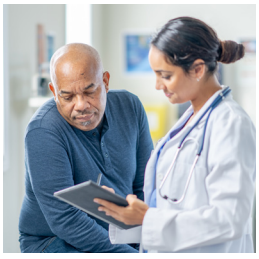
efpia

European Federation of Pharmaceutical Industries and Associations

Designing an effective EU subscription model to support antimicrobial innovation and access








Executive summary:

Antimicrobial resistance (AMR) represents a significant and growing challenge for European patients and health systems. At the same time, the market for antimicrobials does not provide sufficient incentives for sustained innovation: new treatments are used selectively to preserve their effectiveness, limiting the revenues available through traditional volume-based models. Access to new antimicrobials is uneven across European countries.

Recognising these challenges, the EU has legislated for a voluntary subscription model for the joint procurement of antimicrobials as part of the revision of the General Pharmaceutical Legislation. The model is intended to operate through multi-year contracts that delink or partially delink funding from sales volume and include commitments on sufficient supply. Alongside the transferable exclusivity voucher (TEV), this shows EU leadership on antimicrobial innovation. However, the TEV alone is unlikely to provide a comprehensive solution to the range of innovation and access challenges facing the antimicrobial market, highlighting the importance of a well-designed subscription model.

The implementation of this model represents an opportunity to develop a more sustainable European approach to antimicrobial innovation and access. To achieve this, the model should be guided by seven principles:

1. **Support both antimicrobial innovation and sustainable access**, with a reward size that delivers Europe's fair share contribution and incentivizes innovation.
2. **Apply differentiated pathways for different product types,** with a fully delinked subscription approach preferred for innovative products.
3. **Establish clear, broad and predictable eligibility criteria.**
4. **Provide differentiated, value-based payments at a level capable of supporting innovation;** this means payments equating to at least 130m EUR per year.
5. **Secure sufficient and predictable Member State participation** to provide critical mass and fund innovation.
6. **Use standardised multi-year contracts** that provide commercial and operational predictability.
7. **Apply clear but flexible supply obligations** that focus on outcomes rather than prescriptive operational requirements.

Why the EU needs a subscription model for antimicrobials

AMR already has a significant impact on European patients, with more than 35,000 deaths each year in the EU/EEA associated with infections caused by antimicrobial-resistant bacteria.[1] The burden is expected to increase: globally, bacterial AMR was directly responsible for an estimated 1.14 million deaths in 2021, with annual attributable deaths projected to increase to 1.91 million by 2050.[2]

Despite this growing need, antimicrobial innovation remains limited. The World Health Organisation (WHO) identified 90 antibacterial agents in clinical development in 2025, of which only 15 met its criteria for innovation and only 5 were active against at least one pathogen in its highest-priority critical category.[3] Access to new treatments is also fragmented with substantial differences in the availability of newly approved antibacterials across EU/EEA countries, including countries where no or only one new antibacterial assessed was available.[4]

Growing recognition of these interrelated challenges has prompted EU policy action. Under the provisional agreement on the revised General Pharmaceutical Legislation, contracting authorities from different Member States may jointly procure antimicrobials through a multi-year voluntary subscription model, with funding delinked or partially delinked from sales volume and conditions to support sufficient supply.[5]

The implementation of the model therefore represents an important opportunity to address innovation and access by improving the conditions for sustainable investment in antimicrobial R&D and ensuring that effective treatments are available to European patients when they are needed. The design choices made during implementation will determine whether the model can achieve these objectives.

To help ensure the model delivers on this opportunity, we set out below a series of principles to guide its design and implementation. Charles River Associates (CRA) supported EFPIA in developing these principles.

Principles for the design of the EU model

1. The model should explicitly define objectives for both innovation and access, with a fully delinked subscription approach used for innovative antimicrobials

The subscription model should be designed to support both antimicrobial innovation and improve access, with these objectives being viewed as complementary. Ensuring access to existing treatments is important for patients today, while continued innovation is necessary to ensure that effective treatments remain available as resistance evolves.

For innovative antimicrobials, a fully delinked subscription model (as opposed to partially delinked) provides the strongest basis for achieving these objectives. Stewardship often requires new antimicrobials to be used selectively, meaning that increasing sales volume should not be necessary to generate an appropriate return. Because utilisation is influenced by stewardship and prescribing decisions across the health system, delinking revenue from utilisation would allow the reward to better reflect the value of maintaining an effective antimicrobial while remaining compatible with responsible use.

It is important that the model is not only viewed as an alternative procurement route. To meaningfully support innovation, it needs to provide sufficient predictability and value to influence longer-term decisions on investment and R&D.

> **How will we know if this is successful:** *The model should contribute to positive changes in antimicrobial R&D activity, such as the progression of priority antimicrobials through the pipeline or an increase in developer participation; the model should also improve the number of new antimicrobials launched in Europe, support their commercial sustainably, and expand access of new and existing antimicrobials.*

2. Apply differentiated pathways for different product types

The model should be sufficiently broad to respond to the different challenges affecting the antimicrobial market. These are not limited to the development of innovative products, with maturing branded products and generics facing different challenges relating to commercial sustainability and reliable supply.

These challenges also differ across product types and therefore require tailored policy responses. For innovative products, the priority is to create a sufficiently strong incentive for R&D and investment while supporting access. For mature and generic products, the focus should be on sustaining commercial viability, continued availability and security of supply. The model should therefore provide differentiated pathways, with payment approaches, contractual arrangements and supply expectations tailored to the objectives and economics of each product type.

> **How will we know if this is successful:** *The model accommodates innovative, maturing branded and generic antimicrobials through different pathways.*

3. Establish clear, broad and predictable eligibility criteria

Manufacturers need to be able to understand, at an early stage, and with reasonable certainty, whether a product is likely to qualify for the model. Eligibility criteria should therefore be clear, transparent and sufficiently broad to capture antimicrobials that can make a meaningful clinical or public-health contribution.

For innovative antimicrobials, international approaches, including experience from the UK subscription model, should inform the EU eligibility framework. However, eligibility should remain sufficiently broad and should not be restricted solely to newly authorised or TEV-qualified products.

Importantly, eligibility should be assessed separately from valuation and payment tiering. The initial decision should determine whether a product qualifies for the model; the subsequent assessment should determine the appropriate level of reward based on its relative value. Separating these decisions would provide greater clarity for manufacturers and avoid unnecessarily restricting eligibility through criteria intended to differentiate payment levels.

A common EU-level methodology for eligibility assessment would also reduce the risk of inconsistent national interpretations and duplication across participating Member States. This should include clear assessment criteria, decision-making processes and timelines, allowing manufacturers to understand both whether a product may qualify and when that determination will be made.

> **How will we know if this is successful:** *Manufacturers can determine at an early stage whether a product is likely to qualify, and eligibility decisions are consistent across participating Member States. Eligibility is assessed separately from valuation and payment tiering.*

4. Establish differentiated payments that are tiered to appropriately reward value and innovation, and which are additive to the TEV

Antimicrobials often differ in their degree of innovation, clinical value, unmet need and contribution to addressing resistance. Applying the same subscription payment across eligible products would fail to recognise these differences and could weaken the incentive for the development of products with the greatest potential value.

A tiered payment framework would allow the level of reward to reflect product value while maintaining a predictable structure. Relevant considerations could include the degree of innovation, activity against priority pathogens, unmet need, clinical benefit and wider public-health value. The framework should provide sufficient differentiation to ensure that products delivering the greatest contribution to addressing AMR are appropriately rewarded.

Experience from the UK subscription model provides a useful example of how antimicrobial-specific value assessment can support differentiated payments. The model assesses products against a broad range of antimicrobial-specific value dimensions such as public health benefits and uses the resulting assessment to place products into differentiated payment bands, recognising that antimicrobial value may not be fully captured through conventional HTA approaches.[6]

For innovative antimicrobials, the level of payment needs to reflect the EU's fair share contribution to the global development of antimicrobials (the EU's share is estimated to be 1.3bn EUR per antimicrobial).[7,8] This should be separate to the TEV as the two mechanisms operate differently and can address different elements of the AMR market challenge. Subscription payments should align with the EU's fair share and as such qualifying innovative antimicrobials should receive a minimum of ~1.3bn EUR (130m EUR per year over a 10-year period); however, this should be seen as the payment floor and could be adjusted upwards depending on the value of the antimicrobials.

> **How will we know if this is successful:** *The payment framework results in meaningful differentiation in rewards according to product value, with higher-value products receiving higher payments. Across qualifying innovative antimicrobials, the value of the TEV and subscription payments should align with the EU's fair-share contribution to global antimicrobial innovation.*

5. Member State participation should be structured to provide predictable critical mass and funding

The model risks creating a significant challenge for manufacturers: if participation is too limited or uncertain, the resulting reward will not be sufficient to influence manufacturer decisions.

The model should therefore provide a predictable level of critical mass and funding before contracting begins. For innovative antimicrobials, this could involve establishing a minimum participation threshold or equivalent minimum funding commitment before a procurement process is launched. The appropriate threshold could consider a combination of committed funding, share of the EU population represented and the number of participating Member States rather than relying on country count alone. The EC should be responsible for helping to facilitate and coordinate participants and setting a minimum threshold for participation.

To allow for launch and supply planning, manufacturers should have early visibility of which Member States intend to participate and the associated financial commitment within 6 months of EMA marketing authorisation. Confirmation late in the procurement process would make it difficult to assess the commercial viability of participation and could reduce the attractiveness of the model.

Participation requirements may reasonably differ across product pathways. An innovation-focused subscription is likely to require broader participation and greater aggregate funding than an arrangement focused on maintaining the availability of a mature or generic antimicrobial.

Member State participation and funding should be assessed as part of the model's review. Where participation or funding is found to be insufficient to provide a meaningful incentive, the review should identify measures to address the shortfall, which could include additional EU-level financial support or other mechanisms to strengthen participation and funding.

> **How will we know if this is successful:** *The model achieves sufficient and predictable aggregate funding to support a commercially meaningful reward, with manufacturers having clear visibility of participating Member States and committed funding before procurement begins.*

6. Use standardised multi-year contracts that provide commercial and operational predictability

Under the provisional legislative framework, the subscription model would operate through joint public procurement and multi-year contracts. Contract design will therefore be central to translating the model's policy objectives into a commercially and operationally workable mechanism.

Contracts should clearly define what is being purchased. In addition to the antimicrobial itself, this may include commitments relating to availability, supply assurance, and reporting. Defining these services clearly will help establish the relationship between the subscription payment and the commitments expected from manufacturers.

Contracts should also provide sufficient duration (e.g. ~5 years) and stability to support manufacturing, supply and investment planning. Core terms including payment, obligations, and timelines should be clear when manufacturers enter the process.

A standardised contracting framework across participating Member States could reduce administrative burden and minimise the risk of fragmentation. Contract should include regular review points so that terms can be adjusted where implementation issues arise, without undermining the predictability of the model. Agreements should also include processes for renewal and transition following the end of the contract period.

> **How will we know if this is successful:** *Contracts provide manufacturers with multiple years of predictable commercial and operational terms, with core requirements clear before contracting and consistently applied across participating Member States.*

7. Apply clear but flexible supply obligations that focus on outcomes rather than prescriptive operational requirements

Improving antimicrobial availability will require participating manufacturers to make credible commitments on supply. However, these commitments need to reflect substantial differences between products in manufacturing processes, shelf life, use and distribution requirements.

Supply obligations should therefore be defined upfront but sufficiently flexible to reflect product characteristics and demand uncertainty. Fixed requirements on the amount of stock to be maintained, where stock must be located or uniform delivery timelines may not be appropriate across all products or participating Member States.

The model should instead focus on the outcomes that supply arrangements are intended to achieve, including timely patient access. Manufacturers should retain flexibility over how these outcomes are delivered where different approaches such as manufacturer-held inventory, national stockholding or coordinated regional arrangements can achieve the required level of availability.

Supply expectations should also remain compatible with stewardship and appropriate use, which are a shared responsibility across manufacturers, Member States and health systems Where utilisation is intentionally low and difficult to forecast, requirements should not create unnecessary stockholding, expiry or supply-chain costs that reduce the feasibility of participation.

> **How will we know if this is successful:** *Supply arrangements deliver timely, reliable and appropriate patient access while allowing manufacturers flexibility in how availability is maintained.*

Conclusion

The proposed voluntary subscription model represents an important development in the EU's response to AMR. It creates an opportunity to ensure that patients can access effective antimicrobials while creating a more sustainable environment for antimicrobial innovation.

Realising this opportunity will depend on implementation. The model will need to provide a predictable reward that is aligned with the EU's fair share contribution, recognise differences between products, generate sufficient Member State participation and translate policy ambition into workable contracts and supply commitments. Doing so would provide a stronger foundation for antimicrobial innovation and access in Europe.

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