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ADAPTING TO CHANGE:

Examining the Implications of New EU Regulations on Commercialisation from the Perspectives of Patients, Providers, and Pharma Companies

In April, the European Federation of Pharmaceutical Industries and Associations' (EFPIA) 2022 Patient W.A.I.T Indicator found that the average rate of availability for pharmaceuticals in Europe is 45%, down 2% on the previous year. Additionally, the access gap between the highest and lowest country was found to be 83% in the 4-year cohort, and 80% for longer timelines, with an average of 517 days from centralised approval for a new medicine to be available in a European market.

The root cause of delay in availability can be attributed to many things, but it is primarily caused by variance in assessment for pricing and reimbursement by national Health Technology Assessment (HTA) bodies and in some cases, an inability of national healthcare systems to accommodate or afford new therapies.

U.S. vs. Europe

At present, the U.S. is seen as a much more attractive market in which to commercialise. Despite having a lower population than the EU at 330 million compared to 500 million, annual pharma sales are in excess of USD 450 billion, whereas the more populous EU accounts are just more than USD 190 billion. The U.S. also offers a relatively consolidated distribution network and holds the potential for annual drug price increases after launch, whereas price increases post-launch are rare in Europe.

Both regulatory timelines and launch prices are considered to be better in the U.S.; Europe is often seen as "too fragmented" and "laborious," with "challenging infrastructure." Not only is it more difficult to navigate, but it's ultimately less lucrative for manufacturers. However, recent cost-containment developments in the U.S. such as the Inflation Reduction Act (IRA) are changing the global landscape dramatically.

Europe is Changing

Across the pond, European policies are also rapidly changing with the ongoing implementation of the EU joint health technology assessment regulation (HTAR) and the finalisation of the pharma legislation review, which promises to support "innovation, access and affordability."

The European Commission wants to move away from the "EU4+UK" model and "make innovative medicines available to all EU citizens" by reducing administration and speeding up authorisation of

innovative medicines. Europe also wants to lessen its dependence on foreign markets for access to healthcare supplies, as part of an overall goal to try and address the rising cost of medicines.

The reform will move the current system away from its "one-size-fits-all" regulatory protection towards a "more effective incentives framework." Essentially, the current exclusivity period will be cut from 10 years to eight. Many industry voices have pushed back against this proposal, worrying that the shortened timeframe could stifle innovation in Europe.

The eight-year limit, according to the Commission's document, can be extended in the following cases: If medicines are launched in all Member States, if they address unmet medical needs, if comparative clinical trials are conducted, or if a new therapeutic indication is developed.

There is also widespread concern that launching in all 27 Member States in two years is unfeasible, and could be "burdensome," particularly for smaller countries and small to medium enterprises (SMEs), such as smaller biotechs.

HTA in Europe

A new joint EU HTA regulation is set to begin on January 1, 2025, initially assessing oncology medicines and advanced therapeutic medicinal products (ATMPs). The new regulation will implement Joint Scientific Consultations (JSC) and Joint Clinical Assessments (JCA) across countries, but individual markets will still make the final appraisal and reimbursement decision.

Despite the good intention of joint EU HTA, there are inevitably several questions that arise about the actual implementation. Centralising pricing and reimbursement decisions has the potential to use resources more efficiently, reduce the time span of assessments and ultimately strengthen the quality of HTA throughout Europe by mitigating duplicate efforts. However, there are several measures that industry need to carefully consider ahead of 2025. Under the HTAR, a report must be submitted 1.5 months prior to the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) opinion, requiring the manufacturer to submit the dossier "at risk" without a final indication.

On top of this, each country has different standards of care (SoC) and treatment pathways that would be difficult to navigate in a single streamlined process, and processes may not be fit for purposes outside regular assessment pathways, for products such as ATMPs and orphan drugs.

There are also grey areas; the law text states that Member States must "give due consideration" to the assessment, but there is no indication that it is legally binding, which has the potential to lead to divergences.

What Does this Mean for Me?

When navigating Europe and its substantial recent policy changes, companies need to take precautionary steps beginning at the pre-clinical stage, all the way through to market access.

At the preclinical stage, you need to anticipate the likely period of exclusivity your product will be granted based on its ability to meet the Commission's high unmet medical needs (HUMN) criteria, or multiple therapeutic targets, or whether it would benefit from the antimicrobial incentives.

Additionally, what does the environment currently look like for your product? Are there biosimilars and generics available? It is also essential to look ahead and determine how your product will be reimbursed in key markets.

During the clinical stages, companies need to be getting multiple regulatory opinions on matters beyond the regulatory stage, such as government policy matters, whilst being cognizant of collecting data for payors as well as regulators.

Involving patient advocacy groups as early as possible will increase your chances of adoption post regulatory stages, as well as thinking about

the "technology halo" around your product. How can technology help reduce the burden on patients, healthcare professionals (HCPs) and healthcare systems?

When a product reaches the commercialisation stage, companies need to think about enhancing the chances of ensuring successful financing. Considerations include potentially preparing the market outside the clinical trial community for the product, while thinking about ways to maximise both chances of reimbursement and time to patient access.

Ultimately, you need to determine whether it is beneficial to self-commercialise. Are large and mid-size pharmas the best way to get your product to all patients?

EVERSANA is Here to Help

Taking all the changes into consideration, companies need to look at the EU market differently. Most importantly, Europe needs to be looked at through a more holistic lens. The opportunity to access all European Union patients is significant, but failure to address it will result in likely reduced periods of exclusivity. Whilst both legislations, the joint EU HTA and the Legislation Review still have a number of hurdles to clear, directionally the EU wants to rectify the pharmaceutical market in a very significant way that should be navigated with the right preparation and business choices.

> The primarily root cause of delay in availability would be variance in assessment for pricing and reimbursement by national Health Technology Assessment (HTA) bodies and in some cases, an inability of national healthcare systems to accommodate or afford new therapies.