Our response to the EU Pharmaceutical Strategy Roadmap

Eli Lilly & Company (Lilly) welcomes the opportunity to respond to the European Commission's Roadmap to the Pharmaceutical Strategy. Lilly pushes the boundaries of science to make conditions that are incurable today, treatable tomorrow. Our recommendations cut across four areas to make life better for patients and support the EU in being a world leader in life sciences. They also reflect learnings to date from COVID-19 (C-19).

Build on regulatory flexibilities and international cooperation: The European Medicines Agency (EMA) is essential in progressing innovative methods to enable rapid patient access to medicines without compromising safety. Regulatory advances by the EMA, including implementation of its Regulatory Science Strategy to 2025, will be key to achieving success and only possible with a well-resourced Agency. This modernisation will require updated infrastructure technology and capabilities, e.g. real-time review activities, real world data generation, e-labeling, and cloud-based submissions. We commend the EMA's efforts to accelerate the development of potential C-19 treatments, and unprecedented level of communication and cooperation with medicine developers in partnership with other regulators. We strongly support international regulatory cooperation and guidance alignment that encourages efficient review and approval of medicines, diagnostic tools, wearables, and devices. We believe there will be learnings from the flexibilities and accelerations applied during the C-19 crisis that become standard, best practice.

Provide and support a predictable EU intellectual property (IP) framework to drive research and development: Some argue the way to cut healthcare costs is to reduce IP protections. But a strong IP system incentivises innovation, producing breakthroughs today and bargains tomorrow. Investment into high-risk areas such as Alzheimer's depends on the certainty of strong and predictable IP incentives and rewards, which enable the creation of a competitive generic marketplace once IP protections expire. An effective Alzheimer's medicine for example would go on delivering value for decades. Nothing in healthcare is more productive in providing new, effective treatment options. Many of the most promising C-19 treatments came from existing molecules, existing because of IP, further illustrating IP is not a barrier.

Break down barriers to achieve faster, more equitable patient access to innovative medicines: Increasing use of accelerated assessments and reducing the length of the EC's decision-making process after the scientific assessment could help reduce delays to access to medicines for patients by c.100 days. Currently it takes a median of 423 days for the EMA to approve a new active substance, compared to 243 days in the USA, 304 in Japan, 346 in Canada, and 346 in Australia (2020 CIRS, R&D Briefing 77). Most recently, 68% of products were approved in the US by an expedited pathway vs. only 7% for the EMA (2020 CIRS, R&D Briefing 77). Faster access can also be gained through mandatory clinical EU Health Technology Assessment and broader use of free pricing as done in Germany, allowing time for added medical value assessment whilst giving patients immediate access. Such an approach would address many national access barriers.

Maintain diverse, secure global supply chains: We support growing EU advanced manufacturing capabilities, while maintaining a diverse and secure global supply chain. Maintaining flexibility in supply chains protects against shortages, and geographic diversity is key, enabling us to access the resources we need and make adjustments to avoid production disruptions. The innovative biopharmaceutical industry is not reliant on any one country for its APIs and instead uses global supply chains. Supply chain diversity helps mitigate the impact of natural disasters or other public health emergencies. Policy changes to global supply chains could disrupt manufacturing of medicines for the EU.