



European Medicines Agencies Network Strategy to 2025
**Consultation response from the Wellcome Trust's Drug-Resistant
Infections priority programme**

The Drug-resistant Infections programme welcome the proposed strategy put forward by the European Medicines Agencies and anticipate this will provide the network with a strong foundation for their work until 2025.

Overall the objectives within Strategic Theme area 4 – antimicrobial resistance (AMR) and other emerging health threats – do address the challenges ahead adequately. We commend the focus across both development and consumption of antimicrobials (particularly novel antibiotics), as both the development of new medicines and keeping those we already have working for longer will be essential if we are to adequately manage AMR going forward. However, we believe there are some further areas for consideration that, if incorporated, could make the approach to AMR even stronger.

When it comes to antimicrobial stewardship, better practices can only be realised if they are in the context of a supportive environment. Objectives focused on regulation of antimicrobial use and clear prescription guidelines will be necessary but will not be sufficient to realise much needed change. These measures must be coupled with initiatives specifically supporting uptake of tools and changes in behaviour of patients and healthcare professionals in their own context; for example, initiatives that support accessibility and uptake of guidelines by targeting tools to prescribers.

We are supportive of the suite of objectives supporting a stronger economic system for antimicrobial development and delivery. Within this we are pleased to see support for pull incentives and plans to work closely with developers. Within work on these objectives it should be stressed that in the development and implementation of new incentive mechanisms for antibiotics, the generation of high-quality data as part of regulatory approval processes will be essential to ensure that the true value of new antibiotics can be defined.

The commitment to generation of high-quality antimicrobial consumption and AMR surveillance data, as well as provision of this data to countries to support policy development based on evidence is of great importance. We encourage that this data is extended to include drug-bug combinations and patient outcomes following antibiotic treatment to ensure a patient-centred view. Data should be kept into a repository that is easily accessible and supports use of this data in decision-making processes.

We also welcome the consideration of environmental dimensions of AMR as this is a relatively underserved area. We encourage that work within the environmental domain is not limited to the interface with use of antimicrobials in animals and suggest that interface with human health and waste flows are also considered; for example, contamination of the environment with waste from hospitals or manufacturing facilities and implications of this for AMR. While the interface between human health and the environment is not yet fully articulated, regulation of and clearer guidance on environmental impact of human medicines has scope to inform use of medicines that will limit contamination and potentially lessen AMR.

We ask the network to note concrete actions we are undertaking in this field that could support or complement EMA/HMA network activities, as follows:

- We have supported work by UK Office of Health Economics to explore how HTA processes might be improved to properly define and embody the value of novel antibiotics.
- We are actively working with the pharmaceutical industry to make their surveillance data openly accessible on the AMR Register. This includes data at the European level that if made available through the AMR Register might be accessed and used by countries.
- We are working in partnership with pharmaceutical industry to improve AMR surveillance data capture and use to improve patient care in low and middle-income countries, including improving the use of surveillance data to guide infection prevention and control in healthcare settings.

We also ask the network to note planned initiatives that should be considered for this proposed strategic theme area, as follows:

- We are developing a stream of work focused on optimising use of antibiotics. This includes a review initiative focused on developing an understanding of the research needs and priorities to effectively achieve the evidence-based appropriate use of antibiotics, as well as analysis and modelling of existing AMR data to develop tools to inform and improve guidance for optimised use of antibiotics.
- With respect to emerging health threats, surveillance information systems become key to detecting potential threats before they spread widely. Towards this, we are working to support development of Laboratory Information Management Systems (LIMs) that streamline data capture systems so that data is readily available for action.

It should be noted that this consultation response only represents views from an AMR perspective and not across the entire remit of the Wellcome Trust.