

Background

The World Health Organization identified antimicrobial resistance (AMR) as a top five global health threat in 2019¹. In the same year, bacterial AMR was directly responsible for an estimated 1.27 million deaths globally and contributed to an additional 4.95 million deaths – more than HIV and malaria². However, the lack of market recognition for the value of antibiotics targeting AMR and volume-based payment models that do not consider the need for stewardship, disincentivizes research and development (R&D) in this critical area. From 2017 to 2023, only 16 out of 128 antibacterial development programs for priority pathogens gained marketing authorization⁸. Without tangible actions, ~39 million deaths could occur by 2050⁷. This research aims to evaluate and compare pricing and reimbursement (P&R) incentives to promote antibiotic development across eleven European countries.

Methodology

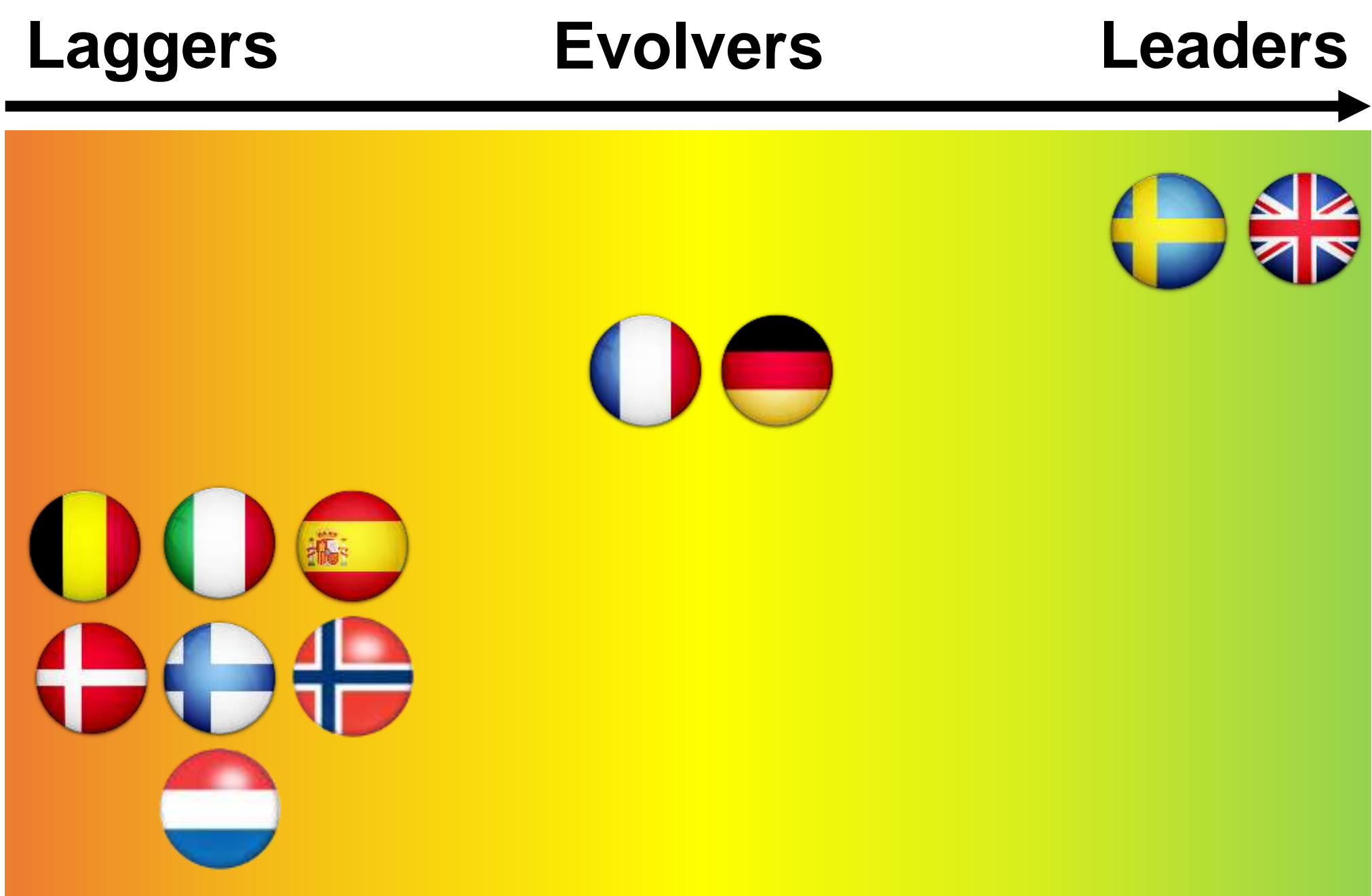
A keyword search and review of health technology assessment (HTA) websites, documents on antibiotics, and governmental organizations was conducted to extract data on AMR policies and antibiotic-specific P&R incentives (including HTA frameworks, pricing methods and purchasing models) in eleven countries. This data was used to assess market maturity in supporting antibiotic innovation. Markets were categorized as leaders (with novel, antibiotic specific P&R frameworks), evolvers (implement modifications to existing P&R frameworks), or laggards (with only national AMR action plans).

Results

Out of the 11 countries investigated, only 4 (UK, SE, DE, FR) have P&R incentives for antibiotics addressing AMR. The UK and SE are the most advanced, implementing novel antibiotic-specific value assessment frameworks and/or novel purchasing agreements denoting them as leaders in this arena (**Figure 1**). DE and FR provide pricing benefits for antibiotics through modifications of their existing P&R frameworks. However, they lack novel purchasing models at present.

The remaining seven countries (ES, IT, NO, DK, FI, NL, BE) have national agreement plans (NAPs) focused on AMR from a "One Health" perspective, focusing on human, animal, and environmental health, but lack mentioning of specific access pathways for antibiotics.

Figure 1. Market maturity as defined by the establishment of specific P&R incentives for antibiotics



Focusing on countries that have implemented antibiotic-specific P&R incentives, a multi-faceted strategy emerges, combining updates to value assessment frameworks, tailored pricing models or novel purchasing models (**Table 1**). So far, 4 different antibiotics have benefited from these incentives across the countries.

Table 1. Overview of P&R approaches and products benefited in more mature markets

		Modifications to Existing P&R Frameworks	Novel, Antibiotic-Specific P&R Frameworks	Products Benefitted
Leaders			<ul style="list-style-type: none">Subscription model with guaranteed annual payments independent of sales⁴STEDI Framework which considers 5 value dimensions not considered in traditional HTA³	<ul style="list-style-type: none">FetcrojaZavicefta
		<ul style="list-style-type: none">N/A	<ul style="list-style-type: none">Minimum guaranteed revenue for originator antibiotics in exchange for guaranteed supply⁵	<ul style="list-style-type: none">RecarbrioZavicefta
Evolvers		<ul style="list-style-type: none">EU price for antibiotics achieving an ASMR IV and assessed in non-inferiority trials¹¹	<ul style="list-style-type: none">NAP to implement a subscription model for antibiotics targeting AMR⁹	<ul style="list-style-type: none">FetcrojaZavicefta
		<ul style="list-style-type: none">Exemption from full AMNOG assessment for reserve antibiotics¹¹Exemption from IRP for reserve antibiotics¹¹		<ul style="list-style-type: none">FetcrojaZaviceftaZerbaxaRecarbrio

Conclusion

The UK and SE lead efforts to incentivize antibiotic commercialization by enhancing access conditions and commercial viability for manufacturers, while also implementing measures to mitigate the risk of antibiotic overuse, such as delinked payment models that reward the value of antibiotics without tying revenue to volume. Notable progress has been made, with products benefiting from P&R incentives in the UK, SE, FR, and DE, but most EU countries lack novel, antibiotic-specific P&R frameworks. To effectively combat AMR and stimulate novel antibiotic development, establishing supportive reimbursement models is essential—especially for small companies and biotech firms, which lead 93% of clinical and 86.7% of preclinical R&D in this area¹⁰. These small players, operating with limited funding, drive innovation but face a fragile pipeline. Introducing antibiotic specific P&R incentives and delinked payment models more widely across Europe could provide the financial stability needed to attract investment and ensure sustainable progress in the fight against AMR.

References

¹World Health Organisation (2019), Accessed on: 01/10/2024,²World Health Organisation (2023), Accessed on: 01/10/2024,³Brassel, S., Al Taie, A. and Steuten, L. (2023) 'Value assessment of antimicrobials using the STEDI framework – how steady is the outcome?', Health Policy, 136, p. 104892. doi:10.1016/j.healthpol.2023.104892., ⁴National Institute for Health and Care Excellence (NICE) (2024), Accessed on: 01/10/2024,⁵Public health Agency of Sweden (2018); Accessed on: 01/10/2024,⁶Professional Community Network on Antimicrobial Resistance (2024), Accessed on: 01/10/2024,⁷Review on Antimicrobial Resistance. Antimicrobial Resistance: Tackling a Crisis for the Health and Wealth of Nations (2014). Accessed on: 01/10/2024,⁸World Health Organisation (2023), Accessed on 06/10/2024,⁹The French government (2024) 'The Interministerial Roadmap 2024-2034: Prevention and Reduction of antibiotic resistance, fight against antimicrobial resistance. Accessed on: 29/10/2024;¹⁰Word Health Organisation (2024), Accessed on: 03/11/2024, 2023 Antibacterial Agents in Clinical and Preclinical Development, an Overview and Analysis; ¹¹Anderson M, Panteli D, van Kessel R, Ljungqvist G, Colombo F, Mossialos E. Challenges and opportunities for incentivising antibiotic research and development in Europe. Lancet Reg Health Eur. 2023 Jul 26;33:100705. doi: 10.1016/j.lanepe.2023.100705. PMID: 37546576; PMCID: PMC10403717.