

Valuing new antibiotics in the context of AMR: challenges and action¹

What is the issue?

- New antibiotics are needed urgently to tackle the growth of AMR and drug resistant infections.
- Work is ongoing to strengthen R&D and bring new antibiotics to market.
- Licensing authorities are developing expedited pathways for the approval of new antibiotics.
- However, HTA (health technology assessment) and other systems for assessing the value of drugs are not well suited to assessing the value that antibiotics offer in the context of AMR.
- As a result, patients may not get access to important new antibiotics, and the prices paid may not provide a sufficient return on investment to incentivise further work by industry.
- There is an urgent need to review and adapt HTA and other systems for assessing the value of antibiotics in the context of AMR.

Box 1: The benefits of new antibiotics for health systems, the wider population and society

- **Transmission benefits** – the benefit of controlling the spread of infection to other patients and the wider population.
- **Insurance benefit** – the benefit of having treatments available in case of future outbreaks or major increases in the prevalence of infection.
- **Enablement benefit** – the benefit of enabling other procedures (such as Caesarian sections, chemotherapy and joint replacement surgery) to proceed in the knowledge that infections that may occur can be treated.
- **Diversity benefit** – using a range of different antibiotics to treat a pathogen across a population of patients can reduce the risk of resistant strains of the pathogen developing; new antibiotics therefore can be important, even if they are no more effective in registration trials than current treatments.
- **Novel action benefit** – antibiotics with a novel mechanism of action are less likely to be affected by current resistance profiles, and they may also provide a platform for the development of further new antibiotics based on the novel mechanism.

What are the challenges in valuing new antibiotics?

- There are two key challenges for HTA and value assessment of antibiotics.
 1. Current systems for HTA and value assessment may not fully recognise the benefits that a new antibiotic offers to the patients treated. This is because:
 - a. Data to demonstrate the clinical effectiveness of new antibiotics typically comes from trials designed to demonstrate non-inferiority, together with non-clinical data (on microbiological action and pharmacodynamics).
 - b. But HTA systems typically expect data from superiority trials and may be unwilling or unable to consider non-clinical data.

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2. Current systems for HTA and value assessment may not recognise the benefits that antibiotics offer health systems, the wider population and society – in addition to the benefits they offer the patients actually treated with them.
 - a. These wider benefits are summarised in Box 1 above.
 - b. Research suggests that these wider benefits may be considerably greater than the benefits antibiotics provide for individual patients treated.
 - c. But there is not yet agreement on how some of these wider benefits should be assessed, and current systems for HTA and value assessment may be unwilling or unable to consider them.
- The result of both these challenges is that current systems for HTA and value assessment may substantially underestimate the value of new antibiotics and therefore limit patient access and incentives for antibiotic development and supply.

How does this relate to paying for antibiotics?

- As for any drug, governments and health systems need to know the value that an antibiotic offers to have a meaningful discussion of how much to pay for it.
- The need for stewardship and the concept of insurance (see Box 1 above) present further challenges for the way we pay for antibiotics. The value of antibiotics may depend on their use being managed to preserve effectiveness or them being reserved as a last line treatment. Agreement on price therefore needs to be accompanied by contractual arrangements that are “de-linked” (at least partially) from volume.
- A further challenge arises in relation to the system by which hospitals receive a fixed payment for treating patients with a given condition (DRG) which may penalise them for using a more expensive antibiotic even if this is likely to improve patient outcome and/or infection control.
- Further discussion and briefing is being planned on these issues.

What needs to happen?

- There is an urgent need to:
 - Ensure that HTA and value assessment systems understand and address the challenges of assessing the value of new antibiotics;
 - Develop tools to support valid value assessments of new antibiotics;
 - Develop contractual arrangements that support stewardship.

What progress is being made?

- A few countries (eg England, France, Germany, Norway, Sweden) have taken steps to get their HTA systems to begin to address these issues. But more work is needed to raise awareness of the challenges and address them adequately.
- Some initial work on developing methods and tools has been undertaken² but more work is needed here as well.

Policy recommendations

- Governments should discuss approaches to assessing the value of antibiotics and paying for them with those responsible for HTA, value assessment and reimbursement in their countries. These discussions should include the licensing authority and experts in infection control and value assessment, and take place in the context of the country’s strategy to address AMR.
- Governments should pilot new approaches to assessing and paying for antibiotics.
- The UN, WHO, G20 and regional bodies such as the EU should co-ordinate this work and ensure learning is shared.
- Research funding bodies should support work to develop methods for assessing the value of antibiotics, and work to develop policies for paying for antibiotics.

²See:

1. <https://www.ohe.org/publications/additional-elements-value-health-technology-assessment-decisions>
2. <http://drive-ab.eu/>
3. https://healthpolicy.duke.edu/sites/default/files/atoms/files/valuebased_strategies_for_encouraging_new_development_of_antimicrobial_drugs.pdf