"TIME-TO-MARKET", INNOVATION, AND BETTER REGULATION
HIGHLIGHTS NOTE 15

- **Market access rules and processes to restrict the introduction of new technologies and to retain existing one on the market seek to protect citizens and nature, as well as building consumer confidence. These goals are met when laws and administrative processes are science-based, proportionate, speedy, predictable, and globally-respected. Indeed the value for citizens of ensuring market access processes meet these standards, specifically for vaccines, has been demonstrated during the COVID-19 crisis.**
- **In contrast, poorly designed and implemented market access restrictions erode incentives to innovate, reduce the availability of technologies (and its benefits), create risk-risk tradeoffs, establish barriers to market participation for SMEs, and trigger delocalisation of capital.**
- **Better Regulation concepts and practices should ensure that such negative outcomes are avoided. Despite recent reforms, there is a lack of consistency in the quality of the performance of too many of the EU's approval and licensing processes. Too many processes are slow, costly, or unpredictable. In consequence, standards set by global peers are not matched on a systemic basis.**
- **A structured programme of reform is needed to overcome these failings.**

This ERF Highlights Note briefly examines the policy objectives of market access laws and highlights global best practices. It examines the EU's approach to regulating market access and identifies the nature and causes of its weaknesses. The note also points to the positive and negative regulatory impacts of approval and licensing processes. It concludes with a brief list of suggested reforms.

MARKET ACCESS REGULATION

Throughout the OECD area, governments have put in place regulatory requirements to restrict market access for a range of technologies, such as pharmaceuticals, crop protection, biocides, speciality chemicals, life sciences, novel foods, and advanced materials. Such requirements take different forms including mandatory pre-market approvals (often for advanced complex technologies), mandatory re-licensing for some product categories, import approvals, and licences for the installation of selected technologies. For other technologies there are normally product standards that must be met before companies can place goods on the market. (This ERIF Highlights Note focuses on mandatory approval and licensing processes undertaken by governments.)

Formal restrictions on market access have three principal policy objectives: (1) Ensure that citizens and nature enjoy a high standard of protection; (2) Make sure that all market participants are subject to the same requirements; and, (3) Give customers confidence in the safety and performance of regulated products, thereby contributing to market confidence and providing incentives to innovate.

A review of good practices across the OECD area points to a number of critical features of high quality mandatory approval and licensing processes:

- They are speedy, predictable, and globally-respected;
- They are science-based and undertaken by relevant and eminent experts;
- Testing and compliance requirements are stable, effective, proportionate, known in advance, and based on credible scientific evidence along with legal requirements and real-world experience;
- Duplication of testing is avoided; and,
- Timeliness and test requirements are benchmarked against global peers, recognising that unjustified delays and costs reduce innovation without necessarily increasing protection.

Product approval regimes that meet these conditions are also more likely to set global standards and thus create market opportunities in other parts of the world.

EU APPROACH

Historically, the EU used a decentralised model of formal market access authorisations. Directives set

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out safety and other performance standards, along with the characteristics of the approval or re-licensing process, substantive guidance set out specific process and test requirements, and Member States assessed individual products to ensure compliance and made recommendations to the European Commission.

This model allowed the EU to make use of the scientific capability of the Member States, but it presented a number of weaknesses. Too many approvals were slow or inconsistent, and outcomes were unpredictable. Levels of technological and scientific knowledge differed between Member States, making it difficult to ensure a consistent high standard of the scientific evidence underpinning approval and leading to market barriers.

To overcome these problems, the EU has, for certain technologies, adopted a new centralised approach for approval and licensing. Regulations, rather than Directives, now set out detailed performance and process requirements, and provide the legal base for implementation using the EU Administrative State. Test requirements are set out in substantive guidance and comitology, whilst assessments are undertaken on behalf of the Commission by EU risk assessment agencies, Technical Working Groups, or 'rapporteur' Member States.

Centralised approval and licensing processes have enabled the EU to protect the Single Market, harmonise interpretations of requirements and expand the pool of available expertise. **At its best, this approach to market access regulation is more expert, consistent, and predictable, and leads to faster access to market without undermining standards of protection.**

Indeed, the Commission has undertaken a series of reforms to try and deliver these policy goals. Independent scientific committees and risk assessment agencies have been set up. Centralised procedures have been strengthened for certain technologies, such as novel foods. Time-based requirements to renew product approvals have been phased out for veterinary medicines. And, EMA has established process requirements based on Better Regulation concepts for the development of substantive guidance, introduced peer review of scientific assessments, and widened access to relevant and eminent experts.

EU PERFORMANCE

Recent research by the ERIF, published in the Monograph *'Risk Management and the EU's Administrative State' (2019)* shows that despite reform, there is a lack of consistency in the quality of the performance of too many of the EU's approval and licensing processes. Too many processes are slow, costly, or unpredictable. In consequence, standards set by global peers are not matched on a systemic basis. There are three main failings:

(1) Overall, the costs and time of test requirements to demonstrate standards of safety and performance in the EU are very high – all too often, the cost and time required in the EU, across a wide range of sectors, technologies, and risk domains, are significantly in excess of those required by global peers to undertake similar processes, without any demonstrable improvement in protection.

(2) There are unjustified delays in assessment and approval of dossiers at EU-level – compared to global peers, the EU undertakes this process of assessment and approval unjustifiably slowly and without any evidence that such delays lead to improved protection for health, safety, or the environment.

(3) EU approval decisions significantly lack predictability – all too often, approval or licensing decisions made through the EU Administrative State are not predictable. Products or substances are not approved, despite satisfying explicit test requirements; additional usage restrictions are recommended without robust scientific justification; or, additional studies are required that fail to demonstrate improvements in protection.

These problems are caused by a number of factors, including:

- Unclear requirements because of the need to comply with draft guidance;
- Changes in requirements during testing processes;
- Additional requirements applied retrospectively during the testing process;
- Lack of pre-submission hearings;
- Lack of technical and scientific capacity and expertise;
- Application of EU-specific requirements that lack robust scientific justification based on risk and relevant real-world exposures;
- Undue focus on scientific curiosity or hypothetical exposures rather than real-world risks;
- Failure to ensure impartiality of experts;
- Failure to accept studies carried out in other parts of the world that meet globally accepted standards;
- Inadequate co-ordination of Member States;
- Inappropriate application of the Precautionary Principles, a risk management strategy, within the risk management phase; and,
- Undue influence of political or ideological conflicts of interest throughout all stages or even after the approval process.

Taken together, these weaknesses delay access to the benefits of technologies, increase the capitalised cost of developing new products and keeping old ones on the market, without enhancing protection, and reduce innovation incentives – this is the "Time-to-Market" regulatory paradigm.

Evidence from a number of different sectors confirms these problems of delay and Capitalised Development Cost:

- **Novel Foods** – prior to recent reforms, it was estimated that the average time needed to approve a new novel food for consumption in the EU was at least 48 months, compared, compared to less than 6 months in the USA, for instance.

- **GM Crop Imports** – approval of an importation for a GM crop into the EU takes, on average, at least 60 months compared to 18 months in the USA, Canada, and Brazil.

- **Crop Protection** – the cash cost, excluding the cost of capital and time values, of developing a new active for the crop protection sector has risen, in real terms, from USD 150 million in 1995 to USD 290 million in 2017, primarily because of increased safety and environmental requirements. Approval for a new crop protection product takes more than 48 months in the EU, compared to 30 months for the USA, Canada, and Australia.

Similar problems have been encountered in the **Human Pharmaceuticals** and **Veterinary Medicines** sectors. For example, time and costs needed to develop new products for major animal species have increased substantially due to increased regulatory requirements, contributing to higher capitalised costs of development, less investment in new technologies, and reduced industry-wide expenditure on R&D.

REGULATORY IMPACTS

High quality mandatory restrictions on market access, (through explicit product approval processes) for new and existing products ensure high standards of protection, strengthen consumer confidence, facilitate the availability of technologies, create incentives for innovation, and speed up access to global markets.

In contrast, poor quality approval processes for new and existing products can trigger a series of negative regulatory impacts. These include:

(1) Higher Capitalised Development Costs for new products – longer periods from inception of investment projects to market access, combined with higher cash costs and regulatory unpredictability, increases the effective cost of innovation and the size of market opportunity required to justify allocation of capital[1]. This has a number of negative consequences, including:

- Fewer investment opportunities;
- Less market participation by SMEs;
- Focus on incremental improvements rather than 'breakthrough' innovations; and,
- Reduced geographic attraction of the EU for R&D investment

(2) Delayed availability of new technologies – slow or unpredictable approval and licensing processes affect incentives to invest in innovation and limit the benefits of technologies to citizens. Impacts include:

- Loss of "first mover" advantages for companies deploying advanced, innovative technologies in the EU (such as Thin Film technology);
- Erosion of value of intellectual property;
- Loss of access to technologies by downstream value chain users;
- Loss of benefits of technologies by citizens, leading to risk-risk outcomes (reduced availability of medicines, for example); and,
- Reduced attraction of the EU for development and dissemination of innovative ideas;

(3) Reduced availability of existing products – in a wide range of sectors, including biocides, crop protection, and veterinary medicine, businesses have responded to high cost, lengthy, or unpredictable approval processes for existing products by cutting back the availability of existing technologies. Negative consequences include:

- Loss of technologies for small markets or applications;
- Loss of resources to fund innovation;
- Loss of SMEs unable to fund product defence
- Barriers to downstream innovation;
- Reformulation costs for downstream users, diverting resources; and,
- Risk-risk outcomes due to substitution or loss of benefits (such as a lack of veterinary medicines)

(4) Higher levels of Defensive R&D – support for existing products facing poor quality approval processes diverts resources away from innovation. This has negative consequences, including:

- Fewer resources for investment in new ideas; and,
- Retention of older technologies;

Overall, poor quality market access regulations and processes reduce incentives to innovate and to allocate capital to the EU. They may restrict access to the benefits of new technologies, limiting the competiveness and preventing citizens from enjoying a higher quality of life. They may lock-in old technologies. Risk-risk outcomes may emerge, whereby net risks are not reduced. And, innovation by SMEs in the EU may face significant barriers.

These outcomes are of significant importance for the EU as it sets out to recover from COVID-19, to build a more resilient economy, to protect the health of its citizens, and to deliver the goals of the Green Deal. Indeed, the EU argues that the objectives of the Green Deal will be delivered through allocation of capital to Europe, investments in innovation, and breakthrough inventions

[1] *Capitalised Development Costs take into account cash outflows, the impact of regulatory uncertainty, time, compounding, and the cost of capital. They represent the investment being made by the innovator and must be recovered fully from net after-tax cash flows, discounted at the cost of capital, if a proposed project is to be funded or similar projects are to receive allocations of capital in the future.*

by SMEs. Achieving these goals will require a significant reform of the market access processes used by the EU for new and existing technologies.

ERF OBSERVATIONS

There are several of causes of these problems. At the **political level, there is a lack of awareness among EU decision-makers of the impact of market access rules and processes on innovation and on levels of protection,** and hence the importance of improving both legislative design and the governance of the EU Administrative State. There is a lack of systematic benchmarking of performance, comparing the EU with global peers, for example.

There are gaps and weaknesses in the EU Better Regulation strategy. Insufficient emphasis is placed on assessing the design of proposed laws to ensure that approval processes meet global standards of best practice. Substantive guidance, the principal implementing mechanism for setting out process and test requirements, is excluded from the scope of the Better Regulation strategy.

Problems of time, cost, and uncertainty that characterise too many of the EU's market access processes result, in part, from **a mismatch between the scope of risk management laws and the resources, expertise and capacity of the EU's Administrative State** – the principal mechanism for implementing EU law.

Weaknesses in governance amplify these issues. The public lacks legally enforceable procedural rights when dealing with the EU Administrative State. Risk assessment agencies have only partly adopted best practice. There is also a lack of uniform and transparent procedural rules for the involvement of Member States in approval processes.

There are policy weaknesses too. Guidance for the application of the Precautionary Principle does not adequately consider its misapplication within scientific assessments, for instance. Detailed 'horizontal' standards of scientific integrity, including guidance for the selection of relevant and eminent experts have yet to be developed and adopted by the EU institutions.

An ambitious package of reforms is needed to resolve the weaknesses of the EU's processes for approving and licensing new and existing products. The Innovation Principle should provide the conceptual framework for this initiative. Possible improvements could include:

Benchmarking – the Secretariat-General of the European Commission, as the guardian of the institution's Better Regulation agenda, should promote periodic benchmarking of the time and cost of product approval processes (encompassing testing and approval for new and existing technologies) and to draw conclusions and recommendations for structural improvements. Evidence on sectoral practices related to the "Time-to-Market paradigm" should be included and addressed in relevant ex post reviews of EU laws. Reports should be published and made available to all EU institutions.

Law of Administrative Procedures – the EU legislature should and adopt a comprehensive Law of Administrative Procedures. This should embed the principles of good administration into law, strengthen judicial review, provide legally enforceable standards and procedural rights and encompass all significant rule-making and adjudication processes used by the EU Administrative State.

Risk Assessment Agencies – building on the Inter-Institutional Joint Statement and Common Approach to Decentralised Agencies of 2012, the EU institutions should establish common decision-making processes and standards for the risk assessment agencies. These should encompass issues such as pre-submission hearings, agreements to define data requirements in advance, independent administrative appeals mechanisms, and common standards for developing substantive guidance. The EU-ANSA network could promote this.

Precautionary Principle – the European Commission should develop supplementary guidelines that clarify the role of the Precautionary Principle in decision-making, complementing, rather than replacing, the related Communication of 2000. The guidelines should re-state the requirements of the Communication, emphasising that the Precautionary Principle should only be used for risk management.

Scientific Integrity Policy – the European Commission should develop and adopt, possibly in the form of a Decision, minimum standards for the quality, collection, validation, and use of scientific evidence that all directorates and agencies must respect. These should be based on global best practices. They should encompass standards for the selection of scientific experts that enable the Commission to have access to the most eminent and relevant experts, and recognise the nature of bias, and its causes.

Better Regulation – the European Commission should revise the Better Regulation Guidelines to further strengthen the focus on comitology, to require legislative design to consider best practices for approval processes, and to encompass within their scope all substantive guidance developed by the Commission and EU risk assessment agencies.

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