

## Why is the UK subscription model for antibiotics considered successful?



Defining success is a crucial component of policy delivery, for where public funds are disbursed, public benefit should follow. Sometimes, the desire to proclaim success and international leadership can precede robust policy evaluation, for reasons of political economy, or in response to a need for a policy win. Since July, 2023, such discourse around the desire for success has developed around the UK's subscription scheme for new antibiotics.

Designed in response to the accelerating global crisis of antimicrobial resistance, the UK subscription pilot is based on the concept of delinking the volume of drugs sold from reimbursement. Setting fixed payments for antibiotic access, rather than linking reimbursement to the volume of drugs sold, could eliminate incentives to oversell antimicrobials.<sup>1</sup> The UK pilot purports to overcome the long-standing innovation dearth in the antimicrobial space by increasing commercial profit margins and encouraging urgently needed innovation in pharmaceutical antimicrobial research and development.

The UK contracted the first two drugs to be reimbursed in this manner in April, 2022 (Shionogi's cefiderocol and Pfizer's ceftazidime-avibactam).<sup>2</sup> The two companies were paid £10 million per year, guaranteed for 10 years (with a 3-year break clause), or £200 million for access to their drugs in England. In 2019, we highlighted that the pilot not only amounted to overpaying for drugs that were already on the market, but was also unlikely to improve stewardship or stimulate research and development (both by Pfizer and Shionogi and in the general field). We thought it unlikely that innovation would filter down to the smaller biotechnology companies that account for the vast majority of ongoing antimicrobial innovation.<sup>2,3</sup> To avoid these issues, we called for "greater transparency regarding decision making and more public debate on the ultimate goals of this process", added safeguards "such as ringfenced funding for truly new drugs", and "regularly published trackers of the effects of subscriptions on antibiotic research and development for novel drug candidates."<sup>2</sup>

The wave of official and unofficial documents speaking of the UK model's success has been

widespread since July, from the National Health Service (NHS) England and the National Institute for Health and Care Excellence (NICE) press release on the consultation (deeming it a "successful world-first pilot"),<sup>1</sup> to corresponding news articles and positive feedback from professional societies, and left us wondering: had we missed something?<sup>4-6</sup> We sought evidence of this success, but unfortunately, publicly available information of either robust trackers or clearly delineated progress being assessed against the stated aims of the scheme remains sparse. Public communications are vague about exactly how the subscription model was successful other than the money having been spent. Meanwhile, international observers such as the German Government's Global Antimicrobial Resistance Research and Development Hub wrote in May, 2023 that "it is currently too soon to evaluate whether this model has stimulated [research and development] and innovation in the sector".<sup>7</sup>

The absence of evidence underpinning current statements begs the question as to why organisations are so keen to declare and disseminate success at an early juncture. One explanation might be that this so-called success is based not on actual data—which were never going to emerge within 1 year of the implementation of such a complex scheme—but on political calendars. In the UK, NHS England and NICE are currently consulting on changes to the pilot that would see pharmaceutical companies' reimbursement doubled in some cases to £20 million per year per drug.<sup>1</sup> Moreover, contracting will be extended from only England to include all four UK nations. At the international level, reporting this so-called success might well be a framing exercise designed to ensure that the UK's pull-scheme does not remain an isolated experiment.<sup>8</sup> With both the EU and the USA contemplating their own pull-incentives via transferable exclusivity vouchers and increased drug reimbursement (eg, the Pioneering Antimicrobial Subscriptions to End Upsurging Resistance Act), showcasing UK success could help ease concerns about subsidising for-profit innovation with substantial injections of public money.

The world urgently needs effective new antimicrobials, and piloting a diverse set of

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antimicrobial resistance policies is important to support this aim. However, to avoid similar charges aimed at other claims of UK leadership (eg, in the arena of climate change), the effect of these policies should not be oversold.<sup>9</sup> 1 year into the UK's subscription model pilot, we have seen no robust or transparent evaluation of the scheme's effect, published evidence, or a priori performance indicators or policy aims. Clear definitions of the rules and parameters of the pilot are needed before it can be considered successful.

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