**Launch statement:**

**NHS England and NHS Improvement and NICE begin project to develop and test innovative models for the evaluation and purchase of antimicrobials**

Antimicrobial resistance (AMR) is one of the most pressing global challenges we face this century. Unchecked, AMR threatens many of the Sustainable Development Goals including those affecting health, food security, trade, and labour supply.

While the UK has made progress in reducing the use of antimicrobials in humans and significantly in animals in the last five years, drug-resistant infections in humans increased by 35% from 2013 to 2017 in England.[[1]](#footnote-1)

For most antimicrobials, there are few replacement or alternative products in development and even fewer that target priority pathogens. Investment in novel antibiotics can be seen as commercially unattractive. The high cost and low returns associated with the research and development of novel antimicrobials have led to potential market failure.

Tackling AMR is a government priority. The UK government published its vision for a world in which AMR is contained and controlled by 2040, and a supporting five-year national action plan, in January this year.

Having a full antimicrobial pipeline as well as supporting appropriate access to and stewardship of new and old antimicrobials, will contribute to the fulfilling that vision.

NICE and NHS England & NHS Improvement were key partners in developing the UK national action plan. NHS England has committed to implementing the human health aspects of the plan through the NHS Long Term Plan.

The national action plan commits to developing and testing a model that pays companies for antimicrobials based primarily on their expected value to the NHS, as opposed to the actual volume used. NICE and NHS England are now jointly leading a project to deliver that commitment, working closely with the DHSC and stakeholders including industry.

Although the UK represents only a small part of the global market for these drugs, the learning from this project will be shared with the rest of the world so that other healthcare systems can also find workable models to support the introduction of these vital medicines.

The need to review and adapt the existing health technology assessment (HTA) approach to antibiotics is widely recognised. In 2018, NICE and DHSC co-sponsored research looking at [HTA methods](http://www.eepru.org.uk/wp-content/uploads/2017/11/eepru-report-amr-oct-2018-059.pdf). The work was undertaken by leading health economics researchers from the National Institute for Health Research (NIHR) Economic Methods of Evaluation in Health & Care Interventions (EEPRU). The research confirmed that capturing the full value of a new antimicrobial is complex. Robustly estimating benefits across all attributes of value, supported by published evidence, may not always be feasible or practical.

However, it concluded that an adapted HTA framework, informed by health economic modelling and expert opinion, could be developed to capture the full value of novel antimicrobials.

NICE and NHS England & NHS Improvement have now established a jointly led project supported by EEPRU to develop and test innovative models for the evaluation and purchase of antimicrobials.

# The project

The project is assessing the extent to which the framework outlined in the EEPRU report can be used by NICE and NHS England & NHS Improvement to inform the assessment of value and reimbursement decisions for antimicrobials.

The first phase will focus on potential adaptations to the current HTA framework, the development of an outline reimbursement and payment model, and the selection of two products which will undergo the trial assessment and commercial discussions. This phase is anticipated to be completed by the end of 2019. The reimbursement and payment model will include a strong emphasis on companies needing to ensure that optimal stewardship arrangements are maintained through the introduction of the product and that they are making efforts to keep environmental contamination of antimicrobials to a minimum.

The second phase of the project will be the undertaking of the assessment of the two selected products, which is expected to conclude by end of 2020.

The project will be evaluated to consider how successfully the challenges of assessing the value for an antimicrobial can be addressed through adaptations to the current HTA framework, and different approaches to pricing and reimbursement.

Evaluation and communication will be ongoing throughout the project and the evaluation will be critical in shaping UK policy on the wider application of the model.

The nine main workstreams of the project can be summarised as follows:

*Phase one:*

* Development of an evaluation framework
* Development of a framework for negotiating levels of delinked payments
* Identification of two products to assess.

*Phase two:*

* The value assessment of the selected products, including the development of NICE guidance by a Committee convened for the project
* Commercial discussion on the selected products informed by the NICE guidance
* Implementation of payments
* Monitoring the use of the selected products

*Throughout the project:*

* Evaluation of the project
* Communication of the project and ongoing learning.

A central project team has been established across NICE and NHS England to lead the work, and to facilitate input from experts and a wide range of stakeholders.

# Next Steps

## Call for products

Two antimicrobials will be used to test the evaluation and commercial arrangements through this project; it is therefore important that companies have notified the project team if they have a product which could be considered through this process. If a company has not yet notified NICE and NHS England & NHS Improvement of a product to be considered, they should get in contact with ABpaymentmodels@nice.org.uk

## Targeted engagement

A stakeholder advisory group will shortly be established bringing together industry, public health experts, experts in the clinical and health economic evaluation of vaccines, with a wide range of national and international representatives to provide advice and challenge to all aspects of the project and to act as global advocates to champion the approach and disseminate learning.

This group will be used to support a period of targeted engagement which will shortly begin, to secure stakeholder input into the development of key areas of the project, including the proposed approach for topic selection, the approach to evaluation, and the outline commercial model.

NICE, NHS England & NHS Improvement and DHSC will work closely to ensure that the findings of the project are communicated in a timely way both to support the development of other payment models internationally and to ensure that pharmaceutical industry and other stakeholders have a clear understanding of the progress and evaluation of the project.

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1. Public Health England, English Surveillance Programme for Antimicrobial Utilisation and Resistance (ESPAUR), October 2018 [↑](#footnote-ref-1)