

## Patients and Pharma: How to achieve a balance of needs and interests

Written by: Dr Clemens Martin Auer, President, European Health Forum Gastein

The stakes, as ever, are high. And the ambition is big. When Stella Kyriakides, EU Commissioner for Health and Food Safety, finally unveils her long-awaited revision of the EU pharmaceutical legislation, she will be delivering on “the most important task in the area of health during our (the current Commission) mandate.” And she might be right in feeling this way.

It’s not just that the proposed revision of the regulations governing the pharmaceutical industry has been long (since 2016) in the gestation. Nor that current legislation is two decades old. It’s that the EU Commission wants to transform the health landscape in Europe after the worst pandemic in a century and during a [permacrisis](#) that is affecting our continent.

Ms Kyriakides and Commission President, Ursula von der Leyen, want nothing less than to match the growing unmet health needs of European citizens with fostering an “innovative and globally competitive” EU pharmaceutical industry. A crucial and complex aspiration, especially given the challenges the industry faces from America (with the Inflation Reduction Act) and Xi Jinping’s China. In this regard “No trade-offs but balance”, is how Ms Kyriakides framed it during an [event](#) jointly organised by the European Health Forum Gastein (EHFG), the Austrian Federal Ministry of Social Affairs, Health, Care and Consumer Protection, and the Permanent Representation of Austria to the European Union, in Brussels in March.

What emerged from our high-level discussion, is that avoiding trade-offs and achieving “[perfect harmony](#)” will be impossible. But a key takeaway is that EU policymakers see patients, their needs and interests, at the heart of this legislation and of the EU’s Health Union.

Industry representatives are already expressing significant concerns about the revised legislation.

Two days after our event, Nathalie Moll, EFPIA Director General, [commented](#) on a leak of the draft legislation and pointed to the “significant gap between the rhetoric and the reality” on EU competitiveness. She said that of much concern is the fact that “no attempt has been made to assess and quantify the impact that the loss of competitiveness will have on access to the latest treatments, jobs, R&D investment, academia, manufacturing and growth across Europe.”

Affordability, Accessibility, Availability. These are the three A's the speakers at the event focused on, emphasising how this trio of critical issues came to the fore for Europe's half a billion citizens during the COVID-19 pandemic and how they gain even more weight in today's world of high inflation, shortages/rationing and, maybe, recession.

This was well encapsulated by Karla van Rooijen from the Ministry of Health in the Netherlands, who urged improved access to generics and biosimilars by addressing pricing issues, promoting greater competition, and opting for joint public-private R&D funding mechanisms.

I believe that the true measure of this new EU pharmaceutical legislation is whether it really deals with the critical question of affordability – that is, fair prices for Europe's citizens whoever and wherever they are.

However, even in our assessment, we have to be honest: getting the pricing mechanism right is tough, and always will be. It may well be that we have driven the price of generic medicines – which supply 75% of our needs – too low. Similarly, it's clear that the price of antibiotics has been so low it has militated against R&D for new ones in a world, including Europe, fearing a wave of antimicrobial resistance (AMR)-related deaths on an undreamt-of scale.

It seems to me that one key lesson from our pandemic experience is the greater need for public-private partnerships to correct market failures – as much as we possibly can – and promote innovation via R&D. This proved successful in the discovery and development of highly effective, safe, and (here in Europe) generally available vaccines to combat COVID-19. As Malta's Minister for Health, Christopher Fearn, told us: [joint procurement](#) should be extended to other products such as OMPs, oncology treatments and other high-price medicines. Moreover, nowhere are more radical approaches needed than in the search for those missing new antibiotics.

### **Tough ask**

What's already clear, however, is that the EU Commission's carrot-and-stick approach to incentivising the pharmaceutical industry and boosting its competitiveness is being met with scepticism. The European Commission wants to offer pull mechanisms such as transferrable exclusivity vouchers (TEVs) that would prolong IP protections in exchange for fair (lower) prices for novel antibiotics. Several participants at our conference considered this solution as a non-runner – as do some [academics](#).

Similarly, the Commission's idea of penalising companies that fail to launch new products in all 27 member states within two years is not perceived as a recipe for boosting industry competitiveness, however well-intentioned the patient-centric concept behind it. However, we are all in agreement that more equitable and faster access to treatments are needed. So how should we best achieve this?

### **What the future holds**

Even if not yet published, the revision of the EU pharmaceutical legislation is already prompting hope and enthusiasm but also fear and some loathing. It's bound to trigger animated discussions among the co-legislators in the European Parliament and the Council of Ministers as well civil society and industry. There is unanimity on the end goal: faster and better patient access for medicines to meet Unmet Need. The "devil" will be in the detailed negotiations about how this is best achieved.