BIA response to DHSC call for evidence on the antimicrobial resistance national action plan

January 2023



The threat of AMR

1. From your experience, how has the scale of the threat of AMR changed since the national action plan was published in 2019?

a) the threat of AMR has increased since 2019

- b) the threat of AMR has stayed the same since 2019
- c) the threat of AMR has reduced since 2019
- d) don't know

2. In your opinion, what are the top 3 drivers of AMR? Please give 3 short answers.

For background, the 2019-24 action plan identified:

- 1. a rise in the incidence of infections, particularly Gram-negative bloodstream infections (including *E. coli*)
- 2. the import of resistant infections through international travel
- 3. antimicrobial use

A rise in the incidence of infections remains a primary driver of AMR, with a recent WHO report finding that bloodstream infections due to resistant E. coli and Salmonella increased by at least 15% compared to rates in 2017.¹ The report also found a similar increase in resistant gonorrhoea infections.

Overuse of antimicrobials remains a top driver of AMR, and one which requires further attention in the next national action plan. There are a number of causes of inappropriate use of antimicrobials, including insufficient availability of rapid diagnostics and a lack of awareness of AMR among medical professionals and the general public.

A lack of support for innovation in the development of new antimicrobial drugs is another key driver of AMR. A recent WHO report found that between 2017 and 2021, 12 new antibacterial drugs were approved, and only one was intended for use against critical priority pathogens.² While there a number of innovative drugs in the pipeline, greater incentives are required to increase capacity to provide replacement drugs for resistant infections.

¹ WHO (2022), Report signals increasing resistance to antibiotics in bacterial infections in humans and need for better data: <u>https://www.who.int/news/item/09-12-2022-report-signals-increasing-resistance-to-antibiotics-in-bacterial-infections-in-humans-and-need-for-better-data</u>

² WHO (2022), 2021 Antibacterial agents in clinical and preclinical development: an overview and analysis: <u>https://www.who.int/publications/i/item/9789240047655</u>

Policy interventions for tackling AMR

3. Which of these areas would you most like to see prioritised over the next 5 years?

- a) reducing the need for, and unintentional exposure to, antimicrobials
- b) optimising the use of antimicrobials
- c) investing in innovation, supply and access

4. Are there any actions you think are required to tackle AMR that do not fall within one of these categories?

a) yes (please specify)

- b) no
- c) don't know

All of the areas listed in the previous question are important for the UK to prioritise over the next five years.

In addition to these, the UK should continue its work to improve the quality of data on AMR in low- and middle-income countries. Improved global surveillance and reporting of resistant infections will help to improve epidemiological understanding of the challenge of AMR, and how to prioritise efforts to address it.

In the UK, improvements could be made to provide data on AMR in a format that is accessible to a range of stakeholders beyond clinicians, including policymakers, academia and industry. There is also an opportunity for the UK to improve data sharing between public and private sector organisations and regionally. Improved data sharing and accessibility will support innovation and provide insights to ensure that the right antimicrobials are being used in the right populations.

Learning from previous action to tackle AMR

5. Within the UK, what are the key successes we should look to maintain or build on in responding to AMR? Please include up to 3 examples in no more than 250 words.

In 2022, the UK became the first country to pilot a subsciption-style model for antimicrobial drugs and NICE and NHS England are now developing plans for routine arrangements. The UK is leading the way in the development of pull incentives for investment into antimicrobials and is working internationally to share lessons learned from the project. It is incumbent on the UK to build on its leadership here by championing the principle of a subscription-style model across the world.

The UK has also made significant progress in providing more push incentives for the development of antimicrobial drugs and diagnostics. DHSC's Global AMR Innovation Fund has provided significant funding for projects including CARB-X, FIND and GARDP.

The UK has been successful in driving international collaboration on AMR. The UK's Special Envoy on AMR, Dame Sally Davies, has been enormously successful in drawing global attention to the urgent challenge of AMR, including through her role on the UN Global Leaders Group on AMR. Meanwhile, Innovate UK's Global Expert Mission Programme has helped to build strategic partnerships with counties and overseas organisations on AMR. During the UK's G7 Presidency in 2021, AMR was brought to the top of the global health agenda, and it was recognised that AMR needed to be tackled through both health and finance policy. Furthermore, through the Fleming Fund, the UK is supporting LMICs to generate, share and use data to improve antimicrobial use and encourage investment in AMR.

6. Within the UK, what are the areas that require more focus or development to address AMR? Please include up to 3 examples in no more than 250 words.

The UK should consider how it can incentivise the development novel diagnostics to minimise the use of broad-spectrum agents and ensure that the right antimicrobials are used at the appropriate time. It is also important that new diagnostic technologies are integrated and utilised in both primary and secondary healthcare settings, and that diagnostic labs are well resourced so that pathogens can be identified quickly.

The UK should also increase its focus on alternatives to antibiotics, such as bacteriophages. It was positive to see a commitment to explore these alternatives in the addendum to the current action plan. The UK House of Commons Science and Technology Committee has recently launched an inquiry into bacteriophages, which will explore the barriers to the development and use of phage therapy in the UK.³ The findings of this inquiry will be important for the Government to consider as it continues to review its approach to tackling AMR.

The UK could also do more to capitalise on its strengths in the R&D of novel antifungals. There are number of UK-based SMEs developing novel antifungal treatments, many of which have been spun out of universities conducting world-leading research in this area. The threat posed by resistant fungal infections is likely to increase in the next decade, and if the UK can capitalise on its existing expertise, then it will be well-placed to help address this threat.

7. Within your sector, do you think the UK has sufficient capacity and capability to tackle AMR?



³ UK Parliament (2022), MPs to examine use of bacteria-killing viruses to treat infection: <u>https://committees.parliament.uk/committee/135/science-and-technology-committee/news/174419/mps-to-examine-use-of-bacteriakilling-viruses-to-treat-infection/</u>

8. What additional capacity and capability is needed in your sector to effectively tackle AMR? Please give up to 3 examples using no more than 250 words in total.

The life sciences sector requires greater incentives for investment into AMR R&D, and while significant progress has been made to increase these incentives, there is a lot more to do, both domestically and internationally. In particular, there should be more public funding dedicated to supporting private sector R&D on AMR. For example, currently Innovate UK's funding for work on AMR comes out of the Biomedical Catalyst and SMART programmes, which cover a wide range of R&D projects.

The Government should also consider how its policies can support higher levels of private investment into AMR, including from venture capital funds. We welcome the recommendations of the Life Sciences Scale-Up Taskforce and urge cross-government cooperation to implement them, including initiatives to encourage greater investment from pension funds into venture capital. We also note that R&D tax reliefs are crucial to incentivising R&D investment, including in AMR, and the recent changes announced at Autumn Statement could make it harder for SMEs to develop technologies to tackle AMR in the UK.⁴

The UK should also increase the capacity of the MHRA so that it has sufficient resource to ensure a streamlined regulatory pathway for innovative antimicrobials and alternatives to antibiotics. With the UK now outside of the authority of the European Medicines Agency (EMA), there is an opportunity for the MHRA to lead the way in the development of novel regulatory approaches to ensure timely approval of innovative medicines to address AMR.

International efforts to tackle AMR

9. What, if anything, do you think we can learn from other countries' responses to AMR? Please be specific about which countries you are referring to in your answer. Please give up to 3 examples using a maximum of 250 words in total.

The UK could learn from the USA's response to AMR, including the approach taken by the Biomedical Advanced Research and Development Authority (BARDA), which has entered into a number of public-private partnerships to incentivise antimicrobial development by providing funding and technical assistance. This approach could be modelled in the UK to provide increased support for companies working in the AMR space. The UK could also learn from the US Food and Drug Administration (FDA)'s work on tackling AMR, and the MHRA could explore closer ties with the FDA on AMR. The FDA has been successful in working closely with the US Center for Veterinary Medicine to combat AMR in both the healthcare and veterinary sectors, an approach that would be valuable for the UK to adopt.

The UK could also learn from both Germany and Switzerland, where a number of key pharmaceutical and biotech companies in the AMR space are based, including Roche, Bayer, Novo Nordisk and BioNTech. The German and Swiss Governments have both invested significant funds to support the development of new antimicrobials and have been central in supporting international collaboration on AMR.

⁴ BIA (2022), Autumn Statement proposes cuts to SME R&D tax reliefs: <u>https://www.bioindustry.org/news-listing/autumn-statement-proposes-cuts-to-sme-rd-tax-reliefs.html</u>

Furthermore, the UK could learn from Sweden's multidisciplinary approach to antimicrobial stewardship, which has contributed to it having one of the lowest rates of AMR in Europe. The establishment of regional Strama groups have ensured that local resistance and prescribing data are shared among relevant stakeholders to inform stewardship decisions.⁵

Opportunities from COVID-19

10. In your opinion, which of these tools should be prioritised for adapting to use in tackling AMR?

- a) diagnostics
- b) surveillance
- c) therapeutics
- d) vaccines
- 11. In your opinion, are there any other tools that should be adapted from use during the COVID-19 pandemic for tackling AMR?

a) yes (please specify)

- b) no
- c) don't know

All of the tools listed in the previous question should be prioritised for adapting to use in tackling AMR. Additionally, the UK could also adapt the data sharing tools it developed during COVID-19 to improve data accessibility for AMR. The Government could also learn from its experience in developing public awareness campaigns for COVID-19 to improve public awareness of AMR. Lessons could also be learnt from ways of working adopted during the pandemic, including faster regulatory decisions, closer working between the public and private sectors and the creation of specific taskforces to enable this.

12. Do you believe the changes in ways of working within your organisation due to the COVID-19 pandemic have affected efforts to respond to AMR, such as delivery of the current national action plan (NAP)?



13. In what way have they affected the response to AMR or delivery of the NAP? Please give up to 3 examples using no more than 250 words in total.

N/A

⁵ Folkhalsomyndigheten (2020), Swedish work on containment of antibiotic resistance: <u>https://www.folkhalsomyndigheten.se/the-public-health-agency-of-sweden/communicable-disease-</u> <u>control/antibiotics-and-antimicrobial-resistance/swedish-work-on-containment-of-antibiotic-resistance/</u>

14. Are there other ways in which the COVID-19 pandemic has altered the AMR risk landscape? Please give up to 3 examples in no more than 250 words in total.

Data from the US Centers for Disease Control and Prevention (CDC) found that resistance to antibiotics and antifungals rose dramatically during the COVID-19 pandemic, reversing previous gains. There was an increase in healthcare-associated resistant infections, especially in hospitals. The CDC also found that almost 80% of patients hospitalised with COVID-19 received an antibiotic from March to October 2020, potentially contributing to increased levels of resistance.⁶

There were some positive impacts from COVID-19, including greater public awareness of the threat of infectious diseases and better hygiene practices. The pandemic also demonstrated that with sufficient resources awe can more rapidly develop novel therapeutics and diagnostics to deal with emerging pathogens far quicker than was thought possible.

15. Are there other global events, such as supply chain disruption or the conflict in Ukraine, that have changed the UK's ability to respond to AMR?

- a) yes (please specify)
- b) no
- c) don't know

Russia's invasion of Ukraine has impacted global collaboration on medical research, with clinical trials disrupted in Ukraine and a number of international pharmaceutical companies deciding to halt clinical trials in Russia following the invasion. The conflict is also likely to have contributed to increased spread of resistant infections within Ukraine, with combat-related injuries often requiring surgery and relying on the use of antibiotics.

The recent rise in strep A infections in the UK and other European countries has resulted in pharmacies experiencing shortages of certain forms of penicillin. Although the exact reasons for these shortages are currently unclear, this highlights how important it is that the NICE subscription model includes a criterion on "surety of supply". This will help to ensure that manufacturers of antimicrobials can produce required quantities of the drug as and when required.

Measures of success

16. In your opinion, what are the best measures of success in tackling AMR? Please give up to 3 suggestions.

Reduce the number of resistant infections Increase the number of new treatments developed and made accessible to patients Increase the number of prescriptions supported by a diagnostic test

⁶ CDC (2022), COVID-19 and Antimicrobial Resistance: <u>https://www.cdc.gov/drugresistance/covid19.html</u>

17. Do you believe that there is sufficient public and professional awareness of AMR?

a) yes

b) no (please specify what should be done to increase awareness of AMR)

c) don't know

As well as maintaining efforts to improve public awareness of AMR, the UK Government should ensure sufficient awareness of among policymakers, who should be aware not only of the threat posed by AMR but of the mechanisms for addressing the threat. Tackling AMR requires a multisectoral approach and it is important that policymakers in the Treasury, BEIS and DIT (as well as DHSC) are involved and aligned with the UK's approach to tackling AMR.

There should also be greater awareness of the disproportionate impact that AMR is likely to have on certain groups of people, such as many cystic fibrosis patients who are heavily dependent on antibiotics. The 2022 ESPAUR report found that the most deprived 10% of the UK were more likely to have carbapenemase-producing Gram-negative bacteria, compared to those from the least deprived 10% of the country⁷. There is a need for further research of the disproportionate impact of AMR on certain demographics of the population, and AMR should be considered in plans to tackle health inequalities in the UK.

⁷ UKHSA (2022), ESPAUR report 2022: <u>https://ukhsa.blog.gov.uk/2022/11/21/espaur-report-2022/</u>