Increased regulatory efficiency; what we need for the next generation of medicine

The revision of the general pharmaceutical legislation presents an opportunity for change at a pivotal moment for healthcare in Europe. Since its introduction in 2004 the general pharmaceutical legislation has ensured that safe, efficacious, and high-quality medicines have reached dozens of millions of EU patients.

Biotechnology continues to push the boundaries of science and innovation. This also means that, as new products become technically feasible, the regulatory system too is challenged to react. In the context of the revision of the general pharmaceutical legislation EuropaBio encourages a forward looking perspective mindful of new technologies and the need for appropriate assessment methodologies to ensure proper functioning of the regulatory network.

Europe has a strong research base that we should seek to support and grow. We share the European Commission's ambition to increase the global competitiveness of Europe's life sciences industry. Regaining a global position as a preferred location for conducting clinical trials, and for being the first to approve innovative medicines will ultimately improve the lives and health of EU citizens. To realise this ambition, the process of developing innovative medicines the EU and interactions with the regulatory network can be improved.

Accelerated, adapted and streamlined regulatory pathways

To deliver medicine to patients faster, and to attract investment and innovation in EU life sciences, requires a competitive assessment timeline and the ability to provide advice throughout the product development lifecycle. Iterative scientific advice is particularly useful for SMEs and their growth, where delays to companies with few products in their pipeline can impact their commercial viability. During the COVID-19 pandemic we have seen the introduction and use of iterative review processes at EMA which ensured rapid access to safe products. We appreciate the intense work this requires of regulators, but would encourage exploration of how this flexibility can be scaled up and applied across the network.

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An adequately resourced regulatory network to ensure delivery of timely scientific advice and approvals

It is essential that the EMA and the EU regulatory network are properly funded and appropriately resourced to be able to increase the competitiveness of the EU. Increased resourcing will ensure available expertise within the network, and improve the ability to provide scientific advice to medicines developers, including SMEs, keeping pace with other regions.

Streamlined regulatory pathways and alignment of data requirements between regulators and HTAs

Pathways for early dialogue with the different stakeholders (EMA/NCA/HTA) on appropriate study designs for evidence generation should be further strengthened. Dialogue with assessors to guide companies through the regulatory process should be seen as a partnership; easier access to assessors improves shared knowledge within the network, and will improve the review cycle, thus further reducing timelines.

Review processes, use of RWE, and IT infrastructure

The EMA should have flexibility to adapt the review process to the nature and need of the product, this may include iterative submission of data for review, or expanded accelerated assessments. Adoption and uptake of new methodologies for data collection must continue in order to streamline and accelerate decision-making for precision medicines and speed up patient access. To achieve this, the underlying IT-infrastructure across the network requires improvement as part of the overarching EU digital transformation. Adequate databases, related data sharing protocols and data governance should be improved as part of a comprehensive digital strategy for medicine regulation (incorporating ongoing discussion on IDMP/DARWIN etc.). Updates to the systems should be done in collaboration with Member States, to avoid disconnect in the system.

Extension of the PRIME scheme/accelerate pathways

PRIME Scheme should explore the automatic extension to all orphan indications to speed up drug development and approval of innovative medicines. The overall eligibility rate (25%) of PRIME is too stringent to facilitate innovation in Europe; earlier entry in the scheme, based on non-clinical data could facilitate early filing, especially when the product is part of global expedited development in multiple regions.

Flexible and innovative clinical trial design – acceptable to both regulators and payers

Flexibility in conducting clinical trials, and in clinical trial design, is also necessary to support future development of ATMPs and novel biotechnology-derived medicines which focus on small populations (e.g. rare disease patients) where RWE can supplement clinical trials, adaptive trial design, or for the conduct of decentralised clinical trials. Adoption of fit-for-purpose RWE for regulatory benefit-risk assessment to provide pivotal evidence of treatment benefits of new therapies, to complement possible evidence gaps is also of increasing importance.