

INTERNATIONAL PARTNERSHIPS FOR LOW-COST ANTIMICROBIAL DISCOVERY AND DEVELOPMENT



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LEADERSHIP IN ENHANCING ANTIMICROBIAL DISCOVERY



RE-INVIGORATING THE SEARCH

Ten years ago, the O’Neill Review on Antimicrobial Resistance called for a major effort to discover and develop new antimicrobials. It outlined a strategy for achieving this through a combination of “push” and “pull” incentives and, importantly, measures to reduce the cost of antimicrobial development. The UK has played an important role in mobilising a global effort to implement this strategy. A lot of progress has been made, but the current situation does not match the expressed ambition.

Recent developments in the science and technology capabilities of several middle-income countries and their pharmaceutical sectors, including in research and development, are creating new opportunities for implementing a strategy that could enable sustainable and affordable antimicrobial discovery, development and manufacturing. This would entail new kinds of international partnership based on the principle of shared commitment to contribute to a global public good but with differentiated responsibilities. The UK is well-placed to continue its catalytic role within international leadership, but a more systematic and implementable approach is required at national and cross-national levels.

Progress

There has been a lot of progress in establishing effective surveillance for antimicrobial resistance. Surveillance findings are essential to the formulation of priorities for drug discovery and development. The focus over the past ten years has been on providing financial support for antimicrobial discovery and early-stage development (push) and on rewarding successful drug approvals (pull). The UK has funded basic research, mostly through short-term academic grants, which are typically insufficient and not directed to support a long-term drug discovery campaign. There are several initiatives aimed at supporting the development of promising candidate drugs, including UK-based initiatives, such as Pathways to Antimicrobial Clinical Efficacy (PACE); UK-supported international partnerships including Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) and the Global Antibiotic Research & Development

Partnership (GARDP); the venture capital AMR Action Fund; and further philanthropic support through the Gram-Negative Antibiotic Discovery Innovator (Gr-ADI).

These initiatives have demonstrated their usefulness in enabling innovation for new drugs, but funding has been limited compared to the scale required. Progress with putting pull incentives in place has been slow and only the UK and Italy have fully operational models. There remains a lot of uncertainty about the levels of funding that other countries will eventually make available so that companies still have little incentive to invest in the development of new antimicrobials. There has been limited progress in reducing the cost of drug development by harmonising regulatory pathways for new antimicrobials and creating cross-national clinical trial networks in regions of highest need and prevalence of resistance.

The outcome of ten years of effort has not kept up with the level of need. There is a small portfolio of promising new drugs. The number of companies actively developing new antimicrobials and the number of skilled researchers employed in antimicrobial discovery has continued to decline. There is a danger that the failure to find exciting new products and pathways to a sustainable discovery and development ecosystem could lead to policy fatigue. The current situation largely reflects the slowness in putting together a truly global effort. New developments in science and the growing capabilities of several large middle-income countries in production, science and research and development are creating opportunities and making possible new solutions to support a re-invigorated effort.

New opportunities

Developments in science are creating new opportunities for drug discovery, as the rapid response to the covid emergency illustrated. These include major technological developments around synchrotrons, which enable better understanding of structural biology to inform rational drug design, especially when coupled with advances in artificial intelligence and machine learning. These technologies are the result of very large investments. So far, they have made limited contributions to the search for new antimicrobials. Strategies for funding antimicrobial discovery need to enable academic researchers and early-stage companies, in the UK and elsewhere, to benefit from these developments. This includes building and training cross disciplinary teams within international partnerships, enabled by a wider degree of open science, driven by surveillance informed global public health priorities, and opportunities for regional R&D and manufacturing.

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Partnerships between the UK and middle-income countries

So far, the involvement of middle-income countries in the search for new antimicrobials has been limited. Several have both a significant incentive to find new antimicrobials, because of the higher incidence of AMR, and a growing capacity to become actively involved in the search. India, China, Brazil, Indonesia and South Africa are examples of countries with a growing capacity in basic science and in different aspects of the discovery, development and manufacturing of new antimicrobials. Some promising antimicrobial candidates are already being developed by

companies in these countries. Since new antimicrobials are unlikely to be commercially successful, individual countries have limited incentive to invest in these products. It may be more appropriate to think of them as global public goods that can best be addressed by international partnerships for more cost-effective drug discovery and development.

The O'Neill Review called for measures that aim at reducing the cost of drug development to complement the provision of financial incentives. According to that report, at least 65% of the cost of developing a new antimicrobial is for clinical trials. This cost can be reduced by carrying them out in places where the incidence of resistant infections is relatively high, allowing for both cheaper development and improved clinical data quality. Beyond clinical trials, partnerships with companies in middle-income countries might open-up other complementary capabilities, such as efficient development and manufacturing of new drugs. To facilitate such partnerships and ensure access to newly approved antimicrobials, there will need to be efforts to improve comparability of surveillance data and regulatory harmonisation internationally.

The UK can bring several strengths to this kind of partnership. It has centres of excellence in cutting-edge science such as the structural biology facilities at the Diamond Light Source synchrotron, including participation in the OpenBind AI-enabled drug discovery project, anti-infective programmes at the University of Warwick and the Oxford University Centre for Medicines Discovery, and University College London and the UK Health Security Agency with the "Open Antibiotics" and "Open Innovation" discovery programmes. The UK also has demonstrated capacity to support small and medium-sized enterprises in the development of promising drug candidates. It has well regarded regulatory agencies and capacity to design and implement high quality clinical trials. The challenge is to build partnerships, training and capacity to enable drug discovery, development, production and access that are of mutual benefit to the UK and partner countries. The UK is well positioned to facilitate the establishment of this kind of international partnership.

This LEAD briefing was written by Gerald Bloom (Institute of Development Studies, UK), Christopher Dowson (Howard Dalton Centre, University of Warwick, UK), David McKinney (ARMoR: Alliance for Reducing Microbial Resistance) and Priya Balasubramaniam (Public Health Foundation of India). The opinions expressed are those of the authors and do not necessarily reflect the views or policies of their organisations or funders.

Images: Page 2, Green capsule medicine pill production line, Industrial pharmaceutical concept. Credit: I viewfinder, Shutterstock

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