European leadership in healthcare innovation?

Six bold actions for regulatory reform

Profound modernisation of the EU regulatory pharmaceutical framework will accelerate science and technology and improve access to innovation for patients.

Roche is calling on European policy-makers to make the vision of European leadership in healthcare innovation a reality. This vision is already shared by many EU regulators. We are committed to working together with other stakeholders to modernise our regulatory framework for the 21st century. We assert that the EMA and the European Medicines Regulators Network need to be integrated, modern, well-resourced with an open governance that is efficient and effective for the long term.

At Roche, our strategy of personalised healthcare aims to advance new discoveries, improve patient outcomes and contribute to more sustainable healthcare systems. Integrated solutions include a combination of therapeutics, diagnostics, technologies, tools, and/or data intended to address current gaps in the patient journey. Today's EU pharmaceutical regulatory system was established in the last century and over the past 27 years, due to revolutionary, highly dynamic developments in science and technology, the system has become complex and difficult to navigate. It is now behind other comparable systems in speed and agility.

There is an urgent need for bold and ambitious action at EU and Member State levels. A fully modernised EU regulatory system will better attract R&D investment into the EU while promoting access to innovative medicines for European patients.

Roche believes that the Pharmaceutical Strategy for Europe[1] and the revision of the EU general pharmaceuticals[2] legislation offers a uniquely historical opportunity to transform the European healthcare ecosystem into a globally competitive powerhouse and to recover the mantle of global pioneer and leader in patient-centred medical innovation.

Our vision is for a structure that can adapt to and anticipate the regulatory needs arising from scientific discovery, and that can authorise highly innovative technologies with speed and agility.

Guided by three core principles we call for six bold, reforming actions to realise this vision.

The core principles

1. Best-in-class care for patients
2. Sustainability and resilience of healthcare systems
3. Purposeful innovation for patients

The six bold actions:

1. Modernising to iterative, dynamic, and digitally enabled regulatory assessments
An upgraded, fast and flexible regulatory pathway through increased use of iterative regulatory advice and dynamic assessment, coupled with decision-making that takes full advantage of digital working tools and streamlines any interactions needed with different stakeholders. It takes on average 408 days to grant a marketing authorisation for a new oncology medicine in the EU[3] . Patients in other developed markets do not wait nearly this long. The EU must deliver high quality assessments much faster!

2. Assigning EMA as an orchestrator authority on integrated solutions
Each component of an integrated solution may fall under a different regulatory definition, framework or procedure with oversight by different public and private bodies. Therefore, developers must navigate a fragmented and overly complex system when developing and seeking regulatory review for these products. To harness the potential of integrated solutions and to keep pace with the rapid advancement of science and technology, it is crucial EMA plays a leading role in orchestrating modern, streamlined regulatory approaches and procedures with all relevant authorities, bodies and stakeholders necessary in order to deliver these innovations to patients more quickly.

3. Creating a sandbox mechanism for future novel healthcare and regulatory solutions
Healthcare innovation needs a framework that allows regulatory experimentation for products and solutions that we cannot yet describe, as they will be the future's discoveries. A "sandbox environment"[4] will accommodate the reality that science and technology typically advances ahead of any needed regulation, and will avoid the risk of regulating innovative new approaches prematurely or inappropriately.

4. Transforming EMA's Committee Structure to focus and leverage scientific expertise
We need to strengthen the use of best expertise in the system through transformation of the EMA's Committee Structure to build systematic expertise and capability, drawing on the region's strongest scientific minds, and underpinned by the inherent trust built over the past 27 years across Member States.

5. Securing sufficient EMA funding and optimal resource allocation
Sufficient funding and excellent resource management are key requirements for EMA and the multi-stakeholder network to fulfil their strategic and operational missions. We are working together - collectively across stakeholders - to benefit patients, health systems and society. We do not accept that patients must wait on a slower approval pace in the EU due to a lack of resources, or waste of available resources, arising from complex, outdated, and resource intensive processes and structures.

6. Formalising the informal collaboration and work sharing of global pandemic times
A truly global scientific work sharing and collaboration (e.g. reliance mechanisms or parallel reviews) between the EU and third countries applying similar standards will reduce redundant scientific activities and optimise approval timelines. The pooling and sharing of leading edge technical expertise in the scientific assessment of new products would accelerate time to access and outcomes within and across health systems.

Roche supports EFPIA's Regulatory Road to Innovation and further highlights and asserts the need for bold and ambitious reforming actions to support the European Commission's goals on innovation, access and availability for the long term.

Do patients, urgently waiting for treatments, not deserve this?

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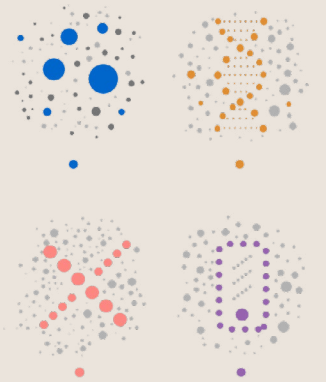
F. Hoffmann-La Roche Ltd
EU Regulatory Policy
4070 Basel, Switzerland

Email:
basel.eupolicy@roche.com



[1] COM(2020) 761 final, Communication from the European Commission on the Pharmaceutical Strategy for Europe. Available at: ***Link***

[2] Revision of the EU general pharmaceuticals legislation, Public Consultation. Available at: ***Link***

[3] Every Day Counts: Improving regulatory timelines to optimise patient access to innovative oncology therapies in Europe, Vintura, 2021. Available at: ***Link***

[4] A regulatory sandbox is a tool developed to prototype and test in a controlled environment customised regulatory approaches to an innovative service, product or business model instead of regulating potentially prematurely or inadequately.