A strong EU-US relationship for patients

With today's health challenges accentuated by the coronavirus pandemic, there's no greater need for common action. Now is the time to push the EU-US relationship to the next level. The recent European Commission proposal on "A new EU-US agenda for global change" is a step in that direction.

As a US-headquartered company heavily invested in and committed to Europe, we believe more **regulatory cooperation** between European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) could help create efficiencies and speed patient access to new medicines.

Regulatory cooperation can be achieved outside of a trade deal, as demonstrated in 2017 when the EU and the US signed a Mutual Recognition Agreement (MRA) on Good Manufacturing Practice (GMP) inspections. The MRA allows EU and US to rely upon manufacturing site inspections conducted by the other region's regulators, avoiding duplication of respective inspections. This MRA has been operational since July 2019, already supporting faster and more efficient delivery of new medicines.

Lilly supports the following future areas of cooperation for the benefit of patients:

1. **Creating an MRA in the area of Good Clinical Practice (GCP).** This MRA could create potential savings of around €55 million per year for the industry alone[1]—in addition to the regulator's resources saved as well. Since clinical research is global in nature, an MRA in GCP would reduce the cost and burden (on both industry and regulatory authorities) by eliminating the duplication of inspections.

2. **Aligning of EU-US paediatric development plans.** Aligning paediatric scientific approaches between EU and US would reduce duplication and streamline medicines development for children, reducing the time and costs of conducting trials for industry while avoiding redundant clinical trials in children.

3. **Expanding the MRA on GMP** to inspections of manufacturing sites in third countries and for vaccines to further eliminate duplicative efforts. The EU and US should also explore further opportunities to expand upon the success of the MRA on GMP.

4. **Establishing an EU-US Trade and Technology Council**. Lilly supports the EU's efforts on setting up an EU-US Trade and Technology Council and encourages cooperation on **digital health with a focus on new health technologies**. EU and US can remain world leaders in regulatory science by setting a precedent on the use of regulatory technological innovations (i.e. cloud-based submissions, advanced analytics) to harness the power of these new technologies.

"As countries continue to recover from the devastating impact of the COVID-19 pandemic, a strong EU and US partnership is needed to help rebuild the world economy. We've seen enhanced cooperation between the FDA and EMA throughout this pandemic and hope to see this continue beyond the pandemic to help speed access for patients."

- Leigh Ann Pusey, Senior Vice President, Corporate Affairs, Eli Lilly and Company

[1] According to an internal EFPIA survey, it is estimated that a GCP inspection costs around €550 000 on average. The potential savings are based on conservative calculations and assuming the number of inspections could be decreased by half to around 100 inspections per year.