Pharma must ramp up access, stewardship efforts in AMR research, new report finds

Ensuring new therapies reach low- and middle-income countries could save hundreds of thousands of lives.



While debate on fighting AMR tends to focus on encouraging big pharma companies to re-enter antimicrobial R&D, the results of such measures will take years to pan out. | Loic Venance/AFP via Getty Images

by Claudia Chiappa • 17 HOURS AGO • 5 MINUTES READ

Pharmaceutical companies involved in antimicrobial research and development must do more to ensure new antimicrobial treatments reach patients across the world, according to a new report that faults their access and stewardship plans.

The study, published by the Access to Medicine Foundation, looked at five late-stage clinical development projects currently in the pipeline to assess their efforts to ensure that new antimicrobial drugs — which can treat drug-resistant pathogens — reach patients in low- and middle-income countries and remain effective as long as possible.

It found that while pharmaceutical companies are already pursuing several access and stewardship strategies, "structured advance planning has not yet become standard, risking patient care globally."

"To save as many lives as possible, it is vital to ensure these much-needed medicines reach the patients who need them most, particularly in countries that face the highest burden of drug resistance," the report reads.

Antimicrobial resistance (AMR) is widely regarded as one of the most pressing threats to human, animal and environmental health — even worse than the Covid-19 pandemic.

Experts and lawmakers are encouraging restraint in the use of antibiotics, to reduce overexposure. They also warn, conversely, that high-quality antibiotics must be made more available to countries that don't have enough, as the lack of effective antimicrobials kills more people than does resistance to the drugs.

There is also a need to develop novel antibiotics and antifungals to treat infections that have grown resistant to existing therapies, and to make these drugs available everywhere they are needed.

Despite the urgency of these needs, however, only a handful of projects are currently in the pipeline, with pharma companies having largely abandoned antimicrobial research and development. Firms that do have projects in the pipeline thus bear an even greater responsibility, because "there is no backup," said Marijn Verhoef, director of operations and research at the Access to Medicine Foundation.

"Especially because the pipeline is ... so empty, there's even more pressure on the few companies that are still developing these novel antibiotics or novel antifungals to reach everybody across the globe," Verhoef told POLITICO.

While debate on fighting AMR tends to focus on encouraging big pharma companies to re-enter antimicrobial R&D — by using incentives such as market-entry rewards — the results of such measures will take years to pan out.

In the meantime, ensuring access to the therapies currently in the pipeline is "the way to catch up," Verhoef said.

Get planning early

The five projects analyzed in the report — submitted by GSK, F2G, Innoviva, Venatorx and Pfizer — could could save at least 160,000 lives from drug-resistant bacterial and fungal infections annually, as long as they are available to patients in low- and middle-income countries, the report found.

But planning shortcomings must be addressed first, the report noted, as researchers found the firms had submitted concrete plans for registration in only five out of 113 low- and middle-income countries.

This was "surprising," said Martijn van Gerven, research coordinator for the AMR program.

"When we look at the big pharmaceutical companies like GSK and Pfizer, which we highlight in the report, we didn't see plans that were really detailed, which is what we kind of expect from these companies because they have all their resources, all the means to do so," he said. "So we were expecting a bit more details from that end."

Another shortfall was the lack of pricing strategies to ensure affordability and stewardship. This was the case in four of the projects analyzed in the report — from GSK, F2G, Innoviva and Venatorx — where no robust plans for making new products affordable to patients could be identified.

Pfizer, meanwhile, reported it would implement equitable pricing strategies for its treatment, and also consider it for its "Accord for a Healthier World" initiative, through which the company offers its full portfolio of medicines and vaccines on a not-for-profit basis to some countries.

The report also showed that pharma companies are increasingly prioritizing children in their clinical trials, with four out of the five companies featured in the report — GSK, Pfizer, Innoviva and Venatorx — conducting or initiating such trials.

The study examined the roles of other actors and stakeholders, including partners such as the Global Antibiotic Research & Development Partnership (GARDP), public and private funders and the government, in promoting access and stewardship planning. For example, funders could help make the product accessible and hold companies accountable.

"This is a worldwide problem, and therefore these funders have an opportunity to put provisions in place that mandate access and stewardship globally," van Gerven said.

At the same time, it's important that big pharma companies "step up" and support smaller firms.

"That really needs to change," van Gerven said. "We cannot depend on organizations like GARDP to take responsibility in low- and middle-income countries. We need companies, big companies, to step up."