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Short communication

Regulatory exclusivity and access to medicines in Europe: balancing innovation and generic competition

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Introduction

Access to medicines is one of the central objectives of contemporary pharmaceutical policy. While the development of new medicines requires strong incentives for innovation, patients and healthcare systems also depend on timely access to affordable generic and biosimilar alternatives. In Europe, this balance is influenced not only by patents, but also by regulatory exclusivity mechanisms, including regulatory data protection and market protection. These mechanisms prevent competitors from relying on originator data or marketing equivalent products for a defined period, even when patent issues are not the only barrier to competition (European Commission, 2020).

The ongoing reform of European pharmaceutical legislation has placed this issue at the centre of policy debate. The objective is to preserve incentives for pharmaceutical innovation while improving availability, affordability and timely access to medicines across European Union Member States. This short communication discusses how regulatory exclusivity can influence access to medicines and why a balanced system is necessary for both innovation and public health (European Commission, 2023).

Regulatory exclusivity and access to medicines

Regulatory exclusivity was introduced to protect the investment required to generate the scientific data necessary for marketing authorisation. From this perspective, it has a legitimate role in supporting innovation. Originator companies invest in preclinical studies, clinical trials, quality documentation and regulatory procedures before a medicine can be approved. If competitors could immediately rely on these data, the incentive to develop new medicines could be weakened, particularly in high-risk therapeutic areas or for medicines addressing unmet medical needs.

However, from the perspective of access to medicines, exclusivity periods must be carefully balanced. During the period of regulatory protection, generic and biosimilar competition is postponed. This may maintain higher prices and delay the savings normally associated with market competition. For patients, delayed competition may result in higher co-payments or restricted access, depending on national reimbursement systems. For public payers, prolonged exclusivity may increase pharmaceutical expenditure and reduce the capacity to finance other medicines or healthcare services.

The access implications are especially relevant for medicines used in chronic diseases, oncology,

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immunology, rare diseases and other areas associated with high treatment costs. In such fields, even a limited delay in generic or biosimilar entry may have considerable budgetary consequences. Biosimilars are particularly important in this context. Biological medicines are often complex and expensive, but biosimilar competition can reduce costs and enable treatment of a larger number of patients. Therefore, regulatory rules that influence biosimilar preparedness and market entry have direct public-health relevance.

The reform of European pharmaceutical legislation reflects an attempt to recalibrate this balance. Under the revised framework proposed in the context of the EU pharmaceutical legislation reform, new medicines are expected to benefit from the eight-year period of regulatory data protection and one year of market protection, with the possibility of additional incentives under defined conditions. Importantly, the reform also emphasises broader patient access, availability of medicines and security of supply. This indicates a policy shift from exclusivity as a purely industry-oriented incentive toward exclusivity as a conditional instrument linked to public-health objectives (Council of the European Union, 2025).

One important element is the strengthened focus on availability across the European Union. A centrally authorised medicine does not automatically become available to all European patients. Differences in pricing negotiations, reimbursement decisions, national budgets and launch strategies often lead to unequal access between Member States. Smaller or lower-income markets may experience delayed availability even after European marketing authorisation. For this reason, incentives that encourage wider and more timely launch may contribute to reducing access inequalities.

Another relevant mechanism is the so-called Bolar exemption, which allows generic and biosimilar manufacturers to perform necessary studies and regulatory preparations before the expiry of relevant protection. Its importance lies in reducing the gap between the end of exclusivity and real market availability. Without such preparation, patients may face additional delay even after legal barriers have formally expired. By enabling earlier regulatory work, the Bolar exemption supports the objective of making affordable alternatives available as soon as protection periods end (European Parliament, 2025).

Nevertheless, regulatory exclusivity must not be assessed only by its duration. Its public-health value depends on whether it stimulates medicines that address real therapeutic needs and whether it contributes to actual patient access. A medicine that receives protection but is launched only in selected markets may provide limited benefit to European patients as a whole. Conversely, a system that links incentives to availability, unmet medical need and meaningful therapeutic value may better align private innovation incentives with public-health priorities.

Conclusion

Regulatory exclusivity should not be viewed simply as a legal or regulatory concept, but as a mechanism with direct implications for access to medicines. By influencing generic and biosimilar entry, it may affect medicine availability, generic substitution, reimbursement decisions and treatment affordability. For pharmacists and other healthcare professionals, understanding regulatory exclusivity is important for interpreting medicine access, pricing dynamics and the balance between pharmaceutical innovation and public-health needs.

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