All Together. No One Left Behind.

Delays and the unavailability of medicines harm patients.

There is a common agreement that the value of innovation is only realized when patients benefit from advances in treatment. Everyone involved in healthcare – from patients to service providers, researchers, clinicians, pharmaceutical companies and policy makers – wants patients across Europe get more equitable access to new treatment options.

Today, the time it takes for Patients getting access to treatments and innovative medicines they need, can be up to 7 times longer from one member state to another. We share the concerns about these delays and the concern that delays could worsen as we consider the consequences of COVID-19.

The medicines appraisal systems and processes in EU member states and their impact on commercial decision-making, are only part of the root causes of unavailability. More interrelated factors explain unavailability and delays. They range from a slow regulatory process, late initiation of market access applications, reimbursement delays due to inefficient processes and duplicative evidence requirements, and finally, a slow uptake of innovation due to local formulary decisions and endorsement by clinicians. As the root causes are multifactorial, they can only be solved if different stakeholders are willing to work together towards a significant change. The industry shares the view that these root causes must be addressed through collaborative work with Member States, the European Commission, European Parliament, Patients and other stakeholders, on proposals to improve availability and reduce delays.

We call on the Commission to create a Multi-Stakeholder: *High-Level Forum on Better Access to Health Innovation* as proposed by the European Health Coalition, to develop concrete solutions for the introduction of new technologies into health systems in a way that is sustainable, widely available and accessible to European citizens.

A High-Level Forum would enable a comprehensive discussion and analysis of the root causes of unequal patient access and supply of medicines, also taking into consideration the fragmentation of the EU single market and the different national approaches to pricing and reimbursement as well as healthcare investment and organisation.
This analysis will show that an effective, targeted response to the access and availability challenges does not lie in a reduction of incentives for innovation or in wholesale changes to the pharmaceutical legislation but rather requires a structured and inclusive dialogue among all relevant stakeholders.

WE STAND FOR:

1. **Health Industries, have a role in EU economic recovery post COVID-19;**
2. **Faster Access, Secure Affordability is possible;**
3. **Enablers to Innovation and Unmet Needs.**

1. Health Industries', a role in EU recovery post COVID-19

Investing in Health is essential for the Economic recovery of the EU post COVID19. Pharma and other healthcare industries are an essential pillar of that recovery. A leading role for the EU in R&D requires sustained incentives and IP protection to deliver on its mission.

Europeans are aware of the importance of Health, Innovation and the Pharmaceutical Industry; Europe can take the lead in developing and supplying innovative technologies, while overcoming the challenge of sustainability in Health. We also see innovation as a key long-term driver for economic growth, and the COVID-19 pandemic has shown how critical a well-functioning R&D ecosystem is.

R&D and innovation are core pillars for Europe's global competitiveness, having China and the US as their main competitors. Research delivers value to the EU economy and to patients and actions must be taken to attract more investment and protect what is done in Europe.

Supporting innovation through a stable incentive framework is key to keep the pace of R&D in Europe and making us competitive and a key contributor to the economy.

The innovative pharmaceutical industry is a key strategic sector for the European economy, driving medical progress by researching and developing new medicines and treatments. Europe is the second largest pharmaceutical market in the world and accounts for 22,2% of world pharmaceutical sales. The EU pharmaceutical sector is considered to be the high-tech sector contributing the most to the EU trade balance with a trade surplus of €70,9 billion, and which sustains around 750,000 jobs throughout Europe.

Pharmaceutical intellectual property, incentives and rewards are the foundation on which pharmaceutical innovation is built. Europe has a role to play by encouraging and protecting innovation, driving research and development investments into areas of unmet medical need.

IP underpins the ability to invest in the long, complex, risky and costly process of delivering new medicines to patients, to healthcare systems and to society, given the central and increasingly important role of IP in Europe's economy as well as its ability to enhancing the EU's resilience to global health threats and address ongoing health challenges. **We expected to see a stronger focus on supporting innovation and IP in the EU. We are glad to see the recognition that trade will continue to evolve in a more innovation-driven way, supported by IP protection**.

2. Faster Access, Securing Affordability

European patients still do not have equitable access to the medical innovations and treatments they need. Different country views on evidence requirements, value assessments and financing decisions markedly affect the time that innovation takes to reach each member state. Additional challenges also affect how effectively patients get access to financed treatments. In order to promote sustainable access to innovative treatments, all stakeholders need to come together and work on solutions to keep the EU as an innovation powerhouse.

Patient access to new medicines is highly varied across Europe, with the greatest rate of availability in Northern and Western European countries and lowest in Southern and Eastern European countries.

The average delay between market authorization and patient access can vary by a factor greater than 7-fold across Europe, with patients in Northern /Western Europe accessing new products 100 - 350 days after market authorization and patients mainly in Southern/ Eastern Europe between 600-850 days. This means unacceptable inequity for patients: after innovative medicines have been proven safe and effective, patients in some Member States have to wait longer than two years for a decision on pricing and reimbursement conditions, while in other Member States the average waiting time is in the range of three months.

We need to reduce delay time to improve patients' access and find solutions to harmonize this assessment period ensuring equity in access to innovation in the European space.

This is also a unique opportunity for greater alignment in Europe on clinical evidence generation requirements, ensuring consistency, transparency and synergies in clinical assessments by Member States and evidence that is relevant for Europe.

Heath Technology Assessment convergence

The benefit of the proposed European joint clinical assessment is that it allows scientific convergence in the overall HTA process, thus replacing a multitude of national and regional clinical assessments. It avoids fragmentation of the internal market and access distortions, duplication of work and patient access delays. It is key that safeguards included in the Commission proposal ensure that this joint clinical assessment is used at national level guaranteeing that there is no duplication at Member State level.

However, there is still the risk that this goal is not achieved as Member States seek to preserve and impose additional requirements and specificities in their own national clinical assessments on top of the joint European process. It is key that the European Parliament raises the European ambition in the HTA Regulation and fights for clear simplification. If duplication and national gold plating of the centralized clinical assessment are not avoided, the Regulation risks imposing an additional layer of assessment on the 27 national processes in place. The current proposal does not impose any decisions upon Member States regarding medicines financing or how to best allocate healthcare resources. This continues to be fully up to each Member State to determine.

- For patients, the availability of one common joint clinical assessment at the time of marketing authorization will expedite patient access to new medicines.
- For national healthcare systems, it would mean avoiding duplicative efforts on clinical assessments, leading to better decisions regarding human and financial resources, while also helping Member States to benefit from each other's expertise.
- For companies, the proposal would move towards more predictable evidence generation requirements at the development stage.

It is now possible to reconcile innovation and sustainability through targeted interventions leveraging data, AI and Innovative models.

Along with many stakeholders in healthcare, we believe that an outcomes-focused, or value-focused approach to healthcare and particularly medicines holds the key to a more sustainable, healthier future for Europe.

The principle behind outcomes-focused healthcare is that health systems should evolve to delivering the most cost-effective health-outcomes to patients, rather than on delivering interventions. Focusing on outcomes prioritizes what actually matters: better health for patients.

Instead of paying for hospital beds, visits to the doctor, pills, screenings and surgical interventions, our focus should be paying for better health and longer lives. By eliminating spending on ineffective interventions, a focus on outcomes can free up the resources required to address the healthcare needs of an ageing population and fund those innovations that deliver positive results for patients and value for systems.

This transition will take both time and investment, and most of all political will. Member States need to invest in integrated health information infrastructures and systems for tracking health outcomes – with disease registries and Electronic Health Records as key components – and standardize outcomes metrics that will make it possible to compare health outcomes across providers, regions and even countries. Patient involvement is key when agreeing on these outcomes metrics.

3. Enablers to Innovation and Unmet Needs

Over the coming years, a stream of innovation is coming to address many unmet needs. In order to meet such innovative pipeline, including some paradigm-shifting treatments, and to keep Europe's leading position as a R&D powerhouse we must substantially reduce attrition through clear advances in regulatory science and greater convergence on technology assessment. However, in order to reap real world benefits for patients, we must also collaborate to ensure that innovative technologies reaching the market get faster medical adoption and patient adherence.

The unprecedented speed of innovation exhibited over the last five years and the promise of the industry pipeline provides an important opportunity to improve outcomes for patients. There is common agreement that the value of innovation is only realized when patients benefit from advances in treatment.

Preserving the incentives contained in the Orphan Regulation is central to the EU's strategy of promoting innovation that meets the needs of patients suffering from rare diseases. Conditions to incentivize research and development in areas of unmet medical need such as of Orphan and Paediatric as well precision medicines can be properly addressed in the framework of an EU Multi-stakeholder High - Level Forum for Better Access to Health Innovation. Given the limited number of patients that can be included in studies, developing medicines for rare and paediatric diseases must be a global collaboration exercise.

We stand ready to increase the level of partnership and collaboration with the wider research community and across other life sciences sectors through programs like the Innovative Medicines Initiative (IMI).

CONCLUSION

It is clear that the reasons behind the unavailability of medicine and delays are multifactorial. It is also clear that there is a shared aspiration to "make sure that patients across Europe have new medicines and therapies in their countries quickly". The need for a dialogue on how to improve availability and reduce delays is clear.

To bring different stakeholders together in a **High-Level Multi-Stakeholder Forum on Better Access to Health Innovation**, will be a vehicle to co-create:

- Proposals to speed up the regulatory process, delivering safe and high-quality diagnostics, vaccines and treatments to patients as fast as possible
- Proposals that aim to increase transparency of information regarding placing on the market of centrally approved products
- Proposals to facilitate a process that allows prices to align with value
- Proposals to improve the efficiency and quality of value assessment
- Proposals to ensure equity of access and solidarity across EU member states

We are ready to work together to ensure that access to medicines is based on the patient's clinical need, not on their "postcode" (political and financial criteria).