WHAT PHARMA COMPANIES NEED TO KNOW ABOUT THE EUROPEAN UNION'S NEW PHARMACEUTICAL STRATEGY FOR EUROPE

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For the first time, the European Union is undergoing a holistic rethink of the framework within which its pharmaceutical industry operates its pharmaceutical industry with the new Pharmaceutical Strategy for Europe, which was launched in late 2020.

The European Union has realised that change is required within its infrastructure to build a holistic, patient-centered, forward-looking EU strategy that covers the whole life cycle of pharmaceutical products, from scientific discovery to authorisation and patient access.

With a focus on ensuring patient access, treatment affordability and sustainable innovation, this progressive, patient-centric plan will require pharmaceutical companies to begin re-aligning drug research and development (R&D) and consider their commercialisation strategies with their R&D plans, starting now.

The European Commission outlines four key areas in which they will take a series of legislative and non-legislative actions over the next five years:

1. Delivering for patients: fulfilling unmet medical needs and ensuring accessibility and affordability of medicines
2. Supporting a competitive and innovative European pharmaceutical industry
3. Enhancing resilience: a diversified and secure supply chain, environmentally sustainable pharmaceuticals, crisis preparedness and response mechanisms
4. Ensuring a strong EU voice in the pharmaceutical industry globally

A mix of policy levers can support this goal (minimising waste and optimising the value of spending on medicines), including ensuring value for money through health technology assessment, exploiting potential savings from generics and biosimilars, encouraging responsible prescribing and improving patient adherence.

Irrespective of domicile, many changes are on the way for pharmaceutical companies wishing to commercialise in Europe, and this will reshape how all companies will operate in Europe and will create a significant focus on which products the EU will prioritize for rapid commercialisation. The EU is also looking to ensure that innovative medicines are made available rapidly for all its citizens. The Pharmaceutical Strategy aims to ensure that the EU can harness new technologies more rapidly and, in particular, that patients with unmet medical needs have access to advanced therapies in a way that benefits them but does not introduce undue burden to national health services.

THIS PAPER AIMS TO:

1. Review some of the key elements of the plan, particularly with respect to the first two initiatives of the proposed strategy: Make drugs cheaper and more accessible to all EU citizens (especially those that qualify as unmet needs), and the EU will respond by making the process of commercialisation simpler and more profitable.
2. Look at what biopharmaceutical companies need to do to prepare for the initiatives. In particular, it examines:
   - Implementing HTA data requirements into clinical trial designs.
   - Balancing costs while providing equal patient access to treatments.
   - Navigating digital expansion and adopting data strategies and new technologies.
   - How to adapt and next steps for pharma.

Changes to Come

> **We cannot wait for the end of the pandemic to repair and prepare for the future. We will build the foundations of a stronger European Health Union in which 27 countries work together to detect, prepare and respond collectively.**
>
> —Ursula von der Leyen, *President of the European Commission, at the World Health Summit*

In her 2020 State of the Union address, Ursula von der Leyen, President of the European Commission, called on Europe to draw lessons from the current COVID-19 crisis to build a European Health Union. With this union, the EU can be equipped to prevent, prepare for and manage health crises both at the EU and global level, with all the societal and economic benefits that it would bring.

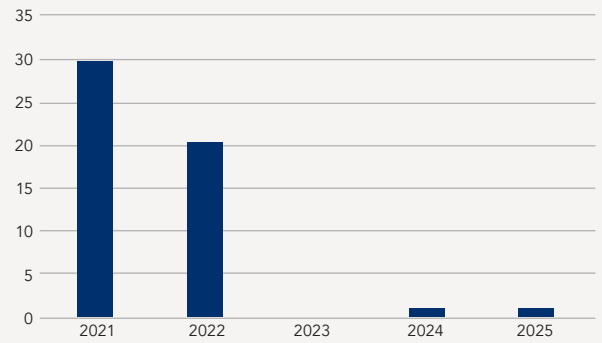
The Pharmaceutical Strategy for Europe aims to be a core part of that objective by addressing these key initiatives:

- **Anti-microbial Resistance**
- **Affordability**
- **Regulatory Efficiency**
- **Innovation**
- **Unmet Needs**
- **Competitiveness**
- **Access to Medicines**
- **International Cooperation**

As part of the European Health Union, the European Commission's overall goal is to improve treatment access for all citizens whilst minimising impact on financial and fiscal sustainability of member states' health systems. In particular, the Commission wants to improve access to innovative medicines and address specific unmet needs that may be unique to the region. The strategy's changes are quickly moving into implementation, with 30 initiatives beginning this year. For patients, the strategy promises to deliver best-in-class treatment access across Europe. But how will the incoming changes affect the top line, bottom line and pipeline for pharmaceutical companies? With increased standardisation and competition and a push for faster-to-market access across all EU countries, companies will see ripple effects throughout the product development and commercialisation life cycle.

If pharmaceutical companies are going to remain globally relevant and competitive, they must take a hard look at their product development and commercialisation strategies – particularly related to clinical trials, pricing, digital technologies and therapeutics.

Number of flagship initiatives or actions by year



Implementing HTA Data Requirements Into Clinical Trial Designs

For the European Union, the pandemic was a wake-up call to the inefficiency of traditional drug development methods and standards. Now, the European Commission is working to optimise clinical development (especially in areas of unmet needs) to ensure enhanced efficiency and efficacy in product development, which could lead to a faster launch.

The EU has addressed many sources of delay in clinical development and commercialisation – for example, different health technology assessment (HTA) organisation requirements (long since a source of highly variable launch timelines across the EU) in member states have led to delays in approval and variable access to medicines across the Union. Whilst at present, the strategy does not go so far as to propose a single HTA authority in Europe, it overtly wants to "break silos so that various public

authorities responsible for authorisation, health technology assessment, healthcare provision, health insurance and financing work together."

The realities of COVID-19 and the presence of new technologies, such as artificial intelligence (AI), have created an urgency to go a step further in pharmacovigilance by implementing health technology assessment data requirements into clinical trial designs. This will be particularly true of companies developing products in areas of unmet patient needs. The EU, in looking at areas such as oncology, neurodegenerative disorders and microbial resistance, is really seeking to drive down development and commercialisation timelines through this initiative in particular. The Commission will also look at incentivising the development of these products – in particular through their PRIME (priority medicines)[1] initiative.

Meeting this standard will require integration of advanced, intuitive technologies into the clinical trial process. Pharma companies will need to acquire digital solutions with artificial intelligence and machine learning (ML) capabilities to understand patient needs earlier in drug development, which ultimately will lead to improved patient outcomes.

In addition to improving efficacy, HTAs will support product legitimisation and authorisation with real-world data (RWD). Improving data generation and HTAs will result in evidence-based investment decisions and add clinical value to products before ever being distributed to patients and providers. If pharma companies neglect to adapt to this significant change in clinical trials, they will be left behind the EU health technology revolution and risk their position in the global market.

Additionally, the Commission is going to promote the use of more patient-centred study designs. It will encourage more representative participation of population groups (e.g., specific gender and age groups) as well as looking at "pragmatic trials" based on more real-world prescription and utilisation.

Balancing Costs Whilst Providing Equal Patient Access

After receiving product approval, the next challenge pharma companies will face is expediting commercialisation and distribution to patients across all of the EU, inevitably increasing company costs. The European Union is becoming increasingly concerned that biopharma companies are choosing to market in a select few countries within the continent. Whilst there is a recognition that this can be due to national pricing concerns, population size, health system organisation or national administrative systems, the EU is planning to review the root causes of this. It is specifically looking at costs of R&D and how those are applied to return on investment and, ultimately, pricing. As a result, the commission will consider certain incentives to ensure that products (particularly those that meet the definition of unmet needs) are made available in all EU countries. However, the Commission is also recommending that the application of broader development incentives is predicated on ensuring EU-wide access to new drugs.

Combined, all 27 member countries in the EU make up the second largest and, arguably, most diverse pharmaceutical market in the world. To achieve equal patient access, manufacturers must establish sales teams with the resources to connect with patients and providers from diverse cultures and backgrounds. Sales teams will need to be equipped with multilingual staff and have digital tools to provide personalised support to all patients.

> **Manage the approach from a pricing standpoint, and think about the new world that we're in. Companies must have robust global price governance. Managing prices on a regional basis is an outmoded way of doing business.**
>
> —Alan Crowther, *General Manager, Global Pricing, Access and Digital Solutions*

But as costs trend upward to meet diverse patient needs, product prices will be standardised to ensure treatment affordability. Manufacturers will fall under increased pressure to prove real-life effectiveness and related over-costs of medicines. As companies look to restructure or add to patient service models, they'll need to be mindful of cost-effective solutions to avoid significantly increasing product pricing and cutting too deep into their bottom line.

More than 50% of households in the EU report that the cost of medicines represents a financial burden.[2] In addition to encouraging competition, the strategy supports collaboration between national authorities to improve treatment access and affordability. In the new EU pharmaceutical landscape, manufacturers will need to be aware of competitor prices as well as their own if they hope to have any success in delivering their product to patients.

At the heart of the EU's proposed strategy is "ensuring affordability of medicines for patients and health systems' financial and fiscal sustainability." In particular, it is looking at "niche-busters," i.e., high-cost, low-volume treatments. The EU is aiming to enforce much greater transparency on pricing to allow all member states to "make better

pricing and reimbursement" decisions. It is also encouraging regional initiatives to encourage smaller member states to work collaboratively in joint negotiations or tendering processes – such as the Beneluxa initiative.[3]

The nature of healthcare provision in the EU is that all member states operate a state-controlled healthcare system. As a result, there is significant focus on cost of healthcare and, in particular, the cost of pharmaceuticals. It is reported in the EU Pharmaceutical Strategy document that "pharmaceutical budgets account for 20-30% of hospital expenditures and are growing faster than retail spending."[4]

Digital Expansion in Data and Technologies

Among the strategy's changes, the Commission is rolling out digital technologies that will standardise data access across member countries while improving access to digital therapeutics.

There are currently more than 7,000 people in the EU living with rare diseases, including cancer and paediatric cancer, and 95% of those patients have no treatment options available. Digital solutions are being further explored to treat rare and complex diseases due to the ease of distribution and cost effectiveness for patients.

Often, digital health and therapy systems rely on artificial intelligence for prevention, diagnosis, treatment improvements, therapeutic monitoring and personalised outreach. To leverage digital therapeutics in the rare and complex community, as well as for all patients, the EU must first focus on mass digital expansion on all healthcare levels – from manufacturers to providers to patients.

Pharma companies must begin expanding their own digital capabilities by gaining secure and efficient access to patient health data. RWD will not only add clinical value to products, but manufacturers will be able to optimise patient outcomes and better support individualised patient adherence as well.

The commission also recognises that in order to develop better medicines more effectively, biopharma companies need "access to health data." It is proposing the establishment of a transnational "interlinked system that gives access to comparable and interoperable health data from across the EU [and] would be a real multiplier in terms of research, regulation and evidence generation." This has long been a key disadvantage when comparing both clinical and commercialisation strategies in Europe. By enabling access to a database such as that proposed, the European Union believes that there will be considerably greater access to RWD, thereby offering biopharma companies and regulators faster pathways to commercialisation and beyond.

In a further application of digital technology, the Commission proposed that "better use of product information in electronic format (ePI) could facilitate the delivery of information on the medicine to healthcare professionals and patients in the EU's multilingual environment." Furthermore, they believe that this will reduce the burden of production and logistics management and consequently ease access to medicines across member states.

Next Steps for Pharma

> **Just because you've launched, it doesn't mean you can relax. You always need to have your ear to the ground globally as to what's going on."**
>
> —Ed Corbett, *Senior Principal, Head of EMEA, EVERSANA CONSULTING*

Shifts in global healthcare, including the strategy and other governance changes, are causing launches to become flatter, faster and riskier. Pharma companies must prepare for chaotic adjustments during global launches as timelines become compressed and interactions between global regions accelerate. Launch sequencing can be further complicated by partnership agreements in which local companies seek to maximise returns that could have a profound impact across the globe.

As companies evaluate product launches to align with global markets, they must take these next steps for future commercialisation success into consideration:

- Proactively monitor and react to the external environment.
- Flatten launch price corridors.
- Prepare the net price corridor to assume transparency and consistency.
- Simulate visible net price impacts.
- Develop strong distribution agreements.
- Establish and maintain robust global price governance.

While most companies put forth maximum effort and resources into launch, they tend to lose momentum

once their product is in market; but that's when the real work begins. In a global market that is ever-changing, companies must bring their "A" game at every phase of commercialisation.

Adapting Starts Now

The Pharmaceutical Strategy aims to ensure the delivery of affordable, safe and effective medicines to 447.7 million people across the EU. If pharma companies begin shifting to proven, tech-supported product development and commercialisation strategies now, they have a greater chance to reach patients on a global scale.

As new therapies are explored, tested and marketed, companies must explore business models that fit the needs of the strategy and break down traditional industry silos. By embracing digital health tools and patient service models that provide personalised patient support, pharma companies have a new opportunity to work hand-in-hand with the Commission to transform healthcare in the EU.

EU SUCCESS FACTORS

*Changes to EU regulations concerning market access may determine which markets companies enter.

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