AmCham EU
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

EU General Pharmaceuticals Legislation

AmCham EU is committed to fostering a regulatory environment that strengthens European healthcare by enhancing accessibility and ensuring a crisis-resistant medicines regulatory system.

Innovative companies worldwide rely on a predictable and reliable intellectual property (IP) framework to support high-risk, resource-intensive investments over extended periods. A robust IP system is essential for driving research and innovation (R&I), which advances healthcare and improves patient outcomes by bringing new technologies and treatments to market. Failure to provide adequate IP protection, including adherence to Trade-Related Aspects of Intellectual Property Rights (TRIPS), risks discouraging investment in the European healthcare sector.

The EU's proposed General Pharmaceuticals Legislation (GPL) seeks to significantly shorten the duration of Regulatory Data Protection (RDP). This reduction could have unintended consequences, hindering the development of new medicines and limiting the number of innovative products expected to enter the market by 2035[1]. Smaller pharmaceutical markets within the EU may struggle to keep pace with launches, as companies prioritize regions with stronger data protection and IP incentives.

Moreover, the proposed RDP reductions could deter companies from launching innovative medicines in Europe, undermining efforts to enhance European competitiveness in life sciences. The added administrative complexity for companies navigating Member State requirements may increase regulatory burdens and discourage investment, ultimately leading to delayed or fewer product launches. Over time, this shift could weaken patient access, reduce economic investment, and erode Europe's leadership in life sciences.

Recommendations

Given the possible repercussions, Member States should considering preserving and/or enhancing RDP to create amore attractive investment and first launch environment. Maintaining the current RDP framework nets allows for further streamlining regulatory and pricing processes between the EMA and national pricing agencies which strengthens market access. Additionally, the current framework avoids a one-size-fits-all RDP reduction that could cause regulatory disruptions and possible increases in litigation process.

[1] https://www.efpia.eu/media/msadqxbf/revision-of-the-general-pharmaceutical-legislation-gpl-impact-assessment.pdf