

Additional Written Evidence to the Science and Technology Select Committee

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Summary

The UK has taken a leading role in driving AMR policy development on the international stage. Most of the “What and Why” battles have been won internationally, and the challenge now is How, in particular how to pay for the incentives to create a badly-needed pipeline of new treatments and diagnostics.

The NICE/NHS England antibiotic subscription payment trial is a great step forward in revitalising the market for new antibiotics. This needs to be implemented permanently and across the whole of the UK, not just England, with a sufficient budget to reward multiple new AMR drugs over the next 10-20 years.

Whereas UK academic science in AMR has been well funded, there are strong silo boundaries between different parts of UKRI that prevent effective translation of science into clinical development and commercialisation. In particular, there is poor translation of great new ideas out into industry, either by company spin-out and creation, or partnering with biotech companies. This is a real lost opportunity for UK plc, both for patient impact and for value creation.

The large majority, over 85%, of AMR treatments are being developed by under-invested small to medium enterprises in the UK around the world, and the WHO reports that the pipeline of new drugs is insufficient to address the threat, and in the UK, we are failing to deliver our 20-year vision for new treatments. Policies need to be tailored to meet the needs of SMEs, in particular innovative funding solutions for the early stages of drug research and development.

The astonishing achievement of the Oxford/AstraZeneca vaccine roll-out was made possible by leadership, urgency, focus and funding. In my view, all parts of the UK’s AMR R&D ecosystem currently report a lack of a similar sense of mission. AMR now kills more people worldwide than HIV or Malaria, and we desperately need new treatments. There is no AMR task force!

Finally, the hugely successful £180m North-West based Infection Innovation Consortium, iiCON, supported by a £19m Strength in Places grant from BEIS, provides a platform for investment to support SMEs develop their new drugs, vaccines and diagnostics for AMR and other infectious diseases. iiCON should form the cornerstone of a new investment strategy for AMR treatment, and can help provide the leadership and sense of mission for the UK’s efforts in the battle against AMR.

UK 5-year AMR Action Plan and 20-year AMR Vision

The second UK 5-year plan is operational and being used to inform and direct the UK's investments in supporting AMR initiatives. The UK also has a 20-year AMR vision to inform longer-term strategy development.

One key element of the vision is:

“New diagnostics, therapies, vaccines and interventions in use, and a full antimicrobial resistance research and development pipeline for antimicrobials, alternatives, diagnostics, vaccines and infection prevention across all sectors; with access to new and old technologies for all.”

<https://www.gov.uk/government/publications/uk-5-year-action-plan-for-antimicrobial-resistance-2019-to-2024>

<https://www.gov.uk/government/publications/uk-20-year-vision-for-antimicrobial-resistance>

UK AID

The UK Government Department for International Development (DFID) provides international project support through UK Aid, including the Fleming Fund, a £265 million programme supporting up to 24 countries across Africa and Asia to tackle antimicrobial resistance.

<https://www.flemingfund.org/about-us/our-aims/>

UK Aid has also funded the £40m UK Global AMR Investment Fund (GAMRIF) that has invested in CARB-X, GARDP and FIND, as well as supporting international collaborations in Canada, China and Argentina.

<https://www.gov.uk/government/groups/the-global-amr-innovation-fund>

Subscription Incentive Trial

The UK has a world-leading subscription model incentive trial organized by the National Health Service (NHS in England) and the National Institute for Health and Care Excellence (NICE) which is operational at the moment. Dr Peter Jackson of Infex Therapeutics is part of the Project Advisory Group. The trial incorporates new health technology assessment (HTA) metrics and has a maximum PULL incentive of up to £100m over 10 years. The project selected two drugs for the subscription model, cefiderocol (Shionogi, Japan) and ceftazidime/avibactam (Pfizer, USA) and will be shortly announcing the result of the contract negotiations. The UK Government has published the project scoring criteria, with a strong focus on novel technologies targeting WHO critical priority infections, as well as the UK NHS's priorities.

<https://www.nice.org.uk/Media/Default/About/what-we-do/Life-sciences/invitation-to-submit-final-tender.pdf>

Similar reimbursement proposals are currently before Congress in the USA as part of the Biden administration's 21st Century Cures Act 2.0 bill. These would offer a payment of up to \$3billion over 10 years for effective new AMR drugs.

<https://degette.house.gov/sites/degette.house.gov/files/CURES%202.0%20Text.pdf>

In the EU, the Commission is expected to publish its recommendations for AMR reimbursement in December, following consultation that is ongoing at the moment.

https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12963-Revision-of-the-EU-general-pharmaceuticals-legislation_en

UK Research and Development funding

Funding mainly comes from the UK Government Department for Business, Energy and Industrial Strategy (BEIS). UK Research and Innovation (UKRI) is the department inside BEIS responsible for grant support to academia and business. There are three main UKRI divisions involved in supporting AMR:

Biotechnology and Biological Sciences Research Council (BBSRC) – providing academic-led grants for pure science, discovery and pre-clinical research. BBSRC has supported over 200 academic-led AMR research projects with over £100m in the last 5 years.

<https://www.ukri.org/what-we-offer/browse-our-areas-of-investment-and-support/bbsrc-research-to-combat-antimicrobial-resistance/>

Medical Research Council (MRC) - providing grant funding for academic-led clinical research from Phase1 - Phase 3 trials

Innovate UK (IUK) – providing grant funding to businesses

Businesses are also encouraged to participate in BBSRC and MRC collaboration projects.

UKRI also has some specific joint international programs that are focused on AMR, for example JPIAMR.

<https://www.ukri.org/opportunity/international-collaboration-to-address-antimicrobial-resistance/>

There is a search web site that can list all UKRI AMR projects here:

<https://gtr.ukri.org/search/project?term=AMR>

The UK Department of Health and Social Care (DHSC) also provide specific AMR funding opportunities for academic-led clinical projects in collaboration with industry, though the National Institute for Health Research (NIHR). In particular, NIHR is the gateway to conduct clinical trials in the NHS.

<https://www.nihr.ac.uk/explore-nihr/campaigns/tackling-antimicrobial-resistance.htm>

Business funding

MRC and IUK grants are competitive and are open to all therapeutics areas, not just AMR.

The main business grant scheme run jointly by IUK and MRC is the BioMedical Catalyst (BMC). This is for all therapeutic areas, not just AMR, and is only available to small-to-medium enterprises (SMEs).

The BMC scheme has awarded over £250 million since 2012, and supported over 180 business-led projects. Over £100m of additional private capital in the form of matched funding has been leveraged. Over £1 billion additional private finance, grant funding, or M&A receipts has been leveraged following BMC grant awards.

The BMC competition is run three times each year has 4 separate stages to apply for:

Feasibility award – Hits to Leads
Primer award – Lead optimisation
Early-stage award – Preclinical development
Late-stage award – Phase 1

<https://www.gov.uk/guidance/biomedical-catalyst-what-it-is-and-how-to-apply-for-funding>

Despite the success of the BMC scheme overall, only a small share of funding has been awarded into AMR projects across therapeutics, diagnostics and vaccines. There are no dedicated calls for funding to support AMR, and the application scoring criteria often penalises AMR applications due to the uncertain market and reimbursement mechanisms for new AMR treatments.

Infection Innovation Consortium (iiCON)

In 2019, the UK Government launched the Strength in Places Fund (SIPF) operated by BEIS, to invest in regional R&D strengths around the UK. The first award in 2020 was for a £19m grant to the Infection Innovation Consortium (iiCON), a public/private/philanthropic partnership proposed by Dr Peter Jackson from Infex Therapeutics and Prof Janet Hemingway from the Liverpool School of Tropical Medicine (LSTM).

iiCON has secured an additional £160m in leverage from the consortium members and other iiCON partners, such as the Gates foundation. iiCON is based at LSTM and has a wide infectious disease remit, including AMR, and is supporting the development of new platforms to translate AMR therapeutics, diagnostics and vaccines from discovery to clinical trials.

<https://www.infectioninnovation.com>

Capital funding

The NIHR has also provided £32m for capital projects to support the development of the AMR R&D infrastructure in the public sector.

<https://www.gov.uk/government/news/32-million-competition-launched-for-amr-research>

IUK also provided a £4m capital grant program for AMR projects in 2016.

<https://www.gov.uk/government/publications/funding-competition-antimicrobial-resistance>