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## Accelerated access to new drugs and technologies

Article (Published version)

**Original citation:**

Naci, Huseyin and Mossialos, Elias (2017) *Accelerated access to new drugs and technologies*. *BMJ*, 359. pp. 1-2. ISSN 1756-1833

DOI: [10.1136/bmj.j5387](https://doi.org/10.1136/bmj.j5387)

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This version available at: <http://eprints.lse.ac.uk/85738/>

Available in LSE Research Online: February 2018

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## EDITORIALS

## Accelerated access to new drugs and technologies

UK government's proposed scheme is unlikely to improve patient outcomes

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In a new report,<sup>1</sup> the UK government has endorsed the recommendations of last year's accelerated access review<sup>2</sup> and announced its plans to introduce a faster route to market for "strategically important and transformative" medicines, devices, diagnostics, and digital technologies. With the accelerated access pathway, scheduled for April 2018, the government has made an unprecedented pledge to "bring forward by up to four years patient access to selected, highly beneficial and affordable innovations."

The proposed pathway adds to an already crowded landscape of regulatory initiatives aiming to expedite the approval, reimbursement, and adoption of promising new technologies in the NHS. The recently reformed Cancer Drugs Fund is one example,<sup>3</sup> along with the early access to medicines scheme allowing patients to use drugs before formal regulatory approval<sup>4</sup> and the National Institute for Health and Care Excellence's "fast track" appraisal process that guarantees expedited funding for highly cost effective technologies.<sup>5</sup>

So, what is new about the new pathway? A core objective is to foster technological advances for previously unmet needs. A newly established collaborative with patient, industry, and clinician representatives will select the most suitable products for the pathway. How the collaborative will define unmet needs is unclear. Enhanced NHS horizon scanning is mentioned, but this method identifies only research and development activities that are planned or under way. Without rigorous assessment of population level needs, the collaborative may end up reviewing and selecting the best technologies among those available rather than those most needed.

### Questionable benefits

What can patients and the public expect from the new pathway? One of the key recommendations is to identify "breakthrough" technologies and expedite their development, approval, and adoption in the NHS. This resembles similar initiatives by the US Food and Drug Administration (FDA) to expedite marketing approval for medicines that treat rare, serious, or life threatening conditions. Research to date shows that most products with expedited approval do not offer a step change in patient outcomes.<sup>6,7</sup>

The US experience also highlights two other important issues that the UK government should consider before launching the new pathway. Firstly, the process relies on early studies to select promising technologies. Early studies tend to exaggerate benefits, which then decline as longer term evidence accumulates.<sup>8,9</sup> Short term surrogate measures such as radiological or laboratory markers do not always materialise into long term clinical benefits such as improved symptoms or survival unless the relation between surrogate and clinical outcome has been validated rigorously.<sup>10</sup> In addition, expedited drugs are more likely to have safety problems later on than drugs approved through regular pathways.<sup>11,12</sup>

Sponsors of technologies selected on the basis of incomplete data should be required to conduct post-marketing studies to establish meaningful benefit and safety. However, these studies are often delayed or terminated and may not confirm the promise of earlier studies.<sup>6,13</sup> Clear incentives to continue meaningful research, coupled with effective oversight and enforcement, should be a priority.

### Balancing act

Secondly, the government's ambition to achieve cost neutrality overlooks the considerable tension between faster access and affordability. Sponsors pursuing expedited approvals often set high prices for their "breakthrough" products, and some of these products are cost effective despite the high price tag.<sup>14</sup> Therefore, faster access to new drugs and technologies is likely to escalate—not control—healthcare spending.

Although the government has committed to offset extra costs by identifying and expediting other products that deliver savings, innovations that save money are exceedingly rare.<sup>15</sup> Even if such technologies existed, it's unclear how they would be identified early in the regulatory process with limited data. Without additional funding or an effective parallel NHS-wide strategy to stop funding ineffective interventions, the feasibility of the fast track proposals is questionable.

What does the government want to achieve with accelerated access? It is a bold attempt to strike a balance between health and industrial policy. The UK is one of the few countries with

a strong life sciences industry. Understandably, it is eager to attract international investment and make the NHS an attractive place for a global industry's research and development activities. Nonetheless, the proposal says too little on expected benefits for patients and wider society. Instead, several concrete pledges are made to industry, including a promise to establish a new commercial unit within the NHS to "immediately streamline the pathway for access discussions" and pave the way for "flexible and confidential commercial arrangements." Why? Because innovators want it, according to the report. Furthermore, the government's preliminary criteria for judging the success of the pathway mention indicators such as "level of industry interest" and "speed of product progression through the accelerated access pathway" ahead of "improved health and quality outcomes."

The UK government has joined the global race to provide faster market access to new drugs and technologies.<sup>16</sup> If the goal is to improve health outcomes, we should focus on better not faster approvals<sup>17</sup> and send a clear message to industry about the needs and priorities of the NHS and all who use it.

Competing interests: We have read and understood BMJ policy on declaration of interests and have no relevant interests to declare.

Provenance and peer review: Commissioned; not externally peer reviewed.

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