Improve and Accelerate Equitable Access to Innovative Therapies

Since the 1990s, the pharmaceutical industry has brought over 1,100 new medicines to patients in Europe.[1] However, major variations in health outcomes remain evident across Europe. For instance, people born today in Sweden can expect to live in good health about 20 years longer than people in Latvia.[2] Among the contributing factors to this discrepancy is the wide variation in access to innovative medicines.

Healthcare systems in Europe are facing affordability challenges both from aging populations and rising healthcare demand, and the COVID-19 pandemic has exacerbated these challenges. Regulatory flexibility and improved market access conditions are needed to ensure that breakthrough innovations such as gene therapies and specialty medicines are appropriately incentivised and reach the patients who need them.

Today's innovative medicines are tomorrow's generics and biosimilars. This is why we already have lower-cost options for treating many common conditions. With over 7,000 medicines in development today, an exciting new wave of innovation can continue to change the lives of European patients.[3]

However, we need to collectively address the complex and multi-faceted barriers which may delay or even prevent access to innovative treatments, impacting the ability of biopharma companies to invest in future breakthrough therapies.

The impact of country variations in evaluating innovative medicines and treatments

Even after being approved by the European Medicines Agency (EMA), innovative therapies are individually evaluated by each country in relation to several aspects, including cost effectiveness, price and, ultimately, coverage and reimbursement. These processes, which include Health Technology Assessments (HTA), can undercut innovation and delay, or even impair, patient access to breakthroughs. Average time to patient access to treatments across EU and European Economic Area (EEA) countries continues to be as long as 504 days after EMA approval, ranging from 127 days in Germany to over 823 days in Poland.[4,5] We support the draft Regulation on EU-level collaboration on HTA as originally proposed by the European Commission in 2019, focused on joint clinical assessments and aiming to reduce duplicative processes and data requirements to accelerate patient access. We however regret that the latest positions from the Council seem to have steered away from the initial intent of the legislation.

An important EFPIA 2020 report sheds light on other key root causes of unavailability and delay of access to innovative medicines in more detail. We believe it is time for a multi-stakeholder discussion around these root causes and support the EU Health Coalition's call for the establishment of a High Level Forum on Better Access to Health Innovation. Holistic approaches to European HTA processes that appropriately value medicines, more timely reimbursement decisions as well as a broader approach to health spend beyond just medicines can help address affordability challenges by rewarding those technologies that deliver the most value to patients, health systems and society.

1 EFPIA. Analysis of Evaluate Pharma database.

2 European Commission. Number of healthy years of life: countries compared." Eurostat.

3 EFPIA. Health Advances analysis; Adis R&D Insight Database.

4 EFPIA. Time to act together: patients wait more than 6 times longer for access to new medicines in neighboring European countries.

5 PhRMA. "The United States vs. Other Countries: Availability of Cancer Medicines Varies."

Lessons from COVID-19

The COVID-19 pandemic illustrated the need for regulatory flexibility to advance innovation and bring valuable treatments to patients as quickly as possible, without compromising on their quality and safety. The pandemic has also highlighted the critical need to support science and innovative new treatments for patients in need.

Policy Recommendations

1. Governments should partner with industry to implement novel payment and financing models for high-value, transformative medicines such as oncology and gene therapies, but also novel anti-infectives tackling resistant bacteria.

2. Support the move to value-based care to bring greater quality and efficiency to the health care system which benefits everyone - patients, insurers, governments, and society.

3. Adopt value-based, patient-centric HTA processes that reduce duplication across Europe, incentivise innovation and recognise the region's shared responsibility to value and investment in health.

4. Urgently establish a High-Level Forum on Better Access to Health Innovation, to allow for an inclusive, multi-stakeholder discussion to identify and address the root causes of unavailability and access delays.