Regulatory Road to Innovation

A future-proof regulatory framework

The revision of the overall pharmaceutical legislation is **a once-in-a-generation opportunity** to enhance and modernise Europe's regulatory rules.

10% **of the total late-stage R&D** pipelines are next-generation biotherapeutics.

20% **of approved products** are now **combination products**, composed of both a medicine and a medical device.

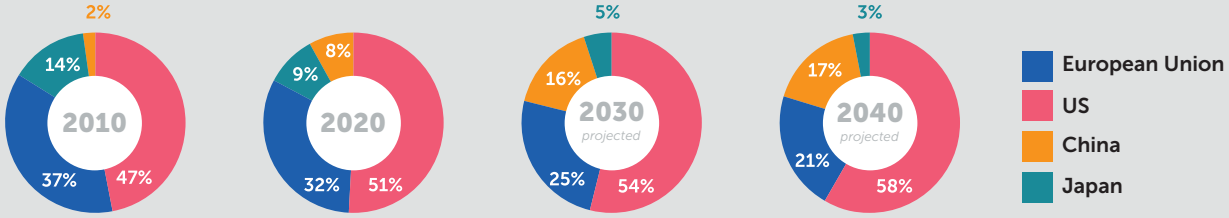
54% increase in the number of applications requiring EMA assessments from 2012 to 2020

The existing European regulatory system has helped to **attract the €42,5 billion** invested by the pharmaceutical industry in European research and development (R&D) each year. This framework also enabled the authorisation of more than 1,500 new medicines since the creation of the European Medicines Agency (EMA) in 1995.

With over 8,000 new treatments in the pipeline, the demand for regulatory support is increasing. As many promising new therapies across different disease areas may become available over the next years, the revised European system must ensure that **EMA will remain a strong and competitive regulatory authority globally**.

However, **Europe is currently facing challenges, with a decrease in R&D investments**.

Share of pharmaceutical R&D expenditure between Europe, US, Japan and China:



Furthermore, Europe is the slowest region to approve new medicines in comparison to the US, Japan, Canada and Australia.

New active substance median approval time in 2011–2020

To remain at the forefront of medical innovation, **Europe needs a robust, world-class, and future-proof regulatory framework**. Such a system will ensure that medicines are **widely available**, **easy to access, and affordable**.

Enhancing the Regulatory Framework

EFPIA has identified several priority areas to **make the European regulatory framework more efficient and agile, while ensuring it has sufficient resources**, to make it ready for upcoming scientific breakthroughs. These include:

Optimising the EMA committee structure to speed up the regulatory approval. **Simplifying processes and bringing together different areas of expertise** will lead to better regulatory science. This means sharing knowledge and lessons learned across different products and disciplines, ultimately helping patients get access to therapies faster.

Enhancing the agility and broadening the scope of expedited pathways, like phased review, PRIME, and conditional marketing approval. The EU has put in place these tools to fast-track the approval of medicines, yet their use has been limited.

Gradually replacing the paper patient information leaflets with electronic versions. The COVID-19 and the Ukrainian crisis have shown how important electronic information leaflets are for patients. The transition can start with products given by healthcare professionals where patients never see the pack, such in hospitals. Later, it can expand to more products in countries that are prepared for this change.

Addressing the rise of combination products (medicines and medical devices), representing 25% of today's pipeline. EFPIA suggests creating a new legal category to regulate them as medicinal products. Clearer rules on combination products will enable the full potential of personalised medicine and integrated healthcare.

Introducing the regulatory sandbox: today's R&D pipeline contains an even more complex category of therapies, which combine drugs, devices, and digital technologies. Under current rules, multiple pieces of EU legislation would apply. With the regulatory sandbox, medicine regulators will collaborate with developers to examine the various legislations and identify the requirements that must be met.

EFPIA's recommendations and innovative approaches aim to ensure that European patients benefit from the latest advances in medical science **without any compromise on quality and safety**.