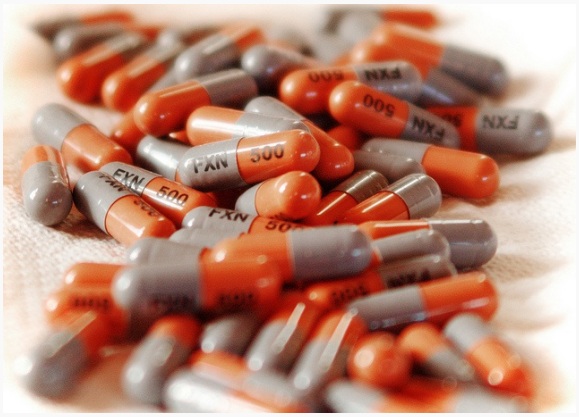
Why a stricter regulation of drugs could foster (not deter) pharmaceutical innovation

Huseyin Naci and Jonathan Cylus provide arguments for how to improve the regulation concerning pharmaceutical drugs. Since drugs are not assessed relative to alternatives on the market, they claim it becomes more difficult to accurately evaluate a drug's successes and harms. Increased innovation and a more streamlined delivery of information are some of the benefits they attribute to more rigorous drug regulations.



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The way medicines are regulated can be improved. At the moment, evidence standards for drugs to gain market authorization require that each new medicine should be evaluated on its own merit, without being assessed against other available treatments. This is the case even when there are numerous existing alternatives on the market.

This is problematic. When a new drug comes on the market, patients, doctors, and health technology assessment agencies such as the National Institute for Health and Clinical Excellence do not have adequate information about its benefits and harms relative to other similar comparators. Second, the current system crowds the marketplace with products that may be less effective or more harmful than existing agents. In this environment, asking healthcare providers to make evidence-based decisions is increasingly difficult. Lastly, by only requiring manufacturers to demonstrate that their products are better than placebos, manufacturers are incentivised to produce medicines in therapeutic areas where they have already had successes. This leads to an excess of similar drugs, and leaves other therapeutic areas with low investment and high unmet need.

We believe that to gain market approval, pharmaceutical manufacturers should have to demonstrate that their products are as good as or better than existing alternatives. Pharmaceutical manufacturers favour the status quo and prefer to test their new products against placebo. They argue that increasing the evidence standards for market entry of new drugs – and testing new drugs against available comparators – will be detrimental to their business because experimental designs, such as active comparator trials, are expensive and time consuming. Especially so, they say, in an environment where innovation is already declining.

However, evidence suggests otherwise. In our recent article published in the BMJ, part of an occasional series prepared in conjunction with the European Observatory on Health Systems and Policies, we review the historical trends in pharmaceutical innovation and find that the perceived decline in pharmaceutical innovation is not substantiated. In fact, the number of medicines entering the market has increased over the past 65 years. In addition, we find no conclusive evidence that past regulation has had a negative impact on the development of new medicines. To the contrary, past legislation requiring pharmaceutical manufacturers to establish evidence of effectiveness in controlled trials has been associated with increased innovation, as measured by the number of new products entering the market. In light of this, we argue that the benefits of raising evidence standards for market entry outweigh the potential risks.

Raising evidence standards for market entry would have numerous benefits. First, patients, doctors, and health technology assessment agencies would have better information about new medicines, facilitating evidence-based practice of medicine. As we move towards value-based pricing in the United Kingdom,

payers would have direct evidence early on about the relative benefits and harms of new medicines and make more informed value-for-money decisions for the National Health Service.

Second, stricter regulations would incentivise the development of new medicines in therapeutic areas with few or low performing alternatives. We expect that requirements for comparative evidence at the time of market approval would send signals to pharmaceutical manufacturers to focus on therapeutic areas with limited treatment options or where comparators have poor efficacy or are fraught with serious side effects.

Finally, requiring comparative evidence of new medicines would streamline the information needs of all stakeholders in the regulatory system. Unlike regulatory agencies, health technology assessment agencies already need manufacturers to provide comparative evidence to support decisions for coverage and reimbursement. In some cases, this discrepancy in evidence requirements results in conflicting decisions by regulatory agencies and country-level health technology assessment agencies. One example is the recent decision by the National Institute for Health and Clinical Excellence in England and Wales not to recommend bevacizumab, cetuximab, and panitumumab for the treatment of colorectal cancer in the National Health Service. The lack of comparative data was one of the cited reasons.

Requiring comparative efficacy evidence at the time of drug market approval will provide payers, providers, and patients with better information so that they can make informed decisions. It would also provide pharmaceutical manufacturers with the right incentives to invest in innovative drugs. We renew our call (see *BMJ* 2011) for the European Medicines Agency to give comparative efficacy evidence a formal role in drug approvals.

This article was first published on LSE's Health and Social Care Blog.

This article discusses: Naci H, Cylus JD, Sato A, Vandoros S, Perampaladas K (2012) Raising the bar for market authorization, *British Medical Journal*, 344, e4261.

Note: This article gives the views of the authors, and not the position of the British Politics and Policy blog, nor of the London School of Economics. Please read our comments policy before posting.

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