



Equity Based Tiered Pricing (EBTP)



EBTP not a solution on its own but part of a broader set of access proposals

Several EFPIA concrete proposals to improve patient access to innovative medicines and reduce inequalities across Europe :

- **A commitment from the industry to file pricing and reimbursement applications in all EU countries no later than 2 years after EU market authorisation**
- **The creation of a European Access Portal** where marketing authorisation holders can provide timely information regarding the timing and processing of pricing and reimbursement (P&R) applications in the various EU-27 countries, including the reasons why there is a delay in the P&R decision or why the MAH has not filed in a particular market
- **A conceptual framework for Equity-Based Tiered Pricing (EBTP)**, to ensure that ability to pay across countries is considered in the prices of innovative medicines, anchored in a principle of solidarity between countries, to reduce unavailability of new medicines and access delays
- **Novel payment and pricing models**, when used appropriately and tailored to the situation, can accelerate patient access, allowing payers to manage clinical uncertainty, budget impact and sustainability of the healthcare system, whilst providing sufficient incentives for innovation
- Contributing to achieving an **efficient system of European assessments of relative efficacy at time of launch** in the context of the implementation of the Health Technology Assessment (HTA) Regulation

Definition of EBTP

Building on Value Based Pricing (VBP), as the foundation for pricing innovative medicines (where the pricing medicines is based on the value they deliver to patients, healthcare systems and society), Equity Based Tiered Pricing (EBTP) is a framework for the pricing of medicines that takes into account a country's ability to pay with the objectives of improving patient access (defined broadly in terms of speed and availability) across Europe.

A shared conceptual framework for implementing EBTP requires a commitment from all stakeholders

1. The current proposal is for a shared framework for the application of EBTP which includes the definition of tiers and pricing principles and commitment from industry, the EU and member states in order to improve the availability of innovative medicines

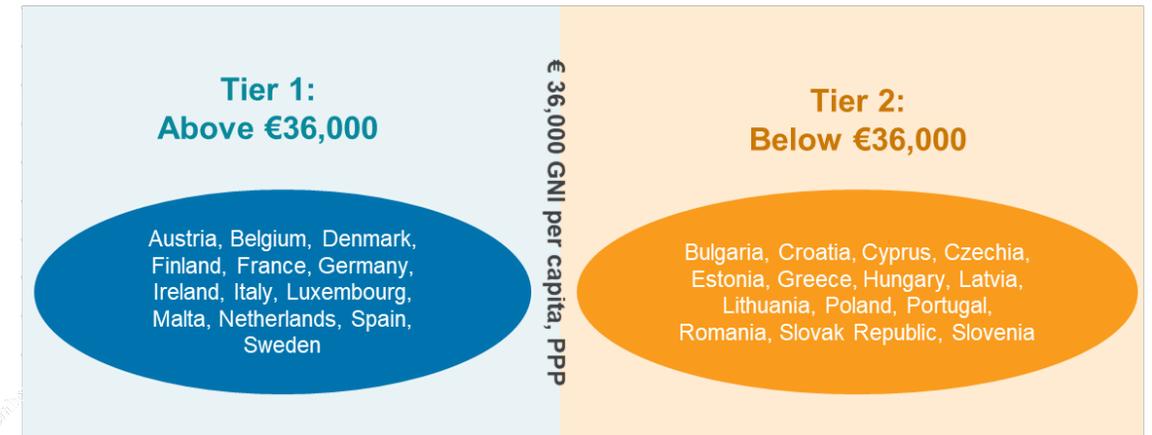
- EBTP is a framework for ensuring that prices reflect affordability and should be seen as building on the foundation of value based pricing.
- This involves a company voluntarily committing to the application of shared EBTP principles to an innovative medicine. Negotiation between companies and Member States continues to determine the price in specific markets.
- In return, there is commitment to the removal of the key barriers (including use of ERP) providing a pathway for EBTP to be applied.
- The shared framework applies to the EU (although companies may apply differential pricing beyond the EU)

A shared framework for implementing EBTP needs meaningful and credible rules

2. The shared framework needs to be meaningful and credible, affecting pricing within Europe and promoting greater access, but leave room for individual pricing agreements

- We considered a range of different tiering structure. We concluded that a simple form – two tiers based on GNI per capita – should be included in the framework.
- There should still be flexibility: companies applying EBTP can apply company specific tiering systems.
- There is an argument for price bands, but we recommend a pricing ‘rule’, such as the **launch price (defined at the net price in the first indication)** in lower tiers must be lower than the lowest price in the tiers above

An example of how tiers could be based on GNI per capita PPP



Note: Based on World Bank GNI per capita in PPP data 2019
Countries are listed in alphabetical order

The shared framework requires confidentiality and verification and a conducive policy environment

3. The resulting price must be commercially confidential

- Though the negative impact of transparency within Europe would be mitigated by changing the external reference pricing (ERP) system, confidentiality would still be necessary given the use of European prices in other parts of the world.

4. Given confidentiality, there will be questions as to the credibility of EBTP. Therefore, there needs to be a process to verify the application of EBTP

- We recommend independent auditors (separate from industry, the European Commission and payers) are used to audit a sample of products to ensure compliance.

5. For EBTP to work in practice the barriers to differential pricing in Europe need to be addressed. There is common consensus that the barrier to the use of EBTP is a lack of solidarity between countries such that any lower price negotiated in relatively less wealthy countries is used as leverage to lower prices in higher income countries

- A political commitment is needed so that Member States will demonstrate solidarity and commit to good practices in ERP and undertaking mechanisms to prevent the unintended consequences from internal trade
- This will require a commitment to accelerate the price and reimbursement process reflecting the application of EBTP

A shared EBTP framework could provide benefits to multiple stakeholders

EBTP could deliver to all stakeholders:

- **Patients:** The fundamental objective is to improve patient access to innovative medicines in less wealthy member states. Reduced delays mean patients across Europe can get faster access to life-saving medicines
- **Member States:** Public payers across all Member States can be satisfied they are getting a price that reflects both the product's value and a country's ability to pay. This means less wealthy member states will have a guarantee that they will receive lower prices relative to richer member states and their patients get access to medicines more quickly
- **European Commission and European Parliament:** Reducing access delays in less wealthy Member States is consistent with the European Commission's objective of reducing health inequalities across the EU and ensuring all member states have better access to healthcare and medicines
- **Industry:** EBTP could be a positive proposal to address unavailability and delays. Faster access ultimately means industry is able to generate revenue from their products earlier. This earlier generation of revenue in less wealthy Member States can help compensate for the lower prices provided in these markets

EBTP relies upon reciprocity of commitments among stakeholders for the EBTP framework to achieve the intended impact.