Our response to the revision of the EU General Pharmaceuticals Legislation Roadmap

Eli Lilly & Company (Lilly) wishes to offer this solution-oriented reply for improving the EU medicines ecosystem, making life better for patients, and facilitating the EU's leadership in life sciences.

Future-proofed system
Policies that enable adaptability and adequate resourcing will ensure that the EU regulatory system is efficient, effective, and competitive. Given the speed of drug and digital innovations, we believe that the EU regulatory system should better leverage simplifications, EU network's vast expertise, and new flexibilities. Such modernisation requires proactive policies, advanced capabilities, and updated infrastructure to enable cutting-edge approaches such as innovative clinical trial designs, real-time regulatory reviews, real world data generation, e-labeling and cloud-based submissions. While non-legislative policies can enable faster regulatory actions today, the current EU regulatory framework is often considered as fragmented, multi-layered, and complex in comparison with other countries. This is illustrated in Annex Visual A and Visual B. We consider that streamlining this process incl. considering transitioning some capabilities to the EMA would offer a future-proofed and more agile system (e.g., Visual C).

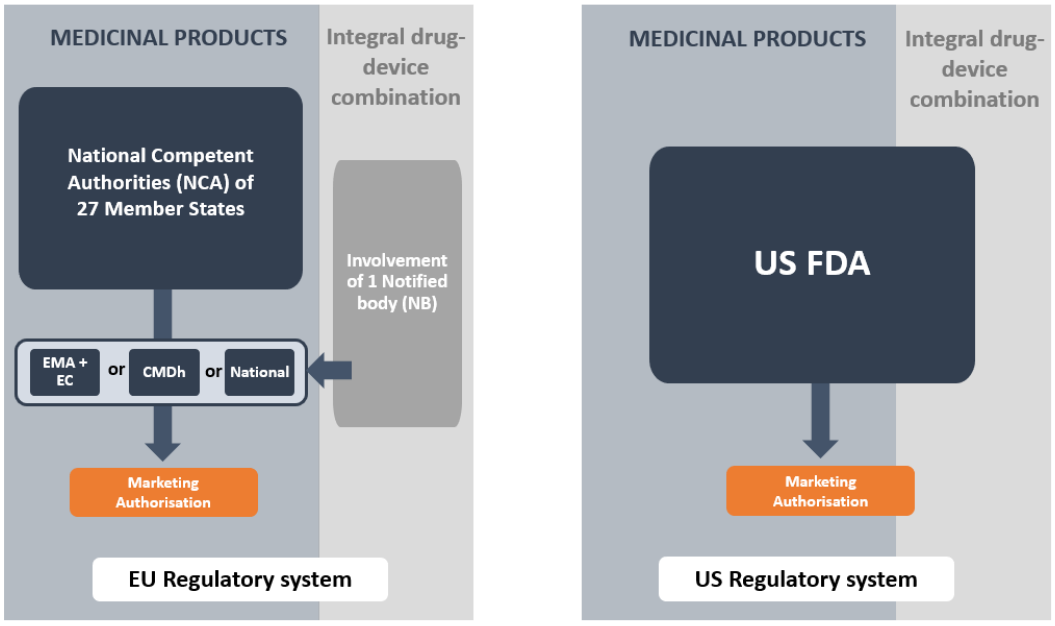
Competitive timelines
We concur that EU's regulatory review timelines could be swifter: in 2019, it took a median of 423 days for the EMA to approve a new active substance versus 243 days in the USA (Visual D). Along with simplifying the approval process, increasing the use of accelerated assessments, and shortening procedures (e.g., moving from 67 days to 7 days for final decision) would help meet this objective (Visual C). Expedited regulatory tools are key to an agile system and although some are available in the EU, their use is limited in comparison to those offered in other countries. As such, the impact of PRIME could be amplified if it (and/or similar approaches) were accessible for any product, indication, and company from early in development. Also, we believe that timelier regulatory dialogue would offer better integration of the EU scientific, clinical, and regulatory expertise into a medicine's global development plan.

Resilient supply chains
Europe's overall support for open trade helps maintain flexibility in global supply chains of medicines and their raw materials. This protects against shortages, with geographic diversity enabling access to the resources needed, and adjustments if necessary, to respond to operational disruptions and demand changes in both volume and location. Policies that mandate wholesale changes to global supply chains, e.g., location, sourcing or inventory, could distort the security and reliability of the supply. Supply chain robustness and resilience can be protected through policies that strengthen the R&D and manufacturing base, including ensuring a vibrant talent pool in STEM, complementary technical partners (SMEs, universities, etc.), strong and predictable IP protection, along with rapidly responding regulatory pathways. These help create a rich life sciences community and enable Europe to be a location of choice for pharmaceutical investment and operations.

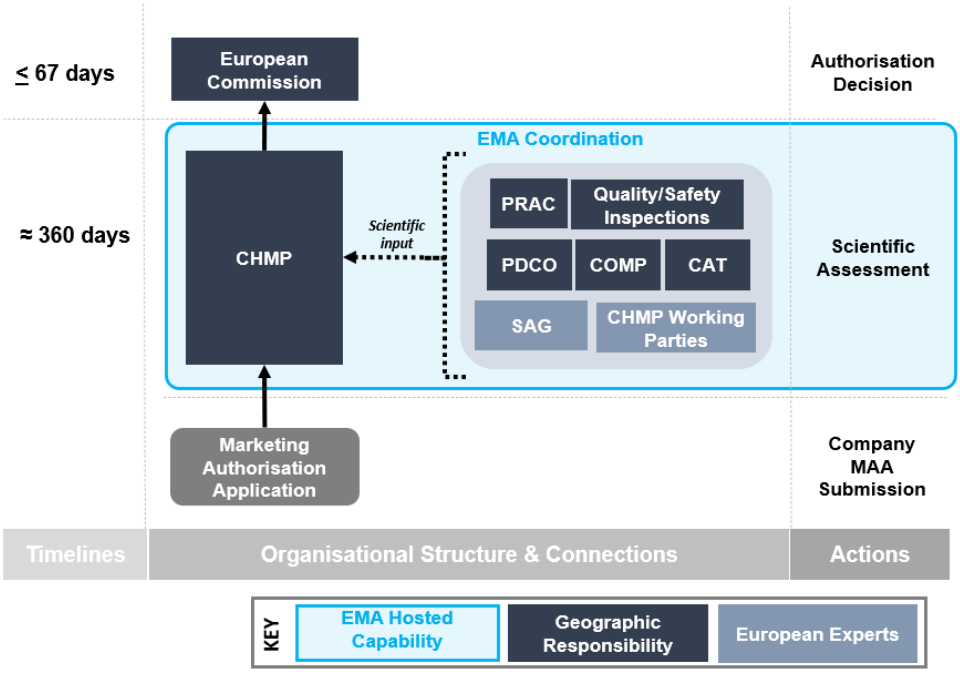
IP incentives
IP and incentives play a vital role to encourage the development of new medicines for patients and R&D investment into Europe. The different incentives complement each other and are necessary. They work across potential differentiated opportunities for new innovative medicines that benefit patients by addressing unmet medical needs (UMNs) in all areas, including medicines for rare diseases and children. There are still many UMNs of all types that need to be addressed. We believe that predictability and certainty of incentives are key at the required point of investment. Additional novel incentives for UMN must also take this into account.

Annex

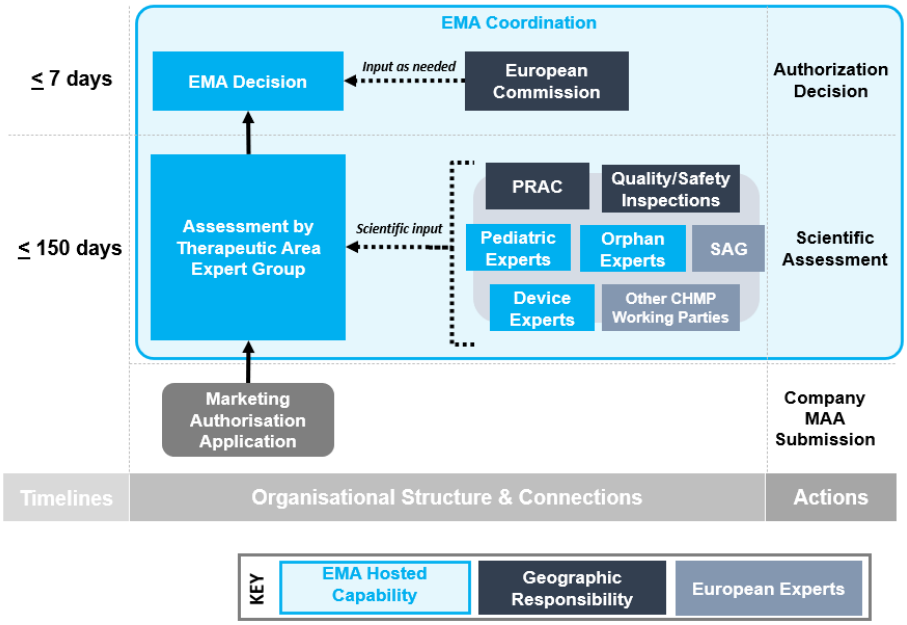
Visual A – Representation of EU and US regulatory bodies involved in the approval of a new medicine



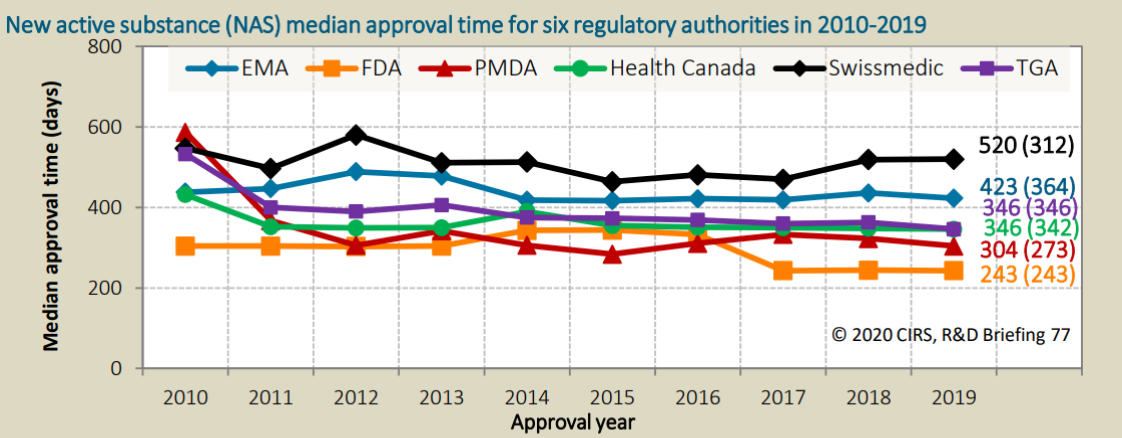
Visual B – Representation of the current EU new medicine approval process and timeline



Visual C – One potential approach considered by Lilly to streamline the EU new medicine approval process and timeline to help achieve EC's objectives



Visual D – New active substance approval times for six regulatory authorities



Approval time is calculated from the date of submission to the date of approval by the agency. This time includes agency and company time. EMA approval time includes the EU Commission time. N1 = median approval time for products approved in 2019; (N2) = median time from submission to the end of scientific assessment (see p.26) for products approved in 2019.

Reference: 2020 CIRS, R&D Briefing 77 https://cirsci.org/wp-content/uploads/2020/06/CIRS-RD-Briefing-77-6-agencies.pdf [accessed 20 April 2021]