AmCham EU
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

To: Estonian Minister of Social Affairs Karmen Joller
Subject: Regulatory Data Protection (RDP) Framework in the EU General Pharmaceuticals Legislation (GPL)

Dear Minister Joller,

On behalf of the American Chamber of Commerce to the European Union (AmCham EU), American Chamber of Commerce in Estonia (AmCham Estonia), and supported by several national AmChams across Europe, we are writing to express our collective concern regarding the proposed changes to the Regulatory Data Protection (RDP) period under the revision of the EU General Pharmaceuticals Legislation (GPL).

As negotiations progress, we urge Member States to consider maintaining or enhancing the current RDP period at 8 years. This framework has proven essential for fostering a vibrant innovation ecosystem, promoting patient access, and enabling Europe to remain competitive in the global life sciences sector. Innovative companies globally, including those invested in Europe, rely on a predictable and reliable intellectual property (IP) system to support high-risk, resource-intensive investments. A robust RDP system is a cornerstone of this framework and is vital to driving research and innovation (R&I) that ultimately benefits European patients.

Reducing the RDP period risks discouraging the development and launch of new treatments in the EU. Industry experts indicate that a reduction could result in fewer innovative medicines being launched in Europe by 2035, with smaller pharmaceutical markets in particular facing significant challenges in ensuring timely access to new therapies. This would erode the EU's attractiveness as a destination for early product launches and delay access for patients across the Union. Moreover, having conditionalities to earn back RDP introduces uncertainty and would thereby disincentivize investments and erode EU's attractiveness.

AmCham Estonia alongside AmCham EU recommends that Member States preserve—and where possible, enhance—the current RDP framework. This approach would:

- Strengthen Europe's position as a lead launch market for innovative medicines;
- Enable smoother alignment between regulatory and pricing processes;
- Maintain Europe's leadership in pharmaceutical innovation and life sciences;
- Avoid one-size-fits-all reductions that could unintentionally increase regulatory complexity and deter access.

As detailed in AmCham EU's consultation responses and echoed by multiple industry associations, enhancing the current RDP framework is not just a matter of IP protection—it is a strategic decision to bolster European competitiveness and safeguard patient access to cutting-edge treatments. In addition, to keep the EU globally competitive we ask that you support the Commission's proposals to streamline and speed up the European Medicines Agency (EMA) process, so that innovative medicines can get to patients faster.

AmCham remains committed to this matter and offers further support in finding solutions that promote innovation, economic resilience, and improved health outcomes for European citizens.

Sincerely,
AmCham Estonia Healthcare Committee in cooperation with AmCham EU

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