The European Federation of Pharmaceutical Industries and Associations answers to Investigate Europe

1. What would we see if we could lift the veil of confidential pricing across Europe? Are richer countries paying more than poorer countries?

There is a broad consensus that prices need to reflect the ability to pay of a country to pay for medicines.

EFPIA and its members propose a system for Europe where the countries who can afford to pay less for medicines, pay less.

This type of agreement would require solidarity among Member States to embed these 'fair principles' and prevent them from being undermined, for example, through international reference pricing or through supply diversion, where a medicine sold more cheaply in one country is immediately exported to a country with higher prices.

2. Why do most pharmaceutical companies shun calls for joint negotiations by groups of countries like Beneluxa?

The industry supports initiatives that deliver the timeliest access to medicines for patients.

This may be achieved through national processes but, in some cases, through cross-country collaborations. There are different forms of cross country collaborations with different objectives e.g. information sharing, horizon scanning, HTA, joint assessment and procurement, pricing and reimbursement negotiations, and these cross country collaborations are likely to only be applicable under particular circumstances.

EFPIA has previously assessed common areas for cross-country collaboration and provided industry perspectives for consideration. Although national approaches, in many cases, are the most effective way to improve access, there are situations where CCCs can improve access if some conditions are met:

• the collective agreement should impose neither additional market access barriers nor additional price-related measures
• collaboration on price should be confined to countries of similar economic and health-related needs
• industry participation in any Member States' collaboration on pricing, reimbursement and access-related issues should be voluntary
• any Member States' collaboration on pricing, reimbursement and access-related issues should guarantee the confidentiality of pricing and reimbursement agreements

3. What is the EFPIA position on calls for joint procurement not just for crisis situations, like Covid, but also for important categories like innovative drugs?

Joint public procurement can take different forms, including coordinated procurement by multiple contracting authorities, each conducting a separate procurement procedure, to procurement where different contracting authorities jointly conduct one procurement procedure either by acting together or by entrusting one contracting authority with the management of the procurement procedure on behalf of the other authorities. Public procurement is regulated by Directive 2014/24/EU on public procurement and, at national level, by implementing laws.

In the context of cross-country collaborations, joint public procurement is complex and does not necessarily guarantee broader and timely access for patients.

In EFPIA's opinion, the use of joint public procurement should be limited to the situation where it will ultimately improve access to patients to treatments. It should be proportionate to the needs identified by the participating Member States and limited to situations where access to medicines cannot be ensured as efficiently by other means.

4. How does EFPIA comment on the fact that a large amount of innovative drugs enter the market with insufficient or immature evidence of added benefit?

It is unclear what study or research data you are referring to, however the assertion is incorrect.

Companies need to present extensive documentation on the quality, efficacy and safety in their marketing authorisation applications to the European Medicines Agency (EMA). EMA then makes a benefit/risk assessment to decide if they should recommend the European Commission (EC) to approve the medicine or not. Only innovative products which are approved by the EC could therefore enter the market.

All medicines undergo rigorous scrutiny for both cost and clinical effectiveness before they can be authorised for use in Member States Health technology assessment (HTA) is a formal, systematic research process designed to synthesize and evaluate the existing evidence for a medical treatment or technology and includes a multi-faceted assessment of the clinical, economic, ethical, legal, and societal perspectives that may be impacted by a new technology, procedure, drug, or process.

5. What is the industry answer to worries that health budgets are stretched by the ever increasing cost of advanced therapies, including cancer therapies?

Pharmaceutical expenditure as a proportion of healthcare expenditure over time has remained either flat or reduced in most countries for two decades despite huge advances in patient care. It is fundamentally incorrect to suggest that it is cause of soaring healthcare budgets.

Innovative treatments and services that reduce demands for long-term care therefore have enormous potential value to society. Medicines should therefore be seen as a

solution to the long term sustainability of healthcare, not a subject of cost containment as they often are.

Discussions about 'affordability' should not focus on pharmaceutical spending in isolation, but according to the value that innovation generates for patients and health systems, social care and welfare system.

6. How would you comment on the fears that the German law on Medical Research, currently under discussion, could bring about higher list prices in Germany and increase prices in the rest of Europe and the world through international reference pricing?

The German law on Medical Research, currently under discussion, could bring a supplementary option in German reimbursement law ('confidential reimbursement amounts' or in German "vertrauliche Erstattungsbeträge"). However, this will not become a new general rule in Germany.

It is not expected to majorly impact payers in Germany, but may offer a slight relief (due to discounts being more likely to be negotiated confidentially than publicly – as in other parts of Europe.

7. Recent research indicates that only 16-21% of pharmaceutical industry revenues were allocated to R&D in a period of 20 years. How can industry maintain that pricing is linked to R&D?

Assessing R&D costs for individual medicines is challenging, as it fails to account for the high attrition rate in pharmaceutical R&D, where many R&D projects fail at different stages of clinical research. This approach fails to acknowledge the pharmaceutical industry's business model, which is built on portfolio investments and not on individual products.

EFPIA recognises the need to move towards value-based pricing, which relies on a greater flexibility across markets and indications, rewarding innovative treatments based on their therapeutic value, and ensuring access to innovative treatments for patients. Therefore, rather than focusing on individual medicines' costs, it is important to ensure that pricing negotiations are based on the value that each medicine brings to patients, health systems, and societies.

8. Countries in Eastern Europe access new medicines with big delays or sometimes not at all. This, in practice means that people in those countries can only access those medicines if they pay full market price. Do you find this acceptable?

We agree that it is not acceptable that some countries wait seven time longer for a new medicine than others.

EFPIA research shows that the reasons for unavailability and delays range from slow regulatory processes to delays in starting national health technology assessments. Delays can be caused by duplicative evidence requirements, delays in a new

medicine getting reimbursed and local formulary decisions from healthcare providers.

As mentioned above in Q1, there is a broad consensus that prices should be based on a country's ability to pay.

Where prices are higher than the perceived value or affordability, there is an inevitable delay as the price is negotiated. This is clearly complicated by external reference pricing this means that the agreed price needs to take into account how this price will be used outside of the country, in addition to whether it aligns with the assessment of value by the national HTA body.

Where it is possible to use flexible contracts to align price and value, this should reduce delays. However, the ability to agree novel payment mechanisms varies considerably around Europe. This is particularly the case in Central and Eastern Europe, where we observe the largest delays.

Industry is working towards reducing delays and has a raft of proposals, ranging from equity-based tier pricing (a country's ability to pay) to novel pricing mechanisms and a commitment to file for pricing and reimbursement within two years of receiving marketing authorisation from the EMA. The detail can be found here.