Innovate and Adapt the Regulatory System

The European regulatory system has helped extend and improve the lives of millions of European citizens and beyond through provision of safe and effective medicines. Since its formation in 1995 the European Medicines Agency (EMA) has recommended the authorisation of over 1,400 medicines. However, in order to keep pace with pharmaceutical breakthroughs as well as remain competitive and respond to global health challenges, it is vital for Europe's regulatory system to continue to evolve.

Regulators need to work with industry and other healthcare partners to adapt the regulatory system within existing legislation to deliver on the new opportunities medical science is offering to patients and to ensure that Europe remains competitive within global biopharmaceutical markets.

EMA Regulatory Science to 2025 Strategy[1]

Published in 2020, the EMA Regulatory Science to 2025 Strategic Reflection outlines the Agency's key goals for the next five years:

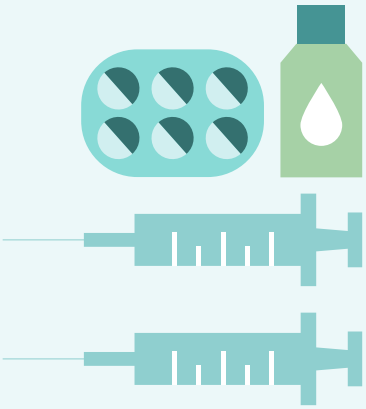
- Catalysing the integration of science and technology in medicine development
- Driving collaborative evidence generation to improve the scientific quality of evaluations
- Advancing patient-centred access to medicines in partnership with healthcare systems
- Addressing emerging health threats
- Enabling and leveraging research and innovation in regulatory science

Successful implementation of this strategy will help to deliver the necessary adaptation of the EU regulatory system. It is imperative that the Agency is provided with the resources it needs (people, expertise, technology) to fully implement the priorities outlined in the Strategy. As a leading regulator, the EU medicines regulatory network also needs to continue to support efforts to harmonise regulatory requirements globally through the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), the Pharmaceutical Inspection Co-operation Scheme (PIC/S) and other relevant organisations.

1 EMA. EMA Regulatory Science to 2025. Published June 2020.

In addition to adapting the regulatory system, Europe's biopharmaceutical sector also needs to evolve in order to remain competitive and responsive, addressing the following areas for focus[2] :

1. **Clinical Trials -** Advancing future and innovative clinical trial concepts and designs (including adopting elements of decentralised trials) will be instrumental in bringing novel medicines to patients earlier and with greater efficiency.



2. **Regulatory Advice -** Medicine development advice needs to be linked and integrated across the EU regulatory system, including with Health Technology Assessment (HTA) bodies. Providing enhanced advice with greater flexibility will reflect the pace and progress of innovation within the sector.

3. **Real World Data (RWD) -** While there is a need for global standards in gathering and analysing RWD, the regulatory framework should advance novel approaches to RWD in order promote its use in decision making.

4. **Precision Medicine -** Supporting the shift from treatment of a disease to prediction and prevention of disease enabled through new diagnostic methods.

5. **Manufacturing and supply -** Facilitating the implementation of novel development and manufacturing technologies and support supply chain resilience through geographic diversity.

The response to COVID-19

The COVID-19 pandemic has highlighted elements of the policy and regulatory framework that have worked well. Regulators have shown to be responsive and flexible in the face of the unprecedented real-time threat of the virus.

The pandemic has also highlighted areas for improvement and lessons that should be learned including: the importance of centralised rapid national response strategies, emergency regulatory flexibility, the need to address liability and other risk mitigation in a pandemic situation, and the opportunity for government and policy makers to facilitate the implementation of new biopharma production technologies.

Policy Recommendations

1. Advance and promote a more flexible, integrated, and fully-resourced European regulatory system, which delivers agile and dynamic regulatory oversight across the medicine lifecycle in close collaboration with the biopharmaceutical industry.

2. Embrace and encourage the implementation of novel regulatory science in collaboration with industry. This will promote greater efficiency, effectiveness, and innovation in clinical trial design, evidence generation, modelling, and statistical analysis by leveraging digital technologies.

3. Establish collaboration and harmonisation with regulatory bodies around the world, with a focus on comparable regulatory systems outside the EU such as those in Asia and the US.

2 EFPIA. Response to Public consultation on EMA Regulatory Science Strategy to 2025. Published 2020.