IFPMA

Revitalizing the antibiotic pipeline by implementing new R&D pull incentives

Annex

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In our position paper **"Revitalizing the antibiotic pipeline by implementing new R&D pull incentives"** , we outline the key challenges undermining antibiotic R&D and the solutions to address them. We stress the urgency of implementing sustainable pull incentive models to support the pipeline of new antibiotics for patients and health systems, and set out core principles to guide their design and delivery.

In this overview, we look at several initiatives that key governments have undertaken.

How have countries approached action on pull incentives?

We applaud the tangible steps taken by the G7 and the EU to implement pull incentives such as the subscription model in the UK and improved valuation of antibiotics in Italy, but recognize that this progress is uneven with many countries yet to implement meaningful programs.

Without sufficient action by all, no single program will deliver the necessary global impact. However, the EU and every single G7 country as well as a few other countries who have acknowledged this challenge, like Australia and Switzerland[1], are now well-positioned to build on these initiatives on the path towards full implementation.

G7 Country →	Canada	EU and Member States	Japan	UK	US
GDP-based fair share required per antibiotic on average* (USD millions)	~160	~1400	~290	~260	~2100
Model(s) discussed	RG	TEV, RG, SUB, PR	RG	SUB	RG/SUB
Implementation progress					

*Fair shares are based on the estimated USD 4.2 billion (2019 USD) per antibiotic on average, globally[2], and relative GDP[3].

RG = Revenue guarantee,
TEV = Transferable exclusivity voucher,
SUB = Subscription model,
PR = Pricing & reimbursement reform.

Canada

Ahead of its 2025 G7 Presidency, Canada joined its predecessors in indicating plans to launch their own incentive pilot. These efforts follow the 2023 report by CCA/CAC[4], commissioned by the Public Health Agency of Canada, which estimated Canada's fair share in the range of CAD 14.5-18 million (ca. USD 10.5-13 million) per drug, per year over 10 years. The CCA proposal approaches Canada's share of the global amount needed, but it is unclear how and at what level model implementation will proceed[5]. Canada has a unique opportunity for meaningful action this year, demonstrating its leading role within the G7 on this issue.

European Union and Member States

The EU is currently undergoing the revision of the General Pharmaceutical Legislation (GPL), which includes a proposal for a Transferable Exclusivity Voucher (TEV). The TEV would enable the developer of an eligible antimicrobial to recoup their investment by either using or selling the voucher. As initially proposed by the European Commission, the TEV would extend the Regulatory Data Protection (RDP) period of a product by 12 months[6]. Several amendments have since been proposed by the European Parliament and Council, some of which alter the initial proposal substantially. The industry believes an appropriately designed TEV remains the most impactful potential pull incentive at the EU level and should be progressed as part of the GPL package.

In 2024, the European Health Emergency Preparedness and Response Authority (HERA) explored an antibiotic procurement pilot, set to provide a revenue guarantee of EUR 40 million (ca. USD 45 million) over 49 months[7]. While this pilot did not proceed, HERA continues to explore the model. Based on the estimated EU fair share, the model would not be at the scale needed to incentivize R&D investment. Instead, it could act as a complement to the TEV, in particular as a joint access initiative for smaller Member States together with meaningful individual models in other Member States, for example, those that are also G7 members. Regardless of the model or combination thereof across EU, it will be crucial that the total value reaches the EU fair share and that appropriate access pathways are established.

Italy

Concurrent with holding the G7 presidency in 2024, Italy announced its own tangible payment reform that better recognizes the value of antibiotics, and which could be consistent with Italy's pull incentive fair share. As part of the 2025 government budget, new and recently approved antibiotics targeting WHO priority pathogens can now access the special USD 100 million per year Fund for Innovative Oncological and Non-oncological Medicines. This pathway also includes additional patient access benefits at the regional level, and exemption from the payback mechanism[8].

Other EU Countries

In addition, several other EU countries have been exploring various national-level measures which could contribute to the EU total, but that are not currently at the scale needed for R&D pull incentives.

Germany has enacted reforms to its pricing policies to favor “Reserve” antibiotics and has established a rule which automatically provides these with an “additional benefit” designation within the AMNOG process. In addition, for a “Reserve” antibiotic that is placed on the market for the first time, the pharmaceutical company's selling price at the time of initial placing on the market applies at the level of reimbursement amount in the outpatient sector. Since “Reserve” antibiotics are overwhelmingly used in hospitals, however, this reform has in practice not delivered the impact that was intended and needed. The use of “Reserve” antibiotics in hospitals is still not being adequately reimbursed, resulting in the policy not achieving fair share[9]. This specific issue in Germany needs to be addressed soon besides a pull incentive at the EU level. Proposals ready for implementation have already been tabled[10].

France, in its 2024-2034 Interministerial AMR Roadmap notes the importance of incentives for innovation[11], but without providing a clear timeline for implementation. In France, antibiotics are considered as providing at least “moderate clinical benefit” (ASMR-III)[12] in pricing, but this has had limited practical impact.

Sweden initially piloted a revenue guarantee model from 2020 to 2022 at SEK 4 million (ca. USD 400 thousand) per product per year, and paid out ca. 50% of this value[13], recognizing the model is intended to support access & availability of antibiotics and is not built to incentivize new R&D. Following this initial period, certain agreements were renewed until the end of 2024[14]. While not at the level of a pull incentive, Sweden’s revenue guarantee can be an example of a successful[15] national access-oriented complement to an EU-wide pull incentive.

Other countries such as Spain, and other Scandinavian countries are also exploring potential models of their own.

Japan

Concurrently with its G7 presidency in 2023, Japan likewise announced its own antimicrobial procurement pilot project[16], which targets only treatments against Carbapenem-resistant Enterobacterales (CRE). Japan has announced the continuation of the pilot in 2025, with a marginally increased budget to JPY 1.3 billion (ca. USD 9 million)[17], which is the total value, for potentially several products. We welcome Japan’s efforts in setting up its own incentive model, but as currently designed it primarily supports national launches of existing products and does not yet reach the levels necessary to incentivize new R&D investment. It will therefore be important to increase the budget for the program, or complement the current access scheme with a separate R&D pull incentive.

United Kingdom

We in particular commend the work done by NHSE and the UK over the last several years which has culminated in the implementation of a full pull incentive program, launched in Fall 2024 and now covering all of the UK[18]. The model provides a good basis for other countries yet to reach this point to learn from the dedicated valuation framework that quantifies antibiotic value, with incentive payments tiered according to product value and aligned with the generally accepted fair share. In addition, the UK leadership on AMR broadly during its 2021 G7 presidency marked a significant step-up in collective G7 attention to the issue[19]. The UK should now prioritize long-term security of its model and support other G7 countries in progressing theirs.

United States

In the US, the PASTEUR Act was reintroduced in Congress in 2023[20] and has seen broad bipartisan and multistakeholder support[21]. It still remains the most potentially impactful proposal on the table anywhere in the world but has not been passed. Congressional champions and stakeholders remain committed to advancing a pull incentive in the US and are exploring opportunities for reintroducing and advancing a revised version of PASTEUR in the current Congress.

Endnotes

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12. Lattice Point Consulting, 2022. "NEW WAYS TO PAY FOR ANTIBIOTICS". https://www.latticepointconsulting.com/wp-content/uploads/2022/01/Antibiotics.pdf

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