COMPASS
LIFE SCIENCES

Insight: The Importance of Flexibility & Innovation in Regulation

#clsinsights

Contents

Introduction

This report/article outlines the importance of flexibility and innovation within the regulation sector of the life sciences industry. Compass Life Sciences has identified the potential issues that could incur if flexibility is not considered and the ideas for potentially mitigating these risks.

In order to address the demands of current and upcoming pharmaceutical, biological, and Medical technologies, the European regulatory system comprises of several networks, including the European Medicines Regulators Network, Notified Bodies, and Health Technology Assessment Body network.[1]

These networks collaborate using various modes and governance structures.[2] However, the current system incurs costs at the systems-level, due to suboptimal information sharing and asynchronous processes.[3]

[1] Heikkinen, I., Eskola, S., Acha, V., Morrison, A., Walker, C., Weil, C., ... & Chlebus, M. (2023). Role of innovation in pharmaceutical regulation: a proposal for principles to evaluate EU General Pharmaceutical Legislation from the innovator perspective. *Drug Discovery Today,* 103526.

[2] Webster, A. (2019). Accelerating innovation: complexity, regulation, and temporality. *Frontiers in Sociology, 4,* 13.

[3] Webster, A., & Gardner, J. (2019). *Aligning technology and institutional readiness: the adoption of innovation. Technology Analysis & Strategic Management*, 31(10), 1229-1241.

Why there is a need for flexibility and innovation

Future legislation should strive to enhance coherence and streamline operations across these networks as the current multi-tiered governance model, which involves Union-wide and national regulations and decision-makers at different levels (central, national, regional), creates complexity that can be challenging to navigate.[4]

The European innovation system involves multiple stakeholders, and for patients to gain access to innovative treatments, there must be a positive endorsement from several decision-makers. These stakeholders have varying needs and expectations for the innovator. To cater to most stakeholders' expectations and respond to emerging scientific discoveries, it is essential to avoid overly prescriptive legislative measures and instead use more dynamic regulatory instruments (sometimes described as 'soft law' measures), such as guidelines, which provide flexibility to adapt as innovation progresses.

However, the existing regulatory systems and ethical frameworks may not be adequate to provide effective and timely oversight of emerging technologies as these technologies are advancing rapidly, and traditional government oversight systems are unable to keep up, as they are hindered by stagnation and bureaucratic inertia. As a result, they are increasingly lagging behind the new technologies speeding into the future.[5]

[4] Dunlop, C. A., & Radaelli, C. M. (2022). Better regulation in the European Union. In *Handbook of Regulatory Authorities* (pp. 303-313). Edward Elgar Publishing.

[5] Marchant, G. E. (2011). Addressing the pacing problem. *The growing gap between emerging technologies and legal-ethical oversight: The pacing problem*, 199-205.

These therapies offer potentially curative outcomes that could significantly benefit patients and the healthcare system.

How a flexible and responsive approach can be adopted

To adopt a more flexible and responsive approach, the authorities at the national level should actively participate in creating and collaborating with EU-level stakeholders on the European innovation system and associated governance. This collaboration is crucial because patients in national healthcare systems are the ultimate beneficiaries.

Gene and cell therapies are examples of complex products that require regulatory agility, as many new technologies are set to be deployed in healthcare systems in the upcoming years.[6] These therapies offer potentially curative outcomes that could significantly benefit patients and the healthcare system. However, innovative therapies often challenge the existing methods and requirements of the wider healthcare system, necessitating a multidisciplinary approach. The development of such products is multifaceted and progressing at a pace that requires developers and regulatory authorities to be adaptive.[7]

Collaboration is necessary to integrate new science that may not fit readily with the current legislation or existing framework. Learnings from the first gene therapy approvals highlight the importance of dynamic dialogue and deep science-based discussions between all stakeholders. Investment in regulatory science will support knowledge gathering by assessors and the wider scientific community, facilitating the development of pragmatic regulatory guidelines.

[6] Drago, D., Foss-Campbell, B., Wonnacott, K., Barrett, D., & Ndu, A. (2021). Global regulatory progress in delivering on the promise of gene therapies for unmet medical needs. *Molecular Therapy-Methods & Clinical Development*, 21, 524-529.

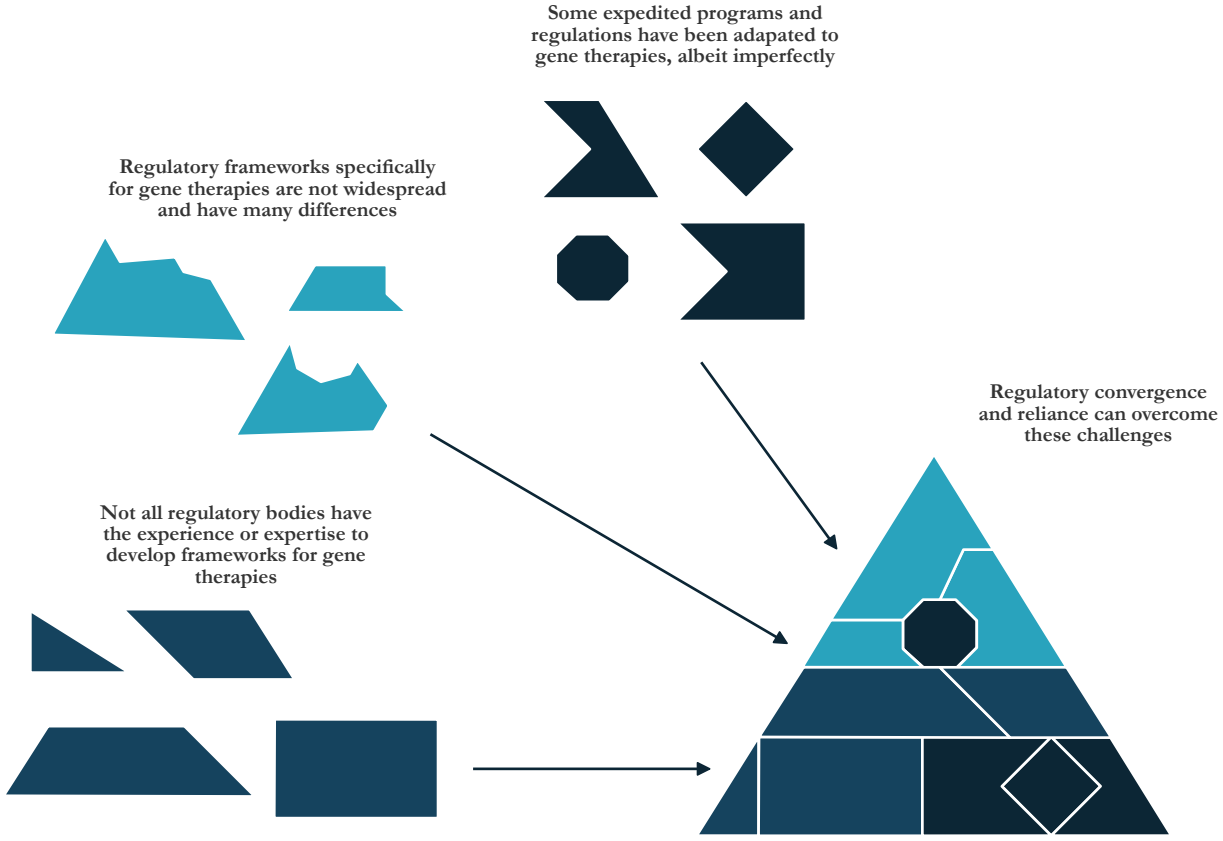
[7] Ten Ham, R. M., Hoekman, J., Hövels, A. M., Broekmans, A. W., Leufkens, H. G., & Klungel, O. H. (2018). Challenges in advanced therapy medicinal product development: a survey among companies in Europe. *Molecular Therapy-Methods & Clinical Development*, 11, 121-130.

[8] Carvalho M, Sepodes B, Martins AP. Regulatory and Scientific Advancements in Gene Therapy: State-of-the-Art of Clinical Applications and of the Supporting European Regulatory Framework. *Front Med (Lausanne)*. 2017;4:182.

Conclusion

The role of regulatory science is critical in ensuring that legislative frameworks remain focused on promoting innovation. By engaging a diverse and multidisciplinary scientific community, regulatory science can help shape evidence-based policies that enable the timely and safe availability of life-saving medicines. It is important that regulatory frameworks remain adaptable to support global innovation and patient access to new treatments.

To achieve this, regulatory convergence between jurisdictions is crucial and should be prioritized to avoid potential delays in access to new therapies.[8] Through science-based decision-making that balances patient safety, public health protection, and innovation, regulatory science can help ensure that the global community moves forward together.



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References

- Heikkinen, I., Eskola, S., Acha, V., Morrison, A., Walker, C., Weil, C., ... & Chlebus, M. (2023). Role of innovation in pharmaceutical regulation: a proposal for principles to evaluate EU General Pharmaceutical Legislation from the innovator perspective. Drug Discovery Today, 103526.
- Webster, A. (2019). Accelerating innovation: complexity, regulation, and temporality. Frontiers in Sociology, 4, 13.
- Webster, A., & Gardner, J. (2019). Aligning technology and institutional readiness: the adoption of innovation. Technology Analysis & Strategic Management, 31(10), 1229-1241.
- Dunlop, C. A., & Radaelli, C. M. (2022). Better regulation in the European Union. In Handbook of Regulatory Authorities (pp. 303-313). Edward Elgar Publishing.
- Marchant, G. E. (2011). Addressing the pacing problem. The growing gap between emerging technologies and legal-ethical oversight: The pacing problem, 199-205.
- Drago, D., Foss-Campbell, B., Wonnacott, K., Barrett, D., & Ndu, A. (2021). Global regulatory progress in delivering on the promise of gene therapies for unmet medical needs. Molecular Therapy-Methods & Clinical Development, 21, 524-529.
- Ten Ham, R. M., Hoekman, J., Hövels, A. M., Broekmans, A. W., Leufkens, H. G., & Klungel, O. H. (2018). Challenges in advanced therapy medicinal product development: a survey among companies in Europe. Molecular Therapy-Methods & Clinical Development, 11, 121-130.
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