
Key messages

- Antimicrobial drugs, such as antibiotics, represent one of the most powerful tools in healthcare, underpinning every aspect of treatment against life-threatening infectious diseases and enabling critical interventions like chemotherapy, and surgical procedures.
- However, rapidly rising antibiotic-resistant infections (also called antimicrobial resistance - AMR) threaten to undermine this. England saw over 90,000 hospital admissions because of antibiotic-resistant infections in 2019/20. ¹
- We urgently need new antibiotics, but there are too few in the pipeline and drug resistant bacteria are developing faster than new products can reach the market. Several factors have hampered their development, particularly the fact that across the world the market has not been viable commercially. It costs significant amounts of money to develop new medicines, that for good reasons, often need to be kept in reserve.
- Over the last few years, the UK Government and the National Institute for Health and Care Excellence (NICE) and NHS England and Improvement have demonstrated global leadership to create and trial a new evaluation and payment model for antimicrobial products – the NICE/NHSE AMR Project.
- ABPI is supportive of this work but, as we look to implementation, we must ensure that:
 - We evolve and learn from the Project to ensure that a sustainable long-term solution is put in place for all new antibiotics which is value-based.
 - The system should act at pace to implement the Project, so learnings on how to value the two antibiotics in the pilot can be taken and applied to the next new antibiotics coming to market.
 - Lastly, recognising that a UK wide scheme will have a greater impact, we must ensure the Devolved Nations are included in the roll-out.
- Industry is also stepping up and has invested \$1bn to bring 2–4 new antibiotics to the market by 2030 through the AMR Action Fund, giving Government much needed time to act.

What is AMR?

- Antibiotics represent one of the most powerful tools in healthcare, underpinning every aspect of treatment against life-threatening infectious diseases such as pneumonia, TB, HIV, and malaria, enabling critical interventions like chemotherapy, and surgical procedures.
- AMR occurs when bacteria, viruses, fungi, and parasites change over time and no longer respond to medicines – making infections harder to treat and increasing the risk of disease spread, severe illness and death. This rising resistance threatens to undermine modern medicine.
- Every year 700,000 people die from infections which are resistant to antibiotics. And this is estimated to increase to 10 million deaths each year by 2050.²¹
- AMR is a global public health issue requiring multiple solutions and a sustained, coordinated response.

Why is the antibiotic pipeline insufficient?

- Given the nature of resistance, we will always need new antibiotics. However, drug resistant bacteria are now developing faster than new antibiotics can reach the market.
- One of the biggest problem areas is the research and development of new antibiotics. The science is hard and there is a problem with the current system for allocating investments into the expensive R&D needed.
- Developing antibiotics is expensive and risky and has bankrupted many smaller companies and caused large companies to exit their own R&D programs.
- Antibiotics are not like other medicines, because companies are working to find new medicines that in some cases will sit on the shelf and only be used against specific bugs that are constantly evolving.
- The high failure rate in antibiotic development leaves just 40 antibiotics in clinical trials globally. The result is a huge public health need for new antibiotics.
- The life sciences sector – including pharmaceutical companies – is key to discovering new antibiotics, but only if we can find innovative solutions to support antibiotic innovation.

The NHSE/NICE AMR Project

- There is an urgent need for policy reforms to create market conditions that enable sustainable investment in antibiotic innovation, including properly valuing and paying for new antibiotics.

- The UK Government has played a leading global role in this fight, launching the AMR Project (formerly the AMR Pilot), a world-first and the subject of close international scrutiny and attention.
- The AMR Project is trialling a new subscription style model for antibiotics, where payment is based on the product's assessed value using a new comprehensive evaluation framework. Two medicines have been selected and contracts are expected to commence in April 2022
- NHS England, NICE and the Department of Health and Social Care (DHSC) have made a significant effort to continue to move this initiative forward despite the challenges of COVID-19.
- However, as we look to implementation, we must ensure that we evolve and learn from the project to ensure that a sustainable long-term solution is put in place for all new antibiotics which is fully and entirely value-based, and that the model works across the whole of the UK.
- The project aimed to select products after first setting a budgetary cap on the amount that could be paid. However, it is critical that long term the system assesses new medicines at the outset with a focus on their broader value before setting commercial terms in line with the value assessed.
- Without adequate reward for the long- term investment needed for R&D, companies may continue to be unable to invest in needed research in this area. Start-up companies will find it difficult to attract venture capital investment. Taking a purely cost rather than value driven approach risks discouraging greater private sector research in this area.
- It is a critical time for industry to be able to have senior level dialogue with government on AMR. **We welcome the re-launched Joint Government Working Group on AMR to help us deliver AMR solutions for patients.**

Recommendations

1. Ensure the re-launched Joint Government Working Group on AMR, collaborates with industry to enable oversight for the implementation and roll-out of the NICE/NHSE AMR project.
2. Implement a new model, informed by the AMR Project, as quickly as possible across the whole UK.
3. Commit to removing artificial assessments for reimbursement (e.g., a current £10m cap currently applied). Reimbursement should be value-based
4. Deliver an interim solution to enable access for all new products available in the UK as needed while the pilot project is running.

The AMR Action Fund

- Putting in place the necessary policy reforms to support antibiotic innovation will take time. This is time the world doesn't have because the antibiotic pipeline is near collapse. Urgent action is needed now, so the pharmaceutical industry is stepping up.
- Last year, industry launched a \$1 billion pharmaceutical industry-led investment fund that aims to bridge the funding gaps facing antibiotic developers.
- The AMR Action Fund will invest in smaller biotech companies focused on developing new antibiotics that address the highest priority public health needs, make a significant difference in clinical practice, and save lives.
- The government needs to be bold and ambitious in putting in place long-term market solutions that can complement the AMR fund.

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ⁱ <https://inews.co.uk/news/health/dame-sally-davies-antimicrobial-resistance-is-the-silent-pandemic-growing-in-the-shadows-1023878>

² <https://www.who.int/news/item/29-04-2019-new-report-calls-for-urgent-action-to-avert-antimicrobial-resistance-crisis>