This report was commissioned and funded by GSK.

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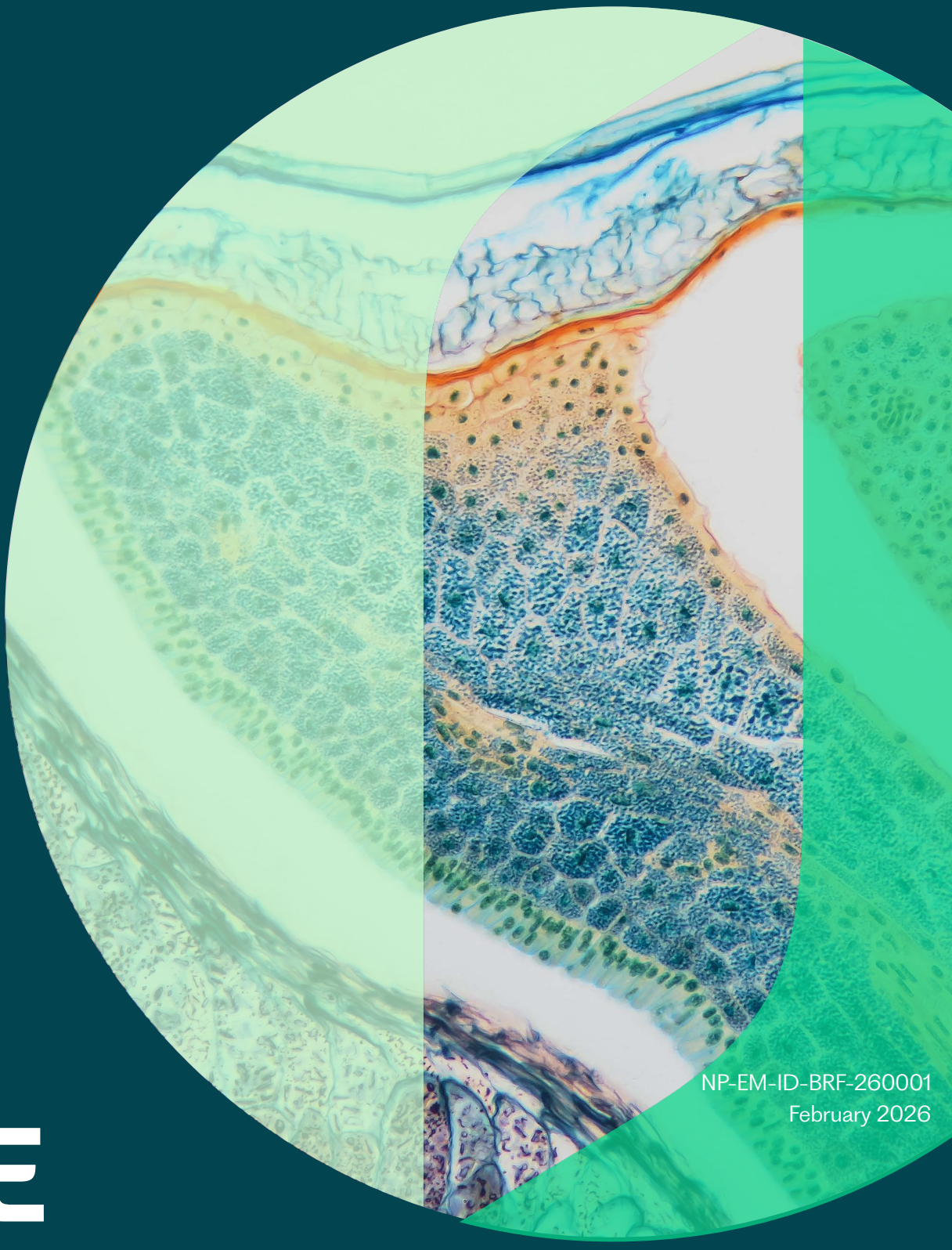
Evaluating novel antimicrobials within EU joint clinical assessments

CONTRACT RESEARCH REPORT
February 2026



Angus Macfarlane
George Bray
Matthias P. Hofer
Grace Hampson

ohe.org

NP-EM-ID-BRF-260001
February 2026

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FEBRUARY 2026

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Angus Macfarlane
Office of Health Economics, London

George Bray
Office of Health Economics, London

Matthias P. Hofer
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Office of Health Economics, London

Please cite this report as:
Macfarlane A., Bray G., Hofer MP., Hampson G., 2026. An opportunity to align EU HTA policy with AMR objectives: Evaluating novel antimicrobials in EU joint clinical assessments. OHE Contract Research Report, London: Office of Health Economics. Available at: https://www.ohe.org/publications/evaluating-novel-antimicrobials-in-eu-joint-clinical-assessments/

Corresponding Author:
Grace Hampson
ghampson@ohe.org

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Funding and Acknowledgements

This Contract Research Report was commissioned and funded by GSK.

We thank all the members of the expert working group for their valuable input and contributions.

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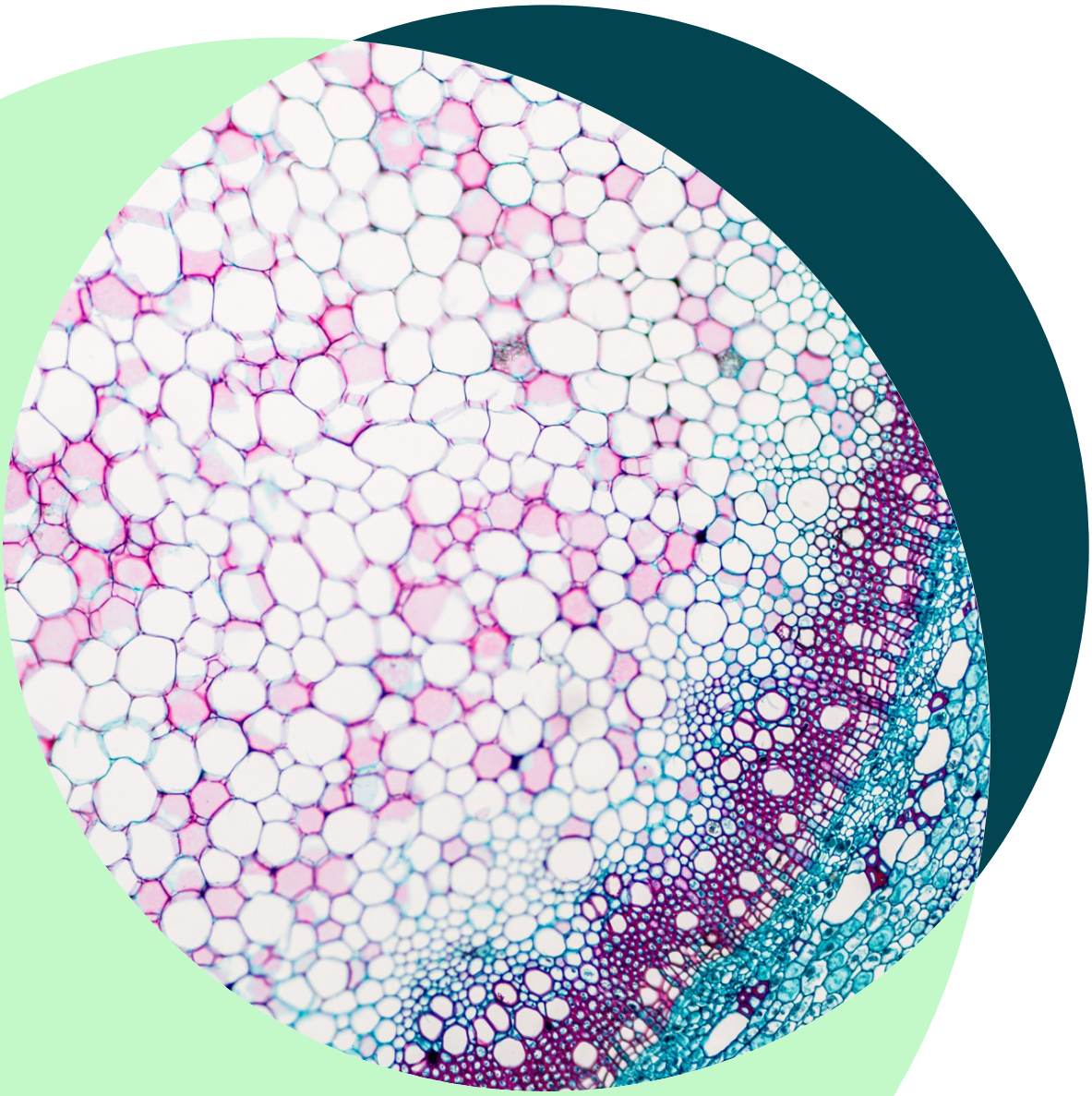


Key takeaways

- The European Union (EU) Joint Clinical Assessment (JCA) offers a unique opportunity to align EU health technology assessment (HTA) policy with objectives around tackling antimicrobial resistance (AMR).
- The current JCA approach is not fit-for-purpose for the assessment of antimicrobials in the context of AMR and potentially risks undermining ongoing European efforts to tackle AMR elsewhere.
- Urgent action is required before 2030 to overcome willingness, capability, and feasibility barriers to adapt the JCA for antimicrobials.
- The flexibility provided in Recital 24 of the EU HTA Regulation should be used to develop technology-specific guidance and a roadmap to extend the evidentiary scope of JCA. Future EU HTA policy reforms should ensure that AMR and antimicrobial assessments receive special consideration in line with wider AMR policy.

Executive Summary

Antimicrobial resistance (AMR) is a growing global health and economic threat. It is responsible for an additional 9.5 million hospital days and costs across the European Union (EU) and European Economic Area (EEA) economies €11.7 billion annually. Globally, in 2021, an estimated 5.8 million deaths related to bacterial AMR occurred. This burden is expected to increase, with projections of up to 10 million deaths per year by 2050.

The pipeline for new antimicrobials to combat AMR remains insufficient, for several reasons which have been already documented extensively, underscoring the need for renewed incentives to stimulate research and development (R&D). As part of this, it is critical that population-level health benefits generated by new antimicrobials, such as reducing transmission, enabling medical procedures, and providing insurance against resistant outbreaks, are recognised and valued. The STEDI framework (spectrum, transmission, enablement, diversity, and insurance) provides a structured approach for this.

Yet current health technology assessment (HTA) approaches rarely capture these broader benefits. The EU's Joint Clinical Assessment (JCA), operational since 2025, offers a harmonised evaluation of clinical effectiveness and safety at the European level, creating an opportunity to facilitate recognition of these wider health benefits in subsequent national HTA processes for antimicrobials.

This study explores how the JCA could be adapted to incorporate wider population-level health benefits like STEDI by leveraging a three-part framework of change focused on willingness, capability, and feasibility. We analysed the literature and convened an expert panel to discuss the current state of play, barriers, and recommendations for adapting JCA for antimicrobials.

Willingness: EU policy documents and some national pilots show high-level recognition of AMR and interest in new incentives, but the HTA regulation and current JCA practice lack an explicit AMR focus. Stakeholders view practical adaptation as unlikely without a stronger European Commission mandate.

Capability: Robust methods to quantify the wider health benefits of antimicrobials (dynamic transmission and risk models; The National Institute for Health and Care Excellence (NICE) and National Health Service (NHS) England pilots) exist but these are not standardised or accepted by decision makers. Data gaps also persist for reliably quantifying these wider health benefits. As a result, further research is required to solidify the selection of outcomes that could usefully be captured within JCA.

Feasibility: The JCA's PICO (Population, Intervention, Comparator, Outcomes) based assessment framework and patient-centred relative-effect mandate limits inclusion of population-level health outcomes. Practical adaptations are possible (e.g. via a structured evidence repository, broader evidence acceptance, and standardised modelling) but would require procedural change and capacity building.

In conclusion, we found that the current approach to JCA is not fit-for-purpose for antimicrobials and risks undermining other European efforts to combat AMR. There is an urgent need to adapt JCA for antimicrobials, but there are significant barriers in willingness to adapting JCA processes, capability barriers in measuring and evidencing wider population-level health benefits of antimicrobials, and feasibility barriers due to JCA's current focus on direct patient-level outcomes within a PICO-based relative effectiveness framework. It is critical that these barriers and challenges are addressed before 2030, when antimicrobials will become part of EU JCA.

Recommendations

Willingness:

- Use the flexibility stated in Recital 24 of the EU HTA Regulation to develop technology-specific guidance for antimicrobials.
- In future HTA revisions, ensure AMR and antimicrobial assessments receive special consideration in line with wider AMR policy.

Capability:

- Broaden JCA's evidentiary scope and agree on a core set of outcome measures capturing population-level health benefits for JCA integration, which can subsequently inform (national) HTA decision making.
- Advance methodological development of the STEDI framework for JCA and HTA.

Feasibility:

- Develop a roadmap for gradual JCA adaptation for antimicrobials under Recital 24.
- Short term: Use JCAs as structured evidence repositories for comprehensive data.
- Medium term: Expand evidentiary scope to include broader outcome measures and surrogate indicators.
- Long term: Build modelling capacity to support population-level health assessments.

1 Introduction

1.1 Background

The burden of antimicrobial resistance (AMR)

Antimicrobial resistance (AMR) poses an escalating threat to public health and healthcare systems worldwide (Naghavi et al., 2024). Across the European Union (EU) and European Economic Area (EEA), recent years have seen sharp increases in infections, deaths, and disability-adjusted life years (DALYs) linked to antibiotic-resistant bacteria (European Centre for Disease Prevention and Control, 2022). In 2019, an estimated 22% of all bacterial infections in the region were caused by resistant organisms, resulting in more than 9.5 million additional hospital days annually (OECD, 2023). The economic impact is similarly significant, with AMR costing EU/EEA economies approximately €11.7 billion per year (OECD, 2023). Globally, in 2021, an estimated 5.8 million deaths related to bacterial AMR occurred, with projections suggesting a worsening burden of up to 10 million deaths per year by 2050 (Naghavi et al., 2024).

This growing burden is amplified by the well-characterised deficiencies in the antimicrobial development pipeline (Tang, Millar and Moore, 2023) amid a market failure for novel antimicrobials (Brassel, Al Taie and Steuten, 2023). The latest WHO review of antibacterials in development (2025) identified 90 antibacterial agents or combinations in the clinical pipeline, but concluded that these, together with all approvals in the past seven years, remain insufficient to address the accelerating threat of AMR (World Health Organisation, 2025).

The population-level benefits of antimicrobials

Given the limitations of the current antimicrobial pipeline (World Health Organisation, 2025) and the need to preserve the future treatability of bacterial infections (Miethke et al., 2021), renewed and sustained action is needed to stimulate the research and development (R&D) of novel antimicrobials (Dutescu and Hillier, 2021), including push and pull incentives (Brassel, Al Taie and Steuten, 2023).

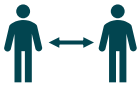
One key avenue for advancing this goal is to fully recognise and appropriately reward the unique value antimicrobials provide (Brassel, Al Taie and Steuten, 2023). The STEDI value framework, based initially on the work of Karlsberg-Schaffer and colleagues (2017) and later adapted by Rothery and colleagues (2018) offers a structured approach to such an assessment. It recognises that antimicrobials can

provide relevant additional population-level health benefits that extend beyond the clinical outcomes of individually treated patients. The framework encompasses five key dimensions of value (Karlsberg Schaffer et al., 2017; Rothery et al., 2018; Brassel et al., 2023):

Spectrum

The use of narrower-spectrum agents limits disruption to the patient's microbiome and thereby reduces the selective pressure on non-target organisms. This lowers the probability that resistant strains will emerge or expand within the individual over time, helping to preserve treatment effectiveness for future patients.

Transmission



Effective antimicrobial treatment reduces pathogen load quickly, shortening the infectious period and thereby decreasing the chance of a bacterium's onward spread. By interrupting transmission chains, antimicrobials with strong early efficacy help prevent secondary cases and reduce population-level incidence.

Enablement

Many medical procedures rely on predictable, effective antimicrobial prophylaxis to manage infection risks. Reliable antimicrobials increase the safety and feasibility of these interventions, allowing them to proceed with lower morbidity and mortality.

Diversity

Introducing new antimicrobial treatment options allows clinicians to rotate or sequence therapies, lowering reliance on a small set of existing ones. This spreads selective pressure across more agents, slowing resistance development and helping to maintain the efficacy of a higher number of antimicrobial agents.

Insurance

Having antimicrobials that remain effective against highly resistant pathogens provides a critical safety net when first line and second-line options fail. These agents also function as preparedness tools, reducing the likelihood that future resistant outbreaks escalate into high-impact events with severe consequences.

Joint Clinical Assessment (JCA)

The Joint Clinical Assessment (JCA), established under EU Regulation 2021/2282 (The European Parliament and the Council of the European Union, 2021), marks a major step forward in EU health technology assessment (HTA). It provides a single, harmonised evaluation of the relative clinical effectiveness and safety of new health

technologies, offering a common scientific basis for national HTA processes across the EU. The JCA will be mandatory with the aim of promoting consistency and efficiency across the EU internal market while preserving each Member State's autonomy over pricing and reimbursement decisions (The European Parliament and the Council of the European Union, 2021).

The JCA process begins with an initial scoping phase. During this phase, assessors draft a preliminary assessment scope using the PICO framework, which defines the population, intervention, comparator, and outcomes to be evaluated. Through a PICO survey, Member States can provide input to ensure this scope reflects their specific needs (European Commission, 2025). At this stage, inputs from patients, clinical experts and healthcare professionals are also considered (HTACG, 2024b). The collected PICOs are then consolidated and shared with health technology developers (HTDs), forming the basis for their dossier (European Commission, 2025). Before finalisation, the consolidated assessment scope is shared with selected patients and clinical experts, who have the opportunity to provide input and may be invited to contribute during the assessment scope consolidation meeting (HTACG, 2024b). Once HTDs submit their dossier, assessors evaluate it and prepare a draft JCA report and summary. These drafts are shared with the HTD for review before being finalised and submitted to the EU HTA Coordination Group (HTACG) for endorsement and subsequent publication. The final JCA reports provide a comprehensive synthesis of the new health technologies' relative effectiveness compared to existing treatments and safety (European Commission, 2025).

The JCA does not make any explicit value judgments, and its conclusions remain non-binding, but member states are required to give due consideration to its findings during their national decision-making process (The European Parliament and the Council of the European Union, 2021). The evidence synthesised through the JCA is therefore likely to play an important role in shaping how new health technologies are valued across Europe.

The JCA has been operational since January 2025 for oncology products and advanced therapy medicinal products (ATMPs) and will be expanded to orphan-designated medicines by 2028 and cover all centrally authorised medicines from 2030 onwards (The European Parliament and the Council of the European Union, 2021). Now is a timely opportunity to explore how JCA processes may capture the population-level health benefits these products can deliver in the context of AMR.

Joint Scientific Consultations (JSCs) are laid out in the HTA regulation and provide a mechanism for HTDs to engage with decision makers in the development phase of new health technologies. These consultations facilitate early dialogue on evidence generation strategies to ensure that planned studies are likely to meet the requirements of a subsequent JCA. JSCs focus on key clinical study design

elements, including the selection of appropriate comparators, interventions, health outcomes, and patient populations (European Commission, 2025). By aligning evidence generation with JCA requirements at an early stage, JSCs can streamline evidence preparation for subsequent assessments and enhance the overall quality of evidence generation (The European Parliament and the Council of the European Union, 2021).

1.2 About this study

Motivation

Given the limitations of the antimicrobial pipeline and the need for novel and diverse antimicrobial treatments, it is critical that decision makers recognise and reward the full population-health value of novel antimicrobials in the context of AMR to incentivise continued R&D investment in this space (Miethke et al., 2021; Dutescu and Hillier, 2021). However, current HTA approaches rarely consider the wider health benefits of antimicrobials (Colson et al., 2021). The introduction of the JCA offers a unique opportunity to highlight the importance of these population level health benefits, and drive change on a pan-European scale. With JCAs due to expand to all centrally authorised medicines by 2030 (The European Parliament and the Council of the European Union, 2021), now is the pivotal moment to ensure that it is able to capture the broader benefits of antimicrobials. A failure to act on this opportunity will serve to undermine other European and global efforts to tackle AMR. Such misalignment in approaches is inconsistent, inefficient, and ultimately risks damaging population health.

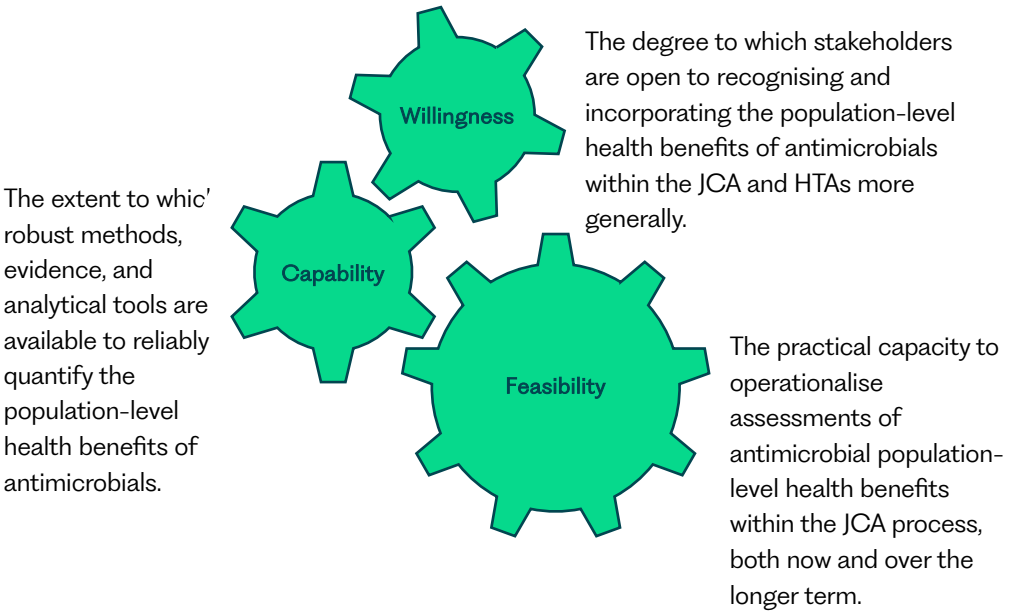
Objective

This study examined the potential for adapting the JCA to incorporate antimicrobials' STEDI-related population health benefits.

Approach

We developed a three-part framework to assess the readiness for integrating STEDI-related population health benefits of antimicrobials into the JCA, building on previous work for HTA policy (Bell, Neri and Steuten, 2021; Theakston et al., 2025). This framework details three key determinants for successful adaption of JCA: willingness, capability, and feasibility.

Figure 1 Analytic framework of the study highlighting three key elements to drive JCA adaption



We conducted a literature review to assess the willingness, capability, and feasibility of JCA adaption for antimicrobials. This review drew on academic literature, EU policy documents, and HTA agency materials. A preliminary analysis of the conceptual basis, the current state of play for methodology and evidencing of STEDI-related population health benefits, and the extent to which these concepts have already been considered in policy and practice was developed into a pre-read document ahead of a multidisciplinary expert roundtable.

The multidisciplinary expert panel brought together five European experts from HTA, JCA, public health, and clinical fields (Table 1). They discussed the urgent need for a change for antimicrobials as part of JCA and the risks of not making an adequate change. Further discussions examined how STEDI-related population health benefits are viewed within existing assessment processes, which barriers and opportunities stakeholders consider most pressing, and what changes would be needed to support their integration in the JCA.

Table 1 Expert panel expertise and country affiliation

	ITALY	SPAIN	GERMANY	UK
HTA	✓	✓	✓	
JCA experience			✓	✓
Infectious disease				✓
Public health	✓	✓		✓

2 Willingness

The degree to which stakeholders are open to recognising and incorporating the population-level health benefits of antimicrobials within the JCA and HTAs more generally.

Across the EU, there is broad recognition of the need for coordinated action to combat AMR, including an understanding that current market and policy conditions are insufficient to sustain antimicrobial innovation. The European One Health Action Plan against AMR (European Commission, 2017) has explicitly called for new economic models and incentives to stimulate antimicrobials discovery and development, while also recognising the need for HTA methods capable of evaluating the "added value" of these technologies. The Council Recommendation on stepping up EU actions to combat AMR (2023) urges Member States and the Commission to address the existing market failure, promote innovation, and pool resources to design a multi-country pull incentive scheme for new antimicrobials. Similarly, the Reform of the Pharmaceutical Legislation (European Commission, 2023) explicitly acknowledges the commercial challenges facing antimicrobials developers. The European Commission's 2022 study on bringing AMR medical countermeasures to market (European Commission, 2022) emphasises the importance of economic analyses and methodological innovation to evaluate incentives, further signalling a willingness to adapt assessment frameworks to reflect the population-level health benefits of new antimicrobials.

At the national level, several countries have also taken steps to adapt their value assessment and reimbursement or procurement systems in recognition of the unique value and development challenges provided by antimicrobials:

Germany has exempted reserve antibiotics (Robert Koch Institut, 2025) from their standard HTAs and reference pricing groups, enabling higher negotiated prices for these products (McEnany and Outterson, 2024).

France has adapted evidence requirements for "last resort" antibiotics within its HTA process (Haute Autorité de Santé, 2023).

Italy has extended its Innovative Medicines Fund, previously reserved for cancer and rare disease therapies, to qualifying anti-infective agents (Agenzia Italiana Del Farmaco, 2025), ensuring more stable dedicated reimbursement.

The **UK** has implemented a subscription model for purchasing antimicrobials in their National Health Service (NHS), reimbursing them based on their score across a set of broader benefit weighted criteria (NHS England, 2023).

Sweden has piloted a revenue-guarantee model that supported earlier access to antibiotics of particular importance and improved stock availability (Public Health Agency of Sweden, 2023).

But in stark contrast to the recognition of AMR as an EU policy priority, there is no explicit recognition of AMR or the challenges surrounding the development and assessment of antimicrobials within the JCA. The HTA regulation - the legal basis of JCA - aims to achieve "a high level of protection of health for patients," but there is no specific mention of the challenges of AMR and the development and assessment of antimicrobials in this context. Experts agreed that the approach to JCA needs to be adapted so it does not impede ongoing European initiatives to tackle AMR.

The HTA regulation suggests a degree of openness to future evolution of JCA methodologies in Recital 24 (The European Parliament and the Council of the European Union, 2021) (see excerpt below). However, experts viewed Recital 24 as signalling theoretical flexibility rather than any practical willingness to change (GSK/OHE European Expert Advisory Board, 2025). They agreed that JCA stakeholders do not currently view the adaption of the assessment framework of JCA for antimicrobials (or any other type of therapeutic) as a priority (GSK/OHE European Expert Advisory Board, 2025).

> "Methodologies for performing joint clinical assessments and joint scientific consultations should be adapted to include specificities of new health technologies for which some data may not be readily available. This may be the case for, inter alia, orphan medicinal products, vaccines and advanced therapy medicinal products."
>
> (Recital 24, The European Parliament and the Council of the European Union)

Experts identified significant willingness barriers and stressed that rapid progress is necessary in order to align EU wide policy on AMR and further develop the recognition of wider population-level health benefits in JCA and subsequent HTA. However, they believed that meaningful changes to its current process would be unlikely without a clear, higher-level mandate from the European Commission (GSK/OHE European Expert Advisory Board, 2025). In this context, aligning the antimicrobial discussions with the ongoing efforts to adapt the JCA for vaccines (Vaccines Europe, 2021) was seen as another area of momentum that could be leveraged to drive adaptation, particularly given that the population-level health benefits of vaccines are, in many respects, analogous to STEDI-type benefits for antimicrobials.

3 Capability

The extent to which robust methods, evidence, and analytical tools are available to reliably quantify the population-level health benefits of antimicrobials.

There are a range of methods discussed in the literature that can capture the STEDI benefits of antimicrobials, but they are not yet standardised, routinely accepted, or easily integrated into current HTA processes. This is critical here, as JCA creates a common scientific basis for national HTA processes across the EU and hence must deliver adequate methodology, data, and evidence to inform national assessments.

The academic literature provides advanced methodological options for quantifying the wider health benefits of antimicrobials (see Table 2 for an overview of methodological capabilities). More recent studies have developed dynamic transmission models linked to economic evaluation frameworks to quantify transmission, enablement and diversity value (Gordon et al., 2020, 2023a; b), while risk-based approaches have been developed to estimate the insurance value of antimicrobials (Chan et al., 2023). While these modelling approaches have not yet been incorporated into routine HTA practice, they could represent a credible future direction. The JCA could play an important enabling role in the more widespread implementation of modelling approaches by requiring certain relevant modelling inputs, even if the models themselves are applied downstream at the national HTA level. Some examples of clinical outcomes that could be used as modelling inputs

are given in Table 2. For example, for transmission and diversity value, capturing treatment duration and rates of acquired resistance are key inputs in capturing transmission and resistance dynamics (Gordon et al., 2020, 2023a; b).

Table 2 also considers outcomes that could be used to assess STEDI elements on a deliberative basis within HTA and JCA, without the need for complex modelling. Several HTA bodies acknowledge the relevance of STEDI-type elements, but generally fall short of providing explicit methodological guidance on how these components should be quantified in practice (Norwegian Medical Products Agency, 2019; Haute Autorité de Santé, 2023). This gap leaves assessors recognising the importance of population-level value but without clear tools for practically incorporating it into evaluations. Including specific outcomes as surrogates or proxies for STEDI elements in JCA can help overcome this barrier. For example, for spectrum value, outcomes measuring microbiome impact can be potential outcomes that could inform deliberative assessments (Table 2).
Some policy initiatives outside traditional HTA processes illustrate what alternative approaches could look like. The National Institute of Health and Care Excellence (NICE) piloted a new HTA process and payment model for antimicrobials to recognise and reward STEDI value. As part of this, the Policy Research Unit in Economic Methods of Evaluation in Health & Social Care Interventions (EEPRU) attempted to model STEDI values for ceftazidime with avibactam (CAZ/AVI) and cefiderocol (Woods et al., 2021; Harnan et al., 2022). The NICE assessment committees judged that the provided data and analyses had not sufficiently captured the potential population-level health benefits and STEDI values of ceftazidime and cefiderocol (National Institute for Health and Care Excellence, 2022a; b). They suggested that the further development of methods was needed before widespread adoption. The subsequently developed NHS England subscription model represented a more practical, qualitative approach to valuing antimicrobials following the modelling challenges that arose in the initial pilot. This takes the form of a weighted scoring system of 17 criteria, with a final score between 0 and 100 given to each antimicrobial (NHS England, 2023). Although not directly transferable to formal HTA, it indicates that population-level value elements can be systematically assessed (at least to some extent) when a bespoke framework is created.

Experts emphasised that a key barrier is the wider recognition of the STEDI framework within the HTA community and the development of robust methods for its integration into HTA decision-making (GSK/OHE European Expert Advisory Board, 2025). For the JCA specifically, the main challenge lies in its clinical assessment framework (as discussed further in the feasibility section below).

Furthermore, experts noted that antimicrobial clinical development is often based on non-inferiority trials. This was not considered to be problematic for JCA's clinical effectiveness assessment, where value is not considered. However, it is challenging

for HTA decision making and value-based pricing when there is no evidence for additional patient-level benefits. In this context, capturing population-level health benefits could significantly strengthen the case for the broader value of antimicrobials, reinforcing the need to embed STEDI into JCA and HTA processes.

Experts concluded that reaching EU-wide consensus on adopting STEDI as the gold standard for evaluating the population-level health benefits of antimicrobials could provide a clearer foundation for future integration into JCA and also subsequent national HTA decision making (GSK/OHE European Expert Advisory Board, 2025).

Table 2 Overview of methodological capabilities of measuring and capturing STEDI-related population health benefits in HTAs and JCAs *

	METHODS AVAILABLE TO QUANTIFY STEDI-RELATED POPULATION HEALTH BENEFITS FOR HTA INTEGRATION*	POTENTIAL OUTCOME MEASURES THAT CAPTURE POPULATION-LEVEL HEALTH BENEFITS IN THE AMR CONTEXT FOR JCA INTEGRATION*
SPECTRUM VALUE	**Economic model** Spectrum value is particularly complex to include in an economic model since much of its benefit is referring to the impact on pathogens that are not related to the immediate decision problem. **Qualitative / Deliberative** Spectrum value can be considered deliberatively using measures of microbiome impact and recovery, allowing judgement of whether the new antimicrobial has a narrower spectrum of activity than existing treatments (NHS England, 2023).	The following outcomes could be collected to inform a deliberative assessment of spectrum value: • Microbiome composition pre/post treatment • Time to microbiome recovery

TRANSMISSION VALUE	**Economic model**
	Whilst current HTA processes do not typically include transmission value in health economic models, methods to incorporate this do exist. These models incorporate transmission and resistance dynamics and therefore incorporate the benefits of reduced transmission as a result of more effective treatment and lower resistance. The inputs listed here (see next column) are based on the dynamic transmission model in Gordon et al (2020, 2023a).
	Qualitative / Deliberative
	Transmission value could also be considered deliberatively, based on the time it takes to treat infection and therefore infectiousness, as in the NICE-NHS subscription model product award criteria (NHS England, 2023).
		The following outcomes can be used as inputs into models for transmission value, or be used deliberatively:
		• Treatment characteristics:
		  ○ Treatment efficacy against target pathogen
		  ○ Treatment duration/length of stay
		• Rate of acquired resistance when exposed to treatment.
		• Rate of natural resistance loss

	METHODS AVAILABLE TO QUANTIFY STEDI-RELATED POPULATION HEALTH BENEFITS FOR HTA INTEGRATION*	POTENTIAL OUTCOME MEASURES THAT CAPTURE POPULATION-LEVEL HEALTH BENEFITS IN THE AMR CONTEXT FOR JCA INTEGRATION*
ENABLEMENT VALUE	**Economic model** These models incorporate transmission and resistance dynamics in Gordon et al (2020, 2023a), but may require model extensions to model the impact of improved treatment and/or lower resistance on other procedure/treatment outcomes (Gordon et al., 2023b). The inputs listed here (see next column) are based on the dynamic transmission model in Gordon et al (2020, 2023a; b). **Qualitative / Deliberative** Enablement value could also be considered deliberatively, based on the antimicrobial treating infections that occur in prophylactic settings, or in particular patient populations.	All outcomes relevant to transmission value could be considered in modelling analyses of enablement value. For outcomes used either in modelling or in deliberative processes, focus should be on pathogens seen in procedure/prophylactic settings: o Treatment efficacy against target pathogen o Treatment duration length of stay Additional outcomes related to procedure: o Time to procedure o Procedural outcomes e.g. major postoperative complications (Futier et al., 2022)
DIVERSITY VALUE	**Economic model** Whilst current HTA processes do not include diversity value in economic models, methods to incorporate this do exist. These models incorporate transmission and resistance dynamics and explore the development of resistance to each antimicrobial within a decision problem when a new antimicrobial is added to a prescribing strategy. The inputs listed here (see next column) are based on the dynamic transmission model in Gordon et al (2020, 2023a). **Qualitative / Deliberative** Diversity value could also be considered deliberatively, as was partly done in in the NICE-NHS subscription model product award criteria (NHS England, 2023). For example, whether the antimicrobial overcomes key resistance mechanisms compared to existing antimicrobials is a potential driver of diversity value.	All outcomes relevant to transmission value can also inform modelling or be considered deliberatively in the context of diversity value.

	METHODS AVAILABLE TO QUANTIFY STEDI-RELATED POPULATION HEALTH BENEFITS FOR HTA INTEGRATION*	POTENTIAL OUTCOME MEASURES THAT CAPTURE POPULATION-LEVEL HEALTH BENEFITS IN THE AMR CONTEXT FOR JCA INTEGRATION*
INSURANCE VALUE	**Economic model** Whilst current HTA processes do not include insurance value in economic models, methods to incorporate it do exist. For example, Chan et al. (2023) explore the value of withholding an antimicrobial in the case of different scenarios (ward closures, shortages, pandemics, catastrophic AMR), using extreme value theory to model the frequency and likelihood of such events occurring. These can be based on dynamic transmission models as in Gordon et al (2020, 2023a) or additional risk-based models covered in Chan et al. (2023). **Qualitative / Deliberative** Insurance value could also be considered deliberatively, as was partly done in the NICE-NHS subscription model product award criteria (NHS England, 2023). For example, whether the antimicrobial overcomes key resistance mechanisms compared to existing antimicrobials and has activity against certain resistance mechanisms could be used as key drivers of insurance value.	All outcomes that are relevant to transmission value may be relevant inputs for modelling analyses for insurance value. For outcomes used either in modelling or in deliberative processes, particular focus should be on evidence on transmission or insurance values regarding pathogens included in the WHO priority pathogens list, including: o Treatment efficacy against multi-drug-resistant pathogens o Treatment duration/length of stay

* Source: analysis and synthesis by OHE based on the literature review and expert discussions.

4 Feasibility

The practical capacity to operationalise assessments of antimicrobial population-level health benefits within the JCA process, both now and over the longer term.

JCAs are organised around the PICO framework and require outcomes to be patient centred. In contrast, the STEDI-related elements capture population-level effects. Examples of outcome measures that may potentially reflect population-level health benefits in the context of AMR are highlighted in Table 2.

Although clinical and other relevant experts can contribute to outcome identification during the development of the assessment scope (HTACG, 2024b), and could in principle propose outcomes that approximate STEDI components, this does not alter or overcome the requirement that JCA outcomes remain patient-centred. Likewise, since neither the Health Technology Assessment Regulations (HTAR) nor the scoping guidance defines criteria for selecting health outcomes (HTACG, 2024a), Member States could hypothetically choose outcomes specific to STEDI, but this is still subject to the patient-centred constraint.

According to the JCA outcome guidance, a validated surrogate may replace a patient-centred outcome when absolutely necessary (HTACG, 2024a). However, the HTD must clearly explain which patient-centred outcome it substitutes and demonstrate the strength of the association between the surrogate and the final outcome (HTACG, 2024a). Surrogates may also be included alongside patient-centred outcomes, but only when their validity has already been clearly established (HTACG, 2024a). Biological plausibility is the lowest level of evidence that Member States may rely on when assessing surrogate validity (HTACG, 2024a). At present, the surrogate measures that could capture STEDI-related benefits generally meet only this lowest evidentiary threshold: they are biologically plausible but lack stronger empirical links to patient-level outcomes. As a result, surrogate outcomes offer only limited potential for reflecting STEDI within the JCA framework, and their inclusion may be difficult to secure.

Another challenge is that the JCA is restricted by Article 9(1)(a) to reporting the "relative effects of a new health technology" compared with its comparator (The European Parliament and the Council of the European Union, 2021). This framework requires that the clinical effectiveness of a technology can be demonstrated by measuring differences in outcomes between treated patients and those receiving an alternative. Most STEDI-related elements cannot be expressed in this way. Their benefits, such as reduced transmission emerge at the population level and do not produce measurable clinical differences between patient groups within a trial or comparative study. As a result, even when these benefits are substantial, they cannot be captured as typical "relative effects" and therefore fall outside what the JCA is designed to assess.

In the context of feasibility, it is worth noting that the HTA Regulation offers JSCs, which facilitate early dialogue between HTDs and HTACG on the development and evidence generation. These will be important in exploring an adequate adaption of the JCA and ensuring convergence in how the population-level health benefit of antimicrobials are captured and measured in the JCA and across EU countries.

Importantly, experts stressed that the current JCA framework is not fit for purpose for assessing the population-level STEDI benefits of antimicrobials. Practically, they also confirmed that the current JCA submission templates provide very limited space for population level benefit considerations (GSK/OHE European Expert Advisory Board, 2025). Even though adaptations are theoretically feasible, implementing them in practice would require substantial procedural changes and faces multiple barriers. Experts also highlighted and expressed concern over the already high workload of national HTA bodies involved in JCA activities, noting that introducing additional evidence requirements for antimicrobials could add significant complexity at a time when capacity is already stretched (GSK/OHE European Expert Advisory Board, 2025).

Experts discussed a short term "exception" approach (whereby antimicrobials would be excluded from JCAs) and a more long-term "adaptation" approach (whereby JCAs would be adapted for antimicrobials) (GSK/OHE European Expert Advisory Board, 2025). An exception was considered as a potential pragmatic short-term solution, particularly given that if antimicrobials enter the JCA "as is" in 2030, their population-level health benefits risk being overlooked entirely, potentially undermining incentives for R&D in other areas of the EU. At the same time, participants recognised the need to support gradual adaptation with an intention to evolve the framework over the longer term (GSK/OHE European Expert Advisory Board, 2025). Participants recommended developing and piloting a methodological framework that sets out how STEDI-related population health elements could be incorporated into JCAs (GSK/OHE European Expert Advisory Board, 2025). Such pilots could test feasibility, clarify data requirements, and generate practical learning before full integration. Collaboration with the HTAR Methods Group was

identified as a potential pathway for supporting these efforts and ensuring methodological rigour (GSK/OHE European Expert Advisory Board, 2025).

5 Conclusions and recommendations

AMR represents a major global health challenge, creating an urgent need for innovative antimicrobials. Addressing this challenge will require renewed international action to stimulate R&D, including a balanced mix of push and pull incentives. One important policy consideration is the need to fully recognise and appropriately reward the value of antimicrobials in terms of direct patient benefit, but also their broader contribution to population health.

From 2030 onwards, the EU JCA will be mandatory for new antimicrobials offering a unique opportunity to align European HTA policy with European AMR objectives. If designed appropriately, the JCA could play a pivotal role in ensuring that both patient-level and population-level health benefits are systematically recognised, thereby strengthening incentives for the development and timely availability of novel antimicrobials in Europe.

This opportunity should also be considered within the wider international and recent US policy context. There is a well-documented divide in launch timing and availability of new antibiotics, with products typically reaching the US market earlier and achieving broader uptake than in the EU and other countries (Outterson et al., 2022; Kållberg et al., 2018). This divergence may be partially driven by comparatively weaker pricing and reimbursement incentives in European system (Sullivan, Fisher and Taenzer, 2024; Savant et al., 2024). The implementation of the US Most-Favored-Nation (MFN) policy introduces explicit international reference pricing (The White House, 2025), potentially considering European-level pricing and reimbursement signals in the US market. It is currently unclear what this could mean for the future trajectory of the global antimicrobial R&D pipeline. This context underscores the importance of adjusting and aligning EU HTA policy with European AMR objectives and international policy developments, to ensure that the full societal value of antimicrobials is recognised and reflected in pricing and reimbursement decisions.

However, in this study we found that the current approach to JCA is not fit-for-purpose for antimicrobials and thus fails to support European efforts to tackle AMR being made elsewhere. We identified significant willingness barriers to adapting JCA processes, capability barriers in measuring and evidencing population health benefits, and feasibility barriers due to JCA's current focus on direct patient-level outcomes within a PICO-based framework.

We conclude that there is an urgent need to address these barriers and challenges before 2030. By addressing willingness, capability, and feasibility in a phased manner, the EU can ensure that the JCA fosters sustainable innovation in antimicrobials and ultimately supports in the fight against AMR.

Willingness

We recommend aligning HTAR legislation with wider EU AMR policy priorities. In the short term, policymakers should leverage Recital 24 of the EU HTA Regulation to develop technology-specific guidance for novel antimicrobials. In the longer term, AMR and the assessment of new antimicrobials should be given special consideration in any future revision of HTA legislation.

Capability

We recommend advancing the methodological development of STEDI within the EU HTA network through pilots. In the short term, the EU HTA network should initiate pilots to agree on a core set of outcome measures that capture population-level health benefits in the AMR context. Over time, this work should evolve into a formal alignment on an assessment framework like STEDI, including guidance on how these methodologies can be integrated into JCA and subsequent national HTA processes.

Feasibility

We recommend creating a roadmap for gradual JCA evolution and adaption for antimicrobials in line with Recital 24 of the EU HTA Regulation. This roadmap should adapt to methodological changes and readiness and ensure sufficient capacity within the EU HTA network. JSCs should play a pivotal role by guiding evidence generation.

There are several ways in which the JCA could be adapted over time:

1. **Structured evidence repository:** In the short term, the output of a JCA for a novel antimicrobial could function as a central repository for all relevant evidence, beyond patient-centred relative effectiveness evidence, including clinical, pre-clinical, epidemiological, and modelling data. The evidence would not necessarily need to be analysed or synthesised, the JCA is instead acting as an information conduit. This would provide a comprehensive evidence base for downstream national HTAs, without requiring the JCA itself to produce final (quantitative) estimates for each STEDI element. This approach can be implemented under existing JCA practices. It hence represents the minimum necessary step to ensure that JCA aligns with ongoing AMR initiatives across Europe.

2. **Analysis of broader evidence:** In the medium term, the JCA could adapt its evidentiary scope for antimicrobials to include a set of outcome measures to be analysed within JCA, which provide insight into population-level health benefits. This could include observational and single-arm data, where comparative evidence is not feasible. Preclinical in vitro and in vivo studies could also be recognised as early indicators of population-level benefits. In

addition, surrogate outcomes could be used where conventional patient-relevant clinical outcomes do not adequately capture population-level value. These measures could potentially be used as modelling inputs or to inform qualitative discussion as part of HTA at the national level. This approach can be implemented through the development of technology-specific guidance, as outlined in the willingness section. It offers the most practical way to align JCAs with ongoing AMR initiatives while operating within the current legislative framework.

3. **Modelling support:** In the long term, the JCA could strengthen population-level health assessments by collecting a standardised set of clinical or laboratory data to serve as inputs for economic or epidemiological models. The JCA could develop appraisal and modelling capacity and capability for STEDI related benefits. Still, any valuation of these different outcomes would remain the responsibility of national HTAs, as valuation remains a national-level responsibility. This approach is aspirational and forward-looking and can be achieved as part of future reforms of the legislative and assessment frameworks. It positions JCAs as an active facilitator of innovation in HTA decision-making, supporting Europe's response to AMR.

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CONTRACT FUNDED REPORT
February 2025

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