Merck & Co's US antibiotic withdrawal sends the wrong signals for combating resistance

BY RACHEL BRAZIL | 12 OCTOBER 2026

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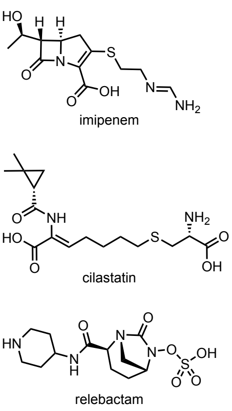
A drug shortage notice posted on 9 September brought to light US pharma company Merck & Co's decision to discontinue its intravenous antibiotic combination Recarbrio in the US. Merck confirmed its decision to voluntarily stop manufacturing and marketing the drug, which is used for serious antibiotic-resistant hospital infections, but stated 'this decision is not related to any product safety or quality issues'.

For now, the drug is still available in the UK and EU. Merck stated that 'availability decisions are made market by market, based on local patient needs, demand, supply and regulatory requirements'. But the move has worried some working to improve the pipeline of new antibiotic drugs to fight the increasing number of infections showing antimicrobial resistance (AMR). 'It's really a bad signal for investors and small companies to understand if there is societal receptivity to value these drugs, even though we're going to need them over the next decades,' says Harry Skinner, chief executive of the AMR Action Fund, a US venture capital initiative dedicated to combating antimicrobial resistance.



Recarbrio is a combination of carbapenem-class antibiotic imipenem; dehydropeptidase inhibitor cilastatin, which prevents the drug being metabolised in the kidneys; and beta-lactamase inhibitor relebactam, which blocks an enzyme made by carbapenem-resistant bacteria

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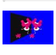
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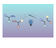
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Recarbrio received US Food and Drug Administration (FDA) approval in 2019 and is a combination of the existing antibiotic combination imipenem-cilastatin with relebactam. Imipenem is part of the carbapenem class of broad-spectrum antibiotics, closely related to penicillins; the enzyme inhibitor cilastatin prevents imipenem being broken down in the kidneys. Adding relebactam, a novel beta-lactamase inhibitor, aims to block the enzyme made by resistant bacteria that can destroy carbapenem antibiotics (known as carbapenemase-producing enterobacterales or CPEs). It was approved for last-resort use when other options are exhausted.

CPE infections are hard to treat and associated with high mortality in hospitalised or critically ill patients. There are two other combination therapies designed for this purpose, but Skinner says Recarbrio's discontinuation could limit options for patients with allergies or other complications. 'At least in the US, they have one less option,' he says.

> A lot of the innovation [in new antimicrobials] comes from small enterprises

Clinician and regulatory practice expert, Aaron Kesselheim from Harvard Medical School, US, is less concerned and says currently Recarbrio is rarely used, partly due to a lack of evidence that it provides a clear clinical advantage over other, cheaper antibiotics. 'We need to have drugs that are shown to work against those resistant infections and I just don't think Recarbrio necessarily did that,' he says. Concerns were raised that the two clinical trials on which its approval was based did not include patients with carbapenem-resistant bacteria, and the vast majority of patients would have responded to imipenem alone. Kesselheim says this uncertainty may explain 'why it wasn't selling a lot and why Merck removed it from the market'.

Big pharma has largely withdrawn from developing new antibiotics and Merck currently has no antibiotics in its pipeline. Its 2024 report on antimicrobial resistance stated: 'without substantial changes to the economic landscape, it will be difficult for the company to continue to justify significant investment into new antibiotic R&D programs.' Merck is not alone, with both Novartis and Sanofi terminating their antibacterial and antiviral research programmes in 2018 .

The profitability problem of developing new 'reserve' antibiotics, which by definition will be used at low volumes, is being tackled in the UK with the new NHS antimicrobial products subscription model, successfully piloted from 2020 . It pays pharmaceutical companies a fixed annual fee for new antibiotics based on their value to the health service rather than the volume prescribed. The initial 2024 rollout contracted two antibiotics for highly drug-resistant Gram-negative bacteria; cefiderocol, marketed by Shionogi and ceftazidime–avibactam, co-marketed by Pfizer and AstraZeneca. The next round of contracts, valued at up to £1.9 billion over 16 years, is expected to be announced in November.

> There are a variety of avenues for a generic to challenge the patent

Skinner says the UK's model is a really wise approach and if adopted elsewhere should help provide the right economic incentives for innovation and investment. 'What the UK has done in leading nations in this model has great promise for public health,' he says. In the US, legislation for a $6 billion (£4.5 billion) federal subscription model, known as the Pasteur Act, is making its way through Congress , although its passage is uncertain. Skinner says he is 'optimistic' that it will eventually pass but cannot put a timeline on it.

A similar subscription model in Sweden is more focused on local market availability guarantees, offering companies a minimum annual revenue of SEK4 million (£300,000) per product in exchange for maintaining strict stock levels within Sweden. The scheme's five products include Recarbrio, which could be a factor in the drug's continued availability outside the US for now.

Merck has continued to support antibiotic develop as one of the backers of Skinner's AMR Action Fund, committing $100 million over 10 years. To date, the fund has invested more than $300 million into 14 biotech companies developing new antibacterials, with one FDA approval so far, and several others making good progress. Skinner thinks small biotechs are now the most likely route to new antibiotics rather than big companies. 'A lot of the innovation, the chemistry, the biology, comes from small enterprises that have great ideas out of a variety of academic centres around the world ,' he says.

Kesselheim also thinks there should be a role for public funding of the basic science to better understand what drives antimicrobial resistance. 'The kind of research that the US government used to lead investment in, but unfortunately under the current administration has been cutting back on,' he says.

If Merck does discontinue Recarbrio globally, could a generic drugmaker step in? There is only one remaining patent covering relebactam, which does not expire until 2033. While companies retain their exclusivity, regardless of a decision to stop selling a drug, 'there are a variety of avenues for a generic to challenge the patent,' says Jacob Sherkow, an expert in intellectual property, drug and biotech regulation from the University of Illinois Urbana-Champaign, US. A challenge would compel Merck to either sue the generic applicant or essentially give up, which, says Sherkow is,'the typical path to generic entry.' The bigger question comes back to profitability and Skinner doubts another drugmaker would be interested on those grounds. 'These are very complicated drugs to manufacture, often needing their own manufacturing facility to avoid cross-contamination, which is an expensive endeavor for a generics company .' he says.

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