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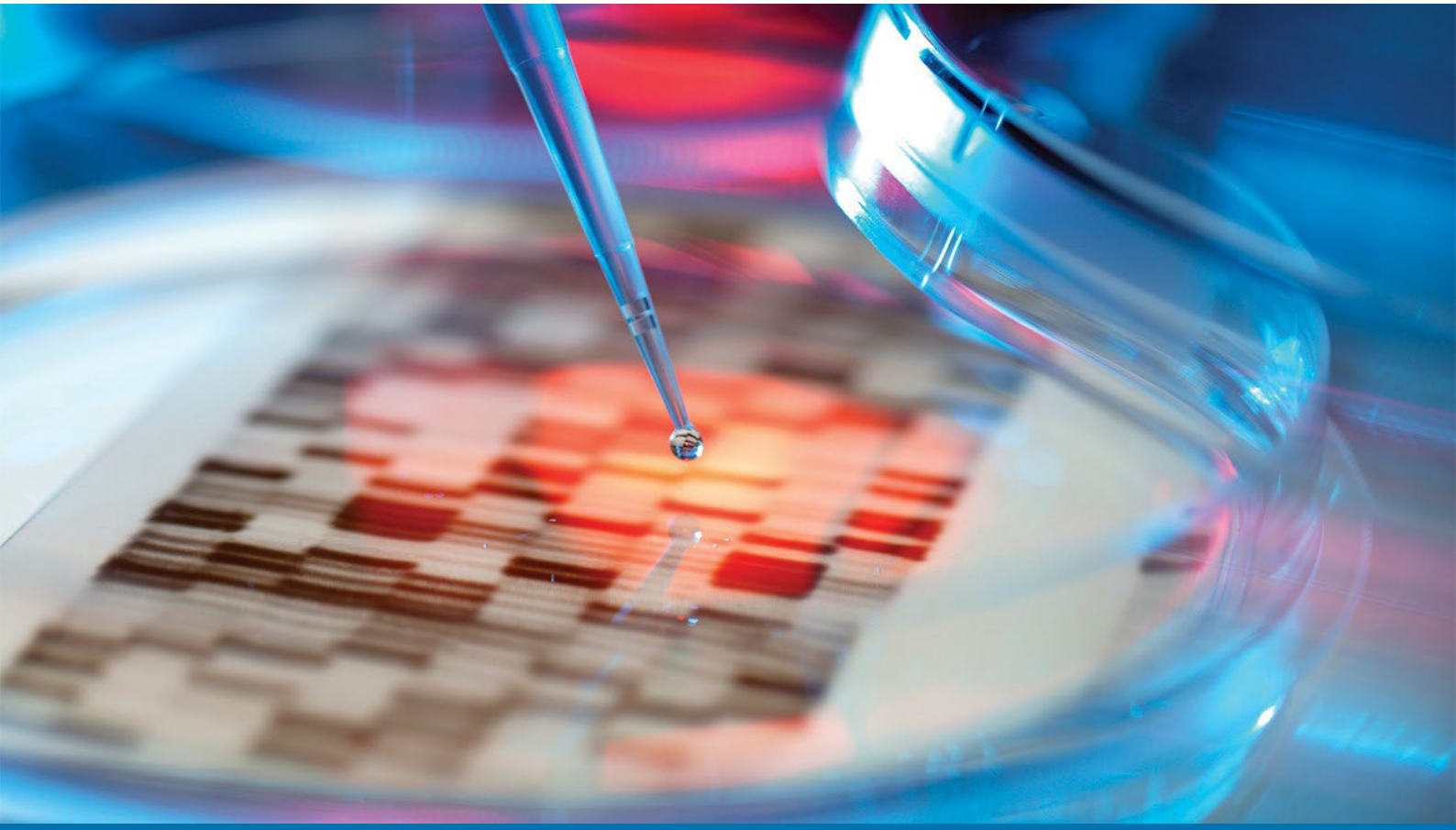

The need for European countries to complement EU-level pull incentives with national provisions for novel antimicrobials

Report

June 2026

The research was initiated and funded by GSK and developed by CRA.

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Executive Summary

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Antimicrobial resistance (AMR) poses an escalating threat to global health, economies, and health-system resilience.[1] Resistant infections already cause more than 35,000 deaths annually in Europe and cost billions in healthcare and productivity losses.[2] The urgent need for new antibiotics to be developed is widely acknowledged; at the same time, the antibiotic market fails to provide adequate incentives for innovation. Although the clinical need for new antimicrobials is well established, the current R&D environment does not offer a viable commercial pathway for developers. Furthermore, current market structures and reimbursement systems are still based on traditional, volume-driven models. This misalignment between stewardship goals and financial returns has made it difficult for developers to achieve sustainable returns on investment, further discouraging innovation in this critical therapeutic area.[3]

Recent progress at the EU level—such as the transferable exclusivity voucher (TEV), the proposed voluntary subscription model for the joint procurement of antimicrobials and the Health Emergency Preparedness and Response Authority (HERA) pilot revenue-guarantee model—represents pivotal steps toward creating a predictable incentive framework in Europe.[4] However, ensuring that these EU-level mechanisms translate into tangible access and sustainable outcomes across member states will require active national participation. The concept of "fair share"—the principle that each country should contribute proportionately to the global effort to sustain antibiotic innovation and access, in line with its economic capacity and the healthcare benefits derived—has been used to assess whether countries are doing enough.[5]

The need for complementary incentives in Europe

Despite renewed political commitment and momentum behind the development of EU-level mechanisms, Europe's response remains fragmented; national engagement, uneven.[6] Recent evidence shows that while some countries, including the United Kingdom and Italy, are contributing their fair share to global antimicrobial incentives, most others are falling behind in proportionate investment and policy implementation.[7] EU-level pull incentives, such as the proposed TEV, are intended to ensure efficiency and reward innovation by providing predictable returns for developers of

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1 OECD (2025). "Antimicrobial resistance". Accessible from: https://www.oecd.org/en/topics/antimicrobial-resistance.html Accessed on: 28/10/2025

2 ECDC (2024). "Antimicrobial resistance targets". Accessible from: https://www.ecdc.europa.eu/assets/amr-targets-2024/index.html Accessed on: 28/10/2025

3 Global AMR R&D HUB & WHO (2024). "Incentivising the development of new antibacterial treatments 2024". Accessible from: https://globalamrhub.org/wp-content/uploads/2024/10/g7progress_2024_hub_who.pdf Accessed on: 28/10/2025

4 CRA (2022). "A framework for assessing the potential net benefits realised through transferable exclusivity extension (TEE) as an incentive for development of novel antimicrobials". Accessible from: https://www.efpia.eu/media/676634/cra-efpia-a-framework-for-assessing-the-costs-and-benefits-of-tee-final-report.pdf Accessed on: 06/11/2025

5 OHE (2023). "Incentivising new antibiotics: designing a value-based delinked pull incentive". Accessible from: https://www.ohe.org/wp-content/uploads/2023/03/OHE_Report_Brassel_et_al_2023_Incentivising_New_Antibiotics.pdf Accessed on: 06/11/2025

6 ECDC (2023). "Reducing antimicrobial resistance: is the EU progressing towards the 2030 targets?". Accessible from: https://www.ecdc.europa.eu/en/news-events/eaad-2023-launch Accessed on: 28/10/2025

7 Goh, M., McEnany, M., Freeman, R., Newton, M., Kesselheim, A.S. and Outterson, K., 2025. Bridging the fair share gap for antibacterial innovation: an observational analysis of antibacterial revenues in the G7 and EU27. EClinicalMedicine, 88.

high-priority antimicrobials. However, these instruments alone cannot secure equitable access, sustained commercial viability, or alignment of national markets with global innovation goals.[8]

To ensure that Europe meets its collective responsibility and benefits from robust antibiotic pipelines, countries need to complement EU-level initiatives with national policy measures that (1) reflect their fair share of the global effort and (2) ensure access to antibiotics that are developed.[9]

This white paper seeks to answer two key questions:

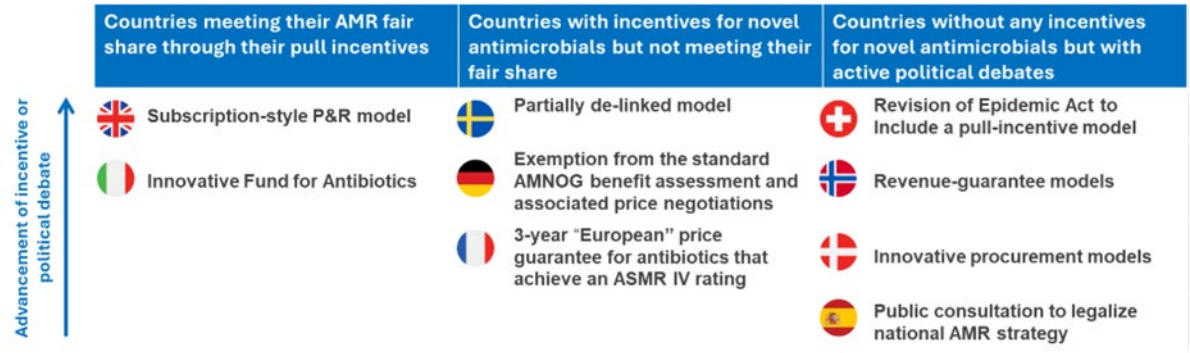
- What the role and need for complementary policy changes at the national level?
- What are the options for countries to ensure they contribute their fair share and deliver access to novel antibiotics?

An overview of progress at country level

At a national level, progress has been positive but uneven, with a handful of countries leading the way in developing are credible pull incentives and addressing access. A 2025 study revealed that among the G7 and EU27 countries, only the United Kingdom and Italy are currently contributing to their fair share of global antimicrobial incentives. The UK has implemented a subscription-style model, while Italy has launched the €100 million Innovative Fund for Antibiotics.[10]

Different approaches are being proposed to stimulate antibiotic innovation and ensure sustainable access. Several countries, including Sweden, Germany, and France, have implemented incentives for novel antimicrobials that fall short of their fair-share obligations. In contrast, many other countries have not yet introduced any incentives for novel antimicrobials, although policy discussions are underway in some of them, including Norway, Switzerland, and Spain **(Figure 1)**. It will be important to assess how these proposals can fit together into a coherent policy approach that delivers Europe's fair share and ensures sustainable access.

Figure 1: An overview of the incentives in place and active policy debates



8 CRA (2022). "A framework for assessing the potential net benefits realised through transferable exclusivity extension (TEE) as an incentive for development of novel antimicrobials". Accessible from: https://www.efpia.eu/media/676634/cra-efpia-a-framework-for-assessing-the-costs-and-benefits-of-tee-final-report.pdf Accessed on: 06/11/2025

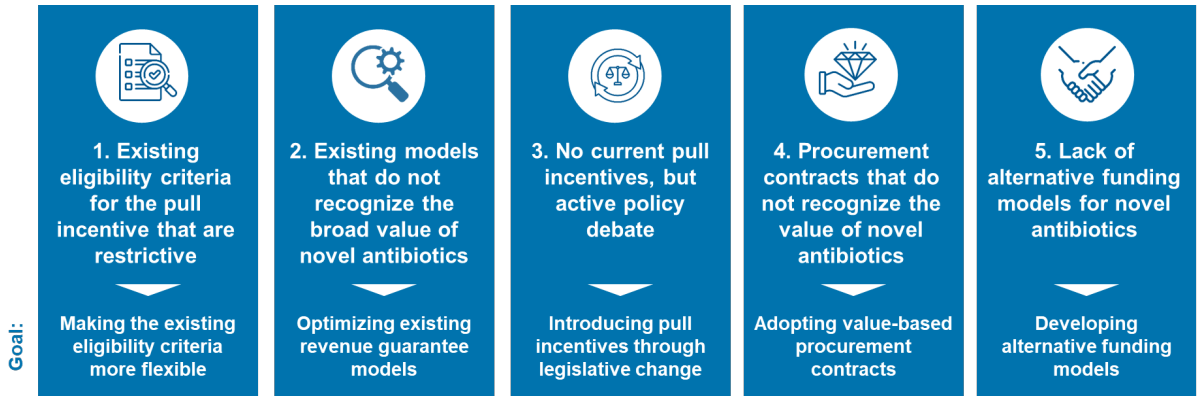
9 Årdal, C., Baraldi, E., Bettiol, E., Ciabuschi, F., Colson, A., Gyssens, I., Monnier, A., Morel, C., Outterson, K., Røttingen, J.A. and Tacconelli, E., 2023. A Pan-EU/EEA pull incentive for antimicrobial innovation and access. *Policy Brief, DRIVE-AB Consortium.* Accessible from: https://drive-ab.eu/wp-content/uploads/2023/11/DRIVE-AB-Policy-Brief-A-Pan-EU-EEA-Pull-Incentive-for-Antimicrobial-Innovation-and-Access.pdf Accessed on: 28/10/2025

10 Goh, M., McEnany, M., Freeman, R., Newton, M., Kesselheim, A.S. and Outterson, K., 2025. Bridging the fair share gap for antibacterial innovation: an observational analysis of antibacterial revenues in the G7 and EU27. *EClinicalMedicine, 88.*

Opportunities for optimising the incentive mix in Europe

Significant progress in recognising the need for pull incentives has been made, and some countries have introduced national incentives to encourage new antibiotics and ensure that access is sustainable, but much more needs to be done. Through a series of workshop in the countries, we have developed five key archetypes that can be used to guide countries in designing and implementing complementary incentives for novel antimicrobials **(Figure 2).** These approaches are intended to strengthen the sustainability and predictability of antibiotic markets while aligning national action with Europe's collective fair-share contribution to global pull incentives. Although policy solutions are likely to be unique to each country, countries seeking to strengthen their national incentives can assess which archetype best aligns with their policy environment and use the corresponding framework to identify policy priorities.

Figure 2: The five key archetypes



Key recommendations

Building on the archetypes outlined above, the following recommendations summarise the concrete actions that countries can take to strengthen national and regional incentive frameworks for novel antimicrobials **(Table 1)**. These actions can be adapted to local market conditions, governance structures, and fiscal capacities while contributing to Europe's collective fair-share commitment.

Table 1: An overview of the key recommendations per archetype

Archetype	Key recommendations
Existing eligibility criteria for the pull incentive that are restrictive	• **Increase funding allocated** to existing revenue-guarantee models. • **Integrate value-based assessments** into payment determination so that guaranteed revenues reflect the demonstrated public-health value of each antimicrobial.
Existing models that do not recognize the broad value of novel antibiotics	• **Adopt value-based procurement approaches** that align purchasing decisions with the demonstrated clinical and societal value of novel antimicrobials. • **Pursue legislative change** to enable value-based procurement contracts.

	• **Secure sustainable funding mechanisms** to maintain access to novel antibiotics once they are procured.
No current pull incentives, but active policy debate	• **Use legislative reforms** to establish a clear legal basis for subscription-style or revenue-guarantee incentives. • **Define governance and eligibility structures** within legislation to ensure transparency, stewardship, and sustained funding.
Procurement contracts that do not recognize the value of novel antibiotics	• **Align national eligibility frameworks** with international standards such as the WHO Priority Pathogens List and the TEV mechanism. • **Ensure transparency and predictability**, defining which products qualify, for how long, and under what evaluation mechanisms. • **Review frameworks periodically** to reflect evolving resistance patterns and maintain clinical relevance.
Lack of alternative funding models for novel antibiotics	• **Create a policy environment** in which the fair-share principle is understood and made a priority by decision-makers by linking AMR investment to broader health-innovation and resilience goals. • **Introduce alternative funding models,** such as de-linked payment schemes, subscription-style contracts, or value-based procurement frameworks. • **Scale funding allocations** to ensure sufficient resources as more qualifying antibiotics reach the market.

Together, these actions provide a roadmap for European countries to strengthen national incentive frameworks, coordinate regional approaches, and collectively deliver their fair-share contribution to sustaining global antimicrobial innovation and access.

1. Introduction

1.1 European commitments to address the antibiotic pipeline crisis

Antimicrobial resistance (AMR) poses an escalating threat to global health, economies, and health-system resilience.[11] Resistant infections already cause more than 35,000 deaths annually in Europe and cost billions in healthcare and productivity losses.[12] Globally, the burden is projected to rise sharply, with recent analyses warning that without stronger investment and innovation, AMR could cause up to 10 million deaths annually[13] and reduce global economic output by up to US$ 1.7 trillion by 2050.[14] The driver is increasing levels of resistance, particularly to last-line antibiotics; for instance, resistance to third-line antibiotics is expected to triple in parts of Europe by 2035, making it substantially more difficult to treat infections such as pneumonia and sepsis.[15] Rising resistance is also evident in common infections in community settings: a 2023 study of women with uncomplicated urinary tract infections in Germany found that 30% of *E. coli* isolates showed resistance to one or more antibiotic classes.[16] Due to the growing global burden, development of new antibiotics is essential. For example, it has been estimated that strengthening the pipeline of antibacterial drugs targeting gram-negative bacteria could avert more than 11 million deaths globally by 2050.[17]

At the same time, the antibiotic market fails to provide adequate incentives for innovation. Although the clinical need for new antimicrobials is well established, the current R&D environment does not offer a viable commercial pathway for developers. Effective antimicrobial stewardship programmes, which are vital for preserving antibiotic efficacy and patient safety, inherently limit sales volumes of new antibiotics. Furthermore, current market structures and reimbursement systems are still based on traditional, volume-driven models. This misalignment between stewardship goals and financial returns has made it difficult for developers to achieve sustainable returns on investment, further discouraging innovation in this critical therapeutic area.[18]

In recognition of these challenges, governments and multilateral bodies have issued a series of commitments to revitalise antibacterial innovation. Over the past ten years, they have included the UN

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11 OECD (2025). “Antimicrobial resistance”. Accessible from: https://www.oecd.org/en/topics/antimicrobial-resistance.html Accessed on: 28/10/2025

12 ECDC (2024). “Antimicrobial resistance targets”. Accessible from: https://www.ecdc.europa.eu/assets/amr-targets-2024/index.html Accessed on: 28/10/2025

13 Naghavi, M., Vollset, S.E., Ikuta, K.S., Swetschinski, L.R., Gray, A.P., Wool, E.E., Aguilar, G.R., Mestrovic, T., Smith, G., Han, C. and Hsu, R.L., 2024. Global burden of bacterial antimicrobial resistance 1990–2021: a systematic analysis with forecasts to 2050. *The Lancet*, *404*(10459), pp.1199-1226.

14 Center for Global Developmnet (2023). “Forecasting the fallout from AMR: economic impacts of antimicrobial resistance in humans”. Accessible from: https://www.cgdev.org/publication/forecasting-fallout-amr-economic-impacts-antimicrobial-resistance-humans Accessed on: 28/10/2025

15 OECD (2025). “Antimicrobial resistance”. Accessible from: https://www.oecd.org/en/topics/antimicrobial-resistance.html Accessed on: 28/10/2025

16 Naber, K.G., Wagenlehner, F., Kresken, M., Cheng, W.Y., Catillon, M., Duh, M.S., Yu, L., Khanal, A., Mulgirigama, A., Joshi, A.V. and Ju, S., 2023. Escherichia coli resistance, treatment patterns and clinical outcomes among females with uUTI in Germany: a retrospective physician-based chart review study. *Scientific Reports*, *13*(1), p.12077.

17 Goh, M., McEnany, M., Freeman, R., Newton, M., Kesselheim, A.S. and Outterson, K., 2025. Bridging the fair share gap for antibacterial innovation: an observational analysis of antibacterial revenues in the G7 and EU27. *EClinicalMedicine*, *88*.

18 Global AMR R&D HUB & WHO (2024). “Incentivising the development of new antibacterial treatments 2024”. Accessible from: https://globalamrhub.org/wp-content/uploads/2024/10/g7progress_2024_hub_who.pdf Accessed on: 28/10/2025

General Assembly (UNGA) political declaration on AMR (2016),[19] EU One Health Action Plan against AMR (2020),[20] G7 communiqués committing to strengthen antimicrobial R&D (2022),[21] and most recently the updated UNGA declaration (2024) that called for continued support for "incentive mechanisms that separate the cost of investment in research and development from the price and volume of sales".[22] Many national action plans have echoed these commitments, pledging to explore push (e.g., research funding), pull (e.g., market entry rewards) and access (e.g., pricing and reimbursement reforms) mechanisms to stimulate development.

Recent progress at the EU level—such as the transferable exclusivity voucher (TEV), the proposed voluntary subscription model for the joint procurement of antimicrobials, and the Health Emergency Preparedness and Response Authority (HERA) pilot revenue-guarantee model—represent pivotal steps towards creating a predictable incentive framework in Europe.[23] However, ensuring that these EU-level mechanisms translate into tangible access and sustainable outcomes across member states will require active national participation. The concept of "fair share"—the principle that each country should contribute proportionately to the global effort to sustain antibiotic innovation and access, in line with its economic capacity and the healthcare benefits derived—has been used to assess whether countries are doing enough.[24]

1.2 Overview of different types of incentives addressing AMR

Incentivising antibacterial innovation requires a coordinated mix of mechanisms that address different stages of the antibiotic life cycle and different market failures. These mechanisms are commonly grouped into three categories: push, pull, and access incentives **(Figure 3)**.[25]

19 UN (2016). "Political declaration of the high-level meeting of the General Assembly on antimicrobial resistance". Accessible from: https://digitallibrary.un.org/record/842813?v=pdf Accessed on: 28/10/2025

20 European Commission (2020). "A European one health action plan against antimicrobial resistance (AMR)". Accessible from: https://health.ec.europa.eu/system/files/2020-01/amr_2017_action-plan_0.pdf Accessed on: 28/10/2025

21 G7 Germany (2022). "G7 Leaders' Communiqué". Accessible from: https://www.g7germany.de/resource/blob/974430/2062292/fbdb2c7e996205aee402386aae057c5e/2022-07-14-leaders-communique-data.pdf Accessed on: 28/10/2025

22 UN (2024) "Political declaration of the high-level meeting on antimicrobial resistance". Accessible from: https://www.un.org/pga/wp-content/uploads/sites/108/2024/09/FINAL-Text-AMR-to-PGA.pdf Accessed on: 06/11/2025

23 CRA (2022). "A framework for assessing the potential net benefits realised through transferable exclusivity extension (TEE) as an incentive for development of novel antimicrobials". Accessible from: https://www.efpia.eu/media/676634/cra-efpia-a-framework-for-assessing-the-costs-and-benefits-of-tee-final-report.pdf Accessed on: 06/11/2025

24 OHE (2023). "Incentivising new antibiotics: designing a value-based delinked pull incentive". Accessible from: https://www.ohe.org/wp-content/uploads/2023/03/OHE_Report_Brassel_et_al_2023_Incentivising_New_Antibiotics.pdf Accessed on: 06/11/2025

25 Renwick, M.J., Brogan, D.M. and Mossialos, E., 2016. A systematic review and critical assessment of incentive strategies for discovery and development of novel antibiotics. *The Journal of Antibiotics*, *69*(2), pp.73-88.

Figure 3: An overview of the different types of incentives addressing AMR

Push incentives	Pull incentives	Access incentives
Push incentives reduce the cost of R&D by providing early-stage grants, tax credits, or public-private partnerships. These mechanisms de-risk scientific discovery but do not guarantee market success.	**Pull incentives** aim to create predictable market rewards for successfully developed products. Models such as market-entry rewards, subscription-based payments ("Netflix models"), and transferable exclusivity vouchers provide revenue certainty and reward innovation that meets unmet medical needs.	**Access incentives** focus on ensuring equitable and sustainable availability of effective antibiotics once developed, including procurement agreements, de-linked payment models, and stewardship-linked reimbursement frameworks.

While each type of incentive plays a distinct role, global experience demonstrates that pull incentives alone are insufficient without complementary national-level measures to ensure equitable access and sustainable uptake.[26] Therefore, a coordinated, multilevel approach, one that combines EU-level pull mechanisms with tailored national provisions, is essential.

1.3 The need for complementary incentives in Europe

Despite renewed political commitment and the momentum behind the development of EU-level mechanisms, Europe's response remains fragmented; national engagement, uneven.[27] Recent evidence shows that while some countries, such as the United Kingdom and Italy, are contributing their fair share to global antimicrobial incentives, most others are falling behind in proportionate investment and policy implementation.[28] EU-level pull incentives, such as the proposed TEV, are intended to ensure efficiency and reward innovation by providing predictable returns for developers of high-priority antimicrobials. However, these instruments alone cannot secure equitable access, sustained commercial viability, or alignment of national markets with global innovation goals.[29]

To ensure that Europe meets its collective responsibility and benefits from robust antibiotic pipelines, countries need to complement EU-level initiatives with national policy measures that (1) reflect their fair share of the global effort and (2) ensure access to antibiotics that are developed.[30]

This white paper seeks to answer two key questions:

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26 Årdal, C., Baraldi, E., Bettiol, E., Ciabuschi, F., Colson, A., Gyssens, I., Monnier, A., Morel, C., Outterson, K., Røttingen, J.A. and Tacconelli, E., 2023. A Pan-EU/EEA pull incentive for antimicrobial innovation and access. *Policy Brief, DRIVE-AB Consortium.* Accessible from: https://drive-ab.eu/wp-content/uploads/2023/11/DRIVE-AB-Policy-Brief-A-Pan-EU-EEA-Pull-Incentive-for-Antimicrobial-Innovation-and-Access.pdf Accessed on: 28/10/2025

27 ECDC (2023). "Reducing antimicrobial resistance: is the EU progressing towards the 2030 targets?". Accessible from: https://www.ecdc.europa.eu/en/news-events/eaad-2023-launch Accessed on: 28/10/2025

28 Goh, M., McEnany, M., Freeman, R., Newton, M., Kesselheim, A.S. and Outterson, K., 2025. Bridging the fair share gap for antibacterial innovation: an observational analysis of antibacterial revenues in the G7 and EU27. EClinicalMedicine, *88*.

29 CRA (2022). "A framework for assessing the potential net benefits realised through transferable exclusivity extension (TEE) as an incentive for development of novel antimicrobials". Accessible from: https://www.efpia.eu/media/676634/cra-efpia-a-framework-for-assessing-the-costs-and-benefits-of-tee-final-report.pdf Accessed on: 06/11/2025

30 Årdal, C., Baraldi, E., Bettiol, E., Ciabuschi, F., Colson, A., Gyssens, I., Monnier, A., Morel, C., Outterson, K., Røttingen, J.A. and Tacconelli, E., 2023. A Pan-EU/EEA pull incentive for antimicrobial innovation and access. *Policy Brief, DRIVE-AB Consortium.* Accessible from: https://drive-ab.eu/wp-content/uploads/2023/11/DRIVE-AB-Policy-Brief-A-Pan-EU-EEA-Pull-Incentive-for-Antimicrobial-Innovation-and-Access.pdf Accessed on: 28/10/2025

- What is the role and need for complementary policy changes at the national level?
- What are the options for countries to ensure that they make fair-share contributions and deliver access to novel antibiotics?

2. Current progress across Europe

This section summarises where Europe stands on delivering incentives to revitalise antibacterial innovation and providing sustainable access. It outlines progress at both EU and national levels, focusing on the evolution of pull mechanisms and each country's contribution toward a fair and sustainable ecosystem for antimicrobial development.

2.1 An overview of progress at the European level

At the European level, the policy debate on how best to stimulate antibiotic innovation has intensified. The European Commission's proposed TEV represents a central pillar in the ongoing pharmaceutical legislation reform and is designed to complement other mechanisms, such as subscription models and joint procurement initiatives.[31] Under the agreement reached by the Council and the European Parliament in December 2025, the TEV would grant one additional year of market protection for a priority antibiotic, which can be applied to a pharmaceutical product of the company's choice. The agreement also retains the Council's proposed "blockbuster clause", preventing the TEV from being used on products with annual gross sales above €490 million in any of the preceding four years. As for next steps, the agreement needs to be endorsed by both the Council of the European Union and the European Parliament before entering into force.[32]

Its purpose is to create a clear, high-value reward for companies investing in the high-risk, low-return field of antibiotic development.[33] When paired with clear eligibility criteria and appropriate safeguards, TEVs could form one part of a broader incentive mix, offering a sufficient reward to encourage private investment in late-stage antimicrobial R&D.[34,35]

Policymakers increasingly view the TEV as part of a broader European strategy rather than a stand-alone solution.[36] Although the TEV provides an incentive, current estimates suggest that issuing a single TEV per year in the EU would cost member states around €162 million. That this level of public payment is unlikely to generate a sufficiently strong incentive for developers[37] reinforces the need for the TEV to be complemented by other well-designed mechanisms to deliver adequate pull funding and

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31 European Parliament (2023). "Antimicrobial resistance - New incentives to improve the accessibility and availability of antimicrobial medicinal products". Accessible from: https://www.europarl.europa.eu/RegData/etudes/STUD/2022/740069/IPOL_STU%282022%29740069_EN.pdf Accessed on: 28/10/2025

32 European Council (2025). 'Pharma package': Council and Parliament reach a deal on new rules for a fairer and more competitive EU pharmaceutical sector. Accessible from: https://www.consilium.europa.eu/en/press/press-releases/2025/12/11/pharma-package-council-and-parliament-reach-a-deal-on-new-rules-for-a-fairer-and-more-competitive-eu-pharmaceutical-sector/ Accessed on: 19/01/2026

33 CRA & EFPIA (2025). "A forward-looking assessment of the impact of introducing transferable exclusivity vouchers (TEV) in Europe". Accessible from: https://www.efpia.eu/media/u3xj1nl1/cra-a-forward-looking-assessment-of-the-cost-of-introducing-tev.pdf Accessed on: 28/10/2025

34 CRA & EFPIA (2025). "A forward-looking assessment of the impact of introducing transferable exclusivity vouchers (TEV) in Europe". Accessible from: https://www.efpia.eu/media/u3xj1nl1/cra-a-forward-looking-assessment-of-the-cost-of-introducing-tev.pdf Accessed on: 28/10/2025

35 European Commission (2023). "A pharmaceutical strategy for Europe." Accessible from: https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe_en Accessed on: 28/10/2025

36 Anderson, M., Panteli, D. and Mossialos, E., 2023. How can the EU support sustainable innovation and access to effective antibiotics. *Policy options for existing and new medicines. Copenhagen (Denmark): European Observatory on Health Systems and Policies*.

37 CRA (2025). "A forward-looking assessment of the impact of introducing transferable exclusivity vouchers (TEV) in Europe." Accessible from: hhttps://www.efpia.eu/media/u3xj1nl1/cra-a-forward-looking-assessment-of-the-cost-of-introducing-tev.pdf Accessed on: 28/10/2025

ensure fair cost-sharing across member states. For this reason, there is growing interest in combining the TEV with other pull mechanisms, such as subscription-style payments or market entry rewards that can provide predictable, multiyear funding streams, and with access models that can provide sustainable access. Together, these tools could form a complementary framework in which the TEV provides high-level incentives for breakthrough innovation while access models ensure ongoing access working alongside stewardship programmes.[38]

One proposal is for the EU to play a role in a coordinated access programme. HERA is increasingly viewed as a natural coordinating body for such a multipronged approach. HERA's remit covers joint procurement, stockpiling, and emergency preparedness for cross-border health threats, including AMR. Through HERA, a pan-European platform could provide revenue-guarantee or subscription-style contracts, thereby ensuring coherent stewardship standards and equitable access to new antibiotics.[39] However, HERA's capacity to deliver on this broader mandate remains untested, and its current activities have focused mainly on improving access to existing antibiotics rather than stimulating innovation. Applying the model to existing antibiotics has faced early challenges. One example is HERA's first attempt to establish an EU AMR procurement initiative. A 49-month pilot project with Menarini was announced in 2024. The company was to make its antibiotic Vaborem (meropenem/vaborbactam) available to hospitals across 21 participating EU member states within 48 hours. However, Menarini ultimately declined to sign the €40 million agreement.[40]

Furthermore, under the agreement reached by the Council and the European Parliament in December 2025, a voluntary subscription model for the joint procurement of antimicrobials will be established. This model will provide for full or partial de-linkage of funding from the volume of antimicrobial sales.[41]

2.2 An overview of progress at the country level

At a national level, progress has been positive but uneven, with a handful of countries leading the way in developing credible pull incentives and addressing access. A 2025 study revealed that among the G7 and EU27 countries, only the United Kingdom and Italy are currently contributing to their fair share of global antimicrobial incentives. The UK has implemented a subscription-style model, while Italy has launched the €100 million Innovative Fund for Antibiotics.[42]

An overview of the countries contributing their fair share through their pull incentives

The **UK** subscription model offers fixed annual payments to companies for access to selected priority antimicrobials, regardless of the volumes used, thereby de-linking the reward from sales volume. This structure, first set out in the UK Government's 2019 Five-Year Action Plan for Antimicrobial Resistance, recognises the broader health-system value, including infection prevention, maintenance of treatment options, and system resilience. The model builds on the joint pilot launched by NICE and NHS England

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38 European Parliament (2024). "Accelerating EU action against antimicrobial resistance". Accessible from: https://www.europarl.europa.eu/news/en/press-room Accessed on: 28/10/2025

39 European Commission (2025). "HERA Annual Work Plan 2025". Accessible at: https://health.ec.europa.eu/publications/hera-annual-work-plan_en Accessed on: 28/10/2025

40 POLITICO (2025). "Biotechs 'cry for help' to fix antibiotics market failure". Accessible at: https://www.politico.eu/article/biotechs-cry-for-help-to-fix-antibiotics-market-failure/ Accessed on: 28/10/2025

41 Crowell (2026). "The New EU "Pharma Package": The Transferable Exclusivity Voucher Compromise Proposal". Accessible at: https://www.crowell.com/en/insights/client-alerts/eu-pharma-package-the-transferable-exclusivity-voucher-compromise-proposal Accessed on: 15/05/2026

42 Goh, M., McEnany, M., Freeman, R., Newton, M., Kesselheim, A.S. and Outterson, K., 2025. Bridging the fair share gap for antibacterial innovation: an observational analysis of antibacterial revenues in the G7 and EU27. *EClinicalMedicine, 88.*

in 2019 and is now guided by national NHS England arrangements that set out clear criteria for eligibility, valuation, and stewardship. It determines eligibility using a point-based approach and drawing on the World Health Organization Priority Pathogen List and broader unmet-need assessments. By embedding transparency and predictable funding, the UK model is broadly recognised as providing a leading example of how de-linked incentives can be implemented in practice.[43] The approach has been applied to two products to date—cefiderocol (Fetcroja) and ceftazidime/avibactam (Zavicefta)—which were selected through the NICE–NHS England pilot.[44]

The Italian approach is more recent. **Italy's** Innovative Fund for Antibiotics, introduced under the 2024–2025 budget plan, provides targeted financial support for the procurement and sustainable use of novel antibiotics. This €100 million fund is designed to stabilise the market for critical antimicrobials by enabling national reimbursement and reducing reliance on fragmented regional procurement practices that can create downward pressure on prices through local discount requests. For a novel antibiotic to be eligible for the fund it must meet three criteria: (i) it must be classified as "Reserve" in the AWaRe list of the World Health Organization (WHO) *and/or* be active against one of the bacteria in the WHO Bacterial Priority Pathogens List; (ii) be used for treating infections caused by multidrug-resistant bacteria; and (iii) be under patent or data protection. This fund enables national reimbursement with an exemption from Italy's standard pharmaceutical payback mechanisms (it is estimated to increase annual revenues by ~15%). Novel antibiotics funded through this fund are required to be monitored through AIFA's registry system to ensure stewardship. Italy's proactive approach signals its recognition of AMR as a national health priority and reflects its commitment to contributing proportionately to global pull incentives.[45] While initially there was ambiguity regarding the longer-term future of the mechanism beyond its launch period, Italy's 2026 Budget Law reduced the overall Innovative Medicines Fund but introduced explicit protections for the allocation dedicated to reserve antibiotics targeting multidrug-resistant pathogens (up to €100 million), supporting continuation of the policy in 2026.[46] The fund currently includes five key antibiotics listed in AIFA's list (Recarbrio, Silvextro, Vaborem, Xerava, and Zavicefta), all of which target multidrug-resistant pathogens and provide therapeutic options for severe infections with limited treatment alternatives.[47]

An overview of countries with incentives for novel antimicrobials but not meeting their fair share

Other European countries have also advanced AMR-related policies but are not seen as providing a significant contribution to paying Europe's fair share; however, these models can provide lessons in enabling access. The ordering of countries below corresponds to the maturity of their incentive models, with those at the top demonstrating more advanced development than those that follow.

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43 NHS England (2024). "Antimicrobial Products Subscription Model: guidance on commercial arrangements". Accessible at: https://www.england.nhs.uk/publication/antimicrobial-products-subscription-model-guidance-on-commercial-arrangements/ Accessed on: 28/10/2025

44 NICE (2025). "A new model for evaluating and purchasing antimicrobials in the UK". Accessible at: https://www.nice.org.uk/what-nice-does/life-sciences-how-to-get-your-product-to-market/a-new-model-for-evaluating-and-purchasing-antimicrobials-in-the-uk Accessed on: 28/10/2025

45 AMR Solutions (2025). Italy initiates its national pull incentive! Accessible at: https://amr.solutions/2025/07/30/italy-initiates-its-national-pull-incentive/ Accessed on: 28/10/2025

46 ilFarmacista (2026). Pharmacies, revised handbook, spending caps, and new AIFA rules: all the new features of the Budget Law. Accessible at: https://www.ilfarmacistaonline.it/governo-parlamento/articolo.php?articolo_id=133791 Accessed on: 19/01/2026

47 AIFA (2025). "Allegato 6". Accessible at: https://www.aifa.gov.it/documents/20142/2971622/Allegato-6_alla_Det-Pres-966-2025.pdf Accessed on: 28/10/2025

Sweden, following its pilot from 2018 to 2022 that guaranteed a minimum annual revenue to manufacturers, has rolled out a partially de-linked national model focused on ensuring sustainable access to critical antibiotics (either older or newer antibiotics) within Sweden. Under the model, companies supplying antibiotics of special medical value, such as those active against carbapenem-resistant bacteria or included on the WHO Priority Pathogens List, receive a guaranteed annual payment of approximately 4 million SEK (about €350,000). The limited payment is aimed at ensuring sustainable access rather than directly incentivising global R&D; however, there is some flexibility in the annual payment amount. The Public Health Agency of Sweden evaluation found that the pilot effectively supported the availability and continued supply of critical antibiotics and helped maintain access to products that might otherwise have been withdrawn from the market. The model, emphasising supply security, stewardship, and stockholding obligations, represents a feasible approach for smaller markets and complements broader EU-level initiatives.[48,49,50,51] Key limitations of the Swedish model include its relatively low annual payment level and the absence of differentiated pricing for higher-value antibiotics. In addition, the scheme does not apply a value-based framework to determine payment amounts. However, Sweden aims to strengthen its stance against AMR, as illustrated by its collaboration with the UK in establishing the Ministerial Alliance of Champions against Antimicrobial Resistance, which holds regular meetings to keep AMR high on the political agenda.[52]

In **Germany**, antibiotic pricing follows the general pharmaceutical pricing and reimbursement framework (called AMNOG), but targeted provisions have been introduced to support access to critical antimicrobials. In 2021, through the Fair Statutory Health Insurance Law, Germany introduced a mechanism for designating certain antibiotics as “reserve antimicrobials” under section 35a of the Social Code Book V. These products are exempt from the standard AMNOG benefit assessment and associated price negotiations, allowing manufacturers to set a free price tied to volume agreements.[53] Several recent developments have occurred:

- In 2025, the Federal Joint Committee and the Federal Institute for Drugs and Medical Devices updated the reserve status criteria, shifting the focus from infection severity to the pathogen targeted. The requirement that a product must treat “serious or potentially serious infections” has been removed. Instead, designation now depends on whether the antibiotic demonstrates

48 PHAS. Questions and answers – Agreements signed for a pilot study of a new reimbursement model. Accessible at: https://www.folkhalsomyndigheten.se/contentassets/c09fd6d5d42243e097be216767686c08/questions_answers_agreements_signed_pilot_study_new_reimbursement_model.pdf Accessed on: 28/10/2025

49 PHAS (2023). Availability to antibiotics of particular importance. Accessible at: https://www.folkhalsomyndigheten.se/contentassets/700919bb88944affbfe814c1b23e53ed/availability-to-antibiotics-of-particular-importance.pdf Accessed on: 28/10/2025

50 PHAS (2024). Availability of antibiotics. Accessible at: https://www.folkhalsomyndigheten.se/the-public-health-agency-of-sweden/communicable-disease-control/antibiotics-and-antimicrobial-resistance/overview-of-swedens-one-health-response-to-antibiotic-resistance/exploring-swedens-approach-to-antibiotic-resistance-in-the-human-health-sector/availability-of-antibiotics/ Accessed on: 28/10/2025

51 PHAS (2024). Swedish experiences regarding access to antibiotics. Accessible at: https://ec.europa.eu/assets/sante/health/amr/docs/amr_20240301_co09_en.pdf Accessed on: 28/10/2025

52 Government Offices of Sweden (2024). Sweden’s efforts to combat antimicrobial resistance – so that we can continue to treat infections in the future. Accessible at: https://www.government.se/government-policy/swedens-work-against-antimicrobial-resistance/swedens-efforts-to-combat-antimicrobial-resistance--so-that-we-can-continue-to-treat-infections-in-the-future Accessed on: 28/10/2025

53 McEnany, M. and Outterson, K., 2024. Changes in revenues associated with antimicrobial reimbursement reforms in Germany. *Humanities and Social Sciences Communications*, *11*(1), pp.1-12.

activity against pathogens on Germany's official list of multidrug-resistant organisms, which is aligned with the WHO Priority Pathogens List.[54]

- Further clarification was added for the evaluation of potential reserve antibiotics: long-term complications of inadequately treated infections (for example, infertility) are explicitly mentioned, alongside the recognition that any infection, if untreated, can lead to sepsis. The guidance also emphasises that reserve status designation should be based solely on the pathogen list and the approved indication, with no additional restrictions related to infection severity. This reform makes the framework more flexible and inclusive, broadening eligibility to antibiotics with clear clinical value against resistant pathogens. By decoupling reserve status and disease severity, Germany has taken a significant step toward a more pragmatic, pathogen-focused incentive model that better aligns with stewardship and access objectives.[55]

Despite these advancements, Germany's current incentive framework does not enable it to meet its fair-share obligations. Evidence suggests that recent reforms, while directionally positive, still fall well short of what is required to make antibiotic development commercially viable. For example, one analysis estimates that Germany would need to increase antibiotic prices by up to 3.3 times current levels (assuming volumes remain constant) to match the impact of a fully de-linked pull incentive. This underscores that the existing model continues to provide insufficient and unpredictable revenue for developers.[56] Another key outstanding challenge lies at the hospital level: inpatient funding uses a diagnosis-related group system in which payment levels are based on the most frequently used therapies (such as low-cost generic antibiotics). Hospital use of reserve antibiotics therefore relies on add-on payment mechanisms (i.e., NUB payments), which may further weaken predictability because reimbursement can depend on hospital-by-hospital funding approvals rather than a consistent national pathway.[57] Nonetheless, the recent reforms signal a clear willingness among German institutions to refine the framework and bring it closer to international expectations.

France has taken steps to improve market conditions for antimicrobials by introducing a three-year European price guarantee for novel antibiotics. Since 2015, antibiotics that achieve an ASMR IV rating (indicating a minor improvement in clinical benefit) qualify for the guarantee, whereas novel medicines in other therapeutic areas must reach ASMR III to be eligible. Even so, achieving ASMR IV can remain challenging for antimicrobials because pivotal studies often struggle to demonstrate sizeable incremental benefit against comparators in heterogeneous resistant populations. This mechanism provides pricing predictability across the EU, reducing financial uncertainty for manufacturers and helping maintain antibiotic availability.[58] While the price guarantee acknowledges that antibiotics face unique hurdles in demonstrating clinical benefit, it does not address the underlying health technology

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54 RKI (2025). "Reserve antibiotics: exemption from the benefit assessment by standardized criteria according to §35a Social Code Book (SGB) V". Accessible at https://www.rki.de/EN/Institute/Organisation/Departments/Department-3/Unit-37/Downloads/Pathogen_list_and_criteria_reserve_antibiotics.pdf Accessed on: 28/10/2025

55 RKI (2025). "Reserve antibiotics: exemption from the benefit assessment by standardized criteria according to §35a Social Code Book (SGB) V". Accessible at: https://www.rki.de/EN/Institute/Organisation/Departments/Department-3/Unit-37/Downloads/Pathogen_list_and_criteria_reserve_antibiotics.pdf Accessed on: 28/10/2025

56 McEnany, M. and Outterson, K., 2024. Changes in revenues associated with antimicrobial reimbursement reforms in Germany. *Humanities and Social Sciences Communications*, *11*(1), pp.1-12.

57 Lattice Point (2022). "New ways to pay for antibiotics—what manufacturers should know when bringing new products to Europe" Accessible at: https://www.latticepointconsulting.com/wp-content/uploads/2022/01/Antibiotics.pdf Accessed on: 28/10/2025

58 Gotham, D., Moja, L., van der Heijden, M., Paulin, S., Smith, I. and Beyer, P., 2021. Reimbursement models to tackle market failures for antimicrobials: approaches taken in France, Germany, Sweden, the United Kingdom, and the United States. *Health Policy*, *125*(3), pp.296-306.

assessment (HTA) processes that continue to undervalue the broader societal benefits of novel antimicrobials. In addition, France's payment model remains tied to sales volumes.

Countries without any incentives for novel antimicrobials, but with an active political debate

Other countries have not implemented policies for addressing the broken market for antibiotics but have proposals in development. The ordering of countries below reflects the maturity of the political debate, with those listed first demonstrating more advanced discussions and being closer to implementing a pull incentive than those that follow.

Switzerland is revising the Epidemics Act to strengthen preparedness and explicitly address antimicrobial resistance. A proposed Article 51a would empower the Federal Council to grant financial assistance for antimicrobial medicines that are needed for infections caused by specified pathogens in Switzerland, conditional on Swissmedic authorisation under the Therapeutic Products Act, demonstrated efficacy against priority resistant pathogens, and assured domestic availability. The support would follow a subscription model in which annual lump-sum payments (available for up to ten years) would begin once the product is on the Swiss market. These payments would be offset by the medicine's Swiss sales; if sales fall below the guaranteed amount, the Confederation would cover the shortfall. The Federal Council may impose conditions to maintain efficacy (for example, on manufacturing or stewardship) and would set a maximum per-product aid level that reflects public-health value and Switzerland's proportionate contribution to global development costs. The implementing ordinance will define assessment criteria (including innovation and efficacy) and procedures, with the Federal Office of Public Health responsible for administration. This framework aims to ensure the availability and responsible use of new antimicrobials in Switzerland and is expected to be operational around 2029.[59,60,61]

Norway is currently discussing the potential introduction of a revenue-guarantee model, which may be extended to novel antimicrobials. This initiative is part of the Directorate of Medical Products' broader work to identify financial mechanisms that strengthen access to both old and new antimicrobial drugs. The model is being considered alongside income-guarantee schemes for generic antibiotics and reflects the government's commitment to ensuring a sustainable supply of critical medicines in line with Norway's National One Health Strategy Against AMR (2024–2033).[62]

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59 Federal Office of Public Health - Switzerland. (2025). Message on the amendment to the Epidemics Act. Accessible at: https://www.bag.admin.ch/dam/de/sd-web/4wOEp7YV2jSo/Botschaft%20zur%20%C3%84nderung%20des%20Epidemiengesetzes%20vom%2020.8.2025.pdf Accessed on: 28/10/2025

60 Federal Office of Public Health - Switzerland. (2025). Message on the revision of the Federal Act on Combating Communicable Diseases in Humans. Accessible at: https://www.bag.admin.ch/de/gesetzgebung-ubertragbare-krankheiten-epidemiengesetz-epg Accessed on: 28/10/2025

61 Swiss Info (2025). "Swiss inaction threatens global antibiotic development push". Accessible at: https://www.swissinfo.ch/eng/new-treatments/swiss-inaction-threatens-global-antibiotic-development-push/89612523 Accessed on: 28/10/2025

62 Government of Norway (2024). "National one health strategy against antimicrobial resistance 2024–2033". Accessible at: https://www.regjeringen.no/contentassets/7ae8eacec9cc4af085b5c113a98a0eb0/national-one-health-strategy-against-antimicrobial-resistance.pdf Accessed on: 28/10/2025

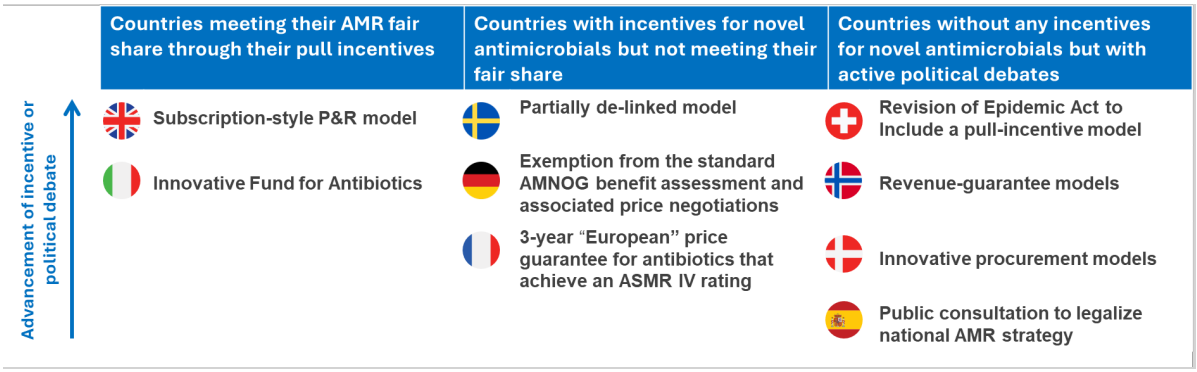
Denmark has launched a new National Action Plan for AMR (2025–2028), which outlines plans to explore and implement an innovative subscription-based procurement model for novel antibiotics with the aim of improving access to antimicrobials.[63]

In **Spain**, the Ministry of Health is advancing two major legislative reforms to strengthen the policy framework for access to and evaluation of medicines. The first reform updates the HTA system, aiming to establish a more transparent and structured evaluation process aligned with EU Joint HTA.[64] The second reform revises the Royal Decree governing pricing and reimbursement, with the objective of improving predictability, accelerating access to innovative therapies, and enhancing the sustainability of pharmaceutical expenditure. Together, these reforms aim to create a more coherent and evidence-based approach to decision-making.[65] In parallel, Spain is reinforcing its governance of antimicrobial resistance through a draft Royal Decree designed to give the National Antibiotic Resistance Plan, first established in 2014, a formal legal basis. The Ministry of Health, seeking to consolidate AMR policy under a single legislative framework, launched a public consultation on this draft in mid-2025.[66]

Summary

In countries across Europe, there is progress on addressing the challenge of AMR. Different approaches are being proposed to stimulate antibiotic innovation and ensure sustainable access. While the United Kingdom and Italy have established pull incentives that meet their fair-share commitments, several other countries, including Sweden, Germany, and France, have implemented incentives that fall short of their fair-share obligations. In contrast, many countries have not yet introduced any incentives, although policy discussions are underway in some, including Norway, Switzerland, and Spain **(Figure 4).** In the next chapter, we consider how the proposals fit together into a coherent policy approach that delivers Europe's fair share and ensures sustainable access.

Figure 4: An overview of the incentives in place and active policy debates



63 Ministry of the Interior and Health of Denmark (2025). "National action plan on antimicrobial resistance in humans". Accessible at: https://www.ism.dk/Media/638918721595453894/National-action-plan-on-antimicrobial-resistance-in-humans-UK-TILG.pdf Accessed on: 28/10/2025

64

65 GLI (2025). "Pricing & Reimbursement Laws and Regulations 2025 – Spain". Accessible at: https://www.globallegalinsights.com/practice-areas/pricing-reimbursement-laws-and-regulations/spain Accessed on: 28/10/2025

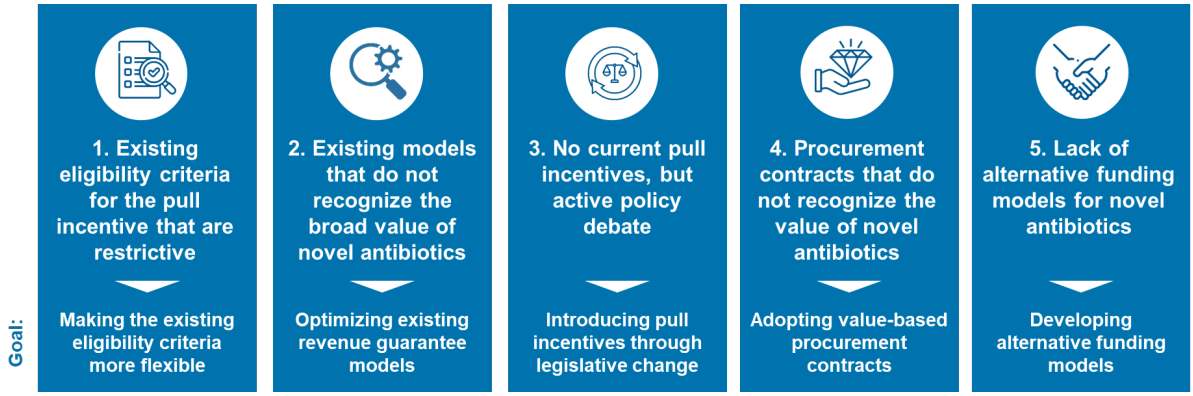
66 Navlin (2025). "Spain opens public consultation on draft decree to combat antibiotic resistance"

3. A national policy agenda to incentivise new antibiotics and sustain access

3.1 Opportunities for optimising the incentive mix in Europe

As set out in Chapters 1 and 2, significant progress in recognising the need for pull incentives has been made and some countries have introduced national incentives to encourage new antibiotics and ensure access is sustainable, but much more needs to be done. Through a series of workshops in each country, we have developed five key archetypes that can be used to guide countries in designing and implementing complementary incentives for novel antimicrobials **(Figure 5)**. These approaches are intended to strengthen the sustainability and predictability of antibiotic markets while aligning national action with Europe's collective fair-share contribution to global pull incentives. Although policy solutions are likely to be unique to each country, countries seeking to strengthen their national incentives can assess which archetype best aligns with their policy environment and use the corresponding framework to identify policy priorities.

Figure 5: The five key archetypes



Existing eligibility criteria for the pull incentive that are restrictive

Countries that fit within this archetype are those that already have a pull incentive for novel antimicrobials in place but with restrictive eligibility criteria:

- The existing eligibility criteria of the pull incentive are not aligned to international frameworks, such as the WHO Bacterial Priority Pathogens List and the WHO AWaRe classification.
- The existing eligibility criteria of the pull incentive do not reflect the eligibility criteria of EU incentives.
- How the eligibility criteria will be applied and the duration of the eligibility period are ambiguous.

Overly restrictive criteria can unintentionally exclude valuable innovations and create uncertainty for manufacturers. To maximize impact, national frameworks should align with international standards, such as the WHO Bacterial Priority Pathogens List and the WHO AWaRe classification, ensuring global relevance and coherence.

Eligibility rules should also enable mutual recognition of products that qualify under other mechanisms, such as the proposed TEV, to promote consistency between EU-level and national pull incentives. Mutual recognition would reduce administrative burden and ensure that antimicrobials benefiting from EU-level incentives can also access national pull incentives without delay.

Transparent, predictable, and clear but adaptable eligibility rules defining both (a) which antimicrobials qualify for pull incentives and (b) the length of time they can benefit from them, as well as the evaluation mechanisms involved, are essential for giving manufacturers greater market confidence and more stable expectations around return on investment. Flexibility should also allow for periodic updates to reflect evolving resistance patterns, ensuring continued relevance and stewardship.

Recent reforms in **Germany**, such as the expansion of "reserve antibiotics" eligibility under section 35a of the Social Code Book V, demonstrate that adjusting criteria can improve access to critical antimicrobials while preserving stewardship and value-based principles.

Example actions to make the existing eligibility criteria more flexible

Italy could further refine the eligibility framework of its Innovative Fund for Antibiotics to strengthen its long-term effectiveness and ensure continued relevance as the antimicrobial pipeline evolves. More broadly, **all countries** should periodically review and update their eligibility frameworks to ensure that they remain fit for purpose and adaptable to the evolving AMR landscape.

Existing models that do not recognize the broad value of novel antibiotics

Countries that fit within this archetype are those that already have a revenue-guarantee model for novel antimicrobials in place, but its design limits its effectiveness as a market incentive. The following are examples:

- The model's primary objective remains focused on maintaining access. The allocated funding is insufficient to ensure a meaningful financial reward for developers and to stimulate innovation.
- No value-based assessment mechanism determines the appropriate level of the guarantee.

To optimise such models, countries could focus on increasing the funding allocation to provide sustainable and predictable revenues for developers of novel antibiotics, supported by a fair-share funding mechanism. Under this approach, governments, payers, and industry would collaborate on a global revenue-guarantee pool, with contributions and rewards tied to demonstrated value and distributed through equitable burden sharing. To align stakeholders, coalitions should develop a clear narrative on the urgency of antimicrobial innovation and the rationale for fair-share contributions; assess (or draw on existing estimates of) each country's current financial participation; and highlight best-practice models from countries that have successfully combined access goals with effective pull incentives for innovation.

In parallel, countries could introduce a value-based revenue guarantee in which the level of revenue commitment is proportionate to the antimicrobial's demonstrated value, as determined through a structured value-based assessment. Embedding such criteria into payment decisions would help ensure that revenues reflect the public-health and societal benefits of innovation while maintaining stewardship and equity as guiding principles. To advance this, stakeholders should develop a refined methodological proposal—ideally aligned with broader industry perspectives, such as through a working group within a national trade association—present this proposal to payers and policymakers, and draw on examples from countries that have implemented robust, value-based assessment frameworks.

Example actions to optimise existing revenue-guarantee models

In **Sweden**, the existing, partially de-linked revenue-guarantee model could be further refined to link the guaranteed revenue more closely to the value demonstrated through structured assessment. Advancing toward an enhanced, value-based model for novel antibiotics would ensure sustainable

and predictable revenues while reinforcing the alignment between financial incentives, innovation value, and public-health objectives.

Germany could introduce a value-based subscription model that de-links developer revenue from sales volumes, providing more predictable returns while supporting stewardship.

No current pull incentives, but active policy debate

Countries that fit within this archetype are those considering broader legislative reforms that can embed pull incentives for novel antimicrobials within a predictable and sustainable legal framework.

Legislative change provides the foundation for long-term market confidence by securing dedicated funding, defining clear governance structures, and formalising eligibility criteria and evaluation mechanisms. Embedding pull incentives in law also enables governments to set the duration and scope of support, apply value-based principles to ensure that rewards are linked to clinical and societal impact rather than sales volume, and ensure transparency and accountability in implementation. As part of this process, stakeholders should engage closely with policymakers and technical committees to define the key elements of the pull incentive, including eligibility criteria, duration of support, and the assessment of value.

Examples of opportunities to introduce formal pull incentives through upcoming legislative reforms

In **Switzerland**, the proposed revision of the Epidemics Act offers a pathway to establish a subscription-style incentive for novel antimicrobials. Similarly, in **Norway**, opportunity exists to advance the ongoing debate around the national revenue-guarantee model to explicitly include novel antimicrobials.

In **Spain**, there is an opportunity to pilot a pull incentive for novel antimicrobials, building on the ongoing reforms to the HTA and P&R frameworks. Embedding these reforms within the forthcoming Royal Decrees would help formalise the inclusion of novel antibiotics in national access and incentive structures, providing a clearer and more sustainable basis for future implementation.

Procurement contracts that do not recognize the value of novel antibiotics

Countries that fit within this archetype are those where procurement frameworks for antimicrobials already exist but are primarily designed to prioritise low-cost, established products rather than support the uptake of novel antibiotics and where existing mechanisms often fail to recognise or reward the broader clinical and public-health value that innovative antimicrobials provide.

To address this gap, countries should consider adopting value-based procurement frameworks that explicitly link purchasing decisions to the demonstrated value of new antimicrobials, allowing health-system and societal benefits to be reflected rather than relying on price alone. Procurement authorities should integrate formal, value-based assessment criteria into purchasing decisions, drawing on flexibilities already used in other therapy areas or in peer countries. In parallel, governments should ensure sufficient and predictable funding within procurement systems to secure ongoing access to novel antimicrobials and support equitable participation in global AMR efforts. Implementing these changes may require legislative reform and sustainable financing mechanisms to guarantee long-term sustainability once products are procured.

Example of an opportunity to adopt value-based procurement contracts

In **Denmark**, opportunity exists to advance national discussions on introducing a value-based procurement for novel antibiotics. Partnering with the national trade association and health authorities to advocate for legislative change could facilitate the adoption of alternative financial models for novel antimicrobials.

Lack of alternative funding models for novel antibiotics

Countries that fit within this archetype include those where there are no specific funding models for novel antimicrobials because

- Political awareness of the AMR burden is limited,
- Political awareness of the need to introduce national incentives to complement international incentives is limited, and
- There is no technical proposal to guide the introduction of a pilot alternative-funding model.

Except for Italy and the UK, nations are not yet contributing their fair share towards addressing AMR. There is an urgent need for countries to adopt alternative financing mechanisms that ensure equitable and sustainable support for antimicrobial innovation and access. Although the **Italian** Innovative Fund for Antibiotics remains a leading example of national commitment to AMR innovation, expanding and indexing its budget allocation to the expected number of qualifying antibiotics in future years would help ensure sufficient resources as more products reach the market and would consolidate Italy's leadership in sustainable, stewardship-aligned pull incentives across Europe.

To make progress, it will be essential to create a policy environment in which the fair-share principle is understood and made a priority by decision-makers. This begins with educating policymakers on the burden of AMR and the economic hurdles in developing novel antimicrobials, positioning AMR as a health security and economic resilience issue and integrating it into broader national health and innovation strategies needed for long-term healthcare sustainability. Policymakers should also be made aware that international initiatives, such as the TEV or HERA's revenue-guarantee model, cannot, on their own, meet a country's fair-share commitment and that dedicated national frameworks are required to match each country's responsibility to help sustain the global antibiotic pipeline.

Building on this awareness, governments can fulfil their fair-share obligations by introducing pull incentives and complementary funding models for novel antimicrobials, including de-linked payment schemes, subscription-style contracts, revenue-guarantee mechanisms, and value-based procurement frameworks. To support this shift, stakeholders should develop a technical proposal for a pilot alternative-funding model, detailing the economic rationale, funding flows, payment mechanisms, eligibility criteria, and governance structure needed to support sustainable antibiotic innovation.

Examples of opportunities to develop alternative funding models

In **France**, advancing the national debate on introducing a de-linked funding model would help ensure that the country contributes its fair share to global AMR efforts.

3.2 Key recommendations

Building on the archetypes outlined above, the following recommendations summarise the concrete actions that countries can take to strengthen national and regional incentive frameworks for novel antimicrobials **(Table 2)**. These actions can be adapted to local market conditions, governance structures, and fiscal capacities while they contribute to Europe's collective fair-share commitment.

Table 2: An overview of the key recommendations per archetype

Archetype	Key recommendations
Existing eligibility criteria for the pull incentive that are restrictive	• **Increase funding allocated** to existing revenue-guarantee models. • **Integrate value-based assessments** into payment determination so that guaranteed revenues reflect the demonstrated public-health value of each antimicrobial.
Existing models that do not recognize the broad value of novel antibiotics	• **Adopt value-based procurement approaches** that align purchasing decisions with the demonstrated clinical and societal value of novel antimicrobials. • **Pursue legislative change** to enable value-based procurement contracts. • **Secure sustainable funding mechanisms** to maintain access to novel antibiotics once they are procured.
No current pull incentives, but active policy debate	• **Use legislative reforms** to establish a clear legal basis for subscription-style or revenue-guarantee incentives. • **Define governance and eligibility structures** within legislation to ensure transparency, stewardship, and sustained funding.
Procurement contracts that do not recognize the value of novel antibiotics	• **Align national eligibility frameworks** with international standards, such as the WHO Bacterial Priority Pathogens List and the TEV mechanism. • **Ensure transparency and predictability**, defining which products qualify, for how long, and under what evaluation mechanisms. • **Review frameworks periodically** to reflect evolving resistance patterns and maintain clinical relevance.
Lack of alternative funding models for novel antibiotics	• **Create a policy environment** in which the fair-share principle is understood and made a priority by decision-makers by linking AMR investment to broader health-innovation and resilience goals. • **Introduce alternative funding models** such as de-linked payment schemes, subscription-style contracts, or value-based procurement frameworks. • **Scale funding allocations** to ensure sufficient resources as more qualifying antibiotics reach the market.

Together, these actions provide a roadmap for European countries to strengthen national incentive frameworks, coordinate regional approaches, and collectively deliver their fair-share contribution to sustaining global antimicrobial innovation and access.

About Charles River Associates

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