Global Access to Innovative Medicines in 2025: Europe's Gaps and the United Kingdoms Continued Decline

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BACKGROUND

Patient access to new medicines in many countries depends largely on whether the medicine is reimbursed by the public health insurance program. Although regulatory approval ensures that a medicine meets standards of safety and efficacy, true patient access often requires an additional step -- recommendation for reimbursement by a Health Technology Assessment (HTA) body and manufacturer agreement on the resulting government-set price for the medicine. HTA processes evaluate the clinical effectiveness, cost-effectiveness, and overall relative value of new treatments to inform government pricing and reimbursement decisions. While HTA is designed to promote the efficient use of healthcare resources and equitable access, it can also become a gatekeeper to innovation. In practice, the additional evaluations and negotiations required for HTA-based reimbursement often introduce excessive delays in patient access to new therapies. These delays are driven not only by the time needed for HTA but also governments' cost containment objectives. As a result, the time between regulatory approval and actual patient availability of new medicines can vary across countries. In contrast, the United States (US) does not have a centralized HTA process for Medicare reimbursement. Once the US Food and Drug Administration (FDA) grants market authorization, physicians can typically prescribe the medicine immediately, and reimbursement under Medicare follows almost concurrently. This fundamental structural difference offers an opportunity to compare how HTA requirements influence both the timeliness and extent of patient access to innovative new medicines. This study focuses on five major European countries with established HTA systems: Germany, France, Italy, Spain, and the United Kingdom. It compares data on relevant patient access measures specific to each country regarding approval and reimbursement. Approval refers to when a medicines receives its first market authorization for use in the country. Reimbursement is defined as the point when patients can first access the medicine with coverage through the country's public health insurance program. The analysis compares the share of new innovative medicines available in each country, in terms of approval and reimbursement, and compares how much longer patients in each country must wait for access.

RESEARCH OBJECTIVES

This study examines the impact of health technology assessment (HTA) on patient access to new medicines by comparing five European countries with HTA to the United States. The analysis looks at the extent to which new innovative medicines are approved and reimbursed in each country's national public health insurance program, as well as how long it takes for new innovative medicines to receive market authorization and then become reimbursed by the national public health insurance program in each country.

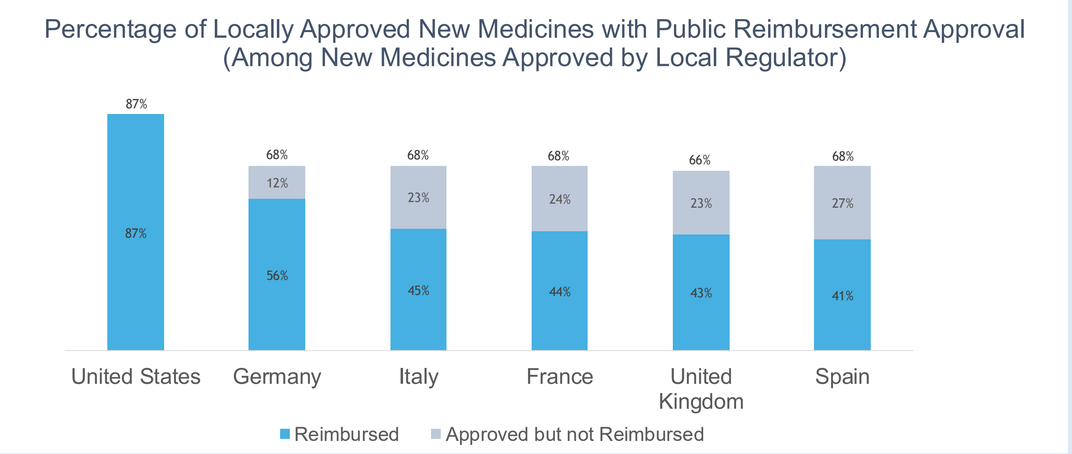
METHODS

- New medicines were identified as new active substances approved by the European Medicines Agency (EMA) or by national European regulatory agencies, Medicines and Healthcare Products Regulatory Agency (MHRA), U.S. Food and Drug Administration (FDA), or Pharmaceuticals and Medical Devices Agency (PMDA) and launched globally between January 1, 2014, and December 31, 2023.
- Regulatory approval refers to first regulatory approval, or market authorization, granted for a new active substance. For Germany, France, Italy, and Spain, it is the earliest first approval by either the EMA or the national regulatory body. For the UK, it is the earliest first approval by either the EMA or the national regulatory body up until 2020, when the MHRA started handling all approvals for the UK market. For the United States, it is the first approval by the FDA.
- Reimbursement refers to when patients can first access the new active substance for any indication and receive some level of reimbursement through their country's national public health insurance program. For Germany, reimbursement begins when the product is first marketed, prior to HTA assessment and pricing. For France, reimbursement occurs after the HTA assessment and pricing has been agreed to – unless early access was granted, in which case reimbursement occurs when early access is granted. For Italy, reimbursement occurs after HTA assessment and pricing at the national level, even though there are additional delays for inclusion on regional formularies for medicines not deemed 'innovative.' For Spain, reimbursement occurs after HTA assessment and national funding and pricing decisions, even though there are additional delays as regional pricing and formulary inclusion are determined. For the UK, reimbursement occurs when a positive HTA recommendation occurs, plus 90 days for non-oncology medicines. For the United States, reimbursement occurs when physicians can prescribe the medicine for Medicare beneficiaries, which is at or shortly after FDA approval – there is no HTA assessment required for Medicare reimbursement.
- Delays in approval are calculated as averages from the first approval anywhere in the world to the first approval for each country market, including cases when the respective country is the country of first approval. Delays in reimbursement measure the additional number of days, on average, that it takes for newly approved medicines to be reimbursed by the national health insurance program.

RESULTS

Across countries, access to new medicines is shaped by differences in national healthcare systems, and in particular their public health insurance program's reimbursement. In Europe, not all approved medicines are reimbursed, limiting patient access compared to the United States, where approved medicines receive coverage. Patients in the included European countries face significantly longer waits for medicines to be reimbursed and made available through national health insurance programs compared to patients in France, Germany, and the United States.

National Public Insurance Plans in Europe Don't Reimburse All Approved Medicines



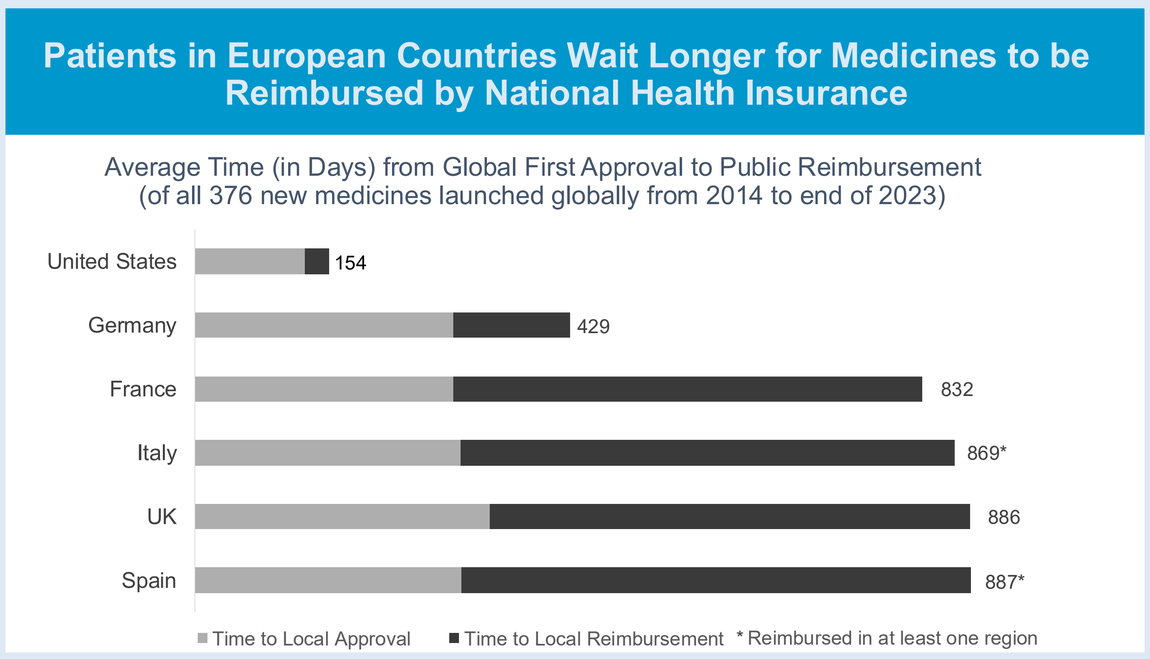
Approval and Public Reimbursement of New Medicines

The share of new innovative medicines approved for market authorization and reimbursement by national public insurance programs varies widely across countries. In the US, 87 percent of new innovative medicines have a market authorisation and all FDA-approved medicines are reimbursed by the Medicare program. In contrast, European countries have a smaller share of new innovative medicines approved for market authorization and even smaller shares for reimbursement in national health insurance programs. Unlike in the United States, patients in European countries cannot access all of the medicines approved for safe and effective use.

Delays in Approval and Public Reimbursement

Analysis indicates that patients in the United States experiences the shortest wait times from first global approval to local approval, largely because many new innovative medicines are first approved by the U.S. FDA. In addition, patients in the United States also experience the shortest wait times to reimbursement by public health insurance because no centralized HTA is performed. In contrast, patients in European countries face considerably longer delays due to later approvals and especially due to wait times for government HTA and pricing decisions.

Patients in European Countries Wait Longer for Medicines to be Reimbursed by National Health Insurance



Limitations

Analysis does not account for uptake/utilization of new innovative medicines. Many HTA entities impose additional criteria on reimbursement such that only some of the approved uses are covered. In countries such as the UK, this can have a profound negative impact on access. Considerations were made for differences in how reimbursement is defined and implemented across countries, but these differences could ultimately impact comparisons of delays. Patient uptake is not considered in this analysis but could add a helpful perspective on access to medicine in real numbers.

CONCLUSION

The use of sound evidence to guide decisions about allocating health care resources is vital. However, HTA processes also delay and prevent patient access to new medicines. Patients in European countries wait much longer than patients in the United States for access to new innovative medicines in their public health insurance programs. Patients in Germany have faster access than in other European countries, due to the fact that HTA and government pricing decisions in Germany do not delay reimbursement. Patients in France benefit from accelerated access for some new medicines, though France's accelerated access is not always for a medicine's first indication. Many patients likely wait even longer that in Spain and Italy for coverage on regional formularies.

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