Drug Approval Delays: 931 Days and Counting for European Patients

Written by The Life Science Feed Editorial Team · Published 17 July 2026 · Edited by Mara Voss

> The promise of a new medicine, often heralded by a positive Phase III trial, frequently meets the reality of bureaucratic inertia. For patients in Europe, that reality translates into an average 931-day delay in accessing novel therapies compared to their counterparts in the United States. This protracted timeline is not merely an administrative footnote; it represents lost opportunities for improved health, prolonged suffering, and, in some cases, preventable mortality.

KEY TAKEAWAYS

- The Pivot: European patients face nearly three-year delays in accessing new drugs compared to US patients.
- The Data: The median time from EMA submission to patient access in Europe is 931 days, contrasting sharply with the FDA's 300-day average.
- The Action: Clinicians must advocate for policy changes to streamline regulatory and reimbursement processes, understanding the profound impact on patient care.

When a new drug demonstrates efficacy in a pivotal trial, the immediate focus shifts to regulatory approval. In the United States, the Food and Drug Administration (FDA) typically processes applications within 10 months for standard reviews and 6 months for priority reviews. The median time from FDA approval to patient access in the US hovers around 300 days. This relatively swift pathway allows clinicians to integrate new treatments into practice, offering patients options that were previously unavailable.1

But the European landscape presents a stark contrast. The European Medicines Agency (EMA) conducts its scientific assessment, which, while rigorous, is only the first hurdle. Following a positive EMA opinion, each of the 27 European Union member states, plus Norway, Iceland, and Liechtenstein, must then undertake its own national pricing and reimbursement negotiations. This decentralised, often opaque, and invariably lengthy process is the primary driver of the 931-day median delay.2

The numbers behind the wait

The average time from EMA marketing authorisation application (MAA) submission to patient access in Europe is 931 days. This figure encompasses the EMA’s scientific review, the European Commission’s decision, and the subsequent national pricing and reimbursement negotiations. By comparison, the median time from FDA approval to patient access in the US is approximately 300 days. This disparity means European patients wait, on average, more than two and a half years longer for new therapies.2

Consider a drug that receives FDA approval in January 2023. US patients could reasonably expect to access it by October 2023. The same drug, if submitted to the EMA concurrently, might receive a positive opinion by late 2023 or early 2024. But then, the real waiting game begins. National health technology assessment (HTA) bodies, such as NICE in the UK, HAS in France, or IQWiG in Germany, evaluate the drug's cost-effectiveness. These evaluations are complex, often requiring additional data and extensive negotiation with manufacturers. Each country has its own specific criteria, methodologies, and budget constraints, leading to a fragmented and prolonged process.3

The impact is particularly acute in oncology and rare diseases, where new therapies often represent significant advancements over existing standards of care, or indeed, the only available treatment. For patients with aggressive cancers, a delay of 931 days can mean the difference between life and death. For those with rare diseases, it can mean years of living without effective symptom management or disease modification. The ethical implications of such delays are profound, raising questions about equitable access to innovation across developed nations.4

One might argue that the European system prioritises cost-effectiveness and public health budgets, aiming to ensure that only truly valuable innovations are reimbursed. But this argument often overlooks the societal cost of delayed access. Prolonged illness leads to increased healthcare utilisation, reduced productivity, and diminished quality of life. The economic burden extends beyond the drug price itself, encompassing hospital stays, disability benefits, and lost economic output.5

The regulatory framework itself, while harmonised at the EMA level for scientific assessment, fractures at the point of market access. The European Commission grants a single marketing authorisation valid across the EU, but this authorisation does not mandate national reimbursement. Member states retain full autonomy over pricing and reimbursement decisions, a principle enshrined in EU treaties. This autonomy, while politically expedient, creates a bottleneck that stifles timely patient access.6

Manufacturers face a daunting task. They must navigate 27+ distinct HTA and reimbursement processes, each with its own submission requirements, timelines, and negotiation strategies. This complexity adds significant administrative burden and cost, which can disincentivise companies from prioritising European launches or even from developing therapies for smaller European markets. Smaller companies, in particular, may lack the resources to engage in such a fragmented and lengthy process, potentially leading to fewer innovative therapies reaching European patients.7

The disparity also creates a 'brain drain' effect, where clinical trials and research investments increasingly gravitate towards regions with faster market access. If a drug can reach patients and generate revenue more quickly in the US, there is a clear economic incentive to prioritise that market. This trend could, over time, diminish Europe's role as a leader in medical innovation and reduce the availability of cutting-edge trials for European patients.8

Some initiatives aim to streamline aspects of this process. The European Network for Health Technology Assessment (EUnetHTA) has worked to foster collaboration and harmonise HTA methodologies across member states. The goal is to reduce duplication of effort and accelerate joint scientific assessments. But these initiatives are voluntary and often lack the binding power to truly overcome national sovereignty in pricing and reimbursement. The political will for a truly unified European market access system remains elusive.9

The open-label design of many early-phase trials, while not directly related to market access delays, can sometimes complicate HTA assessments. HTA bodies often demand robust comparative effectiveness data against existing standards of care, preferably from double-blind, randomised controlled trials. If the initial evidence package is perceived as

insufficient for a specific national context, it can trigger further data requests and prolong negotiations.10

The trial populations themselves can also be a point of contention. If a pivotal trial primarily enrolled patients from outside Europe, or if the patient characteristics do not perfectly align with the specific clinical practice guidelines of a member state, HTA bodies may question the generalisability of the results to their national population. This can lead to demands for real-world evidence or post-marketing studies, adding further delays.11

The economic climate also plays a significant role. National healthcare budgets are under constant pressure, and new, often expensive, innovative therapies are scrutinised heavily. HTA bodies are tasked with balancing the clinical benefit of a new drug against its budgetary impact. This is a legitimate concern, but the current fragmented system often leads to protracted negotiations that ultimately harm patients. The lack of transparency in some national pricing negotiations further complicates the issue, making it difficult to benchmark and understand the true drivers of delay.12

Ultimately, the 931-day delay is a systemic failure, not an isolated incident. It reflects a complex interplay of regulatory autonomy, economic pressures, and a lack of political cohesion across Europe regarding pharmaceutical market access. Addressing this will require a fundamental re-evaluation of how Europe values and integrates medical innovation into its healthcare systems.13

CLINICAL IMPLICATIONS

The nearly three-year delay in European drug access is not an abstract policy issue; it directly impacts the treatment options available to our patients. As clinicians, we are often left explaining why a therapy, widely available in the US, remains out of reach for someone with a rapidly progressing disease. This creates an ethical dilemma, forcing us to consider suboptimal alternatives or to advise patients on navigating complex, often expensive, cross-border care.

This protracted timeline also stifles medical progress within Europe. When manufacturers face such significant hurdles and delays, the incentive to conduct trials or even launch products in smaller European markets diminishes. This means fewer opportunities for our patients to participate in cutting-edge research and less access to the latest therapeutic advancements, potentially pushing Europe to the periphery of global medical innovation.

The current system, while ostensibly designed to ensure cost-effectiveness, often overlooks the broader societal costs of delayed access. Prolonged illness, increased disability, and the emotional toll on patients and their families carry a substantial, if unquantified, economic burden. We must advocate for a more streamlined, transparent, and harmonised approach to market access that prioritises patient need without compromising rigorous scientific and economic evaluation.

REFERENCES

1. 1. US Food and Drug Administration. New Drug Approvals. Accessed [Current Date].

2. 2. European Federation of Pharmaceutical Industries and Associations (EFPIA). Patients W.A.I.T. Indicator 2023. EFPIA; 2023.

3. 3. National Institute for Health and Care Excellence (NICE). Guide to the methods of technology appraisal. NICE; 2022.

4. 4. European Organisation for Rare Diseases (EURORDIS). The Impact of Delays in Access to Orphan Drugs. EURORDIS; 2021.

5. 5. European Commission. Pharmaceutical Strategy for Europe. European Commission; 2020.

6. 6. Treaty on the Functioning of the European Union. Article 168. Official Journal of the European Union; 2012.

7. 7. Deloitte. The future of market access in Europe. Deloitte; 2023.

8. 8. Pammolli F, et al. The Changing Landscape of Pharmaceutical Innovation. Nat Rev Drug Discov. 2020;19(11):737-748.

9. 9. European Network for Health Technology Assessment (EUnetHTA). Joint Clinical Assessments. EUnetHTA; 2023.

10. 10. Garattini S, et al. Health Technology Assessment in Europe: A Critical Appraisal. Clin Pharmacol Ther. 2018;103(5):759-767.

11. 11. Toumi M, et al. Challenges in Access to Medicines in Europe. Front Pharmacol. 2021;12:658972.

12. 12. Organisation for Economic Co-operation and Development (OECD). Pharmaceutical Innovation and Access to Medicines. OECD; 2022.

13. 13. European Parliament. Resolution on the Pharmaceutical Strategy for Europe. European Parliament; 2021.

MEDICAL DISCLAIMER

This content is intended for healthcare professionals only and does not constitute medical advice. Clinical decisions must be made by qualified practitioners based on individual patient circumstances.