



Regulatory Exclusivity: Why It Matters for Patients and Medical Innovation

Regulatory exclusivity is a vital policy tool that helps to correct market failures and strengthen incentives for new drug development, particularly in areas of unmet need.

The problem: Missing incentives for medical innovation

- Developing a new drug can take up to 15 years and cost up to \$2.7 billion. Patents help incentivize this high-risk investment by preventing competitors from immediately copying new therapies and allowing companies to recoup development costs.
- But a patent's 20-year term begins when it's filed — not when a drug is approved. By the time a drug clears clinical trials, earns FDA approval, and reaches patients, a large chunk of its patent protection might already be gone.
- As a result, patents alone often do not provide sufficient incentives for high-risk medical innovation.

The solution: Regulatory exclusivity

- Regulatory exclusivity adds a targeted, time-limited layer of protection, either by preventing competitors from using a drug's clinical data or preventing the FDA from approving copycat versions of approved therapies.
- Exclusivity begins at FDA approval and lasts for a set period of time, helping to ensure predictable returns regardless of how long the R&D process takes.
- Regulatory exclusivity drives investment in new medicines. When companies lose exclusivity on a major drug, their R&D spending typically drops by about 25% within two years.

How regulatory exclusivity helps patients

- Regulatory exclusivity spurs investment in treatments that might not be viable under normal market conditions, including those for complex conditions with high development costs and for rare diseases with limited potential patient populations.
- Exclusivity also encourages continued improvement of existing therapies by helping to justify the substantial costs of additional research and clinical testing after initial FDA approval.

The bottom line

Regulatory exclusivity is a critical incentive for investment in new medicines. Without it, breakthrough innovation would slow, research investment would decline, and patients would have fewer treatment options.

This one-pager is based on an Eira Initiative working paper by Kristina Aciri, "The Economic Functions of Regulatory Exclusivities in Biopharmaceutical Innovation."